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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CITY AND COUNTY OF SAN FRANCISCO, Plaintiff, vs. ALEX M. AZAR II, Secretary of U.S. Department of Health and Human Services; ROGER SEVERINO, Director, Office for Civil Rights, Department of Health and Human Services; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and DOES 1-25, Defendants.	Case No. 3:19-cv-2405-JCS **REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF CITY AND COUNTY OF SAN FRANCISCO'S MOTION FOR PRELIMINARY INJUNCTION** Hearing Date: July 12, 2019 Time: 10:30 a.m. Judge: Hon. Joseph C. Spero Place: Courtroom G, 15th Floor Trial Date: Not set

Plaintiff City and County of San Francisco hereby respectfully requests, pursuant to Federal Rule of Evidence 201, that this Court take judicial notice of the following documents:

1. Attached hereto as **Exhibit A** is a true and correct copy of the regulations entitled "Protecting Statutory Conscience Rights in Heath Care; Delegations of Authority," published in the Federal Register on Tuesday, May 21st, 2019 (the "Final Rule").

2. Attached hereto as **Exhibit B** is a true and correct copy of a memorandum regarding "Key Findings on Conscience Rights Polling" from Kellyanne Conway to "Interested Parties," dated April 8, 2009. This memorandum is available at https://docs.wixstatic.com/ugd/809e70_2f66d15b88a0476e96d3b8e3b3374808.pdf. The memorandum is cited in the Final Rule at this URL. *See* 84 Fed. Reg. at 23247 n. 316-318.

3. Attached hereto as **Exhibit C** is a true and correct copy of a document summarizing polls conducted in April 2009 and May 2011. The document is available at https://docs.wixstatic.com/ugd/809e70_7ddb46110dde46cb961ef3a678d7e41c.pdf. This document is cited several times in the Final Rule at this URL, including at 84 Fed. Reg. at 23246 n. 309, 84 Fed. Reg. at 23247 n. 322, and 84 Fed. Reg. at 23250 n. 340.

4. Attached hereto as **Exhibit D** is a true and correct copy of the Christian Medical and Dental Association's Ethics Statement on "Healthcare Rights of Conscience." This document is available at https://docs.google.com/viewer?url=https%3A%2F%2Fcmda.org%2Fwp-content%2Fuploads%2F2018%2F04%2Fhealthcare-right-of-conscience.pdf.

5. Attached hereto as **Exhibit E** is a true and correct copy of a comment submitted by the City and County of San Francisco in response to the proposed rule entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," published in the Federal Register on January 26, 2018 ("Proposed Rule"). This comment is available on the official "regulations.gov" website at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-69109.

6. Attached hereto as **Exhibit F** is a true and correct copy of a comment submitted by the National Institute of Reproductive Health in response to the Proposed Rule. This comment is available on the official "regulations.gov" website at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-56426.

7. Attached hereto as **Exhibit G** is a true and correct copy of a comment submitted by the American Civil Liberties Union in response to the Proposed Rule. This comment is available on the official "regulations.gov" website at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71138.

8. Attached hereto as **Exhibit H** is a true and correct copy of a comment submitted by Community Catalyst in response to the Proposed Rule. This comment is available on the official "regulations.gov" website at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70258.

9. Attached hereto as **Exhibit I** is a true and correct copy of a comment submitted by the National Women's Law Center in response to the Proposed Rule. This comment is available on the official "regulations.gov" website at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71477.

10. Attached hereto as **Exhibit J** is a true and correct copy of a comment submitted by the Empire Justice Center in response to the Proposed Rule. This comment is available on the official "regulations.gov" website at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71892.

11. Attached hereto as **Exhibit K** is a true and correct copy of a comment submitted by the Family Equality Council in response to the Proposed Rule. This comment is available on the official "regulations.gov" website at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70389.

12. Attached hereto as **Exhibit L** is a true and correct copy of a comment submitted by the National Latina Institute for Reproductive Health in response to the Proposed Rule. This comment is available on the official "regulations.gov" website at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71637.

13. Attached hereto as **Exhibit M** is a true and correct copy of a comment submitted by Lambda Legal Defense and Education Fund, Inc. in response to the Proposed Rule. This comment is available on the official "regulations.gov" website at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72186.

14. Attached hereto as **Exhibit N** is a true and correct copy of a comment submitted by the Williams Institute, Inc. in response to the Proposed Rule. This comment is available on the official "regulations.gov" website at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72082.

Exhibit A is judicially noticeable because it was published in the Federal Register. *See* 44 U.S.C. § 1507 ("The contents of the Federal Register shall be judicially noticed.").

Exhibits B, C, and D are judicially noticeable because each is a matter of public record and is therefore subject to judicial notice. Fed. R. Evid. 201(b); *Lee v. City of Los Angeles*, 250 F.3d 668, 689 (9th Cir. 2001) (a court may judicially notice matters of public record unless the matter is a fact subject to reasonable dispute). **Exhibits B and C** are also documents that HHS relied upon in crafting the final rule and should therefore be part of the administrative record in this case.

Exhibits E, F, G, H, I, J, K, L, M, and N are judicially noticeable because courts can—and do—take judicial notice of comments on proposed rules. *See Tovar v. Midland Credit Mgmt.*, No. 10CV2600 MMA MDD, 2011 WL 1431988, at *1-2 (S.D. Cal. Apr. 13, 2011) (taking judicial notice of comments submitted in response to proposed regulations). They are also judicially noticeable because they are posted to an official government website. *See Daniels–Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998–99 (9th Cir. 2010) (judicially noticing information contained on a government website); *Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 879 (N.D. Cal. 2013) (noting that "public records and government documents available from reliable sources on the Internet" are typically subject to judicial notice) (quotation omitted); *Paralyzed Veterans of America v. McPherson*, No. C 06–4670 SBA, 2008 WL 4183981, at *5 (N.D. Cal. Sept. 9, 2008) (finding that courts commonly take judicial notice of information and documents on government websites).

Dated: June 3, 2019

DENNIS J. HERRERA
City Attorney

By: /s/ Sara J. Eisenberg
SARA J. EISENBERG
Deputy City Attorney

Attorneys for Plaintiff
CITY AND COUNTY OF SAN FRANCISCO

EXHIBIT A

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 88

RIN 0945–AA10

Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

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

ACTION: Final rule.

SUMMARY: The United States has a long history of providing protections in health care for individuals and entities on the basis of religious beliefs or moral convictions. Congress has passed many such laws applicable to the Department of Health and Human Services (''HHS'' or the ''Department'') and the programs or activities it funds or administers, some of which are the subject of existing HHS regulations. This final rule revises existing regulations to ensure vigorous enforcement of Federal conscience and anti-discrimination laws applicable to the Department, its programs, and recipients of HHS funds, and to delegate overall enforcement and compliance responsibility to the Department's Office for Civil Rights (''OCR''). In addition, this final rule clarifies OCR's authority to initiate compliance reviews, conduct investigations, supervise and coordinate compliance by the Department and its components, and use enforcement tools otherwise available in existing regulations to address violations and resolve complaints. In order to ensure that recipients of Federal financial assistance and other Department funds comply with their legal obligations, this final rule requires certain recipients to maintain records; cooperate with OCR's investigations, reviews, or other proceedings; and submit written assurances and certifications of compliance to the Department. The final rule also encourages the recipients of HHS funds to provide notice to individuals and entities about their right to be free from coercion or discrimination on account of religious beliefs or moral convictions.

DATES: This rule is effective July 22, 2019.

FOR FURTHER INFORMATION CONTACT: Sarah Bayko Albrecht at (800) 368–1019 or (800) 537–7697 (TDD).

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.

I. Background

This document adopts as final, with changes in response to public comments, a revised part 88, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority. This preamble to the final rule provides a brief background of the rule, summarizes the final rule provisions, and discusses in detail the comments received on the proposed rule.[1]

A. Statutory History

The freedoms of conscience and of religious exercise are foundational rights protected by the Constitution and numerous Federal statutes. Congress has acted to protect these freedoms with particular force in the health care context, and it is these laws that are the subject of this final rule. Specifically, this final rule concerns Federal laws that provide:

- Conscience protections related to abortion, sterilization, and certain other health services applicable to the Department of Health and Human Services and recipients of certain Federal funds encompassed by 42 U.S.C. 300a–7 (the ''Church Amendments'');
- Conscience protections for health care entities related to abortion provision or training, referral for such abortion or training, or accreditation standards related to abortion (the ''Coats-Snowe Amendment,'' 42 U.S.C. 238n);
- Protections from discrimination for health care entities that do not provide, pay for, provide coverage of, or refer for abortions under programs funded by the Department's appropriations acts (*e.g.,* Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019, Div. B., sec. 507(d), Public Law 115–245, 132 Stat. 2981 (Sept. 28, 2018) (the ''Weldon Amendment''); *id.,* sec. 209);
- Protections from discrimination under the Patient Protection and Affordable Care Act (''ACA'') for health care entities that do 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, applicable to the Federal Government and any State or local government that receives Federal financial assistance (42 U.S.C. 18113); and conscience protections for providers, organizations, or their employees regarding counseling regarding the same (42 U.S.C. 14406(1));
- Conscience protections regarding exemptions applicable to the ACA's individual mandate (26 U.S.C. 5000A; 42 U.S.C. 18081);
- Conscience protections under the ACA for qualified health plans related to coverage of abortion, and for individual health care providers and health care facilities that do not provide, pay for, provide coverage of, or refer for abortions (42 U.S.C. 18023(b)(1)(A) and (b)(4));
- Conscience protections for Medicare Advantage organizations and Medicaid managed care organizations with moral or religious objections to counseling or referral for certain services (42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B));
- Conscience protections related to the performance of advanced directives (42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406(2));
- Conscience and nondiscrimination protections for organizations related to Global Health Programs, to the extent such funds are administered by the Secretary of HHS (the ''Secretary'') (22 U.S.C. 7631(d));
- Conscience protections attached to Federal funding, to the extent such funding is administered by the Secretary, regarding abortion and involuntarily sterilization (22 U.S.C. 2151b(f), *see, e.g.,* the Consolidated Appropriations Act, 2019, Pub. L. 116–6, Div. F, sec. 7018 (the ''Helms, Biden, 1978, and 1985 Amendments''));
- Conscience protections from compulsory health care or services generally (42 U.S.C. 1396f and 5106i(a)), and under specific programs for hearing screening (42 U.S.C. 280g–1(d)), occupational illness testing (29 U.S.C. 669(a)(5)); vaccination (42 U.S.C. 1396s(c)(2)(B)(ii)), and mental health treatment (42 U.S.C. 290bb–36(f)); and
- Protections for religious nonmedical health care providers and their patients from certain requirements under Medicare and Medicaid that may burden their exercise of their religious beliefs regarding medical treatment (*e.g.,* 42 U.S.C. 1320a–1(h), 1320c–11, 1395i–5, 1395x(e), 1395x(y)(1), 1396a(a), and 1397j–1(b)).

For purposes of this final rule, these laws will be collectively referred to as ''Federal conscience and anti-discrimination laws.''

Congress has recognized that modern health care practices may give rise to conflicts with the religious beliefs and moral convictions of payers, providers, and patients alike. The existence of

[1] 83 FR 3880 (Jan. 26, 2018).

moral and ethical objections on the part of health care clinicians about participating in, assisting with, referring for, or otherwise being complicit in certain procedures is well documented by ethicists.[2] Religious institutions and entities, too, have expressed objections to the provision of or participation in insurance coverage for certain procedures or services, such as abortion, sterilization, and assisted suicide. To address these problems, Congress has repeatedly legislated conscience protections for individuals and institutions providing health care to the American public, as outlined below.

The Church Amendments. The Church Amendments were enacted at various times during the 1970s in response to debates over whether judicially recognized rights to abortions, sterilizations, or related practices might lead to the requirement that individuals or entities participate in activities to which they have religious or moral objections. The Church Amendments consist of five provisions, codified at 42 U.S.C. 300a–7, that protect those who hold religious beliefs or moral convictions regarding certain health care procedures from discrimination by entities that receive certain Federal funds, and in health service programs and research activities funded by HHS. Notably, the Church Amendments contain provisions explicitly protecting the rights of both individuals and entities.

First, paragraph (b) of the Church Amendments provides, with regard to individuals, that no court, public official, or other public authority can use an individual's receipt of certain Federal funding as grounds to require the individual to perform, or assist in, sterilization procedures or abortions, if doing so would be contrary to his or her religious beliefs or moral convictions. 42 U.S.C. 300a–7(b)(1). Paragraph (b) further prohibits those public authorities from requiring an entity, based on the entity's receipt of Federal funds under certain HHS programs, (1) to permit sterilizations or abortions in the entity's facilities if the performance of such procedures there violates the entity's religious beliefs or moral convictions, or (2) to make its personnel available for such procedures if contrary to the personnel's religious beliefs or moral convictions. 42 U.S.C. 300a–7(b)(2). The individuals and entities protected by this provision are recipients of grants, contracts, loans, or loan guarantees under the Public Health Service Act (42 U.S.C. 201 *et seq.*), and those entities' personnel.[3]

Second, paragraph (c)(1) of the Church Amendments applies to decisions on employment, promotion, or termination of employment, as well as extension of staff or other privileges with respect to physicians and other health care personnel. 42 U.S.C. 300a–7(c)(1). This paragraph prohibits certain entities from discriminating in these decisions based on an individual declining to perform or assist in an abortion or sterilization because of that individual's religious beliefs or moral convictions. 42 U.S.C. 300a–7(c)(1). It also prohibits those entities from discriminating in such decisions based on an individual's performance of a lawful abortion or sterilization procedure, or on an individual's religious beliefs or moral convictions about such procedures more generally. *Id.* Like paragraph (b), any recipients of a grant, contract, loan, or loan guarantee under the Public Health Service Act must comply with paragraph (c)(1).

Third, paragraph (c)(2) of the Church Amendments applies to the recipients of the Department's grants or contracts for biomedical or behavioral research under any program administered by the Secretary. 42 U.S.C. 300a–7(c)(2). This paragraph prohibits discrimination by such entity against physicians or other health care personnel in employment, promotion, or termination of employment, as well as discrimination in the extension of staff or other privileges, because of an individual's performance or assistance in any lawful health service or research activity, declining to perform or assist in any such service or activity based on religious beliefs or moral convictions, or the individual's religious beliefs or moral convictions respecting such services or activities more generally. 42 U.S.C. 300a–7(c)(2).

Fourth, paragraph (d) of the Church Amendments applies to any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary. For these health service programs or research activities, no individual shall be required to perform or assist in the performance of any part of the program or research activity if doing so would be contrary to his or her religious beliefs or moral convictions. 42 U.S.C. 300a–7(d).

Fifth, paragraph (e) of the Church Amendments applies to health care training or study programs, including internships and residencies. Paragraph (e) prohibits any entity receiving certain funds from denying admission to, or otherwise discriminating against, applicants for training or study based on 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. 42 U.S.C. 300a–7(e). Any recipient of a grant, contract, loan, loan guarantee, or interest subsidy under the Public Health Service Act or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15001 *et seq.*) must comply with paragraph (e).

The Coats-Snowe Amendment. Enacted in 1996, section 245 of the Public Health Service Act (also known as the ''Coats-Snowe Amendment'' or ''Coats-Snowe'') applies nondiscrimination requirements to the Federal government, and to State or local governments receiving Federal financial assistance. 42 U.S.C. 238n. Such governments may not discriminate against any health care entity that refuses to undergo training in, require or provide training in, or perform abortions; refer for abortions or abortion training; or make arrangements for any of those activities. 42 U.S.C. 238n(a)(1)–(2). Furthermore, those governments may not discriminate against a health care entity because the entity attends or attended a health care training program that does not (or did not) perform abortions; require, provide, or refer for training in the performance of abortions; or make arrangements for any such training. 42 U.S.C. 238n(a)(3). The law defines the term ''health care entity'' as including (and, therefore, not limited to) an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions. 42 U.S.C. 238n(c)(2).

[2] *See, e.g.,* Farr A. Curlin M.D., et al., *Religion, Conscience, and Controversial Clinical Practices,* New Eng. J. Med. 593–600 (2007); Stephen J. Genuis & Chris Lipp, *Ethical Diversity and the Role of Conscience in Clinical Medicine,* 2013 Int'l. J. Family Med. 1, 9 (2013); Harris, et al., *Obstetrician–Gynecologists' Objections to and Willingness to Help Patients Obtain an Abortion* 118 Obstet. & Gyn. 905 (2011); Armand H. Matheny Antommaria, *Adjudicating Rights or Analyzing Interests: Ethicists' Role in the Debate Over Conscience in Clinical Practice,* 29 Theor. Med. Bioeth. 201, 206 (2008); William W. Bassett, *Private Religious Hospitals: Limitations Upon Autonomous Moral Choices in Reproductive Medicine,* 17 J. Contemp. Health L. & Pol'y 455, 529 (2001); Peter A. Clark, *Medical Ethics at Guantanamo Bay and Abu Ghraib: The Problem of Dual Loyalty,* 34 J.L. Med. & Ethics 570 (2006).

[3] The Church Amendments also reference the Community Mental Health Centers Act, Public Law 88–164, 77 Stat. 282 (1963), and the Developmental Disabilities Services and Facilities Construction Amendments of 1970, Public Law 91–517, 84 Stat. 1316 (1970). However, those statutes were repealed by subsequent statute and, accordingly, are not referenced here.

In addition, Coats-Snowe applies to accreditation of postgraduate physician training programs. Therefore, the Federal government, and State or local governments receiving Federal financial assistance, may not deny a legal status (including a license or certificate) or financial assistance, services, or other benefits to a health care entity based on an applicable physician training program's lack of accreditation due to the accrediting agency's requirements that a health care entity perform induced abortions; require, provide, or refer for training in the performance of induced abortions; or make arrangements for such training, regardless of whether such standard provides exceptions or exemptions. 42 U.S.C. 238n(b)(1). Additionally, the statute requires the government involved to formulate regulations or other mechanisms, or enter into agreements with accrediting agencies, as are necessary to comply with this accreditation provision of Coats-Snowe. *Id.*

The Weldon Amendment. The Weldon Amendment (or ''Weldon'') was originally adopted in 2004 and has been readopted (or incorporated by reference) in each subsequent appropriations act for the Departments of Labor, Health and Human Services, and Education. *See, e.g.,* Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, and Continuing Appropriations Act, 2019, Public Law 115–245, Div. B., sec. 507(d). Weldon provides that none of the funds made available in the applicable Labor, HHS, and Education appropriations act 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. *E.g.,* Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, and Continuing Appropriations Act, 2019, Public Law 115–245, Div. B., sec. 507(d). Weldon states that the term ''health care entity'' includes 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. *Id.*

Conditions on Federally Appropriated Funds Requiring Compliance with Federal Conscience and Anti-Discrimination Laws. In addition to Weldon, current appropriations acts include other health care conscience protections. For example, one provision, using language similar to the Weldon Amendment, prohibits the Department from denying participation in Medicare Advantage to an otherwise eligible entity, such as a provider-sponsored organization, because the entity informs the Secretary it will not provide, pay for, provide coverage of, or provide referrals for abortions. Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Public Law 115–245, Div. B, sec. 209, 132 Stat. 2981.

The Patient Protection and Affordable Care Act's Conscience and Associated Anti-Discrimination Protections. Passed in 2010, the Patient Protection and Affordable Care Act (ACA) also includes several conscience and associated anti-discrimination protections.

Section 1553 of the ACA prohibits the Federal government, and any State or local government or health care provider that receives Federal financial assistance under the ACA, or any ACA health plans, from discriminating against an individual or institutional health care entity because of the individual or entity's objection to providing any health care items or service for the purpose of causing or assisting in causing death, such as by assisted suicide, euthanasia, or mercy killing. 42 U.S.C. 18113. Section 1553 designates OCR to receive complaints of discrimination on that basis. *Id.*

Section 1303 declares that the ACA does not require health plans to provide coverage of abortion services as part of ''essential health benefits for any plan year.'' 42 U.S.C. 18023(b)(1)(A). Furthermore, no qualified health plan offered through an ACA exchange may discriminate against any individual health care provider or health care facility because of the facility or provider's unwillingness to provide, pay for, provide coverage of, or refer for abortions. 42 U.S.C. 18023(b)(4). And section 1303 of the ACA makes clear that nothing in that Act should be construed to undermine Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion. 42 U.S.C. 18023(c)(2)(A)(i)–(iii). Qualified health plans, as defined under 42 U.S.C. 18021, offered on any Exchange created under the ACA, are required to comply with § 88.3(f)(2)(i) and (ii), which faithfully applies the plain text of section 1303 of the ACA. 42 U.S.C. 18023.

Finally, under section 1411 of the ACA, 42 U.S.C. 18081, HHS is responsible for issuing certifications to individuals who are entitled to an exemption from the individual responsibility requirement imposed under Internal Revenue Code sec. 5000A, including when such individuals are exempt based on a hardship (such as the inability to secure affordable coverage without abortion),[4] are members of an exempt religious organization or division,[5] or participate in a ''health care sharing ministry.'' [6] *See also* 26 U.S.C. 5000A(d)(2). Under section 1311(d)(4)(H) of the ACA, 42 U.S.C. 18031(d)(4)(H), health benefit exchanges are responsible for issuing certificates of exemption consistent with the Secretary's determinations under section 1411 of the ACA.

Other Protections Related to the Performance of Advance Directives or Assisted Suicide. Before passage of section 1553 of the ACA, Congress had passed other conscience protections related to assisted suicide. Section 7 of the Assisted Suicide Funding Restriction Act of 1997 (Pub. L. 105–12, 111 Stat. 23) clarified that the Patient Self-Determination Act's provisions stating that Medicare and Medicaid beneficiaries have certain self-determination rights do not (1) require any provider, organization, or any employee of such provider or organization participating in the Medicare or Medicaid program to inform or counsel any individual about a right to any item or service furnished for the purpose of causing or assisting in causing the death of such individual, such as assisted suicide, euthanasia, or mercy killing; or (2) apply to or affect

[4] *See* Guidance on Hardship Exemptions from the Individual Shared Responsibility Provision for Persons Experiencing Limited Issuer Options or Other Circumstances, Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services (CMS), April 9, 2018. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2018-Hardship-Exemption-Guidance.pdf.* As discussed in the description of § 88.3(g) below, Congress reduced the penalty in 26 U.S.C. 5000A for a lack of minimum essential coverage to $0. SUPPORT for Patients and Communities Act, Public Law 115–271, section 4003, 26 U.S.C. 5000A(d)(2) (2018).

[5] Organizations that are religiously exempt include those with established tenets or teachings in opposition to acceptance of the benefits of any private or public insurance. 26 U.S.C. 1402(g)(1).

[6] A ''health care sharing ministry'' is an organization, described in section 501(c)(3) and taxed under section 501(a) of the Internal Revenue Code, comprising members who share a common set of ethical or religious beliefs and who share medical expenses among members in accordance with those beliefs without regard to the State in which a member resides or is employed. 26 U.S.C. 5000A(d)(2)(B).

any requirement with respect to a portion of an advance directive that directs the purposeful causing of, or assistance in causing, the death of an individual, such as by assisted suicide, euthanasia, or mercy killing. 42 U.S.C. 14406 (by cross-reference to 42 U.S.C. 1395cc(f) (Medicare) and 1396a(w) (Medicaid)); *see also* 42 U.S.C. 1395cc(f)(4) (by cross-reference to 42 U.S.C. 14406); 1396a(w)(3), 1396a(a)(57); 1396b(m)(1)(A); and 1396r(c)(2)(E).[7] Those protections extend to Medicaid and Medicare providers, such as hospitals, skilled nursing facilities, home health or personal care service providers, hospice programs, Medicaid managed care organizations, health maintenance organizations, Medicare+Choice (now Medicare Advantage) organizations, and prepaid organizations.

Protections Related to Counseling and Referrals Under Medicare Advantage Plans, Medicaid Plans, and Managed Care Organizations. Certain Federal protections prohibit organizations offering Medicare+Choice (now Medicare Advantage) plans and Medicaid managed care organizations from being compelled under certain circumstances to provide, reimburse for, or cover, any counseling or referral service in plans over an objection on moral or religious grounds. 42 U.S.C. 1395w–22(j)(3)(B) (Medicare+Choice); 42 U.S.C. 1396u–2(b)(3)(B) (Medicaid managed care organization). Department regulations provide that this conscience provision for managed care organizations also applies to prepaid inpatient health plans and prepaid ambulatory health plans under the Medicaid program. 42 CFR 438.102(a)(2).

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 also 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).

Exemptions from Compulsory Medical Screening, Examination, Diagnosis, or Treatment. This rule incorporates four statutory provisions that protect parents who, on the basis of conscience, object to their children being forced to receive certain treatments or health interventions. 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, 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). Fourth, 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).

Conscience Clauses Related to Religious Nonmedical Health Care. Since 1965, Congress has provided accommodations in Medicare and Medicaid for persons and institutions objecting to the acceptance or provision of medical care or services based on a belief in a religious method of healing through approval of religious nonmedical health care institutions (RNHCIs). RNHCIs do not provide standard medical screenings, examination, diagnosis, prognosis, treatment, or the administration of medications. 42 U.S.C. 1395x(ss)(1). Instead, RNHCIs furnish nonmedical items and services such as room and board, unmedicated wound dressings, and walkers,[8] and they provide care exclusively through nonmedical nursing personnel assisting with nutrition, comfort, support, moving, positioning, ambulation, and other activities of daily living.[9]

Congress has acknowledged RNHCIs through several statutes. For example, although such institutions would not otherwise meet the medical criteria for Medicare providers, *see* 42 U.S.C. 1395x(e) (definition of ''hospital''), 1395x(y)(1) (definition of ''skilled nursing facility''), 1395x(k), and 1320c–11 (exemptions from other medical criteria and standards), Congress expressly included them within the definition of designated Medicare providers. Congress prohibited States from excluding 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)). Finally, Congress permitted patients at RNHCIs to file an election with HHS stating that they are ''conscientiously opposed to acceptance of'' medical treatment, that is neither received involuntarily nor required under Federal or State law or the law of a political subdivision of a State, on the basis of ''sincere religious beliefs,'' yet remain eligible for the nonmedical care and services ordinarily covered under Medicare, Medicaid, and CHIP. *See, e.g.,* 42 U.S.C. 1395x(e), 1395x(y), and 1395i–5 (Medicare provisions). Federal courts have upheld the constitutionality of such religious accommodations. *See, e.g., Kong* v. *Scully,* 341 F.3d 1132 (9th Cir. 2003); *Children's Healthcare* v. *Min De Parle,* 212 F.3d 1084 (8th Cir. 2000).

[7] Similar protections exist under the Department's regulations applicable to hospitals, nursing facilities, and other medical facilities, *See, e.g.,* 42 CFR 489.102(c)(2); Medicare Advantage, 42 CFR 422.128(b)(2)(ii); and Medicare Health Maintenance Organizations and Comprehensive Medical Plans, 42 CFR 417.436 (such organizations, plans, and their agents are not required to implement advance directives if the provider cannot do so ''as a matter of conscience'' and State law allows such conscientious objection).

[8] *https://www.medicare.gov/coverage/rnhci-items-and-services.html.*

[9] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Certificationand Complianc/RNHCIs.html.*

Congress has also provided particular accommodations for persons and institutions that object to medical services and items. 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). 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).

B. Regulatory History

The Department engaged in rulemaking to enforce some of these Federal conscience and anti-discrimination laws on previous occasions: In the 2008 final rule at 45 CFR part 88 (the ''2008 Rule,'' 73 FR 78072, 78074 (Dec. 19, 2008)), in the revocation and replacement of that Rule in 2011 (the ''2011 Rule''), and in existing CMS regulations at 42 CFR parts 422 and 438, which implement 1395w–22(j)(3)(b) and 1396u–2(b)(3)(B), respectively.[10] This section of the preamble briefly summarizes the first two actions.

2008 Rule. The Department issued a notice of proposed rulemaking in 2008 to enforce, and clarify the applicability of, the Church, Coats-Snowe, and Weldon Amendments. 73 FR 50274 (Aug. 26, 2008) (August 2008 Proposed Rule). That proposed rule recognized (1) inconsistent awareness of Federal conscience and anti-discrimination protections among federally funded recipients and protected persons and entities; and (2) the need for greater enforcement mechanisms to ensure that Department funds do not support morally coercive or discriminatory policies or practices in violation of Federal law.

The Department received a ''large volume'' of comments on the August 2008 Proposed Rule. *See* 73 FR at 78074. Comments came 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 whether the rule was needed, what individuals would be protected by the proposed rule, what services would be covered by the proposed rule, whether health care workers would use the regulation to discriminate against patients, what significant implementation issues could be associated with the rule, what legal arguments could be made for and against the rule, and what cost impacts of the proposed rule could be anticipated. Many comments confirmed the need to promulgate a regulation to raise awareness of Federal conscience and anti-discrimination protections and provide for their enforcement.

The Department responded to those substantive comments and issued a final rule on December 19, 2008, codifying the rule at 45 CFR part 88 (''2008 Rule''), which consisted of six sections:

Section 88.1 stated that the purpose of the 2008 Rule was ''to provide for the implementation and enforcement'' of the Church, Coats-Snowe, and Weldon Amendments. It specified that those Amendments and the implementing regulations ''[we]re to be interpreted and implemented broadly to effectuate their protective purposes.''

Section 88.2 of the 2008 Rule defined several terms used in part 88 and applicable to various provider nondiscrimination protections, namely, the terms ''Assist in the Performance,'' ''Entity,'' ''Health Care Entity,'' ''Health Service Program,'' ''Individual,'' ''Instrument,'' ''Recipient,'' ''Sub-recipient,'' and ''Workforce.''

Section 88.3 of the 2008 Rule set forth the scope of applicability of the sections and paragraphs of part 88 as they related to each conscience law implemented in the 2008 Rule.

Section 88.4 of the 2008 Rule set forth the substantive requirements and applications of the Church, Coats-Snowe, and the Weldon Amendments.

Section 88.5 of the 2008 Rule required covered federally funded entities to provide written certification of compliance with the laws encompassed by the 2008 Rule.

Section 88.6 of the 2008 Rule designated HHS OCR to receive complaints based on the three specified Federal conscience and anti-discrimination laws, and directed OCR to coordinate handling those complaints with the Departmental components from which the covered entity receives funding.

Proposed Changes in 2009 Resulting in New Final Rule in 2011. On March 10, 2009, with the advent of a new Administration, the Department proposed to rescind, in its entirety, the 2008 Rule. 74 FR 10207 (Mar. 10, 2009) (2009 Proposed Rule). The Department declared that certain comments on the August 2008 Proposed Rule raised a number of questions warranting further review of the 2008 Rule to ensure its consistency with that Administration's policy. The Department invited further comments to reevaluate the necessity for regulations implementing the Federal conscience and anti-discrimination laws. In response to the proposal to rescind the 2008 Rule, for which the Department received supporting comments, the Department also received comments stating that health care workers should not be required to violate their religious beliefs or moral convictions; expressing concern that health care providers would be coerced into violating their consciences; and identifying the 2008 Rule as protecting First Amendment religious freedom rights, the capacity to uphold the tenets of the Hippocratic Oath, and the ethical integrity of the medical profession. Numerous commenters identified concerns that there would be no regulatory scheme to protect the legal rights afforded to health care providers, including medical students. 76 FR 9968, 9971 (Feb. 23, 2011) (2011 Rule).

On February 23, 2011, the Department rescinded most of the 2008 Rule and finalized a new rule. 76 FR 9968. The 2011 Rule left in place section ''88.1 Purpose,'' but removed the word ''implementation,'' describing the 2011 Rule's purpose as ''provid[ing] for the enforcement'' of the Church, Coats-Snowe, and Weldon Amendments. It then removed the 2008 Rule's sections 88.2 through 88.5, redesignated the 2008 Rule's § 88.6 as § 88.2, and modified that section to consist of two sentences, stating that OCR is designated to receive complaints based on the Federal health care provider conscience protection statutes, and will coordinate the handling of complaints with the Departmental funding component(s) from which the entity with respect to which a complaint has been filed, receives funding.

The preamble to the 2011 Rule stated, ''The Department supports clear and strong conscience protections for health care providers who are opposed to performing abortions.'' 76 FR at 9969. The Department recognized, ''The

[10] For instance, the prohibition against coercion in 42 U.S.C. 1395w–22(j)(3) (section 1852 of the Social Security Act) is regulated within the Medicare Program at 42 CFR 422.206(b), (d).

comments received suggested that there is a need to increase outreach efforts to make sure providers and grantees are aware of these statutory protections. It is also clear that the Department needs to have a defined process for health care providers to seek enforcement of these protections.'' 76 FR at 9969. Accordingly, the summary of the 2011 Rule stated that ''enforcement of the Federal statutory health care provider conscience protections will be handled by the Department's Office for Civil Rights, in conjunction with the Department's funding components.'' 76 FR at 9968. The Department announced that OCR was beginning to lead ''an initiative designed to increase the awareness of health care providers about the protections provided by the health care provider conscience statutes, and the resources available to providers who believe their rights have been violated.'' 76 FR at 9969. The 2011 Rule provided that OCR would ''collaborate with the funding components of the Department to determine how best to inform health care providers and grantees about health care conscience protections, and the new process for enforcing those protections.'' *Id.*

II. Overview of the Final Rule

A. Overview of Reasons for the Final Rule

After reviewing the previous rulemakings, comments from the public, and OCR's enforcement activities, the Department has concluded that there is a significant need to amend the 2011 Rule to ensure knowledge of, compliance with, and enforcement of, Federal conscience and anti-discrimination laws. The 2011 Rule created confusion over what is and is not required under Federal conscience and anti-discrimination laws and narrowed OCR's enforcement processes. Since November 2016, there has been a significant increase in complaints filed with OCR alleging violations of the laws that were the subject of the 2011 Rule, compared to the time period between the 2009 proposal to repeal the 2008 Rule and November 2016. The increase underscores the need for the Department to have the proper enforcement tools available to appropriately enforce all Federal conscience and anti-discrimination laws.[11]

Allegations and Evidence of Discrimination and Coercion Have Existed Since the 2008 Rule and Increased Over Time. The 2008 Rule sought to address an environment of discrimination toward, and attempted coercion of, those who object to certain health care procedures based on religious beliefs or moral convictions.[12] Yet in February 2009, the Department announced its intent to rescind the 2008 Rule just one month after its effective date.[13] It completed that rescission in 2011, despite significant evidence of an environment of discrimination and coercion, including thousands of public comments during the rulemakings that led to the 2008 and 2011 Rules describing that environment. For example, a 2009 article in the *New England Journal of Medicine* argued, ''Qualms about abortion, sterilization, and birth control? Do not practice women's health.'' [14] In a 2009 survey of 2,865 members of faith-based medical associations, 39% reported having faced pressure or discrimination from administrators or faculty based on their moral, ethical, or religious beliefs.[15] Additionally, 32% of the survey respondents reported having been pressured to refer a patient for a procedure to which they had moral, ethical, or religious objections. Some 20% of medical students in that poll said that they would not pursue a career in obstetrics or gynecology because of perceived discrimination and coercion in that specialty against their beliefs. In total, 91% of respondents reported that they ''would rather stop practicing medicine altogether than be forced to violate [their] conscience.''

Comments received during the rulemaking that led to the 2011 Rule were consistent with this survey. Multiple commenters reported that some hospitals had forced health care providers to sign affidavits agreeing to participate in abortions if asked.[16] One obstetrician/gynecologist commented that he had been pressured to participate in abortions and abortion counseling during his entire time in health care—from medical school, through his residency, and during private practice.[17] Medical and nursing students, in twenty-five comments, expressed their reluctance to enter the health care field as a whole, and particularly specialties such as obstetrics, family medicine, and elder care, where their objections to abortion or euthanasia might not be respected.[18] At least ninety commenters said that, if forced to choose between their careers or violating their conscience, they would quit their jobs.[19] Tens of

[11] Since 2011, conscience and coercion in health care have been the subjects of significant litigation at the State and local level. Recently, the Supreme Court held that the State of California likely violated the Free Speech rights of prolife pregnancy resource centers that do not provide information about where to obtain abortions by adopting a statute that required them, among other things, to post notices to which they objected. *See Nat'l Inst. of Family and Life Advocates* v. *Becerra,* 138 S. Ct. 2361 (Jun. 26, 2018).

[12] 73 FR at 78073.

[13] Rob Stein, ''Obama Plans to Roll Back 'Conscience' Rule Protecting Health Care Of Workers Who Object to Some Types of Care,'' The Washington Post (Feb. 28, 2009) *http://www.washingtonpost.com/wp-dyn/content/article/2009/02/27/AR2009022701104.html* (writing that ''The administration's plans, revealed quietly with a terse posting on a Federal website, unleashed a flood of heated reaction'').

[14] Julie D. Cantor, M.D., J.D., ''Conscientious Objection Gone Awry—Restoring Selfless Professionalism in Medicine,'' 360 New England J. Med. 1484–85 (April 9, 2009).

[15] The Polling Company, Inc./WomanTrend, Highlights of The Polling Company, Inc. Phone Survey of the American Public, fielded March 31, 2009 through April 3, 2009), *https://www.cmda.org/library/doclib/pollingsummaryhandout.pdf* (last visited Jan. 18, 2018); *see also* Public Comment from Jonathan Imbody, Christian Medical Association, (''CMA Comment''), available at *https://www.regulations.gov/document?D=HHS-OCR-2018-0002-64461.*

[16] Comment Nos. HHS–OPHS–2009–0001–0739, –52648, –52677.

[17] Comment No. HHS–OPHS–2009–0001–0868.

[18] Comment Nos. HHS–OPHS–2009–0001–0026, –1035, –10522, –12117, –14427, –34439, –11404 (''future physician'' concerned about shortages), –35236 (granddaughter entering the medical profession will change career path), –11579 (son entering the medical profession), –14435 (concerned mother of medical student), –18783 (spoke to student who is distraught and may leave), –5571, –41431 (sister is a medical student), –5638, –0068, –1791 (student would quit job), –2750 (exacerbates healthcare issues), –5255 (opposed and has used exemption), –7058, –7276, –7671, –5270 (has already seen others leave the profession over pressure for their beliefs), –5638, –5566 (nurse who chose not to specialize in obstetrics and gynecology for fear of pressure), –5566 (nurse who chose not to enter obstetrics and gynecology because of pressure to perform abortions).

[19] Almost 90 comments are cited here, but this is merely a sample of the total. *See* Comment Nos. HHS–OPHS–2009–0001–0540, –0017, –0264, –0350, –0356, –0485, –0540, –0880, –0881, –0902, –0917, –0932, –10154, –15148, –20381 (woman in California whose daughter is a nurse), –23290 (already left the profession), –32951, –9188, –47007 (patient's doctor said he would retire), –14287, –19128, –9873, –29603 (physician stating many will retire), –50498 (patient's doctor said he would retire), –27384, –44458, –18837, –14216, –18015, –18015, –34140 (already retired but would have retired earlier), –32593, –15341, –14837, –8582, –16541, –11579 (patient's doctor said he would retire), –0229, –51896 (children would be forced to leave), –32009 (other physicians will be driven out), –10280 (physician with objections), –19029, –33116, –50663, –3675, –24456, –11327, –19221, –34888 (nurse saying others will leave), –14535 (daughter will leave the profession), –21679 (four members in the family who may leave), –0283, –0340, –0905, –9272, –0055 (will give up serving underserved population), –10862 (two sisters who are nurses will leave, hospital shut down), –17401, –29674 (son who is a physician will be forced out), –26795 (physician who says doctors will be forced out), –25742, –49731, –15087, –13138, –17563, –0006 (refuse to accept violation of beliefs in practice), –0815, –7665, –8091, –2598 (private family physician who intentionally avoided obstetrics because it was made clear that ''pro-life candidates need not apply''; also cites strong pressure in universities and organizations in favor of abortion provision, and is concerned physicians

Continued

thousands of comments to the 2009 proposed rule expressed concern that, without robust enforcement of Federal conscience and anti-discrimination laws, individuals with conscientious objections simply would not enter the health care field, or would leave the profession, and hospitals would shut down, contributing to the shortage of health care providers or affecting the quality of care provided.[20] Thousands also feared personnel with objections would be terminated or otherwise unable to find employment, training, or opportunities to advance in their fields.[21]

Commenters also identified a culture of hostility to conscience concerns in health care.[22] Some expressed concern that the rescission of the 2008 Rule would contribute to these problems by inappropriately politicizing, and interfering in, the practice of medicine and individual providers' judgment.[23] Thousands of comments from medical personnel stated their disagreement with the rescission, often stating that they had requested exemptions in the past and were concerned rescission would make it harder to request exemptions in the future.[24] Hundreds of commenters expressed concern over the exclusion and marginalization of health care entities and employees holding religious beliefs or moral convictions, and fears that the moral agency of the medical profession was eroding.[25]

According to news reports, in 2010, Nassau University Medical Center disciplined eight nurses when they raised objections to assisting in the performance of abortions.[26] Nurses in Illinois and New York filed lawsuits against private hospitals alleging they had been coerced to participate in abortions. *Mendoza* v. *Martell,* No. 2016–6–160 (Ill. 17th Jud. Cir. June 8, 2016); *Cenzon-DeCarlo* v. *Mount Sinai Hosp.,* 626 F.3d 695 (2d Cir. 2010). A nurse-midwife in Florida alleged she had been denied the ability to apply for a position at a federally qualified health center due to her objections to prescribing hormonal contraceptives. *Hellwege* v. *Tampa Family Health Ctrs.,* 103 F. Supp. 3d 1303 (M.D. Fla. 2015). Twelve nurses in New Jersey sued a public hospital over a policy allegedly requiring them to assist in abortions and for disciplining one nurse who raised a conscientious objection to the same. Complaint, *Danquah* v. *University of Medicine and Dentistry of New Jersey,* No. 2:11–cv–6377 (D.N.J. Oct. 31, 2011). Many religious health care personnel and faith-based medical entities have further alleged that health care personnel are being targeted for their religious beliefs.[27]

In 2016, the American Congress of Obstetricians and Gynecologists (ACOG) reaffirmed a prior ethics opinion that recommended, ''Physicians and other health care professionals have the duty to refer patients in a timely manner to other providers if they do not feel that they can in conscience provide the standard reproductive services that their patients request,'' and ''In resource-poor areas . . . [p]roviders with moral or religious objections should either practice in proximity to individuals who do not share their views or ensure that referral processes are in place so that patients have access to the service that the physician does not wish to provide.'' [28]

Public comments received on the proposed rule published in January 2018 shared additional anecdotes of coercion, discriminatory conduct, or other actions potentially in violation of Federal conscience and anti-discrimination laws. Commenters also shared their assessments of the knowledge, or lack thereof, among the general public, health care field, health care insurance industry, and employment law field of the rights and obligations that this rule implements and enforces. Examples are detailed in the Regulatory Impact Analysis as part of the Department's analysis under Executive Orders 12,866 and 13,563 regarding the need for this rule.

Recently Enacted State and Local Government Health Care Laws and Policies Have Resulted in Numerous Lawsuits by Conscientious Objectors. The Department has also witnessed an increase in lawsuits against State and local laws that plaintiffs allege violate conscience or unlawfully discriminate. For example, many State and local governments have enacted legislation requiring health care providers offering pregnancy resources as an alternative to abortion to post notices related to abortion, to which plaintiffs objected on First Amendment and analogous grounds. The Supreme Court held that California's version of such a law likely violated the First Amendment free speech rights of centers that object to abortion in *National Institute of Family and Life Advocates* v. *Becerra,* No. 16–1140, 585 U.S. ___, 138 S. Ct. 2361 (Jun. 26, 2018) (''*NIFLA*'').[29]

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will leave the practice more), –3564, –0199, –5230 (discrimination already present), –6603, –1397 (nurse who has been forced to do things against her conscience in the past before the 2008 Rule came into effect, and who will quit if put in that scenario again), –1100 (nurse who says others will leave the practice), –6669, –0272, –0925, –0125, –4668, –6709, –7900, –2544, –3535, –1852, –7684, –1381.

[20] Comment Nos. HHS–OPHS–2009–0001–20613, –43039, –27699, –42804, –6001, –10850, –27147, –50621, –52878, –19586, –40775, –4824, 27384, –11138, –52997, –53001, –4460, –12878, –12575, –43364, –27262, –42942, –26426, –38158, –43672, –52381, –32173, –16541, –19751, –2697, –52935, –6369, –44571, –53022, –48387, –21990, –50837, –42069, –14662, –51974, –45449, –17364, –5370, –2922, –15005, –18783, –23376, –50685, –17401, –52946, –11206, –33828, –38997, –3925, –21036, –50894, –27155, –10529, –47113, –7266, –22291, –4016, –0204, –8788, –25608, –52932, –39199, –12340, –52950 (form letter with 1,916 copies), –31897, –52984 (form letter with 62 copies), –53081 (form letter with 22 copies), –52968 (form letter with 9,532 copies), –52961 (patients concerned about access to pro-life doctors: Form letter with 3,272 copies), –53098 (patients concerned effort to push people out: Form letter with 976 copies), –52977 (form letter with 3,516 copies), –53021 (form letter with 4,842 copies), –52949 (form letter with 688 copies), –53039 (form letter with 742 copies), –0476.

[21] Comment Nos. HHS–OPHS–2009–0001–0558, –10144, –53026 (claims documentation of unaddressed discrimination), –52985 (claims documentation of unaddressed discrimination), –52960 (claims documentation of unaddressed discrimination), –52735 (lack of knowledge about rights), –53048 (evidence of discrimination), –53047 (evidence of discrimination: Form letter with 3,196 copies), –52960 (evidence of discrimination: Form letter with 1,685 copies), –53028 (evidence of discrimination: Form letter with 2,002 copies).

[22] Comment Nos. HHS–OPHS–2009–0001–0739, –52677, –26812, –53013 (form letter with 8,472 copies).

[23] Comment No. HHS–OPHS–2009–0001–10280, –2486, –46903, –19125, –36940, –12020, –41551.

[24] Comment Nos. HHS–OPHS–2009–0001–3107, –15617, –19496, –27506, –9586, –35721, –49748, –1650, –19965, –18365, –23095, –6332, –3405, –1762, –4395, –4569, –6890, –0729, –0943, –1490, –2994, –3248, –3419, –5341, –6479, –7079, –4525, –7093, –2486, –2039, –7750, –6270, –1903, –3293, –3405, –1127, –5505, –1823, –4939, –5881, –4529, –5829, –1773, –2220, –2345, –3089, –7163, –7471, –3840, –0389, –1933, –3493, –3088, –5088, –5702.

[25] Comment Nos. HHS–OPHS–2009–0001–52974 (form letter with 428 copies).

[26] *LI Hospital issues abortion apology to nurses,* N.Y. Post (Apr. 28, 2010), *http://nypost.com/2010/04/28/li-hospital-issues-abortion-apology-to-nurses.*

[27] *See, e.g., Roman Catholic Diocese of Albany* v. *Vullo,* No. 02070–16 (N.Y. Albany County S. Ct. May 4, 2016); *Means* v. *U.S. Conference of Catholic Bishops,* No. 1:15–CV–353, 2015 WL 3970046 (W.D. Mich. 2015); *ACLU* v. *Trinity Health Corporation,* 178 F. Supp. 3d 614 (E.D. Mich. 2016); *Minton* v. *Dignity Health,* No. 17–558259 (Calif. Super. Ct. Apr. 19, 2017); *Chamorro* v. *Dignity Health,* No. 15–549626 (Calif. Super. Ct. Dec. 28, 2015). *See also* U.S. Conference of Catholic Bishops, Ethical and Religious Directives for Catholic Health Services (Nov. 17, 2009) (identifying Catholic objections to performing abortions, tubal ligations, and hysterectomies).

[28] *https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/The-Limits-of-Conscientious-Refusal-in-Reproductive-Medicine* (reaffirming ACOG, ''The Limits of Conscientious Refusal in Medicine,'' Committee Opinion No. 385, 110 Obstet Gyn. 1479 (2007)) The 2007 ACOG opinion had, at least in part, prompted the 2008 Rule. Then-HHS Secretary Leavitt wrote to ACOG and the American Board of Obstetrics and Gynecology (ABOG) and noted that the interaction between the ACOG opinion and ABOG certification requirements could constitute a violation of Federal conscience and anti-discrimination laws.

[29] On January 18, 2019, OCR issued a Notice of Violation to the State of California for OCR Complaint Nos. 16–224756 and 18–292848, finding that California's version of such a law violated the

Courts have also enjoined similar ordinances in New York City; Austin, Texas; Montgomery County, Maryland; Baltimore, Maryland; Illinois; and Hawaii. *Greater Baltimore Center for Pregnancy Concerns, Inc.* v. *Mayor and City Council of Baltimore,* 879 F.3d 101, 105 (4th Cir. 2018), *cert. denied,* 138 S. Ct. 2710, (2018) (holding that Baltimore ordinance requiring pregnancy resource center to State abortion services are not available in their facilities violated the Free Speech Clause); *Evergreen Ass'n, Inc.* v. *City of New York,* 740 F.3d 233 (2d Cir. 2014) (affirming an injunction, based on the First Amendment, of ordinance provisions requiring disclosures about whether pregnancy resource centers refer for abortion and conveying city health department's recommendation to consult a licensed medical provider); *Austin LifeCare* v. *City of Austin,* No. 1:11–cv–00875–LY (W.D. Tex. Jun. 23, 2014) (permanently enjoining enforcement of ordinance as void for vagueness); *Centro Tepeyac* v. *Montgomery County,* 5 F. Supp. 3d 745 (D. Md. Mar. 7, 2014) (applying strict scrutiny in finding that ordinance violated pregnancy resource center's First Amendment rights); *Pregnancy Care Center of Rockford* v. *Rauner,* No. 2016–MR–741 (Ill. 17th Jud. Cir. Dec. 20, 2016) (preliminary injunction entered on free speech grounds); *Prelim. Inj., Nat'l Instit. of Family and Life Advocates* v. *Rauner,* No. 3:16–cv–50310 (N.D. Ill. Sept. 29, 2016) (preliminary injunction entered on free speech grounds); *Calvary Chapel Pearl Harbor* v. *Chin,* No. 1:17–cv–00326–DKW–KSC (D. Haw. Sept. 20, 2018) (permanent injunction and final judgment).

Before *NIFLA,* several courts had rejected challenges to California's law. *See, e.g., Mountain Right to Life* v. *Harris,* No. 5:16–cv–00119 (C.D. Cal. July 8, 2016) (denying preliminary injunction); *A Woman's Friend Pregnancy Resource Clinic* v. *Harris,* 153 F. Supp. 3d 1168 (E.D. Cal. Dec. 21, 2015); *Livingwell Medical Clinic* v. *Harris,* No. 3:15–cv–04939, 2015 WL 13187682 (N.D. Cal. Dec. 18, 2015).

Some of the plaintiffs in these lawsuits also filed complaints with OCR alleging that the State laws violate the Weldon, Coats-Snowe, and/or Church Amendments. Complaints filed with OCR against the State of California, alleging California's Reproductive Freedom, Accountability, Comprehensive Care, and Transparency Act (FACT Act) (Cal. Health & Safety Code Ann. sections 123470, *et seq.*) violated Federal conscience and anti-discrimination laws, were recently resolved with a finding by OCR that the State of California violated the Weldon and Coats-Snowe Amendments.[30] OCR determined that ''California's enactment of the FACT Act violate[d] the Weldon and Coats-Snowe Amendments by discriminating against health care entities that object to referring for, or making arrangements for, abortion.'' [31]

Complaints filed with OCR against the State of Hawaii, alleging Hawaii Revised Statute section 321–561(b)–(c) violated Federal conscience and anti-discrimination laws, were recently satisfactorily resolved when Hawaii Attorney General Clare E. Connors issued a Memorandum to the Department of the Attorney General for the State of Hawaii stating, ''the Department will not enforce section 321–561(b)–(c), HRS, against any limited service pregnancy centers, as defined in section 321–561(a), HRS;'' the memorandum also stated that it ''shall remain in effect indefinitely or until such time as there is a change in the laws discussed above warranting reconsideration.'' [32] In her letter to OCR regarding the Memorandum, Attorney General Connors also said that ''the Department will advise the Hawai'i Legislature of its decision not to enforce section 321–561(b)–(c), HRS, against any limited service pregnancy center.'' [33] Attorney General Connors took appropriate corrective action in Hawaii to assure current and future compliance with the Weldon and Coats-Snowe Amendments, as they apply to Hawaii Revised Statute section 321–561(b)–(c), and the complaints regarding this provision were resolved without having to find Hawaii in violation of Federal conscience and anti-discrimination laws.[34]

Some States have also sought to require health insurance plans to cover abortions, triggering additional conscience-related lawsuits. California, for example, sent a letter to seven insurance companies seeking to enforce a California legal requirement that the insurers include abortion coverage in plans used by persons who objected to such coverage. *See* Letter from California Department of Managed Health Care, *Re: Limitations or Exclusions of Abortion Services* (Aug. 22, 2014) (interpreting State statutes, regulations, and court decisions).[35] The State of California estimates that at least 28,000 individuals subsequently lost their abortion-free health plans, and houses of worship have challenged California's policy in court. *See Foothill Church* v. *Rouillard,* 2:15–cv–02165–KJM–EFB, 2016 WL 3688422 (E.D. Cal. July 11, 2016); *Skyline Wesleyan Church* v. *California Department of Managed Health Care,* No. 3:16–cv–00501–H–DHB (S.D. Cal. 2016). The New York State Department of Financial Services has similarly sought to require individual and small group employers, regardless of the number of employees or any religious affiliation, to provide insurance coverage for abortions, prompting additional lawsuits. *See, e.g., Roman Catholic Diocese of Albany* v. *Vullo,* No. 02070–16 (N.Y. Albany County Sup. Ct. May 4, 2016).

Over the past several years, an increasing number of jurisdictions in the United States have legalized assisted suicide. *See* District of Columbia B21–0038 (Feb. 18, 2017), Colorado Prop. 106 (Dec. 16, 2016); California ABX2–15 (June 9, 2016); 18 Vermont Act 39 (May 20, 2013) (''Act 39''). In Vermont, for example, Act 39 states that health care professionals must inform patients ''of all available options related to terminal care.'' 18 Vt. Stat. Ann. section 5282. When the Vermont Department of Health construed Act 39 to require all health care professionals to counsel for assisted suicide, individual health care professionals and associations of religious health care providers sued Vermont, alleging a violation of their conscience rights. Compl., *Vermont Alliance for Ethical Health Care, Inc.* v. *Hoser,* No. 5:16–cv–205 (D. Vt. Apr. 5, 2017) (dismissed by consent agreement). More recently still, the family of a California cancer patient sued UCSF Medical Center for alleged elder abuse because the cancer patient died after the oncologists on staff declined to participate in assisted suicide, but before she could obtain a new physician.[36]

Weldon and Coats-Snowe Amendments, as discussed *infra.*

[30] Letter from Roger T. Severino, Dir., Dep't of Health & Human Serv's. Office for Civil Rights, to Xavier Becerra, Att'y. Gen., State of Cal. (Jan. 18, 2019), *available at https://www.hhs.gov/sites/default/files/california-notice-of-violation.pdf.*

[31] *Id. at* 9.

[32] Memorandum from Haw. Att'y. Gen. Clare E. Connors to the Dep't. of the Att'y. Gen., State of Haw. 2 (Mar. 15, 2019) (on file with HHS OCR).

[33] Letter from Haw. Att'y. Gen. Clare E. Connors, to Luis E. Perez, Deputy Dir. of the Conscience & Religious Freedom Div., Office for Civil Rights, U.S. Dep't of Health & Human Servs. (Mar. 15, 2019) (on file with HHS OCR).

[34] Letter from Roger T. Severino, Dir., Dep't of Health & Human Serv's. Office for Civil Rights, to Clare E. Connors, Att'y. Gen., State of Haw. (Mar. 21, 2019), *available at https://www.hhs.gov/sites/default/files/hawaii-ocr-notice-of-resolution-final.pdf.*

[35] *https://www.dmhc.ca.gov/Portals/0/082214letters/abc082214.pdf.*

[36] Bob Egelko, *California's assisted-dying loophole: Some doctors won't help patients die,* San

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Finally, some States have passed laws appearing to require health care professionals to provide referrals for implementation of advance directives without accommodation for religious belief or moral conviction. *See* Iowa Code Ann. section 144D.3(5) (2012) (requiring that providers take ''all reasonable steps to transfer the patient to another health care provider, hospital, or health care facility'' even when there is an objection based on ''religious beliefs, or moral convictions''); Idaho Code Ann. 39–4513(2) (2012) (requiring that a provider ''make[ ] a good faith effort to assist the person in obtaining the services of another physician or other health care provider who is willing to provide care for the person in accordance with the person's expressed or documented wishes'').

Since the Department issued the proposed Conscience Rule in 2018, OCR issued a Notice of Violation to the State of California for OCR Complaint Nos. 16–224756 and 18–292848, finding that California's FACT Act violated the Weldon and Coats-Snowe Amendments, as discussed *supra.* Beyond this finding, in this final rule, the Department does not opine on or judge the legal merits or sufficiency of any of the above-cited lawsuits or challenged laws. They are discussed here to illustrate a notable number of disputes about alleged violations of health care conscience, broadly understood, by State and local governments. They also illustrate the need for greater clarity concerning the scope and operation of the Federal conscience and anti-discrimination laws that are the subject of this final rule. The Department anticipates that this final rule will result in greater public familiarity with Federal conscience and anti-discrimination laws, and may inform both State and local governments and health care institutions of their obligations, and individual and institutional health care entities of their rights, under those laws.

Confusion Exists About the Scope and Applicability of Federal Conscience and Anti-Discrimination Laws. Even though Federal conscience and anti-discrimination laws are currently in effect, the public has sometimes been confused about their applicability in relation to other Federal, State, or local laws. One of the purposes of the 2008 Rule was to address confusion about the interaction between Federal conscience and anti-discrimination laws and other Federal statutes.

For instance, some advocacy organizations have filed lawsuits claiming that Federal or State laws require private religious entities to perform abortions and sterilizations despite the existence of longstanding conscience and anti-discrimination protections on this topic. S*ee Means* v. *U.S. Conference of Catholic Bishops,* No. 1:15–CV–353, 2015 WL 3970046 (W.D. Mich. 2015) (abortion); *ACLU* v. *Trinity Health Corp.,* 178 F.Supp.3d 614 (E.D. Mich. 2016) (abortion); *Minton* v. *Dignity Health,* No. 17–558259 (Cal. Super. Ct. Apr. 19, 2017) (hysterectomy); *Chamorro* v. *Dignity Health,* No. 15–549626 (Cal. Super. Ct. Dec. 28, 2015) (tubal ligation). A patient also sued a secular public hospital for accommodating doctors' and nurses' religious objections to abortion in alleged violation of a State law, Washington's Reproductive Privacy Act. *Coffey* v. *Pub. Hosp. Dist. No. 1,* 20–15–2–00217–4 (Wash. 2015).

Congress has exercised the broad authority afforded to it under the Spending Clause to attach conditions on Federal funds to protect conscience rights. Such conditions override conflicting provisions of State law for States that accept the conditioned funds according to the terms of the statutes applicable to such funding streams. States have long been able to harmonize and comply with other ''cross-cutting'' anti-discrimination laws imposed through such conditions on Federal financial assistance. *See, e.g.,* Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d *et seq.,* and Title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et seq.* The Department seeks to clarify the scope and application of Federal conscience and anti-discrimination laws in this final rule as it has with other anti-discrimination laws. *See* 45 CFR part 80 (Title VI) and part 86 (Title IX).

Courts Have Found No Alternative Private Right of Action to Remedy Violations. The government, rather than private parties, has the central role in enforcement of Federal conscience and anti-discrimination laws. In lawsuits filed by health care providers for alleged violations of certain of these laws, courts have generally held that such laws do not contain, or imply, a private right of action to seek relief from such violations by non-governmental covered entities. Thus, adequate governmental enforcement mechanisms are critical to the enforcement of these laws.

The case of a New York nurse who alleged that a private hospital forced her to assist in an abortion over her religious objections illustrates the point. The nurse filed a lawsuit in Federal court in 2009, but her case was dismissed on the ground that she did not have a private right to file a civil action against such a hospital under the Church Amendments. *Cenzon-DeCarlo* v. *Mount Sinai Hospital,* 626 F.3d 695 (2d Cir. 2010). The Second Circuit affirmed the dismissal, holding that the Church Amendments ''may be a statute in which Congress conferred an individual right,'' but that Congress *had not implied a remedy* to file suit against private entities in Federal court. *Id.* at 698–99. After the dismissal of the Federal lawsuit, the nurse then filed a case in State court, but that case too was dismissed for lack of a private right of action. *Cenzon-DeCarlo* v. *Mount Sinai Hosp.,* 962 N.Y.S.2d 845 (Sup. Ct. Kings County 2010), *aff'd by* 957 N.Y.S.2d 256 (App. Div. 2012). The nurse then filed a complaint with OCR on January 1, 2011, and OCR resolved the complaint after the hospital changed its written policy for health care professionals.

Similar results occurred in a Federal lawsuit brought by a nurse in 2014, alleging that a health center had violated the Church Amendments when it denied her the ability to apply for a position as a nurse because she objected to prescribing abortifacients. *Hellwege* v. *Tampa Family Health Centers,* 103 F. Supp. 3d 1303 (M.D. Fla. 2015). Like the court in New York, the court held that the Church Amendments ''recognize important individual rights'' but do not confer a remedy to bring suit against a private entity in Federal court. *Id.* at 1310. More recently, a Federal district court in Illinois held that there is no private right of action for a doctor who alleges that the State required her to refer for abortions in violation of the Coats-Snowe Amendment. Order at 4, *Nat'l Instit. of Family and Life Advocates,* v. *Rauner,* No. 3:16–cv–50310 (N.D. Ill. July 19, 2017), ECF No. 65.

In light of these decisions and the increase in conscience-based challenges to State and local laws in the health care context, OCR has a singular and critical responsibility to provide clear and appropriate interpretation of Federal conscience and anti-discrimination laws, to engage in outreach to protected parties and covered entities, to conduct compliance reviews, to investigate alleged violations, and to vigorously enforce those laws.

Addressing Confusion Caused by OCR Sub-Regulatory Guidance. This final rule also resolves confusion caused by sub-regulatory guidance issued through OCR's high-profile closure of three Weldon Amendment complaints against

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Francisco Chronicle (Aug. 12, 2017), *http://www.sfchronicle.com/news/article/California-s-assisted-dying-loophole-Some-11761312.php.*

the State of California filed in 2014.[37] On June 21, 2016, OCR declared it found no violation stemming from California's policy requiring that health insurance plans include coverage for abortion based on the facts alleged in the three complaints it had received.[38] OCR's closure letter concluded that the Weldon Amendment's protection of health insurance plans included issuers of health insurance plans but not institutions or individuals who purchase or are insured by those plans. Even though California's policy resulted in complainants losing abortion-free insurance that was consistent with their beliefs and that insurers were willing to provide, the letter concluded that none qualified as an entity or person protected under the Weldon Amendment because none was an insurance issuer. Relying on an interpretation of legislative history, instead of the Weldon Amendment's text, OCR also declared that health care entities are not protected under Weldon unless they possess a ''religious or moral objection to abortion,'' and concluded that the insurance issuers at issue did not merit protection because they had not raised any religious or moral objections. Finally, OCR called into question its ability to enforce the Weldon Amendment against a State *at all* because, according to the letter, to do so could ''potentially'' require the revocation of Federal funds to California in such a magnitude as to violate State sovereignty and constitute a violation of the Constitution.[39]

The Department does not opine upon, and has not yet made a judgment on, the compatibility of California's policy with the Weldon Amendment. But clarification is in order with respect to the general interpretations of the Weldon Amendment offered in OCR's closure of complaints against California's abortion coverage requirement. The Department has engaged in further consideration of this general matter and has also further reviewed Federal conscience and anti-discrimination laws, their legislative history, and the record of rulemaking and public comments. Based on this review, the Department indicated, in the preamble to the proposed rule, that the above-mentioned sub-regulatory guidance issued by OCR with respect to interpretation of the Weldon Amendment no longer reflects the Department's position on, and interpretation of, the Weldon Amendment. The Department continues to hold the views it expressed on that issue in the preamble to the proposed rule, *see* 83 FR at 3890–91, and has reflected those views in its analysis contained in the Notice of Violation to the State of California for OCR Complaint Nos. 16–224756 and 18–292848, discussed *supra,* in which OCR discussed the rationale behind its determination that ''California's enactment of the FACT Act violate[d] the Weldon . . . Amendment[ ] by discriminating against health care entities that object to referring for, or making arrangements for, abortion.'' [40]

The Department is concerned that segments of the public have been dissuaded from complaining about religious discrimination in the health care setting to OCR as the result, at least in part, of these unduly narrow interpretations of the Weldon Amendment. For example, Foothill Church, located in Glen Morrow, California, expressed concern that filing a complaint with OCR about California's abortion-coverage requirement was pointless because the Department had already closed three similar complaints, finding no violation of Federal conscience and anti-discrimination laws. *See Foothill Church* v. *Rouillard,* No. 2:15–cv–02165–KJM–EFB, 2016 WL 3688422 (E.D. Cal. July 11, 2016).

With this final rule, the Department seeks to educate protected entities and covered entities as to their legal rights and obligations; to encourage individuals and organizations with religious beliefs or moral convictions to enter, or remain in, the health care industry; and to prevent others from being dissuaded from filing complaints due to prior OCR complaint resolutions or sub-regulatory guidance that no longer reflect the views of the Department.

Additional Federal Conscience and Anti-Discrimination Laws. Finally, in addition to all of the concerns discussed above, the Department is using this rulemaking to address various other conscience protection and anti-discrimination laws not discussed in the 2008 and 2011 Rules. Some of these provisions were enacted after 2008. All provide additional protections, such as for health care providers and patients, from coercion and discrimination including that stemming from moral convictions or religious beliefs.

B. Structure of the Final Rule

This final rule generally reinstates the structure of the 2008 Rule, includes further definitions of terms, and provides robust certification and enforcement provisions comparable to provisions found in OCR's other civil rights regulations.This final rule also encourages certain recipients of Federal financial assistance from the Department or of Federal funds from the Department to notify individuals and entities protected under Federal conscience and anti-discrimination laws (such as employees, applicants, or students) of their Federal conscience rights. In addition, this final rule requires certain such entities to assure and certify to the Department their compliance with the requirements of these laws. It also sets forth in more detail the investigative and enforcement responsibility of OCR, along with the tools at OCR's disposal for carrying out its responsibility with respect to these laws.

Congress has imposed obligations on the Department and funding recipients through these statutes, and the Department is, therefore, required to ensure its own compliance and the compliance of its funding recipients. In 2008 and 2011, the Secretary delegated to OCR the authority to receive complaints of discrimination under the Church, Coats-Snowe, and Weldon Amendments, in coordination with Department components that provide Federal financial assistance. Congress later designated OCR as responsible for receiving complaints under section 1553 of the ACA. Many of the remaining statutes that are the subject of the proposed rule do not have any implementing regulations. To the extent not already delegated to OCR, the Secretary is, therefore, delegating to OCR enforcement authority—that is, the authority to receive complaints, and, in consultation and coordination with the funding components of the Department, investigate alleged violations and take appropriate enforcement action—over those additional Federal statutes as well as the statutes covered by the 2008 and 2011 Rules.

The compliance and enforcement sections specify in much greater detail than either the 2008 Rule or 2011 Rule how OCR will, in consultation and coordination with HHS funding components, enforce the Federal conscience and anti-discrimination laws. Implementation of the requirements set forth in this final rule

[37] OCR Complaint Nos. 14–193604, 15–193782, and 15–195665.

[38] Letter from OCR Director to Complainants (June 21, 2016) *available at http://www.adfmedia.org/files/CDMHCInvestigationClosureLetter.pdf.*

[39] In reaching this conclusion, the letter cited advice from ''HHS' Office of General Counsel, after consulting with the Department of Justice,'' but HHS has not located any written legal analysis from either the HHS Office of the General Counsel or the Department of Justice despite a diligent search.

[40] Letter from Roger T. Severino, Dir., Dep't of Health & Human Serv's. Office for Civil Rights, to Xavier Becerra, Att'y. Gen., State of Cal., *at 9* (Jan. 18, 2019), *available at https://www.hhs.gov/sites/default/files/california-notice-of-violation.pdf.*

will be conducted in the same way that OCR implements other civil rights requirements (such as the prohibition of discrimination on the basis of race, color, or national origin), which includes outreach, investigation, compliance, technical assistance, and enforcement practices. Enforcement will be based on complaints, referrals, and other information OCR may receive about potential violations, such as news reports and OCR-initiated compliance reviews and communications activities if facts suffice to support an investigation. If OCR becomes aware of a potential violation of Federal conscience and anti-discrimination laws, OCR will investigate, in coordination with the Department component providing Federal financial assistance or Federal funds to the investigated entity. If OCR concludes an entity is not in compliance, OCR, in consultation and coordination with the Department funding component(s), will assist covered entities with corrective action or compliance, or require violators to come into compliance. If, despite the Department's assistance, corrective action is not satisfactory or compliance is not achieved, OCR, in coordination with the funding component, may consider all legal options available to the Department, to overcome the effects of such discrimination or violations. Enforcement mechanisms where voluntary resolution cannot be reached include termination of relevant funding, either in whole or in part, funding claw backs to the extent permitted by law, voluntary resolution agreements, referral to the Department of Justice (in consultation and coordination with the Department's Office of the General Counsel), or other measures, as set forth in applicable regulations, procedures, and funding instruments. This final rule clarifies that recipients are responsible for their own compliance with Federal conscience and anti-discrimination laws and implementing regulations, as well as for ensuring their sub-recipients comply with these laws. This final rule also clarifies that parties subject to OCR investigation have a duty to cooperate and preserve documents and to report to their Department funding component(s) if they are subject to a determination by OCR of noncompliance. Finally, this final rule specifies that OCR may remedy claims of intimidation and retaliation against those who file a complaint or assist in an OCR investigation.

III. Analysis and Response to Public Comments on the Proposed Rule

HHS received over 242,000 comments in response to the notice of proposed rulemaking (NPRM).[41] HHS considered all comments filed in accordance with the Administrative Procedure Act and the instructions provided in the NPRM published in the **Federal Register** on January 26, 2018.

The Department's evaluation of the comments led to a number of changes between the NPRM and this final rule. The public comments and the changes made in issuing this final rule are discussed below.

A. General Comments

The Department received many comments on the proposed rule that expressed general support or opposition and did not include substantive or technical commentary upon the rule.

Comment: The Department received comments expressing concern about the impact of the rule on access to care in rural communities, underprivileged communities, or other communities that are primarily served by religious healthcare providers or facilities.

Response: Access to care is a critical concern of the Department. The Department does not believe this rule will harm access to care. When the Department promulgated the 2008 Rule protecting conscience rights in health care, it addressed comments about the rule's impact on access to care.[42] In that response, the Department stated that the regulation did not expand the scope of existing Federal conscience and anti-discrimination laws, and noted that implementation and enforcement of such laws would help alleviate the country's shortage of health care providers.[43] The Department also observed that it was contradictory to argue, as many commenters did, both that the rule would decrease access to care and that the then-current conscience protections for providers were sufficient: If the Department's new rule would decrease access to care because of an increase in providers' exercise of conscientious objections, it would seem that the statutory protections that existed before the regulation did not result in providers fully exercising their consciences as protected by law.[44]

The Department agrees with its previous response. The Federal conscience and anti-discrimination laws pre-exist these regulations. They provide rights and protections to health care providers, including in rural communities, underprivileged communities, or other communities that are primarily served by religious healthcare providers or facilities (together, ''underserved communities'').

There appears to be no empirical data, however, on how previous legislative or regulatory actions to protect conscience rights have affected access to care or health outcomes. Studies have specifically found that there is insufficient evidence to conclude that conscience protections have negative effects on access to care.[45] The Department is not aware of data in its possession, in the public comments, or in the public domain that provides a way to estimate how many health care providers either in general or in underserved communities are—and are not—exercising their conscience rights and protections, even though they are encompassed by Federal conscience and anti-discrimination laws, nor is the Department aware of data to determine how many providers, among those, would exercise their conscience rights and protections once this rule is finalized, and because it is finalized.

Because enforcement of the rule will remove barriers to entry into the health care professions, it is reasonable to assume that the rule may, in fact, induce more people and entities to enter or remain in the health care field. On a broad level, this effect is reasonably likely to increase, not decrease, access to care, including—and perhaps especially—in underserved communities. The Department is not aware of data, including from public commenters, that would provide a useful basis for a quantitative estimate of how many more providers would enter the health care field, or serve

[41] The comments are available at *https://www.regulations.gov/docket?D=HHS-OCR-2018-0002.* While *Regulations.gov* shows 72,417 public submissions were received, many comment submissions attached hundreds or thousands of individual comments, resulting in over 242,000 actual comments.

[42] 73 FR at 78080–81 (Dec. 19, 2008).

[43] 73 FR at 78081.

[44] *Id.*

[45] *See* Chavkin et al., ''Conscientious objection and refusal to provide reproductive healthcare: A White Paper examining prevalence, health consequences, and policy responses,'' 123 Int'l J. Gynecol. & Obstet. 3 (2013), S41–S56 (''[I]t is difficult to disentangle the impact of conscientious objection when it is one of many barriers to reproductive healthcare. . . . [C]onscientious objection to reproductive health care has yet to be rigorously studied.''); K. Morrell & W. Chavkin, ''Conscientious objection to abortion and reproductive healthcare: A review of recent literature and implications for adolescents,'' 27 Curr. Opin. Obstet. Gynecol. 5 (2015), 333–38 (''[T]he degree to which conscientious objection has compromised sexual and reproductive healthcare for adolescents is unknown.'').

underserved communities, as a result of this rule, nor what the corresponding increase of access to care might be. However, no public commenter provided any data that undermines the reasoning that leads the Department to believe that the rule will have such an effect. And several factors support the Department's position.

First, predictions that the rule will reduce services in underserved communities may be based on incorrect assumptions. As the Department has made clear, the rule does not expand the substantive protections of Federal conscience and anti-discrimination laws. Thus, to the extent commenters believe the rule would reduce services in underserved communities, that would seem to be based on an assumption that there are health care providers in underserved communities who are protected by these laws but are offering services to which they object anyway (for example, abortions or abortion referrals) because the laws are inadequately enforced. That is not necessarily a correct assumption. Such health care providers might be responding to a threat to their conscientious practice, not by offering the services despite their objections, but by leaving the health care field or a particular practice area involving that service. One poll suggests that over 80% of religious health care providers in underserved communities would likely limit their scope of practice if they were required to participate in practices and procedures to which they have moral, ethical, or religious objections, rather than provide the services.[46] If that is correct, improving enforcement of Federal conscience and anti-discrimination laws might reduce infringement of conscience protections, not by reducing the availability of services such as abortion, but by increasing the availability of other services by encouraging providers not to self-limit their practices in underserved communities.

Second, and relatedly, the rule might result in an increase in the number of providers overall, or in certain specialties within the health care field. Individuals and entities may have chosen not to enter the health care field because they anticipated they would be pressured to violate their consciences. In some cases, that decision may be the result of discrimination occurring during medical training, such as medical students' experiences of discrimination on the basis of their religious beliefs or moral convictions,[47] or by pressures faced by institutions because of their religious identity or moral convictions. Reducing that discrimination and pressure may lead to more individual and institutional health care providers overall, which could help increase, rather than decrease, services for underserved communities. Another way this effect may manifest itself is if the average facility has access to more highly qualified candidates because there is a larger pool of medical professionals from which to choose. Having more providers overall, so that the field as a whole provides a wide and diverse range of services, is preferable to having fewer providers, particularly with respect to underserved areas.

Third, the rule may prevent some health care providers from leaving the field. A certain proportion of decisions by currently practicing health providers to leave the profession may be motivated by such pressure.[48] With the rule's added emphasis on enforcing protections for rights of conscience, fewer individuals may leave the profession, and in turn they may help meet unmet needs for care. In addition, in some instances where a provider objects, based on conscience, to providing a service, there may be some underserved communities where other providers who have no such objections are available to provide the service. By contrast, without enforcement of Federal conscience and anti-discrimination laws, some providers with religious beliefs or moral convictions could close their doors (rather than violate their consciences), leaving a community even more underserved than if the provider were in practice.

The rule might allow an increase in the provision of health care by religious institutions as well, not just individuals. Religious hospitals or clinics, for example, if they are assured greater enforcement of their rights to practice medicine consistent with their religious beliefs, may find it worthwhile to expand to serve more people, including in underserved communities. Some commenters contend this could lead religious hospitals to move into underserved communities and crowd out other providers who might not have objections to certain services. The Department is not, however, aware of data demonstrating that the expansion of health care services by religious providers, particularly in underserved communities, would crowd out other providers who perform services that they do not, and market forces ordinarily would not dictate that result. Again, the Department is not aware of data demonstrating the dire results predicted by some commenters.

In addition, the relationship between religious or other conscientiously objecting providers and underserved communities may be far more complex than assumed by the prediction that this rule will decrease services. There are reasons to believe that many persons who might make use of protections under Federal conscience and anti-discrimination laws are already more likely to be located in certain underserved areas, and that their patients are similarly likely to share their views on issues such as abortion. According to the Pew Research Center, for example, ''urban dwellers are far more likely than their rural counterparts to say abortion should be legal in all or most cases.'' [49] This suggests that the enforcement of Federal conscience and anti-discrimination laws is not likely to be the cause of religious and other objecting providers being located in rural communities, but that such providers are already in those communities, and Congress passed these laws to protect them, among other individuals and entities, from being driven out of practice, which could exacerbate the lack of access to health care overall in those communities.

There is also reason to believe that religious institutions and individuals are disposed to serve in underserved communities because of elements of their religious mission besides objections protected by Federal conscience and anti-discrimination laws. For example, various commenters

[46] The CMA comment cited poll data from 2009 and 2011, which found that 82% of medical professionals ''said it was either 'very' or 'somewhat' likely that they personally would limit the scope of their practice of medicine if conscience rules were not in place. This was true of 81% of medical professionals who practice in rural areas and 86% who work full-time serving poor and medically-underserved populations . . . 91% agreed, 'I would rather stop practicing medicine altogether than be forced to violate my conscience.' ''

[47] The CMA comment cited a poll finding that twenty percent of responding faith-based medical students chose not to pursue a career in obstetrics/gynecology because of perceived coercion and discrimination in that field.

[48] The Christian Medical Association and Freedom2Care poll of May 3, 2011, found that 82% of medical professionals ''said it was either 'very' or 'somewhat' likely that they personally would limit the scope of their practice of medicine if conscience rules were not in place. This was true of 81% of medical professionals who practice in rural areas and 86% who work full-time serving poor and medically-underserved populations . . . 91% agreed, 'I would rather stop practicing medicine altogether than be forced to violate my conscience.' ''

[49] Pew Research Center, ''What Unites and Divides Urban, Suburban, and Ruran Communities'' (May 22, 2018), available at *https://www.pewsocialtrends.org/2018/05/22/what-unites-and-divides-urban-suburban-and-rural-communities/*.

contend the reason why Catholic hospitals are overrepresented in serving certain underserved populations is because the hospitals are motivated by their Catholic beliefs to serve unserved, underserved, underprivileged, or minority communities, and these commenters argue that Catholic hospitals (and, by extension, other religious providers) provide an overall benefit to underserved communities.[50] This overall benefit is consistent with Congress's apparent intent, in the Federal conscience and anti-discrimination laws, to ensure that the health care system remains open to the vibrant participation of religious and other providers, without barriers that can be created by discrimination against them, or infringements of their conscientious beliefs. Any loss of such providers because of the lack of enforcement of Federal conscience and anti-discrimination laws could decrease access to care for underserved communities. Therefore, when other commenters contend that women of color would be disproportionately harmed by this rule due to the significant services provided by Catholic hospitals, they do not seem to account for the fact that, without those hospitals' overall ability to exercise their religious mission, they would not be providing health care services to those communities in the first place.

The Department also disagrees with the assumption that the rule's enforcement of Federal conscience and anti-discrimination laws will result in harm, or in more harm than the benefits that derive from implementing Federal laws. As explained in the Regulatory Impact Analysis, *infra* at part IV.C.3.vii, the Department expects the rule to enhance, not impede, access to care in areas with fewer providers, such as rural communities. The Department is not aware of data establishing the views of commenters who say the rule will reduce services in underserved communities, or of data establishing quantitatively how much the rule will increase and enhance access to health care services in underserved communities. The Department concludes, instead, that it is reasonable to agree with commenters who believe the rule will not decrease access to care, and may increase it.

The Department finds that finalizing the rule is appropriate without regard to whether data exists on the competing contentions about its effect on access to services. Most significantly, finalizing the rule is appropriate because it enforces Federal conscience and anti-discrimination laws, which represent Congress's considered judgment that these rights are worth protecting even if they impact overall or individual access to a particular service, such as abortion. But finalizing the rule is also appropriate because the Department's belief that the rule will enhance access to care is based on reasonable, informed assumptions unrebutted by public comments submitted in opposition to the rule. Ultimately, the Department believes that this rule will result in more health care provider options and, thus, better health care for all Americans. The Department thus believes that it is appropriate to finalize this rule to enforce Federal conscience and anti-discrimination laws, even though the Department and commenters do not have data capable of quantifying all of its effects on the availability of care.

Comment: The Department received comments stating that protecting health care professionals' moral and religious convictions places health care providers above patients.

Response: The Department disagrees. First, this final rule provides for the enforcement of protections established by the people's representatives in Congress; the Department has no authority to override Congress's balancing of the protections. Second, protecting health care providers' rights of conscience ensures that health care providers with deeply held religious beliefs or moral convictions are not driven out of the health care industry—and, therefore, made unavailable to serve any patients and provide any health care services—because of their refusal to participate in certain objected-to activities, such as abortion, sterilization, or assisted suicide. Third, the Department believes the provider-patient relationship is best served by open communication of conscience issues surrounding the provision of health care services, including any conscientious objections providers or patients may have to providing, assisting, participating in, or receiving certain services or procedures. By protecting a diversity of beliefs among health care providers, these protections ensure that options are available to patients who desire, and would feel most comfortable with, a provider whose religious beliefs or moral convictions match their own. Even where a patient and provider do not share the same religious beliefs or moral convictions, it is not necessarily the case that patients would want providers to be forced to violate their religious beliefs or moral convictions.

Comment: The Department received comments expressing concern that the proposed rule would expand Federal conscience and anti-discrimination statutes to cover areas beyond the scope of the statutes. Several commenters raised concerns about expanding protection to HIV treatment, pre-exposure prophylaxis, and infertility treatment.

Response: The Department drafted the proposed rule to track the scope of each statute's covered activities as Congress drafted them, without being unduly broad or unduly narrow. For example, where the scope of laws that are the subject of this regulation is limited to certain enumerated procedures, the final rule makes clear that OCR will only pursue enforcement under those laws with respect to those enumerated procedures.

The Department is unaware of any cases claiming denial of service regarding these procedures brought under any of the statutes implemented by this rule. Public comments received by the Department did not cite such cases. In the event that the Department receives a complaint with respect to HIV treatment, pre-exposure prophylaxis, or infertility treatment, the Department would examine the facts and circumstances of the complaint to determine whether it falls within the scope of the statute in question and these regulations.

Discussion of this rule's potential application with regard to gender dysphoria is located in the section-by-section analysis regarding comments on the Church Amendments, *infra* at part III.B.

Comment: The Department received many comments expressing confusion or concern as to how the proposed rule would interact with or be in conflict with other Federal laws, such as the

[50] Ascension, REF: Docket HHS–OCR–2018–0002, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (Mar. 27, 2018) (''As the largest non-profit health system in the U.S. and the world's largest Catholic health system, Ascension is committed to delivering compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable. In FY2017, Ascension provided more than $1.8 billion in care of persons living in poverty and other community benefit programs.''); Catholic Health Association, REF: RIN 0945–ZA 03 Protecting Statutory Conscience Rights in Health Care; Delegations of Authority: Proposed Rule, 83 FR 3880, January 26, 2018 (Mar. 27, 2018) (''As a Catholic health ministry, our mission and our ethical standards in health care are rooted in and inseparable from the Catholic Church's teachings about the dignity of each and every human person, created in the image of God. Access to health care is essential to promote and protect the inherent and inalienable worth and dignity of every individual. These values form the basis for our steadfast commitment to the compelling moral implications of our heath care ministry and have driven CHA's long history of insisting on and working for the right of everyone to affordable, accessible health care.'').

Emergency Medical Treatment and Active Labor Act (EMTALA) and Federal anti-discrimination statutes (such as section 1557 of the ACA).

Response: This final rule provides the Department with the means to enforce Federal conscience and anti-discrimination laws in accordance with their terms and to the extent permitted under the laws of the United States and the Constitution. This final rule, like the 2008 Rule and the 2011 Rule, does not go into detail as to how its provisions may or may not interact with other statutes or in all scenarios, but OCR intends to read every law passed by Congress in harmony to the fullest extent possible so that there is maximum compliance with the terms of each law. With respect to EMTALA, the Department generally agrees with its explanation in the preamble to the 2008 Rule [51] that the requirement under EMTALA that certain hospitals treat and stabilize patients who present in an emergency does not conflict with Federal conscience and anti-discrimination laws. The Department intends to give all laws their fullest possible effect.

Comment: The Department received comments stating that the Department should withhold Federal financial assistance from any State that does not provide for religious exemptions to vaccination.

Response: This rule is only intended to provide enforcement mechanisms for the Federal conscience and anti-discrimination laws that Congress has enacted. The creation of a new substantive conscience protection is outside of the scope of this rulemaking. With respect to vaccination in particular, this rule provides for enforcement of 42 U.S.C. 1396s(c)(2)(B)(ii), which requires providers of pediatric vaccines funded by Federal medical assistance programs to comply with any State laws relating to any religious or other exemptions. Under the statute's plain text, this protection applies only to the extent a State already provides (or, in the future, chooses to provide) such an accommodation, and does not require a State to adopt such an accommodation.

Comment: The Department received comments stating that the proposed rule's enforcement mechanisms will not meaningfully further conscience protection because existing laws protecting religious beliefs or moral convictions are sufficient.

Response: The Department disagrees, and believes that the rule would make a meaningful difference in terms of compliance, as compared to the status quo. This rule provides appropriate enforcement mechanisms in response to a significant increase in complaints alleging violations of Federal conscience and anti-discrimination laws. Each law that is the subject of this rule meaningfully differs from the next. Moreover, the Department believes some laws have never been enforced, not necessarily because of widespread compliance with other overlapping laws, but because the Department has devoted no meaningful attention to those laws, has not conducted outreach to the public on them, and has not adopted regulations with enforcement procedures for them.

Comment: The Department received a comment requesting that the Department clarify that health care providers may establish systems to help meet patients' health care needs when a provider holds a religious belief or moral conviction that may affect the service or procedure that a patient is seeking.

Response: Nothing in the rule prohibits an entity from providing a lawful service it wants to provide, even as it respects the rights of personnel who may be protected by Federal laws from being required to provide, or assist in, the service. As discussed later in this preamble, the rule provides incentives for (but does not mandate) notices that parallel notice provisions under other anti-discrimination regulations. The Department believes that the provider-patient relationship is best served by open communication of conscience issues surrounding the provision of health care services, so that the consciences of patients, providers, and employees are respected whenever possible or required. Nothing in the rule precludes such communication or systems that encourage such communication. For example, providers may include notices in patient intake materials notifying patients that a provider's service provision is governed by certain ethical or religious principles. Providers may also encourage communication of moral or religious views by patients with respect to treatment in order to respect patients' wishes to the extent it is mutually acceptable or required. The Department declines to mandate any particular timeline or form in which a provider or patient must raise these sensitive issues. The Department encourages providers, if they are working with, or employing, health care professionals who may have religious or moral objections, especially with regard to certain procedures or treatments, to openly discuss these issues and have processes in place to identify and respect a diversity of views, further the provision of health care, and comply with the law. The final rule's modifications to the definition of ''discrimination'' permit employers of such personnel to accommodate the professionals' religious or moral objections, without interfering in the employer's delivery of health services.

Comment: The Department received comments questioning whether the Department has authority to issue regulations implementing some or all of the Federal conscience and anti-discrimination laws encompassed by this rule.

Response: The Federal conscience and anti-discrimination laws encompassed by this part, including the Church Amendments, section 245 of the Public Health Service Act, and the Weldon Amendment, require, among other things, that the Department and recipients of Department funds refrain from discriminating against institutional and individual health care entities that do not participate in certain medical procedures or services, including certain health services or research activities funded in whole or in part by the Federal government.

Compliance by the Department. Inherent in Congress's adoption of the statutes that require compliance by the Department, by departmental programs, and by recipients of Federal funds from the Department is the authority of the Department to take measures to ensure its own compliance. As explained more fully below, compliance reviews, complaint investigation, and record-keeping are standard measures for ensuring compliance with conditions Congress has imposed upon the Department and on recipients of Federal funds, including statutory nondiscrimination requirements. Moreover, 5 U.S.C. 301 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.''

Compliance through funding instruments and agreements. In large part, the rule's enforcement mechanisms concerning entities that receive funds from the Department involve placing terms and conditions that implement Federal law in contracts, grants, and other Federal funding instruments and agreements. HHS has the authority to impose terms and conditions in its grants, contracts, and other funding instruments, to ensure recipients comply with applicable law, including

[51] 73 FR at 78087–88.

the aforementioned Federal conscience and anti-discrimination laws. The Department, furthermore, will enforce such terms and conditions requiring compliance with such conscience and anti-discrimination law in accordance with existing statutes, regulations and policies that govern such instruments, such as the Federal Acquisition Regulation; the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (HHS UAR), 45 CFR part 75; regulations applicable to CMS programs; the associated regulations relating to suspension and debarment; as well as any other regulations or procedures that govern the Department's ability to impose and enforce terms and conditions on funding recipients to comply with Federal requirements.

Grants and cooperative agreements. With respect to grants and cooperative agreements, the HHS UAR, 45 CFR part 75, requires adherence by award recipients to all applicable Federal statutes and regulations. For example, section 75.300(a) requires that the Department administer Federal awards to ensure that Federal funding and associated programs ''are implemented in full accordance with U.S. statutory and public policy requirements: Including, but not limited to, those protecting public welfare, the environment, and prohibiting discrimination.'' The regulation also requires the Department to communicate to non-Federal entities all policy requirements and include them in the conditions of the award. 45 CFR 75.300(a).

Furthermore, section 75.371 sets forth remedies for non-compliance where the award recipient ''fails to comply with Federal statutes, regulations, or the terms and conditions of the Federal award.'' These remedies include disallowance, withholding, suspension, and termination of funding. 45 CFR 75.371. The HHS UAR also contains provisions relating to recordkeeping (45 CFR 75.503) and program specific audits (45 CFR 75.507), which the Department may invoke when enforcing grant terms and conditions that operate to implement the Federal conscience and anti-discrimination laws. In addition, Federal grant recipients must also sign OMB-approved assurances which certify compliance with all Federal statutes relating to non-discrimination and all applicable requirements of all other Federal laws governing the program.

In sum, the Department's enforcement of the Federal conscience and anti-discrimination laws for grantees will be conducted through the normal grant compliance mechanisms applicable to grants or other funding instruments, with OCR coordinating its investigation and compliance activities with the funding component. If the Department becomes aware that a State or local government or a health care entity may have undertaken activities that may violate any statutory conscience protection, the Department will work to assist such government or entity to comply with, or come into compliance with, such requirements or prohibitions. If, despite the Department's assistance, compliance is not achieved, the Department will consider all legal options as may be provided under 45 CFR parts 75 (HHS UAR) and 96 (regulations addressing HHS block grant programs), as applicable.

Contracts. With respect to Federal contracts and contractors, the Federal Property and Administrative Services Act of 1949 (''FPASA'') authorizes the promulgation of the Federal Acquisition Regulation (''FAR''). 40 U.S.C. 121(c). The FAR, in turn, authorizes agency heads to ''issue or authorize the issuance of agency acquisition regulations that implement or supplement the FAR and incorporate, together with the FAR, agency policies, procedures, contract clauses, solicitation provisions, and forms that govern the contracting process or otherwise control the relationship between the agency, including any of its suborganizations, and contractors or prospective contractors.'' 48 CFR 1.301–(a)(1). In addition, Federal agencies are required to prepare their solicitations and resulting contracts utilizing a uniform contract format, which permits agencies to include a clear statement of any ''special contract requirements'' that are not included in its standard government contract clauses or in other sections of the uniform contract format. 48 CFR 15.204–2–(h). Finally, pursuant to the FAR and other legal authorities, the Department has established the Department of Health and Human Services Acquisition Regulation (''HHSAR'') [48 CFR parts 300 through 370], which establishes uniform departmental acquisition policies and procedures that implement and supplement the FAR. The HHSAR contains departmental policies that govern the acquisition process or otherwise control acquisition relationships between the Department's contracting activities and contractors. The HHSAR contains (1) requirements of law; (2) HHS-wide policies; (3) deviations from FAR requirements; and (4) policies that have a significant effect beyond the internal procedures of the Department or a significant cost or administrative impact on contractors or offerors. *See* 48 CFR 301.101(b); *see also* 48 CFR 301.103(b) (''The Assistant Secretary for Financial Resources (ASFR) prescribes the HHSAR under the authority of 5 U.S.C. 301 and section 205(c) of the Federal Property and Administrative Services Act of 1949, as amended (40 U.S.C. 121(c)(2)), as delegated by the Secretary[ ].''). As a result, the Department has ample authority to include terms and conditions in its contracts consistent with the Federal conscience and anti-discrimination laws. Furthermore, the Federal Acquisition Regulation provides a variety of mechanisms that may be used to enforce such contract provisions (*e.g.,* 48 CFR part 49 ''Termination of Contracts''). Thus, the Department intends to implement and enforce contract terms on the Federal conscience and anti-discrimination laws through the FAR and HHSAR and other Federal laws and regulations that govern the administration and performance of Federal contracts.

Other rulemaking authorities. Under the ACA section 1321(a), 42 U.S.C. 18041, the Department has the authority to promulgate regulations implementing the ACA conscience provisions. Section 1321(a) provides authority to the Secretary to issue regulations setting standards for meeting the requirements under Title I of the ACA, and the amendments made by Title I, with respect to the establishment and operation of Exchanges (including SHOP Exchanges), the offering of qualified health plans through such Exchanges, the establishment of the reinsurance and risk adjustment programs under part V, and such other requirements as the Secretary determines appropriate. This provision authorizes the Secretary to promulgate regulations setting standards for regulated entities to meet the conscience protection requirements in ACA sections 1303(b)(1)(A) & (b)(4), 1411, and 1553, 42 U.S.C. 18023(b)(1)(A) & (b)(4), 18081, 18113, all of which are located in Title I of the ACA.

With respect to the Medicare, Medicaid, and Children's Health Insurance Program (CHIP), section 1102 of the Social Security Act, 42 U.S.C. 1302, authorizes the Secretary to ''make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which [he] is charged under this Act.'' This provides the Secretary with authority to promulgate regulations that provide for compliance by participants in the Medicare, Medicaid, and CHIP programs, including Medicare

providers, State Medicaid and CHIP programs, etc., with applicable Federal conscience and anti-discrimination laws.

Furthermore, with respect to funding instruments administered by the Centers for Medicare & Medicaid Services (CMS), including instruments or agreements authorized by the Social Security Act and ACA, the Secretary has the authority under section 1115(a)(2) of the Social Security Act to authorize Federal matching funds in expenditures by State Medicaid agencies that would not otherwise be eligible for Federal matching in order to carry out a demonstration project that promotes the objectives of the Medicaid or CHIP programs. Under section 1115A of the Social Security Act, Federal funds are available to test innovative payment and service delivery models expected to reduce costs to Medicare, Medicaid, or CHIP, while preserving or enhancing the quality of care furnished to the beneficiaries of these programs. The Secretary has the authority to include terms and conditions addressing Federal conscience and anti-discrimination laws in certain funding instruments or agreements under these authorities. The Secretary also has the authority to impose terms and conditions in certain grant instruments under some of its grant authorities, such as the grants available to States for ACA implementation under section 2794(c)(2)(B) of the Public Health Service Act. In addition, the Secretary has the authority to include such requirements, through rulemaking, with respect to State Medicaid programs generally, Medicaid managed care organizations (section 1902(a)(4) of the Social Security Act), Medicare Advantage organizations (section 1856(b)(1) of the Social Security Act) and Medicare Part D sponsors (section 1857(e)(1) of the Social Security Act), other types of Medicare providers and suppliers of items and services,[52] and Qualified Health Plans offering individual market coverage on State exchanges.

To the extent that terms and conditions relating to Federal conscience and anti-discrimination laws are incorporated into CMS's instruments or agreements, CMS would have the authority to enforce such terms pursuant to the relevant enforcement mechanism for each instrument or agreement. For example, with respect to a special term and condition under a section 1115 demonstration, the demonstration could be terminated for a failure to comply with a term and condition. With respect to section 1115A, it would depend on the legal instrument used. For cooperative agreements, the enforcement mechanism would be Federal grants law. For addenda to existing contracts, the enforcement mechanism would be Federal procurement law. For participation agreements and regulations—through which CMMI operates most of its section 1115A models—CMS could enforce these requirements under the terms of the agreement or regulation itself (which allow CMS to take certain corrective actions, up to and including termination of a non-compliant participant from the model) and, under certain circumstances, under general CMS regulations (*e.g.,* regarding recoupments). In the case of a CMS grant program, it would depend on the terms included in the grant award, but grant funds could be subject to forfeiture in some instances. Medicaid requirements imposed through rulemaking would be enforced through a compliance action under section 1902(a)(4) of the Social Security Act. For Medicare Advantage or Part C contracts, there are intermediate sanctions, civil money penalties, and potential contract termination for violations of contract requirements. In the case of Medicare providers and suppliers, enforcement could involve loss of a provider agreement or certification.

Debarment and suspension. Finally, the Department notes that it has the authority, where appropriate, to initiate debarment or suspension proceedings against entities that are otherwise eligible to receive Federal funding pursuant to grants and cooperative agreements, contracts and other funding instruments. *See, e.g.,* 48 CFR part 9.4; 2 CFR part 376. Entities that are debarred, suspended, or proposed for debarment are also excluded from conducting business with the Government and, thus, are generally not eligible to receive Federal funds during the duration of the suspension or debarment. The Department notes that, under the FAR, an entity may be debarred for the ''[c]ommission of any other offense indicating a lack of business integrity or business honesty that seriously and directly affects the present responsibility of a Government contractor or subcontractor.'' 48 CFR 9.406–2(a)(5). In addition, a contractor may be debarred for a ''[w]illful failure to perform in accordance with the terms of one or more contracts.'' 48 CFR 9.406–2(b). Thus, the Department will consider whether suspension or debarment may be appropriate when enforcing terms and conditions implementing the Federal conscience and anti-discrimination laws.

Receipt and processing of complaints. With regard to the receipt and processing of complaints of violations of the Federal conscience and anti-discrimination laws, it is well settled in case law that every agency has the inherent authority to issue interpretive rules and rules of agency practice and procedure. 1 Richard J. Pierce, Jr., *Administrative Law Treatise* § 6.4 (4th ed. 2002). This rule does not substantively alter or amend the obligations of the respective statutes, *JEM Broad.* v. *FCC,* 22 F.3d 320 (D.C. Cir. 1994), and the definitions offered in this rule are reasonably drawn from the existing statutes. *Hoctor* v. *Dept. of Agriculture,* 82 F.3d 165 (7th Cir. 1996). As a result, the Department and OCR have authority to issue interpretations regarding the Federal conscience and anti-discrimination laws, many of

[52] Through delegation from the Secretary, CMS has statutory authority to place conditions on participation in its programs under the following authorities:

1. Skilled nursing facilities (SNFs)—section 1819(d)(4)(B) of the Act [42 U.S.C. 1395i–3(d)(4)(B)].

2. Medicaid nursing facilities (NFs)—section 1919(d)(4)(B) of the Act [42 U.S.C. 1396r(d)(4)(B)].

3. Hospitals—section 1861(e)(9) of the Act [42 U.S.C. 1395x(e)(9)].

4. Psychiatric hospitals—section 1861(f)(2) of the Act [42 U.S.C. 1395x(f)(2)], cross referencing 1861(e)(9).

5. Long term care hospitals—section 1861(ccc)(3) of the Act [42 U.S.C. 1395x(ccc)(3)], cross referencing section 1861(e).

6. Home health agencies (HHAs)—section 1861(o)(6) of the Act [42 U.S.C. 1395x(o)(6)].

7. Rehabilitation agencies and Clinics as providers of physical, occupational therapy and speech language pathology services—section 1861(p)(4)(A)(v) of the Act and 1861(p)(4) *flush language* [42 U.S.C. 1395x(p)(4)].

8. Comprehensive outpatient rehabilitation facilities (CORFs)—section 1861(cc)(2)(J) of the Act [42 U.S.C. 1395x(cc)(2)(J)].

9. Hospice—section 1861(dd)(2)(G) of the Act [42 U.S.C. 1395x(dd)(2)(G)].

10. Community mental health centers (CMHCs)—section 1861(ff)(3)(B)(iv) of the Act [42 U.S.C. 1395x(ff)(3)(B)(iv)].

11. Religious nonmedical health care institution (RNHCIs)—section 1861(ss)(1)(J) of the Act [42 U.S.C. 1395x(ss)(1)(J)].

12. Portable x-ray suppliers—1861(s)(3) of the Act [42 U.S.C. 1395x(s)(3)]

13. Independent clinical laboratories—section 353(f)(1)(E) of the Public Health Act [42 U.S.C. 263a(f)(1)(E)] (authorizing the Secretary to make additional regulations ''necessary to assure consistent performance by such laboratories of accurate and reliable laboratory examinations and procedures'').

14. Rural health clinics (RHCs)—section 1861(aa)(2)(K) of the Act [42 U.S.C. 1395x(aa)(2)(K)].

15. Intermediate care facilities for individuals with intellectual disabilities (ICF/IIDs)—section 1861(e)(9) of the Act [42 U.S.C. 1395x(e)(9)].

which have been placed in the Department's program statutes.

Comment: The Department received a comment requesting that long-term care and post-acute providers be exempted from the rule because such entities are already heavily regulated.

Response: The Department declines to provide this exemption. The rule provides for appropriate enforcement of statutes protecting foundational civil rights, and Congress did not exempt long-term care or post-acute providers from these civil rights laws.

B. Section-by-Section Analysis [53]

Purpose (§ 88.1)

In the NPRM, the Department's ''Purpose'' section set forth the objective that the proposed regulation would, when finalized, provide for the implementation and enforcement of Federal conscience and anti-discrimination laws. It also stated that the statutory provisions and regulations contained in this part are to be interpreted and implemented broadly to effectuate their protective purposes. The Department did not receive comments on this section beyond the general comments addressed above. Section 88.1 of the final rule reflects technical edits to replace the word ''persons'' with ''individuals,'' for clarity, and to refer to the set of statutes encompassed by this rule collectively as the ''Federal conscience and anti-discrimination laws, which are listed in § 88.3 of this part.'' Throughout the final rule, the Department has made changes to refer to those statutes as ''Federal conscience and anti-discrimination laws,'' rather than ''Federal conscience protection and associated anti-discrimination laws.''

Summary of Regulatory Changes: The Department believes, as discussed above, that there are various reasons why this rule is needed and appropriate to provide for the implementation and enforcement of Federal conscience and anti-discrimination laws. In addition, the Department believes it is appropriate to interpret the rules broadly, within the scope of the text set forth in each statute, to effectuate their protective purposes. Generally, it is appropriate to broadly interpret laws enacted to protect civil rights and prevent discrimination. For the reasons described in the proposed rule [54] and above, and considering the comments received, the Department finalizes this section as proposed, but with technical edits to replace the word ''persons'' with ''individuals,'' add the term ''certain'' in regard to health care services, remove the term ''for example'' and ''comprehensively'' in relation to the degree of the protections, for clarity, and to refer to the statutes part 88 addresses as ''Federal conscience and anti-discrimination laws, which are listed in § 88.3 of this part.''

Definitions (§ 88.2)

In the NPRM, the Department proposed definitions of various terms. The comments and the responses applicable to each definition are set forth below.

Administered by the Secretary. The Department proposed that a federally funded program or activity is ''administered by the Secretary'' when it is ''subject to the responsibility of the Secretary of the U.S. Department of Health and Human Services, as established via statute or regulation.'' The Department did not receive comments specifically on this definition.

In proposing the definition for ''administered by the Secretary,'' the Department noted that the 2008 Rule had not defined the phrase, and that the proposed definition was intended to add clarity. Upon further review and in consideration of general comments received concerning whether the proposed rules are sufficiently clear, the Department has concluded that the proposed definition does not add substantial clarity to the plain meaning of the phrase ''administered by the Secretary.'' No commenters submitted comments on this question, which suggests that there is no confusion about the meaning of this phrase. The Department is finalizing this rule without adopting the proposed definition, or any definition, of ''administered by the Secretary.'' In the event that the Department is asked to consider the meaning of this phrase in its application of the rule, the Department will apply the standard canons of statutory construction.

Summary of Regulatory Changes: For the reasons described above, the Department finalizes the rule without a definition of the phrase ''administered by the Secretary.''

Assist in the Performance. The Department proposed that ''assist in the performance'' means ''to participate in any program or activity with an articulable connection to a procedure, health service, health program, or research activity, so long as the individual involved is a part of the workforce of a Department-funded entity.'' The definition specified that ''[t]his includes but is not limited to counseling, referral, training, and other arrangements for the procedure, health service, health program, or research activity.'' The Department received comments on this definition, including comments generally supportive of the proposed definition and generally opposed to it. Because comments evidenced significant confusion over the proposed definition, the Department amends the definition, as described further below.

Comment: The Department received comments suggesting that the definition of ''assist in the performance'' is unnecessary because employees maintain the option to seek employment elsewhere.

Response: The Department disagrees. Congress established requirements, including the protections interpreted by this final rule, for recipients of certain Federal financial assistance or participants in certain Federal programs. Those obligations are not obviated merely because an employee who desires to make use of the protections that Congress provided could, instead, find employment elsewhere. Indeed, forcing a person to find employment elsewhere (which includes as a result of being fired), because they make certain protected objections to procedures, or because of their religious beliefs or moral convictions, is a quintessential example of the discrimination and coercion that these laws prohibit. The existence of numerous comments employing this line of reasoning provides additional evidence of the need for this final rule, so that the Department may better educate both recipients and the public on the law, and may ensure vigorous enforcement where education proves insufficient to achieve compliance.

Comment: The Department received comments stating that the proposed ''articulable connection'' standard is too broad and would permit objections by persons whom certain commenters contend have only a tangential connection to the objected-to procedure or health service program or research activity. Some commenters included examples such as a person preparing a room for an abortion or scheduling an abortion.

Response: The Department believes that the proffered examples are properly considered as within the scope of the protections enacted by Congress for those who choose to assist and those who choose not to assist in the performance of an abortion. Scheduling an abortion or preparing a room and the instruments for an abortion are necessary parts of the process of providing an abortion, and it is

[53] Unless indicated otherwise, the Department adopts the regulation text as proposed.

[54] 83 FR 3880, 3892.

reasonable to consider performing these actions as constituting ''assistance.''

The definition will ensure a sufficient connection between the conduct for which (or from which) the conscientious objector is seeking relief and the protections Congress established in law. This approach would ensure that health care workers are not driven from the health care industry because of conflicts with their religious beliefs or moral convictions in connection with practices as set forth by Congress, such as abortion. It would also dissuade employers from attempting to skirt protections through improperly narrow interpretations of the term.

Nevertheless, in response to concerns about the potential overbreadth and need for increased clarity of the definition, the Department finalizes the definition with a change to the first sentence, so that it reads: To assist in the performance means ''to take an action that has a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program or research activity undertaken by or with another person or entity.'' The Department believes that replacing the phrase ''to participate in any activity'' with the phrase ''to take an action'' more clearly and precisely explains the conduct covered by ''assist in the performance.'' The phrase ''undertaken by or with another person or entity'' distinguishes ''assisting'' from ''performing,'' as assisting implies working with another. This change would also ensure that any articulable connection must also be ''reasonable'' and ''specific.'' It would, therefore, preclude vague or attenuated allegations that do not support a claim of assisting in a procedure or health service program or research activity. For example, a health care worker who objects to being scheduled to conduct physicals on some patients, when abortions are scheduled on the same day for unrelated patients elsewhere in the building, would not have a claim of being coerced into ''assisting'' with an abortion, barring additional facts. Conversely, where a provider requires the designation and availability of a backup doctor whenever an abortion is to be performed, that designation may constitute assistance in the performance of an abortion even if no complications arise requiring the backup doctor to intervene during or after an abortion in a particular instance. In addition, the Department clarifies that the activities need only to regard ''part of a health service program or research activity,'' in contrast to, for example, furthering the health service program as a whole.

The Department believes these changes adequately respond to commenters who contend the proposed definition of ''assist in the performance'' is insufficiently clear, without narrowing the definition to exclude actions that do constitute assistance in the performance. The Department believes the definition in the final rule, while still requiring OCR to weigh the facts and circumstances of each case, provides additional clarity. Congress did not define ''assist in the performance.'' The Department considered not finalizing a definition of ''assist in the performance,'' but without any definition, there may be confusion about what the term includes, with different employers interpreting it more broadly or more narrowly. For example, in the *Danquah* lawsuit, where nurses contended they were required to assist abortion cases in violation of the Church Amendments, a public hospital receiving Public Health Service Act funds filed a brief in Federal court stating that ''to administer routine pre and post-operative care'' to abortion patients does not constitute assisting in the performance of an abortion under the Church Amendments.[55] Without taking a position on the facts of that case, the Department disagrees with a narrow interpretation of assisting in the performance that excludes pre- and post-operative support to a scheduled abortion procedure. The Department believes that the confusion among covered entities and members of the public about what constitutes assistance in the performance of a health service makes it appropriate for the Department to define ''assist in the performance'' with the changes as set forth in this final rule.

Comment: The Department received a comment requesting that ''articulable connection'' be replaced with ''reasonable connection'' because ''articulable connection'' may be abused by persons articulating connections that are irrational.

Response: The Department agrees in part, to the extent that the reasonableness standard should be included in the definition. As stated above, in response to similar concerns about potential overbreadth, the Department has modified the sentence containing the phrase, ''to participate in any program or activity with an articulable connection to a procedure,'' to add the word ''reasonable,'' and other language to limit its scope and add greater specificity. Specifically, the final rule describes ''to take an action that has a specific, reasonable, and articulable connection to furthering a procedure or health service program or research activity undertaken by or with another person or entity.'' This standard would preclude irrational assertions that an action constitutes assisting in the performance of a procedure, because it requires the action to have a specific, reasonable, and articulable connection to furthering the procedure. If the connection between an action and a procedure is irrational, there is no actual connection by which the action specifically furthers the procedure. The Department does not interpret the language to permit irrational applications.

Comment: The Department received a comment suggesting that the ''articulable connection'' standard be replaced with a standard that connects that assistance to the clinical setting and includes a complete, not illustrative, list of activities subject to the protections.

Response: The Department believes this concern is adequately addressed by the changes described above to clarify the definition of ''assist in the performance.'' The Department disagrees with the recommended approach because the statutory protections for objecting to assisting in the performance of procedures encompasses situations beyond the narrow scope proposed by the commenter. For example, an unlawfully coerced assistance in an abortion is no less unlawful if the coercion takes place outside a particular clinical setting, as opposed to within such clinical setting. Furthermore, creating an exhaustive list of potentially protected conduct does not allow for variations from State to State, or even clinic to clinic, in how procedures are handled. Such an approach also does not consider the diverse ways in which protected moral or religious objections may manifest, and would not account for changes in practices over time.

Comment: The Department received comments stating that the scope of persons protected by the definition of ''assist in the performance'' is too broad because it extends beyond health care professionals and includes other members of the workforce.

Response: The Department acknowledges that inclusion of a reference to workforce members in the definition of ''assist in the performance'' has caused confusion among commenters. The Department has concluded this reference is not necessary because the scope of persons and entities protected from being forced to ''assist in the performance'' of an

[55] Defs.' Brief in Opp. To Pls.' App. For Prelim. Inj. at 26, *Danquah,* No. 2:11–cv–06377–JLL–MAH, doc. # 26 (D.N.J. filed Nov. 22, 2011).

objected to procedure is already governed by provisions in the relevant law and this rule. Accordingly, the Department is finalizing the definition of ''assist in the performance'' to delete the reference to workforce members. Similarly, the Department is removing the reference to ''any program or activity'' as part of the definition of ''assist in the performance'' because the new language in the definition—''to take an action that has a specific articulable connection''—makes the reference to ''any program or activity'' unnecessary. The Department is also removing the reference to ''health program or activity'' because that term is no longer defined in the final rule, as discussed further below.

Comment: The Department received comments expressing concern that the definition of ''assist in the performance'' would cover ambulance drivers.

Response: EMTs and paramedics are treated like other health care professionals under this definition. Federal conscience and anti-discrimination laws would apply to them, or not, based on whether the elements of the law (and this final rule) are satisfied in a particular circumstance. To the extent the commenters contend that the kinds of actions that ambulance crews perform never count as assisting in the performance of a procedure encompassed by a Federal conscience or anti-discrimination law, the Department declines to take such a categorical approach. As discussed earlier, where EMTALA might apply in a particular case, the Department would apply both EMTALA and the relevant law under this rule harmoniously to the extent possible. EMTs and paramedics are trained medical professionals, not mere ''drivers.'' If commenters contend that driving a patient to a procedure should never be construed to be assisting in the performance of a procedure, the Department disagrees and believes it would depend on the facts and circumstances of each case. For example, the Department believes driving a person to a hospital or clinic for a scheduled abortion could constitute ''assisting in the performance of'' an abortion, as would physically delivering drugs for inducing abortion.

To the extent commenters are referring to emergency transportation of persons experiencing unforeseen complications after, for example, an abortion procedure, the Department does not believe such a scenario would implicate the definition of ''assist in the performance of'' an abortion, because the complications in need of treatment would be an unforeseen and unintended byproduct of a completed procedure. Further, the Department is not aware of any entities or medical professionals that would object to treating someone, or transporting someone to treatment, under these circumstances.

To the extent commenters are referring to emergency transportation of persons with conditions such as an ectopic pregnancy, where the potential procedures performed at the hospital may include abortion, the question of whether such transportation falls under the definition of ''assist in the performance'' would depend on the facts and circumstances. However, as a general matter, the Department does not believe that mere speculation that an objected-to service or procedure may occur suffices to establish a specific and reasonable connection between the objected-to service or procedure and the act of transporting the patient.

The Department's existing regulation implementing EMTALA at 42 CFR 489.24 defines EMTALA's statutory language ''comes to the emergency department'' [56] to include an individual who is en route to a hospital in an ambulance owned and operated by the hospital, with limited exceptions, as well as, in certain circumstances, an individual who is en route to a hospital in an ambulance that is not owned and operated by the hospital.[57] Federal Appeals Courts in the Ninth and First Circuits have examined the Department's regulatory definition of ''comes to the emergency department,'' and have upheld the Department's regulatory definition for EMTALA as reasonable, and have distinguished other Federal Circuits' cases interpreting EMTALA by differentiating the cases by their facts or by the nature of the courts' analyses.[58]

Comment: The Department received comments stating that the inclusion of counseling and referral in the definition of ''assist in the performance'' was not the intent of Congress in enacting the Church Amendments. Some commenters pointed to differing language in the Church, Weldon, and Coats-Snowe Amendments to support this assertion.

Response: Congress did not define the phrases ''assist in the performance,'' ''counsel,'' or ''recommend'' in the Church Amendments; ''refer'' or ''referral'' in Weldon or Coats-Snowe; or ''make arrangements for'' in Coats-Snowe. Some commenters contend that the meaning of these terms are completely distinct and should never be interpreted as overlapping. The Department disagrees. When Congress enacted paragraphs (b) and (c)(1) of the Church Amendments in 1973, and paragraphs (c)(2) and (d) in 1974, it used the phrase ''assist in the performance'' regarding certain medical procedures. Congress then enacted paragraph (e) in 1979 to protect applicants for medical training or study from discrimination based on their reluctance or willingness ''to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations.''

Counseling and referral are common and well understood forms of assistance that materially help people reach desired medical ends. Indeed, because referrals are so tightly bound to the ultimate performance of medical procedures, Congress banned many forms of referral fees or ''kickbacks'' among providers receiving Medicare and Medicaid reimbursements. *See* the Medicare and Medicaid Patient Protection Act of 1987, as amended, 42 U.S.C. 1320a–7b (the ''Anti-Kickback Statute'') and the Ethics in Patient Referrals Act of 1989, as amended, 42 U.S.C. 1395nn (the ''Stark Law''). Similarly, counseling of some form regarding abortion is often *required* before the procedure can be performed, as is the case in 33 States,[59] and many hospitals and health care facilities likely require some kind of counseling as a prerequisite to abortion of their own accord.

Based on the text, structure, and purpose of the statutes at issue, the Department interprets ''assist in the performance'' broadly and does not believe the presence of more specific terms of assistance elsewhere in the Church Amendments, or in other laws that are the subject of this rule, narrows the meaning of the phrase. It would be contrary to the structure and history of the Church Amendments to interpret provisions protecting conscience in the *study* of abortion procedures significantly more broadly than provisions protecting conscience in the actual *performance* of an abortion procedure.

The Department, however, does not believe that every form of counseling, training, or referral (as defined under

[56] 42 U.S.C. 1395dd(a).

[57] 42 CFR 489.24(b)(3) and (4).

[58] *Morales* v. *Sociedad Espanola de Auxilio Mutuo y Beneficencia,* 524 F.3d 54, 60–61 (1st Cir. 2008) (holding that the HHS regulatory definition comports with EMTALA's purpose and remedial framework and distinguishing cases from the Fifth and Seventh Circuits); *Arrington* v. *Wong,* 237 F.3d 1066, 1073–74 (9th Cir. 2001) (same).

[59] Counseling and Waiting Periods for Abortion, Guttmacher Institute (Oct. 1, 2018), *https://www.guttmacher.org/state-policy/explore/counseling-and-waiting-periods-abortion.*

this rule) necessarily constitutes assistance in the performance of a procedure under this rule. The Department, therefore, finalizes the definition of ''assist in the performance'' by changing the second sentence to read ''This may include counseling, referral, training, or otherwise making arrangements for the procedure or health service program or research activity, depending on whether aid is provided by such actions.''

Comment: The Department received comments expressing concern that the definition of ''assist in the performance'' combined with the language of 42 U.S.C. 300a–7(d) could impact counseling or referrals for LGBT persons.

Response: Several provisions of statutes that are the subject of this rule are specific to abortion, sterilization, assisted suicide, or other procedures, and provide specific protections. In 42 U.S.C. 300a–7(d) (and 300a–7(c)(2)), Congress directed the protection of conscientious objections in contexts not tied to specific treatments. When the previous administration finalized 45 CFR part 88 in 2011, it affirmed its commitment to enforce Federal conscience and anti-discrimination laws, including 42 U.S.C. 300a–7(d). (76 FR at 9972). The Department continues and expands on that commitment in this rule. The Department does not pre-judge matters without the benefit of specific facts and circumstances, and particular claims under 42 U.S.C. 300a–7(d) will be evaluated on a case-by-case basis.

Nevertheless, the Department believes that some commenters may misunderstand the scope of paragraph (d). Generally, the protections of paragraph (d) follow the funds provided by any program administered by the Secretary. But paragraph (d) does not encompass every medical treatment or service performed by any entity receiving Federal funds from HHS for whatever purpose. Instead, Congress narrowly focused paragraph (d) to prohibit the coercion of persons ''in performance of'' health service programs funded under a program administered by the Secretary. As explained more fully in response to other comments below with respect to paragraph (d), many medical treatments and services performed by health care providers are not ''part of'' a health service program receiving funding from HHS. In such circumstances, paragraph (d) would not apply.

Comment: The Department received comments expressing concern that the definition of ''assist in the performance'' will result in conscientious objectors refusing to provide information to patients about objected-to treatment options, potentially in violation of principles of informed consent.

Response: The Department disagrees that the rule would violate principles of informed consent. Medical ethics have long protected rights of conscience alongside the principles of informed consent. The Department does not believe that enforcement of conscience protections, many of which have been in place for nearly fifty years, violates or undermines the principles of informed consent. This rule will not change the obligation that, absent exigent circumstances, doctors secure informed consent from patients before engaging in a medical procedure.

Summary of Regulatory Changes: For the reasons described in the proposed rule [60] and above, and considering the comments received, the Department adopts the definition of ''assist in the performance'' with changes to read that it means ''to take an action that has a specific, reasonable, and articulable connection to furthering a procedure or health service program or research activity undertaken by or with another person or entity.'' The definition specifies that ''[t]his may include counseling, referral, training, or otherwise making arrangements for the procedure or health service program or research activity, depending on whether aid is provided by such actions.'' This new definition removes ''so long as the individual involved is a part of the workforce of a Department-funded entity'' for accuracy and clarity and makes other minor language changes, for example, changing ''includes but is not limited to'' to ''may include.''

Department. The Department proposed that ''Department means the Department of Health and Human Services and any component thereof.'' The Department did not receive comments on this definition.

Summary of Regulatory Changes: For the reasons described in the proposed rule [61] and above, the Department adopts the definition of ''Department'' as proposed.

Discriminate or *Discrimination.* The Department proposed ''*discriminate* or d*iscrimination*,'' to mean one of four categories of adverse actions or treatment, for which each paragraph or type of action within each paragraph would apply as permitted by the applicable statute. Paragraph (1) of the definition addressed prohibited adverse actions or treatment, as permitted by the applicable statute, as those actions relate to any grant, contract, subcontract, cooperative agreement, loan, license, certification, accreditation, employment, title, or other similar instrument, position, or status. Paragraph (2) addressed prohibited adverse actions or treatment, as permitted by the applicable statute, as those actions relate to any benefit or privilege. For both paragraphs, prohibited adverse actions or treatment included those to withhold, reduce, exclude, terminate, restrict, or otherwise make unavailable or deny the categories listed in paragraphs (1) and (2). Paragraph (3) addressed the use of any criterion, method of administration, or site selection, including the enactment, application, or enforcement of laws, regulations, policies, or procedures directly or through contractual or other arrangements, that tends to subject individuals or entities protected under the rule to any adverse effect described in this definition, or has the effect of defeating or substantially impairing accomplishment of a health program or activity with respect to individuals, entities, or conduct protected under the rule. Finally, paragraph (4) of the definition set forth a catch-all for which discriminate or discrimination means to otherwise engage in any activity reasonably regarded as discrimination, including intimidation or retaliatory action.

The Department received comments on this definition, including comments generally supporting or opposing the proposed definition.

Comment: The Department received comments stating that the definition of ''discriminate or discrimination'' would encompass situations in which States apply neutral laws of general applicability that require the performance of abortion, and such commenters disagreed that a neutral law of general applicability can be deemed an act of discrimination.

Response: The term ''neutral law of general applicability'' is a legal term of art that derives from case law interpreting the Free Exercise Clause of the First Amendment. What renders a law ''neutral'' in the Free Exercise context is that the law is not by its text, history, motive, or operation targeted at the protected activity of religious exercise. If commenters are contending that States that might otherwise be prohibited by a Federal conscience or anti-discrimination law from discriminating against doctors who refuse to perform abortions may nonetheless do so pursuant to a neutral State law of general applicability, the Department disagrees. States that accept

[60] 83 FR 3880, 3892 (stating the reasons for the proposed definition of ''assist in the performance,'' except for the modifications adopted herein).

[61] 83 FR 3880, 3892.

applicable Federal funds and thereby subject themselves to Federal conscience and anti-discrimination laws cannot evade the requirements of those laws through neutral laws of general applicability. For example, the Weldon Amendment flatly prevents State laws from discriminating against doctors because they do not perform abortions against their will regardless of whether the law is ''neutrally'' worded or applied. Subjecting persons to penalties or adverse treatment because they decline to perform abortions is a form of discrimination encompassed by the Weldon Amendment. Even if a State law were to impose penalties on OB/GYNs because they decline to perform any lawful procedure they are competent to perform (the Department is not aware of such a law), and that law were used to impose penalties on OB/GYNs because they do not perform abortions, that would also constitute discrimination encompassed by the Weldon Amendment. The Coats-Snowe Amendment similarly prohibits discrimination against a health care entity, such as an individual physician, who (among other things) declines to perform abortions. Additionally, under both the Coats-Snowe and Weldon Amendments, protected entities and individuals need not specify a motive, or provide a justification, for declining.

Paragraph (c)(1) of the Church Amendments provides that a covered entity cannot discriminate against any physician or other health care personnel (1) because he or she performed or assisted in the performance of a sterilization or abortion procedure, (2) because he or she refused to so perform or assist ''on the grounds that'' doing so ''would be contrary to his [or her] religious beliefs or moral convictions,'' or (3) ''because of his religious beliefs or moral convictions respecting sterilization procedures or abortions.'' The last provision covers circumstances where a covered entity's motive is arguably driven by anti-religious animus. But the second prohibition of discrimination does not rely on animus on the part of the entity committing the discrimination; it rests solely on whether the person refused to perform or assisted in the performance of a sterilization or abortion procedure on the grounds of the person's religious beliefs or moral convictions with respect to such procedures. Therefore, under paragraph (c)(1), a covered entity cannot discriminate against a doctor, for example, because of his or her refusal to perform abortions on the grounds of religious beliefs or moral convictions regardless of whether the covered entity's discrimination is accompanied by anti-religious animus, or whether the entity would also penalize doctors who refuse to perform abortions for non-protected reasons. Nothing in the legislative history of the Church Amendments suggests that Congress intended to permit entities receiving applicable funds to coerce religiously or morally motivated doctors to perform abortions, so long as those entities also require doctors who do not have qualms about abortions to perform them.

Consequently, the Department concludes that the concept of discrimination, as used in Federal conscience and anti-discrimination laws, can encompass a situation where a State takes adverse action against a doctor because of the doctor's refusal to perform an abortion, even under a general or ''neutral'' law mandating the performance of abortions.

Comment: The Department received comments stating that the phrase ''any activity reasonably regarded as discrimination'' is overbroad or impermissibly vague.

Response: Discrimination standards usually do not limit themselves to an exclusive list of discriminatory actions, because adverse action based on prohibited grounds can take various forms depending on the facts and circumstances of the case. This rule encompasses several statutes barring discrimination. As such, the Department believes it is appropriate for this definition to encompass an array of actions that might be taken against a person on the basis of such person's exercise of the rights protected by Federal conscience and anti-discrimination laws. On the other hand, the Department agrees in part with commenters that the language ''any activity reasonably regarded as discrimination'' does not provide precise guidance on the scope of the definition. Therefore the Department will finalize the definition of ''discriminate or discrimination'' by deleting proposed paragraph (4). The Department will also change the word ''means'' to ''includes'' in the opening phrase of the discrimination definition, and change the phrase ''as permitted by the applicable statute'' to ''to the extent permitted by the applicable statute.'' This will maintain the definition's description of types of discrimination, and ensure that the definition only applies to the extent it is authorized by the applicable statute, while also rendering the descriptions in the definition non-exclusive, so OCR can consider other actions that might constitute discrimination in violation of an applicable Federal conscience and anti-discrimination law to which this part applies.

Any allegation of discrimination under the laws to which this part applies will be considered in light of a reasonable interpretation of applicable law and an application of that law to the facts. By making the definition inclusive, instead of exclusive, by use of the word ''includes,'' the definition will not exclude the types of actions that constitute discrimination but might not fall squarely into one of the descriptions set forth in paragraphs (1) to (3) of the definition. Additionally, in light of the language added to address concerns with respect to how this definition interacts with reasonable accommodations, the Department believes that making the definition inclusive, while eliminating proposed paragraph (4), ensures that the definition is not overly broad.

Comment: The Department received comments stating that the proposed definition of ''discriminate or discrimination'' conflicts with or is inconsistent with other Federal laws such as Title VII of the Civil Rights Act and Title X of the Public Health Service Act.

Response: The Department disagrees that these regulations conflict with statutes applicable to the Title X family planning program under the Public Health Service Act. The Department agrees that regulations finalized in 2000 governing the Title X program, which in some cases required referrals, information, and counseling about abortion, conflicted with certain Federal conscience and anti-discrimination laws and, consequently, with this rule. The Department acknowledged this conflict in the preamble to the 2008 Rule (73 FR at 78087), in the preamble to the notice of proposed rulemaking for the Title X regulations in 2018 (83 FR 25502, 25506 (June 1, 2018)), and in the preamble to the Title X final rule published in 2019 (84 FR 7714, 7716 (March 4, 2019)). In all three instances the Department stated it would operate the Title X program in compliance with Federal conscience and anti-discrimination laws, notwithstanding the language of the 2000 Title X regulations.[62] The

[62] In addition, in the preamble to the 2000 Title X regulations, the Department acknowledged the implications of the Church Amendment when it addressed a comment that the requirement to provide options counseling ''should not apply to employees of a grantee who object to providing such counseling on moral or religious grounds,'' and rejected it, contending that it is not necessary because, under the Church Amendments, ''grantees may not require individual employees who have such objections to provide such counseling,'' but ''in such cases the grantees must make other arrangements to ensure that the service is available

recently published Title X final rule revised the 2000 Title X regulations to eliminate that conflict and achieve consistency with Federal conscience statutes. Nothing in the Title X statute itself or in appropriations restrictions applicable to Title X funding requires abortion referrals, counseling, or information. This includes Congress's directive that, in Title X programs, ''all pregnancy counseling shall be nondirective.'' [63] That provision does not address referrals or information, only counseling, and does not require pregnancy counseling, but merely specifies that, if pregnancy counseling occurs, it shall be nondirective—and now the regulation permits, but does not require abortion counseling and information (and bars abortion referrals). Accordingly, this rule is consistent with both Title X and the Federal conscience and anti-discrimination laws.[64]

With respect to Title VII, the Department agrees with some commenters that the definition of ''discriminate or discrimination'' as proposed does not function in the same way as the approach set forth in Title VII, specifically regarding parts of the reasonable accommodation of religion standard set forth under Title VII. The Department believes components of that approach are appropriate in this context and is therefore adding a new paragraph (4) to the definition of ''discriminate or discrimination'' to properly recognize that the voluntary acceptance of an effective accommodation of protected conduct, religious beliefs, or moral convictions, will not, by itself, constitute discrimination. Further, the Department will take into account an entity's adoption and implementation of policies to accommodate objecting persons in making determinations of discrimination. The Department finds this approach appropriate because it is generally consistent with the text and intent of Federal conscience and anti-discrimination laws to respect objections based on religious beliefs by accommodating them. The Department's approach will differ from Title VII, however, by not incorporating the additional concept of an ''undue hardship'' exception for reasonable accommodations under Title VII. Despite having previously enacted Title VII, Congress did not adopt an undue hardship exception for the protections found in Federal conscience and anti-discrimination laws that are the subject of this rule. The Department believes Congress's decision to take a different approach in Title VII as compared to Federal conscience and anti-discrimination laws is consistent with the fact that Title VII's comprehensive regulation of American employers applies in far more contexts, and is more vast, variable, and potentially burdensome (and, therefore, warranting of greater exceptions) than the more targeted conscience statutes that are the subject of this rule, which are health care specific, and often procedure specific, and which are specific to the exercise of Congress's Spending Clause authority. Therefore, the Department deems it appropriate to recognize that, when appropriate accommodations are made for objections protected by Federal conscience and anti-discrimination laws, those accommodations do not themselves constitute discrimination. The Department also finds it appropriate not to adopt the undue hardship exception for enforcing Federal conscience and anti-discrimination laws because Congress chose not to place that limitation on the protections set forth in the Federal conscience and anti-discrimination laws.

Comment: The Department received comments expressing concern that the proposed definition of ''discriminate or discrimination'' would prohibit employers from accommodating religious objections by placing the conscientious objector in a different position, potentially requiring the double-staffing of certain positions.

Response: The Department agrees with this concern in part. As discussed above, the Department is adding language in response to public comments to acknowledge the reasonable accommodations that entities make for persons protected by Federal conscience and anti-discrimination laws. In this way, the Department recognizes that staffing arrangements can be acceptable accommodations in certain circumstances. The Department has addressed this through the addition of a new paragraph (4) in the definition of ''discriminate or discrimination'' that recognizes the effective and timely accommodation of an employee (which may include non-retaliatory staff rotations) as not constituting discrimination. Additionally, to address concerns raised by these commenters, the Department is adding new paragraphs (5) and (6) to clarify that, within limits, employers may require a protected employee to inform them of objections to referring for, participating, or assisting in the performance of specific procedures, programs, research, counseling, or treatments to the extent there is a reasonable likelihood [65] that the protected entity or invidivdual may be asked in good faith to refer for, participate in, or assist in the performance of such conduct, and that the employer may use alternate staff or methods to provide or further any objected-to conduct, subject to certain limitations designed to protect the objecting person.

On the other hand, as a general matter, it is not an acceptable practice under Federal conscience and anti-discrimination laws for covered entities to deem persons with religious or moral objections to covered practices, such as abortion, to be disqualified for certain job positions on that basis. For example, a hospital receiving Public Health Service Act funds could not deem a doctor or a nurse with a religious objection to performing abortions to be ineligible to practice obstetrics and gynecology on that basis. An important purpose of laws such as the Church Amendments is to prevent fields such as

to Title X clients who desire it.'' 65 FR 41270, 41274 (July 3, 2000). At the time, the Department apparently did not consider the implications of the Coats-Snowe Amendment, adopted in 1996, with respect to Title X grantees and applicants; the Weldon Amendment was adopted subsequently.

[63] See Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Public Law 115–245, Div. B, 132 Stat. 2981, 3070–71.

[64] The Department acknowledges that, as of the date of publication of this final rule, several district courts have issued preliminary injunctions, on a nationwide basis, against the enforcement or implementation of the 2019 Title X final rule, and requiring the Title X program to maintain the status quo under the 2000 Title X regulations. Those injunctions do not purport to otherwise enjoin the Department's enforcement of the Federal conscience and anti-discrimination laws. Since at least 2008, under the 2000 Title X regulations, the Department has recognized that it cannot, by regulation, require abortion counseling or referral by a Title X applicant, grantee, project, clinic, or provider where such requirement would constitute a violation of one or more of the Federal conscience and anti-discrimination laws, and the Department has stated that it operates the Title X program accordingly. The 2019 Title X final rule memorialized HHS's longstanding recognition that Federal conscience and anti-discrimination laws bar enforcement of certain requirements of the 2000 Title X regulations, but the 2019 Title X final rule did not alter HHS's preexisting policy dating back at least to 2008 of not enforcing requirements of the 2000 regulations where they may conflict with the Federal conscience statutes as explained in this rule. This rule, similarly, does not alter that status quo, but sets forth general processes for enforcement of the Federal conscience and anti-discrimination laws. The Department will implement all of its programs consistent with the Federal conscience and anti-discrimination laws and with any applicable court orders.

[65] For example, nurses assigned exclusively to nursing homes for elderly patients would not be expected to refer or assist in the performance of any sterilization procedures or abortions, and, thus, it would be inappropriate for an entity subject to the prohibitions in this rule to require such nurses to disclose whether or not they have any objections to referring or assisting in such procedures.

obstetrics and gynecology from being purged of pro-life personnel just because abortion is legal and some health care entities perform them. In this sense, the Department disagrees with commenters who essentially contend that pro-life medical personnel can be placed outside of women's health positions for that reason. The Department need not address in this rule whether a covered entity could disqualify a person with religious or moral objections to covered practices if such covered practices made up the primary or substantial majority of the duties of the position, as the Department is not aware of any instances in which individuals with religious or moral objections to such practices have sought out such jobs.

Overall, under new paragraph (6) of the definition, taking steps to use alternate staff or methods to provide for or further the objected-to conduct would not run afoul of the definition of discrimination, or constitute a prohibited referral, if the employer or program does not require any additional action by the objecting individual or health care entity and if such methods do not exclude individuals from areas or fields of practice on the basis of their protected objections. The employer may also inform the public of the availability of alternate staff or methods to provide or further the objected-to conduct, if doing so does not constitute retaliation or other adverse action against the objecting individual or health care entity. For example, an employer may post such a notice and a phone number in a reception area or at a point of sale, but may not list staff with conscientious objections by name if such singling out constitutes retaliation.

The definition also clarifies that employers cannot use information gained from this process to discriminate against any protected entity or employee, and any attempts to, for example, ask questions of prospective employees or grant applicants concerning potential objections before hiring or a grant award will require a persuasive justification because of the risk of unlawful but difficult-to-detect ''screening'' of applicants.

The Department believes these modifications to the scope of prohibited discrimination under this final rule strike the right balance by respecting the interests of employers and entities that wish to provide services allowed by their consciences; respecting the interests, privacy, and conscience of patients and customers; and respecting the conscience of employees and health care entities protected by the laws passed by Congress that are the subject of this rule.

Comment: The Department received comments stating that the proposed definition of ''discriminate or discrimination'' would turn any adverse action taken against a protected party for any reason into *per se* unlawful discrimination.

Response: The Department disagrees. The definition of ''discriminate or discrimination'' does not trigger violations based on any adverse action whatsoever, but must be read in the context of each underlying statute at issue, any other related provisions of the rule, and the facts and circumstances. In this rule, the prohibition on discrimination is always conditioned on, and applied in the context of, violating a specific right or protection, and each protected right is typically associated with a particular Federal funding stream or streams. For example, in § 88.3(c)(2), ''discrimination'' is unlawful when done ''*on the basis that* the health care entity''—the protected entity in the provision—''does not provide, pay for, provide coverage of, or refer for, abortion.'' Thus, an adverse action taken for reasons wholly unrelated to abortion or the health care entity's actions or beliefs objecting to abortion would not constitute a violation under this provision. In addition, as noted above, whether an action is regarded as adverse is subject to a standard of reasonableness.

Comment: The Department received comments suggesting that the definition of ''discriminate or discrimination'' should not include elements of disparate impact. Because circuit courts of appeals handle disparate impact analysis differently, its inclusion here will lead to confusion and differing outcomes depending on the circuit in which the conduct occurred, and including elements of disparate impact would create incentives to manipulate data in order to bring illegitimate complaints.

Response: The Department agrees in part and disagrees in part. Because there is uncertainty about which laws, or parts of laws, implemented by this rule may or may not support a disparate impact claim, the Department is choosing to finalize the rule without explicitly including terms traditionally associated with disparate impact theories. It is specifically replacing the phrase ''adverse effects'' with ''adverse treatment'' and is deleting ''otherwise,'' ''tends to,'' and ''defeats or substantially impairs accomplishment of a health program or activity'' as elements of the definition of ''discrimination.'' However, because the definition of ''discrimination'' as adopted in this final rule is non-exclusive, as discussed above, OCR is not prejudging any complaints of violations of part 88 that are based on a claim of disparate impact, and will consider the circumstances of each complaint and apply each statute according to its text and any applicable court precedents.

Comment: The Department received comments stating that the proposed definition of ''discriminate or discrimination'' is either unconstitutional or violates precedential definitions of what constitutes discrimination.

Response: The Department disagrees that the definition of ''discriminate or discrimination'' finalized in this rule generally violates legal standards, constitutional or otherwise, as to what constitutes discrimination. There is no universal definition of discrimination that governs all Federal statutes. Discrimination can take different forms depending on the particular context and language of each statute prohibiting it. The Department nevertheless has drawn substantially from definitions and interpretations of ''discrimination'' found in other anti-discrimination statutes and case law, and has made various changes in response to public comments. The Department believes that the definition finalized here reasonably describes forms and methods of discrimination that are likely to be encountered in the context of the Federal conscience and anti-discrimination laws at issue in this rule, and that are encompassed by the protections set forth in those statutes and this rule.

Summary of Regulatory Changes: For the reasons described in the proposed rule[66] and above, and considering the comments received, the Department finalizes the definition of ''discriminate or discrimination'' (with additional minor changes for accuracy and clarity); changing ''means'' to ''includes;'' limiting the definition ''to the extent'' permitted by the statute; changing ''exclude'' to ''exclude from;'' deleting ''otherwise'' from paragraphs (1) and (2); adding ''or impose any penalty'' to the end of paragraph (2); in paragraph (3), deleting ''defeating or substantially impairing accomplishment of a health program or activity,'' changing ''tends to subject'' to ''subjects,'' and adding ''on grounds prohibited under an applicable statute encompassed by this part;'' deleting the proposed paragraph (4) and

[66] 83 FR 3880, 3892–93 (stating the reasons for the proposed definition of ''discriminate or discrimination,'' except for the modifications adopted herein).

adding new paragraph (4) as described above regarding entities that ''shall not be regarded as having engaged in discrimination;'' adding paragraph (5) as described above allowing an entity subject to any prohibition in this part to ''require a protected entity to inform them of objections;'' and adding paragraph (6) as described above addressing what actions by the entity subject to this part ''would not, by itself, constitute discrimination.''

Entity. The Department proposed that ''*Entity* means a 'person' as defined in 1 U.S.C. 1; or a State, political subdivision of any State, instrumentality of any State or political subdivision thereof, or any public agency, public institution, public organization, or other public entity in any State or political subdivision of any State.'' The Department received comments on this definition.

Comment: The Department received comments requesting that the definition of ''entity'' include non-profit religious corporations as well.

Response: Non-profit religious corporations are already encompassed by the definition of ''person'' in 1 U.S.C. 1. *See Burwell* v. *Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2768 (2014).

Comment: The Department received a comment noting that the definition of ''entity'' does not mention foreign governments, the United Nations, and related bodies. The comment proposed explicitly excluding foreign governments and the United Nations from the definition of ''entity'' because of sovereignty concerns.

Response: The Department agrees that the term ''entity'' should address foreign governments, foreign nongovernmental organizations, intergovernmental organizations (such as the United Nations), and related bodies, but the Department disagrees that they should be explicitly excluded. Some of the Federal conscience statutes to be enforced by the Department may implicate foreign entities,[67] but Congress did not exempt certain kinds of foreign entities that would otherwise be covered. Accordingly, the definition of ''entity'' is modified to clarify that ''entity'' may include a foreign government, foreign nongovernmental organization, or intergovernmental organization (including the United Nations and its affiliated agencies). The Federal statutes at issue apply their protections to the funds at issue, regardless of whether those funds are awarded to domestic or foreign entities. If foreign entities wish not to be bound by these conscience protections, they may choose not to accept the relevant funds.

Comment: The Department received a comment stating that the definition of ''entity'' would permit any employer to deny its employees coverage for abortion or other objected-to services, even if otherwise required by law. Other comments expressed concern that defining ''entity'' to include State or local governments expands covered entities beyond the health care industry.

Response: The Department disagrees. The definition section must be read in conjunction with other sections of the rule when determining whether any particular entity must comply with any particular provision of the rule. For example, the fact that private employers are a type of organization that falls under the definition of ''entity'' does not make every private employer in America automatically subject to the Federal protection statutes for which this rule provides enforcement mechanisms. Similarly, the fact that natural persons fall under the definition of entity does not mean that every person in America is automatically granted protection under the rule. Rather, obligations and protections apply only to those entities that are subject to a relevant provision of a statute under the rule. Each provision in this final rule that addresses a Federal conscience statute has a paragraph titled ''*Applicability*'' (*see* § 88.3), which specifies whether an entity is subject to any given provision of a Federal statute at issue. For some statutes or some portions of statutes, the *Applicability* paragraph by its own terms may only implicate certain types of entities or only entities receiving certain types of funding.

Summary of Regulatory Changes: For the reasons described in the proposed rule[68] and above, and considering the comments received, the Department finalizes the definition of ''entity'' by including ''or, as applicable, a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).'' The Department also adds the term ''the Department'' to the definition of ''entity,'' for clarity.

As described further below, to ensure uniformity, the Department also modifies the definitions of ''recipient'' and ''sub-recipient'' to include, as applicable, a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).

Federal financial assistance. The Department proposed that *Federal financial assistance* align with the definition of this term in the Department's regulations implementing Title VI of the Civil Rights Act of 1964 at 45 CFR 80.13, which includes the provision of assistance of Federal funds and non-cash assistance, such as the detail of Federal personnel. The Department received comments on this term.

Comment: The Department received a comment stating that the uses of the word ''arrangement'' and the ''provision of assistance'' were difficult to interpret, and that the definition of ''Federal financial assistance'' should clarify whether it ''includes any claim for payment, payments in exchange for health care services, or applications to participate in a Federal program through which payment would be made.''

Response: The Department disagrees. The proposed definition of ''Federal financial assistance'' mirrors the definition used in the Department's regulations implementing Title VI and is intended to carry the same meaning as it has traditionally been understood to carry in the application of those regulations. *See* 45 CFR 80.13(f). The Department believes that entities subject to this regulation will be sufficiently familiar with that meaning to understand its application in this final rule. Further, numerous Federal courts have recognized that Federal financial assistance encompasses subsidies, but not fair market value compensation paid in return for services. *See, e.g., Jarno* v. *Lewis,* 256 F. Supp. 2d 499, 504 (E.D. Va. 2003); *DeVargas* v. *Mason & Hanger-Silas Mason Co.,* 911 F.2d 1377, 1382 (10th Cir. 1990); *Cook* v. *Budget Rent-a-Car,* 502 F. Supp. 494 (S.D.N.Y. 1980); *Shotz* v. *American Airlines,* 420 F.3d 1332 (11th Cir. 2005); *Venkatraman* v. *REI Systems,* 417 F.3d 418 (4th Cir. 2005). In light of the comments, the Department finalizes this definition with a minor clarifying change to avoid a circular definition, by replacing ''funds, support, or aid'' with ''subsidy'' in paragraph (5) of the definition.

Summary of Regulatory Changes: For the reasons described in the proposed

[67] Such as funds administered by the Secretary of Health and Human Services under section 104A of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2); under Chapter 83 of Title 22 of the U.S. Code; or under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008.

[68] 83 FR 3880, 3893 (stating the reasons for the proposed definition of ''entity,'' except for the modifications adopted herein).

rule [69] and above, and considering the comments received, the Department finalizes the definition of ''Federal financial assistance'' as proposed, with a modification in paragraph (5) to remove references to a ''Federal'' agreement and ''arrangement'' so that the text now refers to ''any agreement or other contract between the Federal government and a recipient,'' and to clarify the terminology by referring to ''provision of a subsidy to the recipient'' to avoid a circular definition related to the provision of ''assistance.''

Health care entity. The Department proposed that ''health care entity'' includes an individual physician or other health care professional; health care personnel; a participant in a program of training in the health professions; an applicant for training or study in the health professions; a post-graduate physician training program; a hospital; a laboratory; an entity engaging in biomedical or behavioral research; a provider-sponsored organization; a health maintenance organization; a health insurance plan (including group or individual plans); a plan sponsor, issuer, or third-party administrator; or any other kind of health care organization, facility, or plan. The Department also proposed that the term may also include components of State or local governments. The Department proposed a single definition of the term ''health care entity,'' a term used in the Weldon Amendment, the Coats-Snowe Amendment, and ACA section 1553. The Department received comments on this definition.

Comment: The Department received a comment stating that ''health care entity'' should include social workers and schools of social work.

Response: The Department declines to make an explicit inclusion of social workers and schools of social work to the definition of health care entity. It is unclear in many circumstances that such entities deliver health care. The Department's intention in this definition is to provide a non-exclusive list of entities Congress has intended to include as a health care entity. Because the list is non-exclusive, there may be circumstances where a social worker is considered a health care entity under a Federal conscience or anti-discrimination law, but that will depend on the facts and the circumstances in each case as they arise.

Comment: The Department received comments questioning how entities that are not natural persons can hold moral or religious beliefs.

Response: Federal law routinely recognizes corporations, organizations, or other non-natural persons as holders of legal rights and subject to legal obligations. The Federal Government has long recognized the Free Speech and Free Exercise rights of non-profit organizations with charitable missions related to the religious beliefs or moral convictions of its members, and has recognized the Free Speech rights of public corporations. *Citizens United* v. *FEC,* 558 U.S. 310, 365 (2010). The definition of ''person'' that is protected under the Religious Freedom Restoration Act includes both natural and non-natural persons (corporations, partnerships, etc.).[70] In *Hobby Lobby,* having found that the text of the Religious Freedom Restoration Act, 42 U.S.C. 2000bb–2000bb–4 (''RFRA''), does not preclude its application to corporations, the Supreme Court held that a closely held for-profit corporation can assert the religious beliefs of its owners. More specifically, from the enactment of the first paragraph of the Church Amendments in 1973, Federal conscience and anti-discrimination laws have recognized that entities such as hospitals can possess ''religious beliefs or moral convictions'' when prohibiting their facilities from being used for abortions or sterilizations. In addition, the Coats-Snowe and Weldon Amendments, and ACA section 1553, protect organizations or institutions as ''health care entities'' when they object to certain activities concerning abortion or assisted suicide without regard to the motivation for the objection. Both the Coats-Snowe and Weldon Amendments contain definitions of ''health care entity'' that include, as examples, both natural persons and corporate persons. The same is true of the definition of ''health care entity'' in ACA section 1553.

Finally, religious faith and moral convictions are often the organizing principle for entities covered in this rule, and natural persons form these organizations for the purpose of asserting their faith or convictions more forcefully and effectively in the public realm. As the Supreme Court has recognized, there is nothing about organizing in a group that diminishes the rights they would enjoy as individuals.[71] Therefore, the Department considers it appropriate to finalize the definition of health care entities to include non-natural persons.

Comment: The Department received comments stating that the proposed definition of ''health care entity'' exceeds the Department's statutory authority under the Weldon Amendment and the Coats-Snowe Amendment.

Response: The Weldon and Coats-Snowe Amendments and ACA section 1553 each provide a definition of ''health care entity'' that contains a non-exhaustive list of entities that are ''health care entities.'' The Coats-Snowe Amendment says that ''health care entity'' ''includes an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions.'' The Weldon Amendment and ACA section 1553 state that the term ''includes 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.'' All three laws use the word ''includes,'' which means the lists of such entities in the definitions are non-exhaustive, and other entities could also be ''health care entities'' under the plain meaning of the term as used in those statutes. The Coats-Snowe Amendment also uses a catch-all phrase for entities in ''any other program of training in the health professions.'' The Weldon Amendment and ACA section 1553 likewise include catch-all provisions such as ''other health care professional'' and ''any other kind of health care facility, organization, or plan.'' Thus, in defining the term for purposes of this rule, it is consistent with the statutory text to list certain entities that are not explicitly

[69] 83 FR 3880, 3893 (stating the reasons for the proposed definition of ''Federal financial assistance,'' except for the modifications adopted herein).

[70] *See, e.g.,* 42 U.S.C. 2000bb–1 (''Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability, except as provided in subsection (b).''); 1 U.S.C. 1 (''In determining the meaning of any Act of Congress, unless the context indicates otherwise . . . the words ''person'' and ''whoever'' include corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals.''); *Burwell* v. *Hobby Lobby Stores, Inc.,* 134 S. Ct. 2751, 2768 (2014) (''We see nothing in RFRA that suggests a congressional intent to depart from the Dictionary Act definition . . . .'').

[71] *See, e.g., Hobby Lobby,* 134 S. Ct. at 2768 (''When rights, whether constitutional or statutory, are extended to corporations, the purpose is to protect the rights of these people [who constitute the corporation] . . . And protecting the free-exercise rights of corporations like Hobby Lobby . . . protects the religious liberty of the humans who own and control those companies.''); *Citizens United,* 558 U.S. at 391–93 (Roberts, C.J., concurring) (''[T]he individual person's right to speak includes the right to speak *in association with other individual persons* . . . [The First Amendment's] text offers no foothold for excluding any category of speaker, from single individuals to partnerships of individuals, to unincorporated associations of individuals, to incorporated associations of individuals.'').

mentioned in the statutes, because the statutory lists are non-exhaustive; including those entities is consistent with the plain meaning of the terms set forth in those statutes. As explained in the following discussion, however, the Department is finalizing the definition of health care entity to better conform the definition to the varying texts of the specific Federal conscience and anti-discrimination laws that use the term.

Comment: The Department received comments stating that the inclusion of ''a plan sponsor'' in the definition of ''health care entity'' would subject all employers who sponsor group health plans to the conscience statutes using that term. Other commenters contended the laws using those terms did not intend to protect plan sponsors that are not otherwise health care entities. Other commenters suggest that the term ''health care entity'' should not be the same for the Coats-Snowe Amendment, the Weldon Amendment, and ACA section 1553.

The Department received other comments supporting the inclusion of ''plan sponsor'' and ''third party administrator'' in the definition of ''health care entity.'' One comment expressed that faith-based organizations that fund health plans should not be required to fund services or procedures that violate their religious beliefs.

Response: Commenters contending that including particular types of entities in the definition of ''health care entity'' would require such entities to comply with the Coats-Snowe Amendment, the Weldon Amendment, or ACA section 1553 are incorrect. The term ''health care entity'' is used in those statutes—and in this final rule—to specify not which entity must comply with the statute, but which kinds of entities are protected from discrimination. Thus, including an entity in the term ''health care entity'' under those statutes does not expand or affect which governmental or non-governmental fund recipients must comply with those statutes.

The Department concludes it is appropriate to include ''a plan sponsor'' in the definition ''health care entity'' for purposes of the Weldon Amendment and ACA section 1553. The Weldon Amendment explicitly protects entities that do not pay for or provide coverage of abortions, and includes ''health insurance plans, or any other kind of health care facility, organization, or plan'' within its own illustrative list of protected health care entities. ACA section 1553 applies to government entities receiving Federal financial assistance under the ACA, and any health plan created under the ACA. It uses the same definition of ''health care entity'' as the Weldon Amendment, in specifying that health care entities cannot be subject to discrimination for choosing not to provide certain items or services related to assisted suicide. Because the focus of both laws includes protection of health plans, it is consistent with their language and scope to include ''a plan sponsor'' as a protected ''heath care entity.'' In the action of sponsoring a health plan or health coverage, the plan sponsor engages in an important function with respect to health care. Although the sponsor, the plan, and the issuer are all distinct entities, sponsoring a plan and paying for coverage (by an issuer, in the case of a fully insured plan) or for health care services (in the case of a self-insured plan) are part and parcel of the provision of health coverage under a group health plan. The Weldon Amendment is written to prohibit discrimination against, among others, entities that do not provide abortion in health coverage; ACA section 1553 is similarly written to protect entities from being required to provide certain health care items or services in connection with health plans and the ACA. Both laws define health care entity to include the catch-all phrase ''any other kind of health care facility, organization, or plan,'' in order to protect a broad range of entities that might be engaged in providing coverage or services and subject to discrimination for not providing or covering abortion or assisted suicide, respectively. Therefore, treating a plan sponsor as a protected health care entity is consistent with the text of the Weldon Amendment and ACA section 1553.

In further consideration of public comments, however, the Department has concluded that the definition of ''health care entity'' should be different for the Coats-Snowe Amendment than for the Weldon Amendment and ACA section 1553, including with respect to whether to include a plan sponsor. The Coats-Snowe Amendment, while providing a non-exclusive list of entities and individuals included in the term ''health care entity,'' contains a different list of entities and individuals than that set forth in the Weldon Amendment and ACA section 1553. Moreover, the nature and scope of protections set forth in the Coats-Snowe Amendment—which can assist in understanding the intended range of protected health care entities—also differ. The Coats-Snowe Amendment focuses generally on the performance of, training for, and referral for abortions, whereas the Weldon Amendment focuses more broadly on not just providing and referring for, but also providing coverage of, and payment for, abortions. Similar to the Weldon Amendment, and unlike the Coats-Snowe Amendment, ACA section 1553 focuses on the context of health plans and coverage in addition to the provision of items and services. Consequently, the Department concludes that it is appropriate to finalize a definition of health care entity for the Coats-Snowe Amendment that is somewhat different from the definition applicable to the Weldon Amendment and ACA section 1553, and to not include in the definition for purposes of the Coats-Snowe Amendment entities pertaining specifically to the health insurance and coverage context, namely, a provider-sponsored organization, a health maintenance organization, a health insurance plan (including group or individual plans), a plan sponsor, an issuer, or a third-party administrator. Likewise, the Department deems it appropriate not to list in the definition applicable to the Coats-Snowe Amendment the catch-all phrase that is in the statutory text of the Weldon Amendment and ACA section 1553: ''or third-party administrator; or any other kind of health care organization, facility, or plan.''

Otherwise, the Department deems it appropriate to include in both definitions of health care entity the proposed rule's non-exhaustive enumeration of various individual and organizational entities that engage in health care practices or services: ''an individual physician or other health care professional; health care personnel; a participant in a program of training in the health professions; an applicant for training or study in the health professions; a post-graduate physician training program; a hospital; a medical laboratory; [or] an entity engaging in biomedical or behavioral research.'' [72] Because the Department intended these entities to be health care entities, and the term ''laboratory'' could be interpreted to include laboratories that are not related to health care, the Department finalizes the term ''laboratory'' in these definitions to add the word ''medical'' to clarify its health care scope.

These entities are health care entities under the ordinary meaning of that term because they are engaged in health care practices, training, or research. They are also similar to the types of individuals and entities listed in the non-exclusive lists of health care entities in the Coats-

[72] That is not to say that certain types of health plans could not also be health care providers, *e.g.,* staff model health maintanence organizations.

Snowe Amendment, the Weldon Amendment, and ACA section 1553. All three statutes list individuals and personnel in the health professions, not just corporate entities. This demonstrates that Congress explicitly intended the term health care entity in all three to protect individuals, not just organizational entities. All three definitions also list organizational entities, and of course they all contain the basic term ''health care entity,'' which must be interpreted to encompass terms included in its ordinary meaning.

Finally, the proposed definition of ''health care entity'' concludes by specifying that it ''may also include components of State or local governments.'' To clarify the meaning of this sentence, the Department finalizes it with a change in each definition of ''health care entity,'' to read: ''As applicable, components of State or local governments may be health care entities under'' the Coats-Snowe Amendment, the Weldon Amendment, and ACA section 1553.

Comment: The Department received a comment stating that pharmacies and pharmacists are sometimes not understood to be health care providers and asking that pharmacists and pharmacies be included in the provisions of this rule.

Response: The Department accepts this recommendation and is including pharmacies and pharmacists in the definitions of ''health care entity.'' A pharmacy is a health care entity, considering the ordinary meaning of that term, because it provides pharmaceuticals and information, which are health care items and services. Regarding pharmacists, because Congress specified that the term ''health care entity'' in the Coats-Snowe Amendment, the Weldon Amendment, and ACA section 1553, includes certain individuals in the health professions, and does not provide an exclusive definition, the Department deems it appropriate to include pharmacists, who are also health care professionals. Whether a particular protection in those three laws applies to a pharmacist or pharmacy in a particular case, or whether it applies to any of the examples in these definitions, is a separate question that will be determined in the context of the factual and legal issues applicable to the situation. For the purpose of specifying whether a pharmacist or pharmacy could possibly be covered by the term health care entity in these three laws, depending on the circumstances, the Department deems it appropriate to include them in the list of individuals and entities set forth in these definitions.

Comment: The Department received comments suggesting that ''health care entity'' should include public school districts that provide on-campus medical care or manage vaccination records.

Response: The definition specifies that ''health care entity'' also includes components of State or local governments. The Department does not believe the definitions need to specify further that public school districts providing on-campus medical care are included. The Department will evaluate the applicability of the rule to public school entities with health care functions according to the facts and circumstances of each case as they arise and the applicable laws.

Comment: The Department received a comment proposing that ''health care entity'' exclude occupational therapists.

Response: To the extent that occupational therapists are health care personnel qualifying as ''other health care professionals,'' the Department disagrees that they would be necessarily excluded from protection. While some questions concerning who qualifies for protection in a particular circumstance are relatively straightforward, such as physicians under certain conscience protection laws, some questions are closer and depend on the facts and the applicable law. The Department, therefore, declines to make explicit exclusions, such as for occupational therapists, to the definitions of health care professionals, and will instead consider individual cases based on the facts and circumstances presented in each case as they arise and the applicable law.

Comment: The Department received comments stating that the inclusion of ''health care personnel'' exceeds the definition of ''health care entity'' under the Weldon Amendment or other laws using that term.

Response: The Department disagrees. The list of individuals, persons and entities included as a ''health care entity'' in the Weldon Amendment and ACA section 1553 includes ''an individual physician,'' and also the catch-all phrases ''or other health care professional.'' The Coats-Snowe Amendment says the term includes ''individual physician'' and ''a participant in a program of training in the health professions.'' Because the term ''health care entity'' includes individuals, and the definitions are non-exclusive, the Department deems it appropriate to include other individuals who are health care personnel. Including ''health care personnel'' and/or ''health care professional'' in the definition of ''health care entity'' is, therefore, consistent with Congress's explicit inclusion of individual persons in the health care field. Doing so effectuates the remedial purposes of the Coats-Snowe Amendment, the Weldon Amendment, and ACA section 1553, and is consistent with their texts.

Comment: The Department received comments requesting that ''health care professional'' and ''health care personnel'' be defined terms.

Response: The Department declines to define these terms. The Department believes it is appropriate to determine remaining potential questions about the scope and application of the term ''health care entity'' based on an analysis of facts and circumstances presented in each case as they arise. Regarding health care professionals, State and local law might also be relevant concerning which persons are considered health care professionals. Because those laws differ, the Department considers it appropriate not to specify a single definition of health care professional or health care personnel in this rule. Parts of the Church Amendments use the terms ''personnel'' and ''health care personnel,'' but do not define those terms. Although this rule also does not define those terms, the Department believes this rule provides some additional clarity to the application of Federal conscience and anti-discrimination laws.

Summary of Regulatory Changes: For the reasons described in the proposed rule [73] and above, and considering the comments received, the Department finalizes the definition of ''health care entity'' with changes to bifurcate the definition into two: One applicable for purposes of the Coats-Snowe Amendment, and the other applicable for purposes of the Weldon Amendment and ACA section 1553. Both definitions add pharmacies and pharmacists. Both add the word ''medical'' before the term ''laboratory'' to more clearly describe its health care scope, and both note that ''as applicable, components of State or local governments may be health care entities.'' The definition applicable to the Coats-Snowe Amendment omits the terms ''a provider-sponsored organization; a health maintenance organization; a health insurance plan (including group or individual plans); a plan sponsor, issuer, or third-party administrator; or any other kind of

[73] 83 FR 3880, 3893 (stating the reasons for the proposed definition of ''health care entity,'' except for the modifications adopted herein).

health care organization, facility, or plan.''

Health program or activity. The Department proposed that ''*Health program or activity*'' includes the provision or administration of any health-related services, health service programs and research activities, health-related insurance coverage, health studies, or any other service related to health or wellness, whether directly through payments, grants, contracts, or other instruments, through insurance, or otherwise.

Under the proposed rule the terms ''health program or activity'' and ''health service program'' differed mainly in that the former included ''the provision or administration of any health-related services,'' while the latter included any ''plan or program that provides health benefits.'' Because ''health service program'' could be seen as narrower, the phrase health program or activity incorporated ''health service program'' explicitly as part of its definition. The Department asked for comment ''on whether the terms mean the same thing and should or could be defined interchangeably for purposes of this regulation.'' [74]

The Department did not receive specific comments on this question, but the comments received regarding the two definitions generally treated the two phrases as identical. Upon further consideration the Department has concluded that there are insufficient grounds for defining such similar terms differently under the rule.

The Department is finalizing the rule without defining ''health program or activity'' because other revisions have eliminated the use of the phrase in the regulation text as finalized. However, for reasons explained below, the Department adopts (with minor edits) the definition proposed for ''health program or activity'' as the definition for ''health service program.'' All questions and responses to comments concerning ''health program or activity'' apply fully and ''transfer'' to ''health service program.''

Comment: The Department received comments stating that the definition of ''health program or activity'' should explicitly include vaccination programs or the processing of vaccination records.

Response: Because of the broad scope of what could constitute a ''health program or activity'' (now ''health service program''), the Department declines to attempt a comprehensive listing of examples of such programs or activities and instead relies on the general standard proposed. The Department believes vaccination programs would reasonably be considered a health program or activity (or a health service program) and notes that one of the statutes that is the subject of this rule concerns vaccination explicitly (42 U.S.C. 1396s(c)(2)(B)(ii)).

Comment: The Department received comments stating that the definition of ''health program or activity'' (now ''health service program''), when combined with the definition of ''assist in the performance'' and ''refer,'' could result in disparate impact against women, LGBT persons, and religious minorities.

Response: The Department disagrees. This rule implements underlying statutory requirements and prohibitions set forth by Congress. The terms defined in this rule do not apply to women, LGBT persons, or religious minorities in any way that differs from how Congress applied the terms in the statutes it adopted. To the extent commenters contend that some Federal conscience and anti-discrimination laws themselves adversely impact women because they concern abortion, the Department disagrees, but is in any event required to implement and enforce Federal conscience and anti-discrimination laws as Congress wrote them.

Comment: The Department received comments stating that the definition of the term ''health program or activity'' (now ''health service program''), is overly broad; and, when combined with section 104A of the Foreign Assistance Act of 1961, could result in otherwise unauthorized discrimination against minority groups or persons in sex trafficking in programs funded under section 104A.

Response: The Department disagrees. The relevant language of section 104A, ''any program or activity'' (22 U.S.C. 7631(d)(1)(B)), is broader than, and clearly includes, any ''health service program.'' As the Department only administers section 104A funds (as relevant to this rule) with respect to health, the definition of ''health program or activity'' is not intended to limit, and in no way limits, any protection from discrimination provided in section 104A of the Foreign Assistance Act of 1961. Additionally, nothing in 22 U.S.C. 7631(d)(1)(B) exempts certain programs or activities from its conscience protections.

Summary of Regulatory Changes: For the reasons described in the proposed rule,[75] above and below, and considering the comments received, the Department adopts the definition of ''health program or activity'' as proposed as the definition of ''health service program,'' except makes a technical edit for clarity by replacing commas with semicolons after ''directly,'' the phrase ''through payments, grants, contracts, or other instruments,'' and after ''through insurance.'' Additionally, it deletes the reference to ''health service program'' from the proposed definition as circular.

Health service program. The Department proposed that ''Health service program includes any plan or program that provides health benefits, whether directly, through insurance, or otherwise, and is funded, in whole or part, by the Department. It may also include components of State or local programs.'' The Department received comments on this definition.

Comment: The Department received comments stating that the definition of ''health service program'' expands the scope of the Federal conscience and anti-discrimination laws ''to include virtually any medical treatment or service, biomedical and behavioral research, and health insurance.''

Response: The Department disagrees. Among the statutes that are the subject of this rule, the phrase ''health service program'' appears only once, in paragraph (d) of the Church Amendments. That paragraph addresses the right of persons to decline to ''perform or assist in the performance'' of ''any part'' of a health service program or research activity funded in whole or in part under a program administered by the Secretary of HHS if such performance or assistance would be contrary to the person's religious beliefs or moral convictions. Many commenters' objections to this definition are fundamentally objections to the text of paragraph (d) of the Church Amendments as passed by Congress. The Department believes that other commenters may misunderstand the scope of paragraph (d). Generally, the protections of paragraph (d) follow the funds provided by any program administered by the Secretary. But paragraph (d) does not encompass every medical treatment or service performed by any entity receiving Federal funds from HHS for whatever purpose. Instead, Congress narrowly focused paragraph (d) to prohibit the coercion of persons ''in performance of'' health service programs funded under a program administered by the Secretary. Many medical treatments and services performed by health care providers are not ''part of'' a health service program receiving funding from HHS. In such

[74] 83 FR 3880, 3894.

[75] 83 FR 3880, 3893–94 (stating the reasons for the proposed definition of ''health program or activity,'' except for the modifications adopted herein).

circumstances, paragraph (d) would not apply.

This distinction can be illustrated by considering the parallel term used in paragraph (d), ''research activity.'' For example, if an entity receives a grant from a program administered by HHS to conduct research on a new cancer treatment, paragraph (d) of the Church Amendments would protect individuals involved in the performance of any part of that research activity. But if the entity engages in other research activities that are not funded by HHS (*i.e.,* not related to the cancer treatment for which the research grant was issued in this example), paragraph (d) would not apply to those other activities. This would hold true even if other statutory provisions that are the subject of this rule would apply to those other research activities.

Similarly, Medicaid is funded in whole or in part under a program administered by the Department. Nevertheless, if a health care provider receives Medicaid reimbursements for some medical treatments, but is providing other medical treatments that are not being reimbursed by Medicaid or otherwise funded by the Department, the provider—with respect to the non-Medicaid treatment—is not performing ''part of a health service program'' funded by a program administered by HHS. Because Medicaid generally provides reimbursements for particular treatments, not for a medical practice overall, providing a treatment not reimbursed by Medicaid would generally not be ''part of a health service program . . . funded in whole or in part under'' Medicaid for the purposes of paragraph (d) of the Church Amendments, even if the overall medical practice also receives Medicaid reimbursements for other treatments.

The Department intends to enforce paragraph (d) of the Church Amendments consistent with the text of the statute. It would be inappropriate for the Department to define ''health service program'' to exclude programs that involve health services and that are funded (in whole or in part) under a program administered by HHS, when Congress specified that paragraph (d) of the Church Amendments covers such programs. The Department believes that the specific limitations in paragraph (d) concerning the circumstances in which it applies has already (under the statute) prevented the realization of many overbreadth concerns raised by commenters, and will continue to do so under this rule, notwithstanding the plainly broad meaning of the term ''health service program'' itself.

Comment: The Department received a comment stating that the definition of ''health service program'' should only apply in the context of biomedical research.

Response: The Department disagrees. Congress used the disjunctive phrase ''health service program or research activity'' in paragraph (d) of the Church Amendments. Nothing in the phrase or its context (the surrounding text) indicates that the protection provided by Congress is limited only to biomedical research. If ''health service program'' meant only research activities, then Congress's addition of ''or research activity'' would be superfluous. Further, in a separate provision of the Church Amendments enacted at the same time as paragraph (d), paragraph (c)(2), Congress provided specific prohibitions for entities that receive grants or contracts ''for biomedical or behavioral research'' alone, without including health service programs. This demonstrates that Congress's inclusion or omission of ''health service program'' was a considered decision intended to have substantive effect.

Summary of Regulatory Changes: The Department asked for comment on whether ''health program or activity'' and ''health service program'' should or could be defined interchangeably for purposes of this regulation [76] but received no specific comments on the question. Upon further consideration the Department has concluded that there are insufficient grounds for defining such similar terms differently under the rule.

The Department's definition for ''health service program'' in the proposed rule mirrored the definition of the term in the 2008 Rule.[77] The 2008 Rule, in turn, incorporated the phrase ''health benefits'' into the definition of ''health service program'' by borrowing from Section 1128B(f)(1) of the Social Security Act's (42 U.S.C. 1320a–7b(f)(1)) definition of ''Federal health care program''—the rationale being that ''Federal health care program'' was similar enough to ''health service program,'' to warrant the borrowing. With respect to the inclusion of ''health benefits,'' in the definition of ''health service program,'' this was appropriate because the Federal health service programs implemented under the Social Security Act are programs administered by the Secretary—and, thus, consistent with the language of the Church Amendment. However, the Social Security Act is not (and was not) the exclusive basis for defining the scope of ''health service program.'' The Department believes that it is also appropriate to consider the Public Health Service Act (PHSA) as a source for defining the term ''health service program'' because, (1) the Church Amendments themselves cite the PHSA to help establish what programs are covered and (2) the PHSA uses the phrase ''health service program'' and ''health services'' numerous times. For example, the PHSA provides grant authority to assist States and other public entities ''in meeting the costs of establishing and maintaining preventive health service programs'' (42 U.S.C. 247b), and grants the Secretary permission to enter into contracts to ''furnish health services to eligible Indians'' (42 U.S.C. 238m).

The terms ''health services'' and ''health service program,'' as used by the PHSA, clearly include the provision of health care or health benefits, but they also include health-*related* services. For example, the PHSA uses the phrase ''environmental health services'' to describe programs that deal with the detection and alleviation of ''unhealthful conditions'' associated with water supply, chemical and pesticide exposures, air quality or exposure to lead. 42 U.S.C. 254b(b)(2)(C). These are health-related programs. Moreover, the PHSA uses the phrase ''health service programs'' explicitly and includes ''preventive'' programs within its ambit including—for example, programs for ''the control of rodents'' and ''for community and school-based fluoridation programs.'' 42 U.S.C. 300w–3(a)(1)(B). These are health-related programs.

In light of the above, and for the sake of consistency and to avoid confusion, the Department finalizes the term ''health service program'' as equivalent to ''health program or activity'' (with minor changes). The Department is no longer including a definition of ''health program or activity'' but in light of public comments, is finalizing a definition of ''health service program'' with changes that incorporate some of the elements of both terms, based on concerns raised about both definitions in the public comments. The finalized definition states that ''health service program includes the provision or administration of any health or health-related services or research activities, health benefits, health or health-related insurance coverage, health studies, or any other service related to health or wellness, whether directly; through payments, grants, contracts, or other instruments; through insurance; or otherwise.''

[76] 83 FR 3880, 3894.

[77] *Id.*

Individual. The Department proposed that ''*Individual* means a member of the workforce of an entity or health care entity.'' The Department received comments on this definition.

Comment: The Department received a comment stating that the definition of ''individual'' should include ''persons exercising their right of informed consent to decline a healthcare service on the basis of religion or conscience.''

Response: Upon considering this comment and reviewing the use of the word ''individual'' throughout the proposed rule, the Department agrees that the term has multiple meanings depending on the context of its use in the rule and in applicable statutes. Sometimes it refers to members of the workforce of an entity or health care entity, and other times it refers to persons who are not health care providers and yet are protected by the Federal conscience and anti-discrimination laws at issue in this rule, such as an individual who makes use of a religious nonmedical health care institution or an individual who ''is conscientiously opposed to acceptance of the benefits of any private or public insurance.'' Because ''individual'' has multiple meanings throughout the rule, and the meaning of ''individual'' is clear in each instance from its context, the inclusion of a definition for ''individual'' introduces unnecessary confusion. Consequently, the Department is deciding not to finalize the proposed definition, or any definition, of the word ''individual'' in the final rule. As ''individual'' is no longer a defined term, additional comments on the definition of the word ''individual'' are either addressed by that change, or not necessary to address further.

Summary of Regulatory Changes: For the reasons described above, and considering the comments received, the Department does not finalize the proposed definition of ''individual'' and removes the word ''individual'' and its definition from the list of defined terms.

Instrument. The Department proposed that ''*Instrument* is the means by which Federal funds are conveyed to a recipient, and includes grants, cooperative agreements, contracts, grants under a contract, memoranda of understanding, loans, loan guarantees, stipends, and any other funding or employment instrument or contract.'' The Department did not receive comments on this definition.

Summary of Regulatory Changes: For the reasons described in the proposed rule [78] and above, the Department adopts the definition of ''instrument'' as proposed.

OCR. The Department proposed that OCR means the Office for Civil Rights of the Department of Health and Human Services. The Department did not receive comments on this definition.

Summary of Regulatory Changes: For the reasons described in the proposed rule [79] and above, the Department adopts the definition of ''OCR'' as proposed.

Recipient. The Department proposed that ''*Recipient* means any State, political subdivision of any State, instrumentality of any State or political subdivision thereof, and any person or any public or private agency, institution, organization, or other entity in any State including any successor, assign, or transferee thereof, to whom Federal financial assistance is extended directly from the Department or a component of the Department, or who otherwise receives Federal funds directly from the Department or a component of the Department, but such term does not include any ultimate beneficiary. The term may include foreign or international organizations (such as agencies of the United Nations).'' The Department received comments on this definition.

Comment: The Department received a comment stating that while the proposed definition of ''recipient'' recognizes that an individual or organization must comply with the provider conscience regulations if the individual or organization receives funds ''directly from the Department or component of the Department' to carry out a project or program,'' the proposed rule does not explain how ''compliance with the regulations would not be required for products or services offered by the individual or organization that are unrelated to the Federal funding.''

Response: Fitting within the definition of a ''recipient'' alone does not necessarily subject an entity to all of the requirements of the statutes implemented through this rule. In each paragraph of § 88.3 of this rule, there is an ''*Applicability*'' paragraph and a ''*Requirements and prohibitions*'' paragraph that describe, in more particularity for each Federal conscience and anti-discrimination law being implemented by the paragraph, the scope of the statute and, thus, this regulation.

As discussed concerning the definition of the term ''entity,'' the Department is finalizing the terms ''entity,'' ''recipient,'' and ''sub-recipient'' with parallel language to clarify that they all may encompass ''a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).''

Summary of Regulatory Changes: For the reasons described in the proposed rule [80] and above, and considering the comments received, the Department finalizes the definition of ''recipient'' with a change to the last sentence, so that rather than referring only to ''foreign or international organizations,'' it reads ''The term may include a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).''

Referral or *refer for.* The Department proposed that ''Referral or refer for'' be defined as including the provision of any information (including but not limited to name, address, phone number, email, website, instructions, or description) by any method (including but not limited to notices, books, disclaimers or pamphlets online or in print), pertaining to a health care service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or directions that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, when the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral. The Department received comments on this definition, including general comments in support of and opposition to the proposed definition.

Comment: The Department received comments stating that the proposed definition of ''referral or refer for'' should be maintained as it appropriately allows healthcare professionals to abide by their own professional and ethical judgments.

Response: The Department agrees that the definition of ''referral or refer for'' is appropriate, except for the addition of relatively minor narrowing and clarifying changes as discussed below.

Comment: The Department received comments stating that the proposed definition of ''referral or refer for'' exceeds the scope of the Weldon Amendment or the Coats-Snowe Amendment.

[78] 83 FR 3880, 3894.

[79] 83 FR 3880, 3894.

[80] 83 FR 3880, 3894 (stating the reasons for the proposed definition of ''recipient,'' except for the modifications adopted herein).

Response: The Department disagrees. Neither the Weldon nor Coats-Snowe Amendment defines ''referral'' or ''refer for.'' The definition is a reasonable interpretation of these terms and faithfully effectuates the text and structure of Congress's protection of health care professionals and entities from being coerced or compelled to facilitate conduct (with respect to Weldon and Coats-Snowe, concerning abortion) that may violate their legally protected rights through the forced provision of referrals. For example, in the Weldon Amendment and section 1303 of the ACA, Congress did not merely protect the action of declining to refer to an abortion provider, but of declining to refer ''for'' abortions generally. This more broadly protects a decision not to provide contact information or guidance likely to assist a patient in obtaining an abortion elsewhere.

The rule's definition of ''referral'' or ''refer for'' also comports with dictionary definitions of the word ''refer,'' such as the Merriam-Webster's definition of ''to send or direct for treatment, aid, information, or decision.'' *Refer, Merriam-Webster.com*, available at *https://www.merriam-webster.com/dictionary/refer* (last accessed April 9, 2019) (emphasis added); *see also Refer, Dictionary.com*, available at *https://www.dictionary.com/browse/refer* (last accessed April 9, 2019) (defining *refer* as ''to direct for information or anything required'' and ''to hand over or submit for information, consideration, decision, etc.'').

This interpretation properly serves the remedial purposes of these protections. Recent attempts at coerced referrals for abortion, such as California's Reproductive FACT Act, have taken the form of compelled display of information discussing the availability of State-subsidized abortions. The purpose, design, and effect of such displays of information is precisely to assist patients in obtaining abortions if they so choose. As discussed elsewhere in this rule, OCR found that the FACT Act's compelled display of such information to members of the public is a type of referring or referral ''for'' abortion that Congress prohibited in the Weldon and Coats-Snowe Amendments.[81]

Nevertheless, the Department has made significant modifications to the definition of ''discrimination'' that address the concerns raised by commenters concerning the definition of referral. Specifically, the Department recognizes greater latitude for accommodation procedures by employers and entities and has added additional exclusions and exemptions under the rule. In doing so, the rule narrows the scope of possible bases of a violation under the rule.

For example, the rule allows an employer, when there is a reasonable likelihood it may ask its employees in good faith to refer for, participate in, or assist in the performance of potentially objected to conduct, to require its employee to inform it of any objections. Thus, a hospital that regularly performs elective abortions may ask a nurse hired to work in the OB/GYN department if he or she anticipates having any objections to assisting in the performance of elective abortions to allow the hospital to make appropriate, non-discriminatory staffing arrangements. Barring other facts, if the nurse refuses to answer, the Department would not treat any resultant adverse action by the employer against the nurse as ''discrimination'' under the rule.

These significant changes to the rule's definition of discrimination respect the laws provided by Congress and the interests of all parties—employers, health care entities, and individual physicians—who wish to provide services allowed by law according to their consciences.

Additionally, the Department agrees that some proposed terms in the definition of refer or referral were unnecessarily broad, and therefore the Department finalizes the definition with narrowing edits as set forth in response to comments regarding specific phrases discussed below.

Comment: The Department received comments stating that the proposed definition of ''referral or refer for'' would interfere with legal and ethical duties of doctors to provide information to their patients.

Response: The Department disagrees. The rules do not prohibit any doctor or health care entity from providing information to their patients—or referring for a medical service or treatment—if they feel they have a medical, legal, ethical, or other duty to do so. The rules simply enforce existing laws that prevent doctors or other protected entities from being forced to refer for abortions against their will or judgment. The rule's definition of ''referral or refer for'' ensures that doctors can use their own professional, medical, and ethical judgment without being coerced by entities receiving Federal funds to violate their moral or religious convictions. To the extent a State subject to this rule (under, for example, the Coats-Snowe Amendment or the Weldon Amendment) legally mandates that protected individuals and entities refer for abortion, Congress has indicated such mandates are inconsistent with Federal law.

Comment: The Department received comments stating that the proposed definition of ''referral or refer for'' would violate the requirement that patients receive informed consent before performing treatments.

Response: A similar objection is discussed above concerning the definition of ''assist in the performance'' and its inclusion of referrals. The Department disagrees with the objection. Federal conscience and anti-discrimination laws specifically shield certain persons and entities from being required to provide referrals for abortion. Indeed, medical ethics have long protected rights of conscience alongside the principles of informed consent. The Department does not believe that enforcement of conscience protections, many of which date to the era of *Roe* v. *Wade* and *Doe* v. *Bolton,* violates or undermines the principles of informed consent. This final rule will not change existing laws requiring doctors to secure informed consent from patients before performing medical procedures.

Comment: The Department received comments stating that the proposed definition of ''referral or refer for'' conflicts with Title X of the Public Health Service Act.

Response: As discussed above, the Department concluded in 2008 and again in the preamble to the proposed rule in this rulemaking that the 2000 Regulations governing the Title X program, which required Title X projects and providers to provide abortion counseling, information and referrals in certain circumstances, conflict with certain Federal conscience and anti-discrimination laws. Notably, that requirement was imposed by the Department, not by Congress in Title X itself, which has long prohibited the use of Title X funds ''in programs where abortion is a method of family planning.'' 42 U.S.C. 300a–6. The Department has amended the Title X regulations to remove the requirements for abortion counseling, information, and referrals, while permitting the provision of nondirective counseling on, and information about, abortion. Under the 2019 final rule governing the Title X program, the Title X regulations no longer conflict with Federal conscience and anti-discrimination laws or this final rule. Regardless, as the Department

[81] Letter from Roger T. Severino, Dir., Dep't of Health & Human Serv's. Office for Civil Rights, to Xavier Becerra, Att'y. Gen., State of Cal. (Jan. 18, 2019), *available at https://www.hhs.gov/sites/default/files/california-notice-of-violation.pdf.*

recognized in the 2008 Rule, a Federal regulatory requirement that a Title X applicant, grantee, program, or clinic—a recipient of Federal funds in carrying out a HHS program—provide abortion counseling, information, and referrals cannot be enforced against such entities whose refusal to do so is protected by applicable Federal conscience and related nondiscrimination statutes.

Comment: The Department received comments stating that including ''the provision of any information . . . by any method'' in the definition ''referral'' or ''refer for'' goes beyond the meaning of those words in the statutes.

Response: The definition's breadth reflects the fact that conscientious objections to, or the nonperformance of, acts that facilitate the conduct of a third party may take many forms and occur in many contexts. Nevertheless, the Department agrees that the phrases ''any information'' and ''any method'' as well as ''any assistance'' are unnecessarily broad, and therefore deletes the three appearances of the word ''any'' from the definition. The rule instead relies on the non-exhaustive list of illustrations to guide the scope of the definition. Additionally, the rule permits the description of specific methods of transmitting information, namely, ''any method (including but not limited to notices, books, disclaimers or pamphlets, online or in print),'' and replaces the list with the clearer and more concise statement of ''in oral, written, or electronic form.''

Comment: The Department received comments stating that the proposed definition of ''referral or refer for'' could permit a provider to turn away a patient experiencing complications from an objected-to medical drug, device, or service without providing any information.

Response: To the extent the comments concern providers that decline to volunteer certain information or make referrals to other providers, the applicability of the rule would turn on the individual facts and circumstances of each case. In making a determination, the Department will consider the relationship between the treatment subject to a referral request and the underlying service or procedure giving rise to the request. The Department, however, is not aware of any providers that would refuse to treat or refer a person with unforeseen and unintended complications arising from, for example, an abortion procedure that the provider would not perform.

Comment: The Department received comments stating that the proposed definition of ''referral or refer for'' could result in a health care professional refusing to refer a woman for treatment of ovarian cancer because sterilization would be a ''possible outcome of the referral.''

Response: The Department agrees that ''possible outcome of the referral'' is unnecessarily broad. The Department is therefore changing the word ''possible'' to ''reasonably foreseeable,'' which still recognizes robust protection to conscientious objectors as provided by Congress, but requires a stronger connection between the referral and the objected-to activity or result. The Department also finalizes the definition with a change to eliminate subjective language concerning what an entity ''sincerely understands'' out of similar concerns about overbreadth.

Comment: The Department received a comment suggesting that ''referral or refer for'' should be defined as ''active facilitation of access.''

Response: The Department disagrees and believes such a definition would risk improperly narrowing the protections provided by Congress. For example, California's Reproductive FACT Act (which the Supreme Court ruled in *NIFLA* likely violates the Constitution, 138 S. Ct. at 2371–76), involved a requirement that health care facilities opposed to abortion tell women that the State may provide free or low cost abortion, and provide the women a phone number for further information on how to access those abortions. After investigating complaints related to the FACT Act, the Department found that mandating the communication of such information to members of the public is a type of referring or referral ''for'' abortion that Congress prohibited in conscience protection statutes.[82] Narrowing the definition to the ''active facilitation of access'' may subject many health care providers to coercive requirements that the Department has already found violate the law. The definition finalized here better includes the full range of referral activities protected by Congress.

Comment: The Department received comments stating that the definition of ''referral or refer for,'' when applied to employees of health plans, could hinder people who are attempting to determine what services are covered by their insurance plans and what doctors are in their plans or could be used to not process claims for objected-to services under a health plan. The comments suggested limiting conscience protections to health plans themselves rather than including the plans' employees, exempting administrative tasks performed by a health plan's employees, or limiting the definition of ''referral or refer for'' to not include health plans or their employees.

Response: The Department replaced paragraph (4) to the definition of ''discriminate or discrimination'' to make clear that employers can use, and are encouraged to pursue, accommodation procedures with protected employees. Additionally, the Department added paragraphs (5) and (6) to the definition of discrimination to clarify that, within limits, employers may require protected employees to inform them of objections to referring for, participating in, or assisting in the performance of specific procedures, programs, research, counseling, or treatments to the extent there is a reasonable likelihood[83] that the protected entity or member may be asked in good faith to refer for, participate in, or assist in the performance of such conduct.

Consistent with the terms of paragraphs (5) and (6) of the definition of discrimination regarding advance notice by an employee of the potential for a conscientious objection, an employer may similarly require an employee to notify them in a timely manner of an actual conscientious objection that the employee has to a specific act, in the day-to-day course of work, that the employee would otherwise be expected to perform.[84]

[82] Letter from Roger T. Severino, Dir., Dep't of Health & Human Serv's. Office for Civil Rights, to Xavier Becerra, Att'y. Gen., State of Cal. (Jan. 18, 2019), *available at https://www.hhs.gov/sites/default/files/california-notice-of-violation.pdf.*

[83] For example, nurses assigned exclusively to nursing homes for elderly patients would not be expected to refer or assist in the performance of any sterilization procedures or abortions, and thus, it would be inappropriate for an entity subject to the prohibitions in this rule to require such nurses to disclose whether or not they have any objections to referring or assisting in such procedures.

[84] The Department notes material legal and factual distinctions between, on the one hand, an employer requiring an employee to notify it of a conscientious objection covered by this rule and, on the other, the accommodation process for religious employers in the Department's previous regulations mandating employer coverage of contraception and sterilization. 80 FR 41318 (July 14, 2015). Numerous religious organizations brought challenges under RFRA concerning the ''accommodation'' process promulgated under those rules. RFRA prevents the Federal Government from substantially burdening a person's religious exercise unless in furtherance of a compelling governmental interest and in the manner least restrictive of that exercise. Under the accommodation, objecting religious organizations that self-insured would have been required to notify either the third-party administrator of their health plan, via a certain prescribed form, or HHS, via a letter containing certain prescribed information, of their objection to including contraception and sterilization in their health plans. Plaintiffs in those cases argued that providing such notice would itself have violated their religious beliefs. But a crucial element of the plaintiffs' argument in the context

Continued

Employers and programs that subsequently take steps to use alternate staff or methods to provide for or further the objected-to conduct would not be considered to engage in discrimination—nor would the requirement for the objecting entity to provide notice to the employer or program be considered a referral—if the employer or program does not take any adverse action against the objecting person or entity, if such methods do not exclude persons from fields of practice on the basis of their protected objections, and if the employer or program does not require any additional action by the objecting person or entity beyond the provision of notice discussed above. The employer may also inform the public of the availability of alternate staff or methods to provide or further the objected-to conduct if it does not constitute taking any adverse action against the objecting person or entity.

The Department believes that incorporating these significant limitations to the scope of discrimination and, thus, addressing issues that may arise for an employer when a health care entity objects to making a referral, solves concerns such as those raised by this comment.

Comment: The Department received comments stating that the proposed definition of ''referral or refer for,'' because it applies to public notices, would prohibit California's Reproductive FACT Act, ''which requires facilities specializing in pregnancy-related care to disseminate notices to all clients about the availability of public programs that provide free or subsidized family planning services, including prenatal care and abortion.''

Response: As discussed above, the Department has already found that the FACT Act violated the Weldon and Coats-Snowe Amendments, and the Supreme Court, in *NIFLA,* 138 S. Ct. at 2371–76, ruled that it likely violates the First Amendment's free speech protections for targeting pro-life health care entities and compelling them to provide information about how to obtain abortions.

Comment: The Department received comments stating that the proposed definition of ''referral or refer for'' conflicts with the DeConcini Amendment, which states, ''[I]n order to reduce reliance on abortion in developing nations, funds [to carry out the provisions of chapters 1 and 10 of part I of the Foreign Assistance Act of 1961] shall be available only to voluntary family planning projects which offer, either directly or through referral to, or information about access to, a broad range of family planning methods and services'' (Consolidated Appropriations Act, 2019, Public Law 116–6, Div. F, sec. 7018).

Response: The Department disagrees. The DeConcini Amendment's reference to ''a broad range of family planning methods and services'' does not include abortion. Rather, the amendment itself contrasts abortion with that broad range of family planning methods and services and excludes abortion as a method of family planning. Another proviso bars the use of ''funds made available under this Act . . . to pay for the performance of abortion as a method of family planning or to motivate or coerce any person to practice abortions'' and ''[t]hat nothing in this paragraph shall be construed to alter any existing statutory prohibitions against abortion under section 104 of the Foreign Assistance Act of 1961.'' The Department believes the best reading of that amendment is that the broad range of family planning methods and services is viewed as an alternative to abortion, not that the amendment mandates referrals for abortion as if they are part of family planning. In the context of foreign assistance, since the 1980s, four different presidential administrations have implemented policies to prohibit foreign assistance for family planning to go to entities that perform or actively promote abortion as a method of family planning, and Congress has been aware of those policies.[85] Furthermore, the DeConcini Amendment's discussion of a broad range of family planning methods and services is nearly identical to the scope of the Title X statute, 42 U.S.C. 300. In that context, Congress made clear that it does not consider abortion to be a method of family planning and, in fact, prohibits the use of Federal funds in programs where abortion is a method of family planning. *See* 42 U.S.C. 300–6.

Comment: The Department received comments stating that the definition of ''referral or refer for'' could permit a health care provider to refuse to ever refer a patient to an OB/GYN for any reason because a future possible outcome of such a referral could be that the patient seeks an abortion or sterilization from the OB/GYN, even though the direct referral is not for such service.

Response: The commenters' concerns seem far-fetched, but are, nevertheless, addressed by the change from the word ''possible outcome'' to ''reasonably foreseeable outcome,'' which requires a stronger connection between the referral and the objected-to conduct. The Department does not find there to be reason to foresee that objectors would use the Weldon or Coats-Snowe Amendments or these rules to refuse to refer women to every OB/GYN.

Summary of Regulatory Changes: For the reasons described in the proposed rule [86] and above, and considering the comments received, the Department finalizes the definition of ''referral or refer for'' with changes as described above. The comments lead the Department to believe the text as originally proposed was unduly long, confusing, and repetitive and therefore finalizes the definition with numerous stylistic changes and deletions and nonsubstantive reordering of text to substantially improve readability. The Department also finalizes the rule to clarify that assistance related to a ''program'' is also encompassed by the definition in order to track the use of that phrase in statutes, including the Weldon and Coats-Snowe Amendments,

of self-insured plans was that the notice, via either method, was a prerequisite without which the plan's third-party administrator would lack legal authority to deliver the objected-to coverage. ''If a self-insured religious organization uses Form 700, the form becomes 'an instrument under which the plan is operated [and is] treated as a designation of the [third-party administrator] as the plan administrator under section 3(16) of ERISA[, 29 U.S.C. 1002(33),] for any contraceptive services required to be covered. 29 CFR 2510.3–16(b). Form 700 authorizes the [third-party administrator] to 'provide or arrange payments for contraceptive services . . . 29 CFR 2590.715–2713A(b)(2) . . . If the self-insured religious organization instead self-certifies by HHS Notice, DOL's ensuing notification to the [third-party administrator] also operates to 'designate' the [third-party administrator] 'as plan administrator' under ERISA for contraceptive benefits. 79 FR at 51095; see also 29 CFR 2510.3–16(b).'' *Sharpe Holdings* v. *U.S. Dept. of Health & Human Services,* 801 F.3d 927, 935 (8th Cir. 2015). The provision of notice triggered coverage of the objected-to contraceptives by the religious employer's third party administrator, thus—in the eyes of the objecting religious employers—making them complicit in a grave wrong.

The provision of notice by an employee to her employer differs from the accommodation's notice requirement in key respects. First, absent unusual circumstances, burdens placed by a private employer on an employee's religious exercise would not be subject to the stringent demands of RFRA. Second, under the accommodation, the third-party administrator of an objecting employer's self-insured plan would have had no legal obligation to provide the objected-to coverage absent the employer's provision of notice, but if under this rule an objecting employee refuses to provide her employer with notice of her objection, her employer would nevertheless retain its authority and ability to provide the objected-to service without the employee's involvement.

[85] U.S. Policy Statement for the International Conference on Population, 10 Population & Dev. Rev. 574, 578 (1984) (reproducing the Policy Statement of the United States of America at the United Nations International Conference on Population, also known as the Mexico City Policy).

[86] 83 FR 3880, 3894–95 (stating the reasons for the proposed definition of ''referral or refer for,'' except for the modifications adopted herein).

that protect against forced referrals in certain programs. The revised definition includes the provision of information in oral, written, or electronic form (including names, addresses, phone numbers, email or web addresses, directions, instructions, descriptions, or other information resources), where the purpose or reasonably foreseeable outcome of provision of the information is to assist a person in receiving funding or financing for, training in, obtaining, or performing a particular health care service, program, activity, or procedure.

State. The Department proposed that ''*State* includes, in addition to the several States, the District of Columbia. For those provisions related to or relying upon the Public Health Service Act, the term 'State' includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands. For those provisions related to or relying upon the Social Security Act, such as Medicaid or the Children's Health Insurance Program, the term 'State' follows the definition of, State, found at 42 U.S.C. 1301.'' The Department did not receive comments on this definition.

Summary of Regulatory Changes: For the reasons described in the proposed rule [87] and above, the Department adopts the definition of ''State'' with one change, omitting ''follows'' and replacing it with ''shall be defined in accordance with.''

Sub-recipient. The Department proposed that sub-recipient means any State, political subdivision of any State, instrumentality of any State or political subdivision thereof, and any person or any public or private agency, institution, organization, or other entity in any State including any successor, assign, or transferee thereof, to whom Federal financial assistance is extended through a recipient or another sub-recipient, or who otherwise receives Federal funds from the Department or a component of the Department indirectly through a recipient or another sub-recipient, but such term does not include any ultimate beneficiary. The term may include foreign or international organizations (such as agencies of the United Nations). The Department received comments on this definition.

Comment: The Department received a comment stating that the proposed definition of ''sub-recipient'' is overly broad and could be read to include every contracting party with a recipient of Federal financial assistance. The commenter proposes that ''sub-recipient'' should be limited ''to those for whom there is a direct pass-through of Federal financial assistance and who are identified as sub-recipients of such dollars in contracts with the direct recipient.''

Response: The Department agrees that the definition should be clarified so that it does not include every entity that contracts with a recipient of Federal financial assistance. The Department, therefore, finalizes this definition with a change to the definition of ''sub-recipient'' replacing the phrase ''to whom Federal financial assistance is extended through a recipient or another sub-recipient,'' with ''to whom there is a pass-through of Federal financial assistance through a recipient or another sub-recipient.'' The Department disagrees, however, that a sub-recipient must be explicitly declared as a sub-recipient in a contract (or a grant). Requiring explicit designation as a sub-recipient could permit sub-recipients in fact to avoid such designation by contracting around such designation.

As discussed concerning the term ''entity,'' the Department is finalizing the terms ''entity,'' ''recipient,'' and ''sub-recipient'' with parallel language to clarify that they all may encompass ''a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).''

Summary of Regulatory Changes: For the reasons described in the proposed rule [88] and above, and considering the comments received, the Department finalizes the definition of ''sub-recipient'' changing ''and'' to ''or,'' replacing the phrase ''to whom Federal financial assistance is extended through a recipient or another sub-recipient, or who otherwise receives Federal funds from the Department or a component of the Department indirectly through a recipient or another sub-recipient'' with ''to whom there is a pass-through of Federal financial assistance or Federal funds from the Department through a recipient or another sub-recipient,'' and to change the last sentence previously referring to ''foreign or international organizations'' to read, ''The term may include a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).''

Workforce. The Department proposed that workforce means employees, volunteers, trainees, contractors, and other persons whose conduct, in the performance of work for an entity or health care entity, is under the direct control of such entity or health care entity, whether or not they are paid by the entity or health care entity, as well as health care providers holding privileges with the entity or health care entity. The Department received comments on this definition.

Comment: The Department received comments stating that the inclusion of volunteers, trainees, and contractors within the definition of ''workforce'' is too broad.

Response: The Department does not agree. Under the revised rule text adopted in this final rule, the defined term ''workforce'' is used in a limited number of places and for limited purposes related to voluntary notice provisions in this rule. Limiting ''workforce'' to employees fails to acknowledge the complexity of the health care system. The Department adapted the proposed definition from the definition of ''workforce'' in the regulations implementing the HIPAA administrative simplification provisions, including the HIPAA Privacy Rule. *See* 45 CFR 160.103 (definition of ''workforce''). That definition has worked well to ensure, among other things, the protection of the privacy and security of protected health information. Just as is the case with the HIPAA Rules, compliance with Federal conscience and anti-discrimination laws would not be appropriately comprehensive if only the employees of covered entities were protected, or if institutional entities chose to avoid providing notice to contractors, volunteers, and trainees.

Comment: The Department received a comment suggesting that volunteers and contractors be included in the definition of ''workforce'' only if they are performing or assisting in the performance of health care activities.

Response: The Department disagrees. As stated above, the defined term ''workforce'' is used in only a limited number of places and for limited purposes under the rule. Generally, the statutes enforced under these rules apply to health care activities and entities, but where they do not, the terms of the statute govern.

Summary of Regulatory Changes: For the reasons described in the proposed rule [89] and above, and considering the comments received, the Department

[87] 83 FR 3880, 3895.

[88] 83 FR 3880, 3895 (stating the reasons for the proposed definition of ''sub-recipient,'' except for the modifications adopted herein).

[89] 83 FR 3880, 3895.

adopts the definition of ''workforce'' as proposed.

Applicable Requirements and Prohibitions (§ 88.3)

The Department proposed a statute-by-statute recapitulation of the substantive provisions of each statute that is the subject of this rule, and of the applicability and scope of requirements and prohibitions of each such statute. The proposed ''Applicability'' provisions outlined the specific requirements of the Federal conscience and anti-discrimination laws that apply to various persons and entities. These provisions were taken from the relevant statutory language and would direct covered entities to the appropriate sections that contain the relevant requirements that form the basis of this regulation.

The ''Requirements and Prohibitions'' provisions explained the obligations that the Federal conscience and anti-discrimination laws impose on the Department and on entities that receive applicable Federal financial assistance and other Federal funding from the Department. These provisions were taken from the relevant statutory language. The Department received comments on this section. The responses to comments are provided below following the proposed applicability and requirements and prohibitions provisions for each Federal conscience and anti-discrimination law.

One conforming revision to the proposed rule that the Department has made throughout the ''Requirements and Prohibitions'' provisions is to remove § 88.5 of 45 CFR part 88 (provision of notice) from the list of sections with which applicable persons and entities must comply. As described in the section-by-section analysis for § 88.5 of this rule, the provision of a notice of rights of Federal conscience and anti-discrimination laws is no longer a requirement for the Department and recipients.

Another conforming revision to the proposed rule that the Department has made throughout the ''Requirements and Prohibitions'' provisions is to modify the phrase ''entities to whom'' various paragraphs apply '' to ''entities to which.'' The Department believes the word ''which'' avoids confusion regarding the nature and scope of entities to whom the rule applies.

88.3(a). The Church Amendments. The Department received comments generally supportive of the Church Amendments and supportive of the inclusion of the Church Amendments in the rule, as well as comments opposed to the Church Amendments themselves or to the Department's enforcement of them.

Comment: The Department received comments stating that the proposed rule only protects health care providers who hold moral or religious convictions against the provision of abortion or sterilization, but provides no protection for health care providers whose moral or religious convictions motivate them to provide abortions or sterilizations.

Response: To the extent the commenters' concerns reflect an accurate reading of the Church Amendments, these concerns raised by the commenters are a result of choices Congress itself made. This final rule reasonably interprets the protections that Congress established, but it can neither eliminate nor transform the policy judgments embedded in the text of the Church Amendments or of any other applicable law. To the extent the Church Amendments apply because someone performed or assisted in the performance of a lawful sterilization procedure or abortion, this rule would enforce those provisions to the extent consistent with other statutory and constitutional requirements. *See, e.g.,* § 88.3(a)(2)(iv), (v), and (vii).

Comment: The Department received comments stating that proposed § 88.3(a)(2)(v) and (vi), which apply 42 U.S.C. 300a–7(c)(2) and (d), are too broad, and that 42 U.S.C. 300a–7(d) should be or has been interpreted to provide protections only for participation in abortion or sterilization procedures.

Response: The Department disagrees that these paragraphs should be limited to situations involving abortion and sterilization. Paragraphs (b), (c)(1), and (e) of the Church Amendments clearly specify they apply concerning abortions or sterilizations. But paragraphs (c)(2) and (d) do not use that language; instead, as Congress specified, they encompass ''any lawful health service or research activity'' or ''any part of a health service program or research activity,'' respectively. The Department is required to implement the statutes as written by Congress. Reading paragraphs (c)(2) and (d) to address only abortion and sterilization procedures would narrow the scope of those statutory provisions in contravention of the clear text of the statute. Furthermore, court opinions interpreting 42 U.S.C. 300a–7(d) have varied in their interpretations, but recognize that it applies to more than abortion or sterilization procedures.[90]

Regarding the breadth and accuracy of § 88.3 overall, however, the Department finalizes the paragraph with changes to more accurately reflect the statutory text. With respect to § 88.3(a)(2)(v), however, the Department agrees that the proposed rule was imprecise in omitting one limiting phrase that Congress had included in paragraph (c)(2) of the Church Amendments. The proposed rule ended § 88.3(a)(2)(v) with, ''because of his or her religious beliefs or moral convictions,'' while the statute reads, ''because of his religious beliefs or moral convictions respecting any such service or activity.'' The Department finalizes this paragraph to add the phrase ''respecting any such service or activity'' that Congress included in this part of the statute.

Comment: The Department received a comment stating that the rule should clarify that the protections provided by Congress under 42 U.S.C. 300a–7(b) and (c) apply only to abortions and sterilizations in the circumstances provided for in the statute.

Response: Paragraphs (b) and (c)(1) of the Church Amendments specify that they apply in the context of abortion and sterilization procedures specifically. Paragraph (c)(2) has a broader reach, encompassing ''any lawful health service or research activity.'' As discussed in response to the similar comment asking that (c)(2) and (d) be interpreted to encompass only abortion and sterilizations, Congress limited paragraphs (b), (c)(1), and (e) to abortions and sterilizations, but used different language in paragraphs (c)(2) and (d). The rule tracks the text of paragraphs (b) and (c)(1) accordingly, as established by Congress. Paragraphs (a)(2)(i) through (iv) and (vii) in § 88.3 of the rule explicitly relate to abortions or sterilizations,[91] while § 88.3(a)(2)(v) through (vi) relate to any lawful health service or research activity.[92]

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[90] *See, e.g., Vt. Alliance for Ethical Healthcare, Inc.* v. *Hoser,* 274 F. Supp. 3d 227, 232 (D. Vt. 2017) (''Section 300a–7(d) is one of several so-called Church Amendments. It excuses individuals engaged in health care or research from any obligation to perform abortions *or other procedures* which may violate religious beliefs or moral convictions.'' (emphasis added)); *Franciscan Alliance, Inc.* v. *Burwell,* 227 F. Supp. 3d 660, 683 (Dec. 31, 2016) (''The Church Amendment forbids requiring any individual 'to perform or assist in the performance of any part of a health service program . . . if his performance or assistance in the performance of such part of such program . . . would be contrary to his religious beliefs or moral convictions.' '' (alterations)).

[91] Paragraph 88.3(a)(2)(i) implements subparagraph (b)(1) of the Church Amendments; paragraphs 88.3(a)(2)(ii) and (iii) implement paragraph (b)(2) of the Church Amendments; and paragraph 88.3(a)(2)(iv) implements paragraph (c)(1) of the Church Amendments.

[92] Paragraph 88.3(a)(2)(v) implements subparagraph (c)(2) of the Church Amendment.

Comment: The Department received comments asking for clarification whether the provisions in § 88.3(a) that relate to sterilization include only intentional sterilizations, or whether they also include procedures or services that have sterilization as a side effect, such as hysterectomies performed for reasons other than sterilization, or chemotherapy.

Response: Congress did not provide a definition of sterilization in the Church Amendments, or further specify the scope of objections under those statutes, but provided broad protections for religious and moral objections to sterilization procedures. Generally speaking, the Department understands the term ''sterilization'' as used in the Church Amendments to encompass the ordinary meaning of that term, and does not understand the term to include treatment of a physical disease where sterilization is an unintended side effect of the treatment, such as chemotherapy to treat uterine cancer or testicular cancer. To the extent that a Church Amendment complaint with respect to sterilization is filed, the Department would examine the facts and circumstances of each such claim to determine whether an act falls within the scope of the statute and these regulations.

Comment: The Department received comments asking for clarification about whether provisions in § 88.3(a) apply to sterilizations performed in the context of gender dysphoria.

Response: The Department is aware of three cases brought at least in part under the Church Amendments, in which the claimants argued that the Church Amendments' sterilization provisions protect the claimants' conscientious objections to performing gender dysphoria related surgery. In one case, *Franciscan Alliance, Inc.* v. *Burwell,* 227 F. Supp. 3d 660 (Dec. 31, 2016), enforcement of the challenged regulation, which plaintiffs contended would have required the performance of procedures such as hysterectomies to treat gender dysphoria, was preliminarily enjoined on other grounds. In the other two, consolidated as *Religious Sisters of Mercy, et al.,* v. *Burwell,* No. 3:16–cv–386 (D.N.D. 2017), which challenged the same regulation, the court issued an order staying enforcement of the regulation in light of the nationwide preliminary injunction issued in *Franciscan Alliance.* In the event the Department receives any such complaints, the Department will consider them on a case-by-case basis.

Comment: The Department received comments contending that the paragraphs of the rule concerning the Church Amendments were too broad or did not faithfully apply the statutory text.

Response: The Department intended § 88.3 to faithfully apply the text of applicable statutes, including the Church Amendments. As a result of comments, the Department became aware of instances in which the proposed rule text did not accurately reflect the content of the statute. Accordingly, the Department finalizes the rule with changes to more accurately reflect the statute. Specifically, in § 88.3(a)(2)(ii) and (iii), concerning paragraphs (b)(2)(A) and (B) of the Church Amendments, the Department finalizes the rule by changing the phrase ''entities to whom this paragraph . . . applies shall not require any entity funded under the Public Health Service Act'' to ''the receipt of a grant, contract, loan, or loan guarantee under the Public Health Service Act by any entity does not authorize entities to which this paragraph . . . applies to require such entity to . . . .''

The Department also finalizes § 88.3(a)(1)(vi) by changing ''Any entity that carries out'' to ''Any entity that receives funds for any health service program or research activity under any program administered by the Secretary of Health and Human Services.'' The Department makes this change to provide clarity regarding which entities are required to comply with paragraph (d) of the Church Amendments.

Comment: The Department received a comment stating that the rule should clarify that the protections provided by Congress under 42 U.S.C. 300a–7(d) apply only to individuals.

Response: The rule tracks the statutory language. Namely, § 88.3(a)(2)(vi) states that covered entities ''shall not require any *individual* . . . '' (emphasis added) to act contrary to their religious beliefs or moral convictions in the performance of certain health service programs or research activities. The Department maintains such language in this final rule.

Summary of Regulatory Changes: For the reasons described in the proposed rule [93] and above, and considering the comments received, the Department makes certain changes in this paragraph in this final rule. The Department finalizes § 88.3(a)(1)(vi) by changing ''Any entity that carries out'' to ''Any entity that receives funds for any health service program or research activity under any program administered by the Secretary of Health and Human Services.'' The Department finalizes § 88.3(a)(2)(ii) and (iii) by changing the word ''entity'' to ''recipient'' where applicable, in order to avoid confusion potentially created by the use of the word ''entity'' to refer both to protected entities and entities obligated to comply with 88.3(a). Additionally, in § 88.3(a)(2)(i) through (vii), concerning paragraphs and paragraphs of the Church Amendments, the Department finalizes paragraphs (a)(2)(i) through (vii) by changing the language of each paragraph to adopt the statutory text as closely as possible in relevant part, including by adding the words ''respecting any such service or activity'' to the end of § 88.3(a)(2)(v); amending § 88.3(a)(2)(i) to clarify that the statute enforces a rule of construction regarding the receipt of certain Federal financial assistance; by rephrasing the requirements to state that the receipt of relevant funds ''does not authorize entities to which this paragraph [ ] applies to require'' practices specified by 42 U.S.C. 300a–7(b); adding in the parenthetical from the statute, ''(including applicants for internships and residencies)'', to § 88.3(a)(2)(vii); and replacing short form descriptions of the statutory text with the full statutory text, such as by changing the words ''doing so'' in § 88.3(a)(2)(v) to ''his performance or assistance in the performance of such service or activity.'' The Department also eliminates some articles and terms, like ''the'' and ''or her,'' and replaces the term ''whom'' with the term ''which'' for readability and accuracy.

88.3(b). Coats-Snowe Amendment. The Department received comments generally supportive of the Coats-Snowe Amendment and supportive of the inclusion of the Coats-Snowe Amendment in the rule, as well as comments opposed to the Coats-Snowe Amendment or the rule's implementation of that statute.

Comment: The Department received comments on the definition of terms used by the Coats-Snowe Amendment, such as what constitutes a ''health care entity.'' All such comments are addressed in the responses to comments on definitions under § 88.2.

Comment: The Department received a comment stating that the Coats-Snowe Amendment was only a ''narrow response to a specific problem''—correcting a loophole that could have conditioned Federal financial assistance on the provision of abortions indirectly through the Accrediting Council on Graduate Medical Education's accreditation standards for obstetrics and gynecology graduate programs—not

[93] 83 FR 3880, 3895 (stating the reasons for the proposed § 88.3(a), except for the modifications adopted herein).

a pronouncement of new national policy and ''cannot justify the rulemaking authority the Department claims in the NPRM.''

Response: The Department disagrees. While the Coats-Snowe Amendment may have been motivated by the situation involving the Accrediting Council on Graduate Medical Education's accreditation standards for obstetrics and gynecology graduate medical education programs and standards for the receipt of Federal financial assistance based on accreditation, the plain language of the text of the Coats-Snowe Amendment is broader than that situation. While paragraph (b) of the Coats-Snowe Amendment addresses the accreditation and treatment of postgraduate physician training programs (and physicians trained in such programs) that are or are not accredited by accrediting agencies that require the performance and training in the performance of induced abortions, paragraph (a) of the Coats-Snowe Amendment establishes far broader protections for health care entities that refuse, among other things, to provide or undergo training in the performance of induced abortions, to perform such abortions, or to provide referrals for such training or such abortions. The Amendment was, thus, drafted with separate language to provide both general protections, relating to the training, performance of, and referral for abortions, and specific protections, relating to governmental treatment of physicians and physician training programs where the accreditation agency had accreditation standards that requires performance or training in the performance of induced abortion.

This rule must be governed by the text of the law, not legislative intent or legislative history that may or may not have been reflected in the text passed by Congress and signed by the President. The Department finds it appropriate for this rule to follow the text of the Coats-Snowe Amendment, and not to narrow its scope based on what may have been the impetus for the introduction, passage or enactment of the statute. The Department intends to provide enforcement mechanisms for the protections that Congress actually enacted.

Comment: The Department received comments stating that the Coats-Snowe Amendment only provides protections for entities that object to abortions for religious or moral reasons.

Response: The Department disagrees. As the text of the Church Amendments makes clear, when Congress wants to limit a protection to situations in which the protected party acts or refuses to act on the basis of religious beliefs or moral convictions specifically (as distinct from other reasons), it explicitly includes such a limitation. The text of the Coats-Snowe Amendment, unlike the text of the Church Amendments, does not include any such limitation. It encompasses objections concerning such activities as training, performing, providing referrals for, or making arrangements for referrals for abortions or abortion training, without specifying that the objections are only protected if they are based on religious beliefs or moral convictions. Limiting the application of the Coats-Snowe Amendment to only situations in which the protected entity is acting on the basis of religious beliefs or moral convictions would be to add narrowing language to the Coats-Snowe Amendment that Congress did not include.

Comment: The Department received a comment stating that parts of proposed § 88.3 could affect the ability of independent institutions to set standards for accreditation or licensure.

Response: The Department agrees in part. As other commenters have noted, one purpose leading to enactment of the Coats-Snowe Amendment was to prevent States from basing their accreditation or licensure decisions on grounds that eliminate medical schools or their graduates from the medical profession on the basis that they refuse to be involved in abortion. The Coats-Snowe Amendment prevents States that receive Federal financial assistance from engaging in discrimination that would, for example, refuse accreditation to medical schools, or licensure to physicians or nurses, because they did not provide training for, train on, or perform, abortions. The Amendment does not directly regulate any non-governmental entity. The amendment, however, would preclude a State from relying on a private entity's refusal to accredit on the bases just described in order to, among other things, deny recognition to the medical school as a medical school, or to deny recognition of the medical degree of a graduate of that school.

The Department finalizes § 88.3 with other changes from the proposed rule to include language from the statute as follows. Specifically, the proposed rule did not reflect, as set forth in paragraph (b)(1) of the statute, that ''the government involved,'' meaning Federal, State, or local, ''shall formulate such regulations or other mechanisms, or enter into such agreements with accrediting agencies, as are necessary to comply with this subsection.'' In response to comments, the Department has included language at the end of § 88.3(b)(2)(ii) reflecting this relevant statutory text.

Summary of Regulatory Changes: For the reasons described in the proposed rule [94] and above, and considering the comments received, the Department finalizes § 88.3(b) with the following changes.

Further consideration led the Department to determine that the proposed text of § 88.3(b)(1)(i) presented concerns regarding the scope of entities to which the proposed § 88.3(b) would apply. Accordingly, the Department is finalizing § 88.3(b)(1)(i) to read ''The Department is required to comply with'' in lieu of the proposed rule's statement that ''The Federal government, including the Department, is required to comply with.''

The Department removes references to ''individual or institutional'' in § 88.3(b)(2)(i), in order to avoid confusion regarding the definition of the term ''health care entity.'' While the Department makes this change, it is not intended to change the scope of protection provided by the Coats-Snowe Amendment (and this final rule)—namely, both individuals and organizations (or institutions) that constitute health care entities. The Department also removes a reference to ''require attendees to'' in (b)(2)(i)(C) in order to more accurately track the language of the statute. The Department finalizes § 88.3(b)(2)(ii) by changing ''an accreditation standard or standards'' to ''accreditation standards'' and changing ''such standard provides'' to ''such standards provide;'' and adding ''that require an entity to'' in order to more clearly articulate the requirements of the statute. Finally, in order to fully incorporate the text of the Coats-Snowe Amendment, the Department also adds the sentence ''Entities to which this paragraph (b)(2)(ii) applies and which are involved in such matters shall formulate such regulations or other mechanisms, or enter into such agreements with accrediting agencies, as are necessary to comply with this paragraph.''

Additionally, the Department removes the Federal government from the applicability section in § 88.3(b)(1)(i) but leaves ''the Department.'' Although the relevant statutory provision applies to the Federal government, this rule concerns the activities and programs funded or administered by the

[94] 83 FR 3880, 3895 (stating the reasons for the proposed § 88.3(b), except for the modifications adopted herein).

Department rather than the entire Federal Government.

88.3(c). Weldon Amendment. The Department received comments on this paragraph, including comments generally supportive of the Weldon Amendment and supportive of the inclusion of the Weldon Amendment in the proposed rule, as well as comments opposed to the Weldon Amendment itself or the proposed rule's implementation of the Amendment.

Comment: The Department received comments on the definition of terms used by the Weldon Amendment, such as what constitutes a ''health care entity.'' All such comments are addressed above in the responses to comments on definitions under § 88.2.

Comment: The Department received comments stating that the Weldon Amendment does not provide authority for the Department to impose any burdens or obligations on health care entities, such as the requirement of an assurance of compliance and the notice requirement.

Response: Assurance requirements to remedy past discrimination or prevent future discrimination are common regulatory features of anti-discrimination laws like those that are the subject of this rule and such authority has been affirmed by the Supreme Court. *See Grove City College* v. *Bell,* 465 U.S. 555 (1984) (affirming partial termination of institution's Federal funds for refusing to sign a Title IX assurance of compliance form). In response to comments, the Department has revised the proposed notice provisions from being a requirement to being one factor that OCR considers in its determinations as to whether a covered entity is in violation of this part. Comments concerning assurance and notice provisions are discussed in more detail below in §§ 88.4 and 88.5, proposing to impose those provisions.

Comment: The Department received comments stating that the proposed rule impermissibly extends the Weldon Amendment to apply to non-governmental entities, and that the proposed rule disagrees with the position taken by the government in *National Family Planning and Reproductive Health Association* v. *Gonzales,* 391 F. Supp. 2d 200 (D.D.C. 2005), regarding whether the Weldon Amendment extends to non-governmental entities through those entities' receipt of Federal financial assistance.

Response: The Department agrees that, as proposed, § 88.3 was worded to extend the Weldon Amendment to non-governmental entities in ways not encompassed by the text of the Amendment as written. This was due to the inclusion of paragraph (c)(1)(iii) in that section, which required compliance with the Weldon Amendment by ''any entity'' that receives funds to which the Weldon Amendment applies. This paragraph would render superfluous paragraphs (c)(1)(i) and (ii), which require compliance with the Weldon Amendment by the Department and its programs and by any State or local government that receives funds to which the Weldon Amendment applies. The Department is therefore finalizing § 88.3(c)(1) by removing paragraph (c)(1)(iii).

The Department notes, however, that the conduct and activities of contractors engaged by the Department, a Departmental program, or a State or local government is attributable to such Department, program, or government for purposes of enforcement or liability under the Weldon amendment.

Comment: The Department received comments stating that the Department cannot engage in permanent rulemaking based on an annual appropriations amendment that may or may not be reenacted with each appropriations act.

Response: The Department disagrees. The Department has outlined, above, the authority that it relies upon to promulgate regulations containing the substantive requirements established in the Weldon Amendment. The Department further notes that it has promulgated rules based on the Weldon Amendment in 2008 and 2011 and has operated under such rules based in part on the annual appropriations amendment cited. The Department has similarly issued regulations to implement annual appropriations amendments, such as the Hyde Amendment.[95] Paragraphs (c)(1)(i) and (ii) in § 88.3 of this rule specify that compliance is only effective ''under an appropriations act . . . that contains the Weldon Amendment.'' Therefore, the provisions of this rule enforcing the Weldon Amendment will only be applicable to a State or local government that receives funds subject to such appropriation. If Congress were to substantially change or not renew the Weldon Amendment, the final rule would not apply to that extent.

Comment: The Department received comments stating that the Weldon Amendment cannot be interpreted to prevent States from requiring abortion coverage, because the Affordable Care Act, at 42 U.S.C. 18023(c)(1), states, ''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.''

Response: The Weldon Amendment is not part of the Affordable Care Act. Therefore, 42 U.S.C. 18023(c)(1), which states, ''[n]othing in this Act'' shall be construed to have an effect on State laws requiring abortion coverage, does not apply to the Weldon Amendment. More importantly, ACA section 1303 also provides that ''[n]othing in this Act shall be construed to have any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' 42 U.S.C. 18023(c)(2). In addition, the Weldon Amendment has been renewed more recently than Congress enacted the Affordable Care Act, and therefore is generally owed deference if the two laws did conflict, which they do not.

Comment: The Department received comments stating that the Weldon Amendment, as evidenced by its legislative history, does not apply to refusals unrelated to conscience-based (that is, religious or moral) objections, such as purely financial or operational motives.

Response: The Department disagrees, for similar reasons described above in response to comments arguing for a narrow interpretation of the Coats-Snowe Amendment. As the text of the Church Amendments makes clear, when Congress wants to limit a protection to situations in which the protected party acts or refuses to act on the basis of religious beliefs or moral convictions, it explicitly includes such limitation in the text of the statute. The text of the Weldon Amendment, unlike the text of the Church Amendments, does not include any such limitation. On its face, the Weldon Amendment encompasses a decision by a health care entity not to provide, pay for, provide coverage of, or refer for abortions, without specifying that such decisions must be based on religious, moral, conscientious, or any other particular motive. Limiting the application of the Weldon Amendment only to situations in which the health care entity is acting on the basis of conscientious, moral or religious convictions would be to refuse to apply the Weldon Amendment according to the text enacted by Congress.

Comment: The Department received comments asking for clarification that

[95] *See, e.g.,* 42 CFR 441.202, 441.203, 441.206 (prohibiting the use of Federal funds under Medicaid to pay for abortions except when continuation of the pregnancy would endanger the mother's life).

the Weldon Amendment only applies with respect to abortions.

Response: The Department agrees with the commenter. The text of the proposed rule already makes clear that, as stated in the text of the Weldon Amendment and as described in this rule, the Weldon Amendment only protects against discrimination on the basis that a health care entity does not provide, pay for, provide coverage of, or refer for abortions.

Comment: The Department received a comment stating that the proposed rule would impermissibly extend the Weldon Amendment's protection beyond the abortion context to protect refusals to provide, pay for, provide coverage of, or refer for ''any lawful health service.''

Response: The Department disagrees. Nothing in the proposed rule or in this final rule extends protections under the Weldon Amendment outside of the abortion context. As § 88.3(c)(2) states, ''The entities to whom this paragraph (c)(2) applies shall not subject 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, *abortion*'' (emphasis added). The regulatory provision in the proposed rule and in this final rule that makes reference to ''any lawful health service'' addresses and would implement paragraph (c)(2) of the Church Amendments, which prohibits certain discrimination against a physician or other health care personnel because, among other things, ''he performed or assisted in the performance of any lawful health service or research activity.'' [96]

Summary of Regulatory Changes: For the reasons described in the proposed rule [97] and above, and considering the comments received, the Department finalizes § 88.3(c) as proposed, except for changes to the citation to the most current Public Law where the Weldon Amendment may be found, and the removal of proposed paragraph (c)(1)(iii). Additionally, the Department is adding the phrase ''and its programs'' after ''the Department'' to track the statutory language more closely.

88.3(d). Medicare Advantage, Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Public Law 115–245, Div. B, sec. 209. The Department did not receive comments on this paragraph. The Department has updated the title of this paragraph for the most recent appropriations rider for the current fiscal year. For clarity and accuracy, in paragraph (d)(1), the Department changed ''under the Medicare Advantage program'' to read ''with respect to the Medicare Advantage program,'' and updated the citation therein.

Summary of Regulatory Changes: For the reasons described in the proposed rule [98] and above, the Department finalizes § 88.3(d) primarily as proposed, but updates the header and citations in paragraph (d)(1) to reflect the citation for this appropriations ride for FY 2019, and replaced ''under,'' and adds ''informs the Secretary that it'' for clarity in paragraph (d)(2).

88.3(e). Section 1553 of the Affordable Care Act, 42 U.S.C. 18113. The Department received comments on this paragraph, including comments generally supportive of section 1553 of the Affordable Care Act and supportive of the inclusion of section 1553 in the rule, as well as comments opposing that section and the Department's enforcement of it.

Comment: The Department received comments stating that section 1553 cannot allow a health care professional to omit information about ''all choices'' available at end-of-life because a patient has a right to be informed.

Response: The Department disagrees with this comment. Congress specified in section 1553 that a health care entity is protected in its decision not to provide ''any health care item or service furnished for the purposes of causing, or for the purpose of assisting in causing'' assisted suicide, euthanasia, or mercy killing. The Department is unaware of any Federal requirement that an individual or health care entity provide information about a service that it does not provide. Medical ethics have long protected rights of conscience alongside the principles of informed consent. The Department does not believe that enforcement of conscience protections, many of which date to the era of *Roe* v. *Wade* and *Doe* v. *Bolton,* violates or undermines the principles of informed consent. In fact, in *Roe* the Supreme Court favorably cited an American Medical Association resolution on abortion affirming ''[t]hat no physician or other professional personnel shall be compelled to perform any act which violates his good medical judgment. Neither physician, hospital, nor hospital personnel shall be required to perform any act violative of personally-held moral principles.'' [99] Similarly, in *Doe* the Court spoke favorably about Georgia's statutory language giving a hospital the freedom not to admit a patient for an abortion, and protecting a physician or other hospital employee ''for moral or religious reasons'' from participating in an abortion procedure.[100] The Department interprets section 1553 as specifically encompassing the decision by a health care entity not to provide information about, or referrals for, assisted suicide.[101]

Comment: The Department received a comment stating that, while Congress explicitly granted the Department the authority to promulgate regulations to implement section 1557 of the ACA, Congress did not provide such a grant for section 1553, but only gave the Department the authority to ''receive complaints of discrimination'' under section 1553.

Response: As discussed *supra* at part III.A, multiple statutes and regulations authorize the Department to issue these rules—including with respect to ACA section 1553—to ensure that the Department and covered entities comply with Federal conscience and anti-discrimination laws that apply to certain Federal funding. With respect to section 1553 specifically, that section imposes specific provisions, including construction provisions, and mandates that the Department's Office for Civil Rights implement section 1553 by receiving complaints. This rule follows that language and provides Departmental mechanisms for acting upon complaints under section 1553. Such authority is implicit in the authority to receive complaints set forth in 1553. If that were not the case, OCR would not be able to comply with Congress's direction under section 1553 to handle and respond to complaints it receives, making the authority designated to OCR in section 1553 mere surplusage, hollow, or inoperative.[102]

The fact that section 1557 of the Affordable Care Act specifically authorized, but did not require, the Department to issue regulations to

[96] *See* 42 U.S.C. 300a–7(c)(2); *compare* 45 CFR 88.3(a)(2)(v) (implementing Church (c)(2) *with* 45 CFR 88.3(c) (implementing Weldon Amendment).

[97] 83 FR 3880, 3895 (stating the reasons for the proposed § 88.3(c), except for the modifications adopted herein).

[98] 83 FR 3880, 3895.

[99] 410 U.S. at 143–44.

[100] 410 U.S. at 197–98.

[101] A referral is a health care service, and the phrase ''assisting in causing'' is reasonably interpreted to carry the same meaning as ''assisting in performing,'' which the Department interprets to include the act of referring.

[102] *See Hibbs* v. *Winn,* 542 U.S. 88, 101 (2004) (statutes should be construed so as to avoid rendering superfluous any statutory language; ''statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant. . . .'').

implement that section, does not negate the authority Congress provided the Secretary under 5 U.S.C. 301 and the other statutory and regulatory authorities cited *supra* at part III.A to carry out the duties Congress designated to OCR under section 1553 of the ACA. In particular, as discussed above, section 1321(a) of the ACA authorizes the Department to ''issue regulations setting standards for meeting the requirements under [title I of the ACA] with respect to . . . the offering of qualified health plans through such Exchanges . . . and . . . such other requirements as the Secretary determines appropriate.'' Section 1321(a), thus, provides the Department with the authority to issue regulations setting setting standard for meeting the requirements established in section 1553, which is part of title 1 of the ACA.

Summary of Regulatory Changes: For the reasons described in the proposed rule [103] and above, and considering the comments received, the Department finalizes § 88.3(e) as proposed with minor technical changes for clarity and adherence to the text of section 1553 of the ACA, for example changing ''any amendment'' to ''an amendment'' and clarifying that ''the Act'' refers to the ''Patient Protection and Affordable Care Act.'' Paragraph (e)(1)(iv) clarifies that the amendment would have been ''made by the Patient Protection and Affordable Care Act,'' and paragraph (e)(2) deletes ''provided, that.''

88.3(f). Section 1303 of the Affordable Care Act, 42 U.S.C. 18023. The Department received comments on this paragraph, including comments generally supportive of section 1303 of the Affordable Care Act and supportive of the inclusion of section 1303 in the rule, as well as comments critical of this proposed paragraph.

Comment: The Department received a comment stating that the inclusion of section 1303 of the ACA in this rule is redundant, as the conscience protections provided for in section 1303 are also provided by other conscience protection statutes, and by the Religious Freedom Restoration Act, 42 U.S.C. 2000bb *et seq.*

Response: The Department disagrees. Section 1303 contains several distinct provisions relating to conscience and conscience protections, in section 1303. While section 1303(c)(2) references and preserves the applicability of Federal laws regarding conscience protection,[104] section 1303(b)(1) and (b)(4) provide standalone conscience protections that are independent of other Federal conscience protection provisions. While the language used in section 1303(b)(1) and (b)(4) is similar to other conscience protection statutes, these provisions provide independent conscience protections both with respect to governmental requirements of qualified health plans, and with respect to qualified health plans' discrimination against individual health care providers and health care facilities. Additionally, were other Federal conscience and anti-discrimination laws to be revoked, the conscience protections in section 1303(b)(1) and (b)(4) of the ACA could remain in effect. The Department does not presume that separate Federal conscience and anti-discrimination laws enacted by Congress are redundant. It is a principle of statutory construction that effect should be given to overlapping statutes as long as there is no ''positive repugnance'' between them. *See, e.g., Connecticut Nat'l Bank* v. *Germain,* 503 U.S. 249, 253 (1992). And there is no such positive repugnance here.

Summary of Regulatory Changes: For the reasons described in the proposed rule [105] and above, and considering the comments received, the Department finalizes § 88.3(f) as proposed, with a technical correction to reflect that 42 U.S.C. 18023(b)(1)(A) is a rule of construction regarding Title I of the Patient Protection and Affordable Care Act, rather than a substantive prohibition. In paragraph (f)(2)(i), the Department clarifies that the entities shall not ''construe anything in Title I of the Patient Protection and Affordable Care Act (or any amendment made by Title I of the Patient Protection and Affordable Care Act) to.''

88.3(g). Section 1411 of the Affordable Care Act, 42 U.S.C. 18081. The Department did not receive comments on this paragraph.

The Department intended § 88.3 to faithfully apply the text of applicable statutes, including section 1411 of the Affordable Care Act, while at the same time, providing clarity to regulated persons and entities. To this end, the final rule clarifies in § 88.3(g)(2) that the Department is required not only to provide a certification documenting a religious exemption from the individual responsibility requirement and penalty under the Affordable Care Act, which appeared in the proposed rule, but also to coordinate with State Health Benefit Exchanges (State Exchanges) in the implementing of the certification requirements of 42 U.S.C. 18031(d)(4)(H)(ii) where applicable. The Department works closely with State Exchanges to implement the Affordable Care Act, and for clarity, the final rule reflects that coordination. For similar reasons, the Department modified § 88.3(g)(2)(i) to reflect changes Congress made to 26 U.S.C. 5000A through section 4003 of the SUPPORT for Patients and Communities Act, which became law October 24, 2018.[106] Those changes retained a reference in 26 U.S.C. 5000A to 26 U.S.C. 1402(g)(1), which sets out various conditions for eligibility for the conscience exemption from the individual responsibility requirement. Among those conditions is a requirement that the religious sect or division thereof to which the applicant for the exemption belongs must have been in existence at all times since December 31, 1950. The Department has omitted this particular requirement from § 88.3(g)(2)(i) out of concern that it may conflict with the Establishment Clause.

The Department understands that Public Law 115–97 (December 22, 2017) reduced the penalty in 26 U.S.C. 5000A for a lack of minimum essential coverage to zero dollars,[107] and that the implications of this law is the subject of substantial litigation. The Department, nevertheless, believes it is prudent to implement the certification requirements as proposed because we understand the law still requires individuals to submit proof of essential coverage or be certified as exempt despite the penalty being zeroed out.

Summary of Regulatory Changes: For the reasons described in the proposed rule [108] and above, the Department finalizes § 88.3(g) as proposed, with technical corrections to reflect that the individuals to whom the Department grants certifications under 42 U.S.C. 18081 are individuals who have applied for such certifications and to ensure the language follows that of the statute, a typographical correction to change the reference to ''5000A(2)(B)(ii)'' to ''5000A(d)(2)(B)(i),'' modifications to comport with Congress's revisions to 42 U.S.C. 5000A(d) through the October 24, 2018, enactment of the SUPPORT for Patients and Communities Act, which broadens the application of the exemption and discusses exclusions regarding what constitutes medical

[103] 83 FR 3880, 3895.

[104] 42 U.S.C. 18023(c)(2) (''[n]othing in this Act shall be construed to have any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion'').

[105] 83 FR 3880, 3895.

[106] SUPPORT for Patients and Communities Act, Public Law 115–271, sec. 4003, 26 U.S.C. 5000A(d)(2) (2018).

[107] Budget Fiscal Year, 2018, Public Law 115–97, Part VIII, sec. 11081, 131 Stat. 2092 (Dec. 22, 2017).

[108] 83 FR 3880, 3895.

health services, and the Department adds clarification for the Department to comply with the applicable prohibitions in coordination with State Exchanges.

88.3(h). Counseling and referral provisions of 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B). The Department received comments on this paragraph.

Comment: The Department received a comment stating that, while the statutory text of 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B) established rules of construction, the proposed rule converted these statutes into freestanding exemptions.

Response: The Department agrees that the proposed rule is worded imprecisely to treat 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B) as freestanding exemptions, rather than as rules of construction as set forth in the statutory text. The Department, therefore, modifies the final rule accordingly to conform to the statutory text.

Summary of Regulatory Changes: For the reasons described in the proposed rule [109] and above, and considering the comments received, the Department finalizes § 88.3(h)(2)(i) by referring to regulations that also implement the statutes containing the requirements and prohibitions, for example by adding ''construe 42 U.S.C. 1395w–22(j)(3)(A) or 42 CFR 422.206(a) to,''; by deleting ''offer a plan that provides, reimburses for, or provides'' and replace it with ''provide, reimburse for, or provide,''; inserting ''offering the plan'' to the end of paragraph (h)(2)(i); and adding paragraph (h)(2)(i)(B) regarding making information available to prospective enrollees and enrollees. The Department also made changes to paragraph (h)(2)(ii) by changing the phrase ''shall not require a Medicaid managed care organization to provide'' to ''shall not construe 42 U.S.C. 1396u–2(b)(3)(A) or 42 CFR 438.102(a)(1) to require,''; deleting ''objects to the provision of such service on moral or religious grounds,''; and adding paragraphs (h)(2)(ii)(A) and (B), (A) stating the organization objects on moral or religious grounds and (B) regarding the policies to prospective enrollees and enrollees.

88.3(i). Advance Directives, 42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406. The Department received comments on this paragraph.

Comment: The Department received a comment stating that 42 U.S.C. 1395cc(f) requires that certain entities maintain written policies and procedures to inform patients of their ''individual rights under State law to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advanced directives,'' but the proposed rule ''attempt[s] to rewrite this provision by prohibiting this statute from being construed to require covered entities to provide full information to patients about services to which they may object.''

Response: The Department disagrees. This final rule provides for the enforcement of 42 U.S.C. 14406, which states, ''. . . section 1395cc(f) . . . shall not be construed (1) to require any provider or organization, or any employee of such a provider or organization, to inform or counsel any individual regarding any right to obtain an item or service furnished for the purpose of causing, or the purpose of assisting in causing, the death of the individual, such as by assisted suicide, euthanasia, or mercy killing. . . .'' This statutory language is adopted almost verbatim into § 88.3(i)(2)(i). Far from ''attempt[ing] to rewrite this provision,'' this rule merely adopts Congress's rule of construction provision as Congress enacted it.

Comment: The Department received comments stating that advance directives should be followed regardless of a physician's personal objections.

Response: Paragraph (i) in § 88.3 provides for the implementation and enforcement of provisions at 42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406, which assure that applicable Federal laws (relating to Medicare and Medicaid) are not used contrary to statute to prohibit health care providers from exercising their rights of conscience with respect to advance directives, including with respect to assisted suicide. This provision does not affect State laws governing the enforceability of advance directives. But, in general, the Department believes that protecting health care providers' rights of conscience with respect to advance directives ensures that doctors, nurses, and other persons in the health care industry are not forced to choose between continuing to serve as health care providers and remaining faithful to their deepest convictions. Such conscience protection ensures diversity in the health care industry and maximizes the number of health care professionals in the United States, which helps all patients.

Summary of Regulatory Changes: For the reasons described in the proposed rule [110] and above, and considering the comments received, the Department finalizes § 88.3(i) with a change to correct a typographical error in § 88.3(i)(2)(i), where ''1395a(w)'' should instead read ''1396a(w)(3).''

88.3(j). Global Health Programs, 22 U.S.C. 7631(d). The Department received comments on this paragraph.

Comment: The Department received comments in opposition to the Department's enforcement of Federal conscience and anti-discrimination laws outside of the United States, because populations served by U.S. foreign aid often have less financial resources and access to fewer medical providers than persons in the United States.

Response: The Department disagrees with the underlying premise of this comment. As described above, the Department believes that enforcing statutory conscience rights will increase, not decrease, the availability of quality medical care because it will prevent the exclusion of health care professionals motivated by deep religious beliefs or moral convictions to serve others, often the most underprivileged. Moreover, this rule merely provides for the enforcement of laws enacted by Congress that, by their own terms, may apply abroad.

Comment: The Department received a comment stating that the provisions with respect to foreign policy may lead to confusion as to which laws properly govern foreign aid.

Response: Upon reviewing the text of this paragraph, the Department has revised the language to make it clearer to which entities the requirements apply, and the circumstances in which they apply, and to more closely track the language enacted by Congress. The proposed rule would have applied the requirements of this paragraph to the Department and recipients of relevant Federal financial assistance. However, 22 U.S.C. 7631(d) does not impose requirements on what recipients of assistance can and cannot do; rather, it imposes requirements on the conditions that may be placed on receipt of assistance. The statute does not provide a description of the entities that the statute governs—*i.e.,* entities that are in a position to place conditions on the receipt of assistance of assistance. The Department believes that class of entities is best described as those that are authorized to obligate the assistance. Accordingly, the Department is modifying § 88.3(j)(1) to apply to the Department and entities that are authorized by statute, regulation, or agreement to obligate Federal financial

[109] 83 FR 3880, 3895 (stating the reasons for the proposed § 88.3(h), except for the modifications adopted herein).

[110] 83 FR 3880, 3895.

assistance under section 104A of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2), under Chapter 83 of Title 22 of the U.S. Code or under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, to the extent such Federal financial assistance is administered by the Secretary, and is deleting the reference regarding the Federal financial assistance being ''for HIV/AIDS prevention, treatment, or care to the extent administered by the Secretary.''

Summary of Regulatory Changes: For the reasons described in the proposed rule [111] and above, and considering the comments received, the Department finalizes § 88.3(j) with technical changes clarifying the language regarding to which entities the requirements apply, and the circumstances in which they apply, to more closely follow the language of such statutes and amendments as enacted by Congress, eliminating in paragraph (j)(2)(i) ''To the extent administered by the Secretary'' and inserting ''Require an organization, including a faith-based organization, that is otherwise eligible to receive assistance,'' deleting ''require applicants for'' and replacing it with ''to the extent such assistance is administered by the Secretary, . . . as a condition of such assistance.'' The Department also changed ''applicant'' to ''organization'' and removed ''as a condition of assistance'' in (j)(2)(i)(B), and made significant edits to paragraph (j)(2)(ii) for accuracy regarding the statutory text and references to other paragraphs of this part.

88.3(k). The Helms, Biden, 1978, and 1985 Amendments, 22 U.S.C. 2151b(f); e.g., Consolidated Appropriations Act, 2019, Public Law 116–6, Div. F, sec. 7018. The Department received comments on this paragraph.

Comment: The Department received a comment stating that the provisions with respect to foreign policy may lead to confusion as to which laws properly govern foreign aid.

Response: Upon reviewing the text of this paragraph, the Department has revised the language to make it clearer as to which laws and amendments are implicated by this paragraph, and to more closely track the statutory language enacted by Congress. For clarity, the heading of the paragraph has been revised to refer to each of the four separate statutory provisions implemented by the paragraph, rather than only to the Helms Amendment. For consistency with the statute, the paragraph includes a new paragraph in the ''Applicability'' paragraph identifying as a distinct class of covered entities those entities that are authorized to obligate or expend the Federal financial assistance in question, separate from entities that merely receive such Federal financial assistance. The paragraph also now specifies that the Federal financial assistance in question for this paragraph is that which is appropriated for the purposes of carrying out part I of the Foreign Assistance Act of 1961.

The proposed rule would have applied the requirements of this paragraph to the Department and recipients of relevant Federal financial assistance. However, 22 U.S.C. 2151b(f) and section 7018 of the Consolidated Appropriations Act of 2019 impose both requirements on what recipients of assistance can and cannot do and also requirements on the entities providing that assistance to recipients. The statute does not provide a description of the entities that provide assistance to recipients. The Department believes that class of entities is best described as those that are authorized to obligate the assistance. Accordingly, the Department is modifying § 88.3(k)(1) to apply to the Department, to recipients of relevant assistance, and to entities that are authorized by statute, regulation, or agreement to obligate the relevant assistance. Additionally, considering that the 1985 Amendment [112] has been included in annual appropriations acts rather than codified as a statute, the Department is modifying the description of covered entities' obligations under § 88.3(k)(2) to clarify that the rule's provisions regarding the 1985 Amendment apply only to funds under an appropriations act containing the 1985 Amendment.

Summary of Regulatory Changes: For the reasons described in the proposed rule [113] and above, and considering the comments received, the Department finalizes § 88.3(k) with technical changes clarifying the citations and language as to which statutes and amendments are referenced, and to more closely follow the language of such statutes and amendments as enacted by Congress, and adding clarity through citations to paragraphs within this part.

88.3(l). Newborn and Infant Hearing Loss Screening, 42 U.S.C. 280g–1(d). The Department received comments on this paragraph.

Comment: The Department received a comment asking that the rule interpret 42 U.S.C. 280g–1(d) to provide an affirmative conscience exemption for parents who do not want their children to receive a hearing loss screening.

Response: 42 U.S.C. 280g–1(d) is a rule of construction that the Department is unable to convert into an affirmative exemption. The Department can, however, enforce such rules to assure that entities administering the statute do not misapply the statute to the detriment of the conscience rights of parents and their children.

Comment: The Department received comments stating that the proposed rule would endanger public health by providing conscience protections for parents to object to compulsory medical procedures such as hearing loss screenings.

Response: The Department disagrees. 42 U.S.C. 280g–1(d) is a rule of construction, and this final rule does not convert it into an affirmative Federal exemption. This rule's enforcement provisions do not create a right for parents to object to a hearing loss screening for their children generally or as against other State or Federal laws. Rather, they only prevent interpreting this Federal law to override State laws that already provide a religious exemption regarding the screening at issue.

Summary of Regulatory Changes: For the reasons described in the proposed rule [114] and above, and considering the comments received, the Department finalizes § 88.3(l) with minor changes to ensure clarity and consistency with the statute, for example by deleting ''newborn infants or young,'' changing articles, and making other minor changes.

88.3(m). Medical Screening, Examination, Diagnosis, Treatment, or Other Health Care or Services, 42 U.S.C. 1396f. The Department received comments on this paragraph.

Comment: The Department received numerous comments supporting the rule's provision of enforcement mechanisms for 42 U.S.C. 1396f.

Other commenters opposed the enforcement mechanisms, alleging they create an affirmative mandate that a State agency that administers a State Medicaid Plan may not compel any

[111] 83 FR 3880, 3895 (stating the reasons for the proposed § 88.3(j), except for the modifications adopted herein).

[112] *See, e.g.,* the Consolidated Appropriations Act, 2019, Public Law 116–6, Div. F, sec. 7018 (''None of the funds made available to carry out part I of the Foreign Assistance Act of 1961, as amended, may be obligated or expended for any country or organization if the President certifies that the use of these funds by any such country or organization would violate any of the above provisions related to abortions or involuntary sterilizations.'')

[113] 83 FR 3880, 3895.

[114] 83 FR 3880, 3895.

person to undergo any medical screening, examination, diagnosis, or treatment if such person objects on religious grounds.

Response: The Department disagrees with commenters opposing the paragraph. 42 U.S.C. 1396f is a rule of construction, and this rule does not convert it into an affirmative Federal exemption. This rule's enforcement provisions do not create a freestanding right for persons or their families to be free to decline certain medical screenings or treatments. Rather, they only prevent an interpretation of 42 U.S.C. 1396f as requiring States to compel the acceptance of such screening or treatment when the Medicaid statute has no such requirement.

Summary of Regulatory Changes: For the reasons described in the proposed rule [115] and above, and considering the comments received, the Department finalizes § 88.3(m) as proposed.

88.3(n). Occupational Illness Examinations and Tests, 29 U.S.C. 669(a)(5).

Comment: The Department received comments generally supporting the concept of conscience protections for occupational medical examinations, immunizations, and treatments, and other comments generally opposing that concept. The Department did not receive specific comments on § 88.3(n) or its implementation of the rule of construction described in 29 U.S.C. 669(a)(5).

Response: Although Congress granted HHS authority to conduct research, experiments, and demonstrations related to occupational illnesses in the Occupational Safety and Health Act of 1970, such authority did not include the power to 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). The Department is required to abide by this limitation, and considers it appropriate to issue a final rule ensuring compliance.

Summary of Regulatory Changes: For the reasons described in the proposed rule [116] and above, and considering the comments received, the Department finalizes § 88.3(n) with minor changes, for example, deleting ''With respect to occupational illness examinations and tests, the entities'' and replacing it with ''Entities.''

[115] 83 FR 3880, 3895.

[116] 83 FR 3880, 3895.

88.3(o). Vaccination, 42 U.S.C. 1396s(c)(2)(B)(ii). The Department received comments on this paragraph.

Comment: The Department received comments suggesting that the scope of this paragraph be expanded beyond pediatric vaccines to encompass all vaccines, or that it should be expanded to create a personal right to decline vaccinations based on moral or religious objections.

Response: The Department is aware of complaints asserting religious or moral objections to administering or receiving vaccines, including, for example, objections to administering or receiving vaccines derived from aborted fetal tissue. Because § 88.3(o) of the rule provides enforcement mechanisms for 42 U.S.C. 1396s, it is therefore limited to the scope of 42 U.S.C. 1396s. As 42 U.S.C. 1396s applies only to the pediatric vaccine program under Medicaid (the Vaccines for Children Program), the Department is unable to expand the scope of this paragraph beyond such programs. Likewise, as 42 U.S.C. 1396s requires compliance with religious or other exemptions under State law with respect to pediatric vaccines, the Department is unable to expand this rule provision to preempt State laws that do not provide such conscience protections.

Comment: The Department received comments asking for clarification as to how the proposed § 88.3(o) interacts with State laws such as school immunization requirements.

Response: Upon reviewing the proposed § 88.3(o), the Department agrees that the language can be clarified regarding how the paragraph might interact with State law. The Department therefore finalizes § 88.3(o) to more accurately reflect the text of 42 U.S.C. 1396s(c)(2)(B)(ii) by changing the applicability of the requirement of § 88.3(o)(2) to reflect the statute's requirement that, under any State-administered pediatric vaccine distribution program, the provider agreement executed by any provider registered to participate in the program includes the requirement that the program-registered provider comply with applicable State law, including any such law relating to any religious or other exemption. In order to further clarify the scope of § 88.3(o), the Department finalizes this paragraph to specify that applicable State ''law'' may include State statutory, regulatory, or constitutional protections for conscience and religious freedom, where applicable.

Summary of Regulatory Changes: For the reasons described in the proposed rule [117] and above, and considering the comments received, the Department finalizes § 88.3(o) with changes to ensure it follows the language of 42 U.S.C. 1396s(c)(2)(B)(ii), which applies to program-registered providers of pediatric vaccines, not to States generally, and to specify that applicable State law may include State statutory, regulatory, or constitutional protections for conscience and religious freedom, where applicable.

88.3(p). Specific Assessment, Prevention and Treatment Services, 42 U.S.C. 290bb–36(f), 5106i(a).

Comment: The Department received comments on this paragraph expressing concern that the provision of conscience protections for parents who object to youth suicide assessments for their children should be balanced with the risk to the child's life.

Response: Paragraph (p) in § 88.3 is a rule of construction that prevents persons or entities administering programs under 42 U.S.C. 290bb–36 or 42 U.S.C. 5106i(a) from relying on the particular statutes at issue to require assessments or treatments that conflict with religious belief. The provisions in this rule related to these statutes do not, however, prevent or interfere with any other State or Federal law that reaches a different (or the same) conclusion on these questions.

In reviewing this paragraph in light of the comments received on it, however, the Department has determined that paragraph (p)(2)(iii) needs to be modified to more closely track the statutory language, in order to ensure it operates as a rule of construction consistent with 42 U.S.C. 290bb–36(f).

Summary of Regulatory Changes: For the reasons described in the proposed rule [118] and above, and considering the comments received, the Department finalizes § 88.3(p) with changes to paragraph (p)(2)(iii) to more closely track the language of 42 U.S.C. 290bb–36(f), which establishes it as a rule of construction.

88.3(q). Religious nonmedical health care, 42 U.S.C. 1320a–1, 1320c–11, 1395i–5, 1395x(e), 1395x(y)(1), 1396a(a), and 1397j–1(b). The Department received comments on this paragraph.

Comment: The Department received comments opposed to the provision of Federal funds to religious nonmedical health care facilities because such funding could be interpreted as legitimating such facilities, resulting in

[117] 83 FR 3880, 3895 (stating the reasons for the proposed § 88.3(o), except for the modifications adopted herein).

[118] 83 FR 3880, 3895 (stating the reasons for the proposed § 88.3(p), except for the modifications adopted herein).

patients of such facilities not seeking other treatment options.

Response: Whether to permit Federal funds to be used to pay religious nonmedical health care facilities for particular services provided to Medicare or Medicaid beneficiaries has been determined by Congress through 42 U.S.C. 1320a–1, 1320c–11, 1395i–5, 1395x(e), 1395x(y)(1), 1396a(a), and 1397j–1(b), and the Department is unable to alter that decision. The purpose of including these provisions in the proposed rule and this final rule is only to provide enforcement mechanisms for the determination of Congress with respect to funding of religious nonmedical health care facilities. Nevertheless, the Department believes that most if not all persons who make use of religious nonmedical health care facilities do so because they hold religious objections to the receipt of medical care and would be unwilling to seek other treatment options regardless of the religious nonmedical health care facilities' funding status.

Comment: The Department received comments expressing concern that providing conscience protections for attendees of religious nonmedical health care facilities could prevent people, particularly children, from accessing necessary medical health care.

Response: This rule only provides for enforcement mechanisms for conscience protection statutes that Congress has enacted, and determinations of policy matters raised by these comments are outside the scope of this rulemaking to the extent they conflict with decisions made by Congress. That said, this provision regarding religious nonmedical health care does not prevent people from accessing care, but rather, has a role in enabling people to access care that does not violate their religious beliefs, which will benefit all patient populations, including children.

Comment: The Department received a comment stating that exempting religious nonmedical health care facilities from State standards for cleanliness and quality of care potentially threatens the quality of care that attendees of such facilities receive. The commenter proposed striking these provisions from the rule and ensuring that religious nonmedical health care facilities adhere to the same standards as other skilled nursing facilities and providers.

Response: Requiring religious nonmedical health care facilities to adhere to the same standards as other skilled nursing facilities and providers would contradict Congress's determination to exempt religious nonmedical health care facilities, as provided for in 42 U.S.C. 1396a(a) and as upheld in *Children's Healthcare Is a Legal Duty, Inc.* v. *Min De Parle,* 212 F.3d 1084 (8th Cir. 2000) (''[S]tate plans may not establish State agency oversight of the quality of care provided in RNCHIs [sic].''). The Department, therefore, rejects this proposal.

Nonetheless, the Department recognizes that the structure and description of the relevant exemptions in § 88.3(q) was unclear in many respects, and so the Department makes substantial changes to the ''Requirements and prohibitions'' to correct and clarify § 88.3(q) to more accurately describe the activities from which the applicable covered entities are required to exempt religious nonmedical health care institutions, including a change to more fully incorporate the exemption established in 42 U.S.C. 1396(a)(31).

Comment: The Department received a comment requesting that the exemptions for religious nonmedical health care facilities concerning Medicare Part A funding be explicitly applied to Medicare Advantage as well because, while Medicare Advantage is required to provide coverage for all services that are covered by Medicare Part A and Part B, many Medicare Advantage organizations do not recognize religious nonmedical health care.

Response: As noted by the commenter, because Medicare Advantage organizations are required to cover services covered by Medicare Parts A and B pursuant to 42 U.S.C. 1395w–22(a)(1)(A), the exemptions for religious nonmedical health care facilities related to Medicare Part A funding apply to Medicare Advantage as well. Because the applicability paragraphs of § 88.3(q) follow the statutory language concerning religious nonmedical health care exemptions, the Department declines to adopt the commenter's suggested modification.

Summary of Regulatory Changes: For the reasons described in the proposed rule [119] and above, and considering the comments received, the Department made significant changes to the structure of § 88.3(q) to clarify applicable statutes and paragraphs, correct typographical errors, and more closely track the statutory language. The Department more clearly articulates which paragraphs are applicable to different entities by, for example, changing ''(q)(2)(i) through (iii)'' so that it now clearly states ''(q)(2)(i), (ii), (iii), and (iv).'' The Department added ''(h)'' to the reference to 42 U.S.C. 1320a–1 to clarify the particular paragraph containing relevant information. The Department clarified in paragraph (q)(1)(ii) that some State agencies are required to comply, in paragraph (q)(1)(iii) that entities receiving Federal financial assistance from Medicare have compliance obligations, and in paragraph (q)(1)(iv) that entities including States that receive Federal financial assistance from Medicaid have compliance obligations, and in paragraph (q)(1)(v) clarified the authority related to an elder's right to practice his or her religion through reliance on prayer alone is subtitle B of Title XX of the Social Security Act (42 U.S.C. 1397j–1397m–5) and eliminated what was the last paragraph regarding the Elder Justice Block Grants. The paragraph incorporates multiple references to 42 U.S.C. 1395x(ss)(1), which defines a religious nonmedical health care institution, to add clarity to the regulation. The paragraph clarifies the application of various provisions to entities that make an agreement with the Secretary of the Department pursuant to 42 U.S.C. 1320a–1(b), or receive Federal financial assistance from Medicare, Medicaid, or Subtitle B of Title XX of the Social Security Act (42 U.S.C. 1397j–397m–5). Last, the Department removed the references requiring compliance with § 88.5, as compliance with that section is now voluntary.

Assurance and Certification of Compliance Requirements (§ 88.4)

In the ''Assurance and Certification of Compliance'' section of the proposed rule, the Department proposed to require certain recipients of Federal financial assistance or other Federal funds from the Department or that the Department administers to submit written assurances and certifications of compliance with the Federal conscience and anti-discrimination laws, as applicable, as part of the terms and conditions of acceptance of Federal financial assistance or other Federal funding from the Department. The Department stated its belief that both an assurance and a certification provide important protections to persons and entities under these laws and would be consistent with requirements under other civil rights laws. The Department noted its concern that there is a lack of knowledge on the part of States, local governments, the health care industry, and the public of the rights of protected persons and entities, and the corresponding obligations on covered entities provided by Federal conscience and anti-discrimination laws.

[119] 83 FR 3880, 3895 (stating the reasons for the proposed § 88.3(q), except for the modifications adopted herein).

Section 88.4 proposed to require certain applicants for Federal financial assistance or other Federal funds from the Department to which this part applies to submit assurances and certifications of compliance with Federal conscience and anti-discrimination laws and this part. The Department proposed that covered applicants operationalize the assurance and certification requirement by filing revised versions of applicable civil rights forms, such as the HHS–690 Assurance of Compliance Form once per year and incorporate such filing by reference in all other applications submitted that year, rather than for every application that year. To this end, and as consistent with other civil rights regulations requiring assurances or certifications, the Department proposed in § 88.4(b)(6) to permit an applicant to incorporate the assurance by reference in subsequent applications to the Department. The proposed rule explained that both the assurance and certification would constitute a condition of continued receipt of Federal financial assistance or other Federal funds from the Department. With respect to the certification required in proposed § 88.4(a)(2), proposed § 88.4(b)(7) clarified that, as with other anti-discrimination laws, a violation of the requirements of the certification may result in enforcement by the Department, as provided in § 88.7 of this part.

Noting the need to increase public awareness of Federal conscience and anti-discrimination laws, the Department solicited public comment on the various options available for public education and outreach.

Proposed paragraph (b) identified specific requirements for the proposed assurance and compliance requirements: (b)(1) Addressed the timing to submit the assurance for current applicants or recipients as of the effective date of this part; (b)(2) addressed the form and manner of such submittals; and (b)(3) addressed the duration of obligations for both the assurance and certification.

Proposed § 88.4(b)(2) explained that applicants would submit assurance and certification forms in an efficient manner specified by OCR, in coordination with the relevant Department component, or alternatively in a separate writing.

The Department proposed that its components be given discretion to phase in the written assurance and certification requirement by no later than the beginning of the next fiscal year following the effective date of the regulation. The Department stated its intent to work with recipients of Federal financial assistance or other Federal funds from the Department to ensure compliance with the requirements or prohibitions promulgated in this regulation. If the applicant or recipient would fail or refuse to furnish a required assurance or certification, the Department proposed that OCR, in coordination with the relevant Department component, would be authorized to effect compliance by any of the remedies provided in § 88.7. *See Grove City College,* 465 U.S. 555 (affirming partial termination of institution's Federal funds for refusing to sign a Title IX assurance of compliance form).

The Department also proposed that, while both recipients and sub-recipients, as defined herein, must comply with the substantive requirements of Federal conscience and anti-discrimination laws, as applicable, sub-recipients would not be subject to the requirements of § 88.4 regarding assurance and certifications of compliance. The Department invited comment on whether this approach strikes the appropriate balance between achievement of this rulemaking's policy objectives and avoidance of undue burden on the health care industry.

Proposed § 88.4(c) also contained several important exceptions from the proposed requirements for written assurance and certification of compliance, including (1) physicians, physician offices, and other health care practitioners participating only in Part B of the Medicare program; (2) recipients of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration for Children and Families, whose purpose is unrelated to health care provision as specified; (3) recipients of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration on Community Living, whose purpose is unrelated to health care provision as specified; and (4) Indian Tribes and Tribal Organizations when contracting with the Indian Health Service under the Indian Self-Determination and Education Assistance Act. The Department sought public comment on whether further exceptions should be made to the requirements of § 88.4 in contexts where the requirements would be unduly burdensome or in contexts unrelated to health care or medical research. The Department received comments on this section, including general comments in support of this section.

Comment: The Department received comments requesting that exemptions for religious beliefs or moral convictions, such as for vaccinations, be included in form HHS–690.

Response: The Department's implementation of the assurance and certification of compliance will address the Federal conscience and anti-discrimination laws implicated by this rule. Because none of the statutes that this rule implements create across-the-board exemptions on the basis of religious beliefs or moral convictions to vaccination requirements, the assurance and certification of compliance requirement does not either.

Comment: The Department received comments requesting that any assurance of compliance be acquired through form HHS–690 to avoid the increased administrative burden of adding new forms or procedures.

Response: The Department agrees with this proposal and is working to obtain Paperwork Reduction Act clearance for updates to the HHS–690 form entitled *Assurance of Compliance,* which previously had OMB PRA clearance as OMB No. 0945–0006. (The Department's operationalization of the certification of compliance required in § 88.4(a)(1) is described in the RIA and PRA portions of this rule.)

The HHS–690 form enables an applicant to provide an assurance that it will comply with certain Federal civil rights laws and regulations ''in consideration of and for the purpose of obtaining Federal grants, loans, contracts, property, discounts, or other Federal financial assistance'' from the Department.[120] By signing the assurance of compliance, the applicant ''agrees that compliance with this assurance constitutes a condition of continued receipt of Federal financial assistance, and that it is binding upon the Applicant, its successors, transferees and assignees for the period during which such assistance is provided.'' [121]

As finalized, § 88.4(b)(1) requires entities that are already recipients as of the effective date of the rule and applicants to submit the assurance and the certification as a condition of any application or reapplication for funds to which the rule applies. Pursuant to the finalized § 88.4(b)(6), it would be permissible to incorporate assurances and certifications by reference in subsequent applications, which is consistent with the Department's Grants Policy Statement, which states that

[120] U.S. Dep't of Health & Human Servs., Assurance of Compliance, HHS 690, *https://www.hhs.gov/sites/default/files/hhs-690.pdf.*

[121] *Id.*

because recipients file an assurance of compliance form ''for the organization and . . . not . . . for each application,'' a recipient with a signed assurance on file assures through its signature on the award application that it has a signed Form 690 on file.[122]

The Department proposed to add a provision to § 88.4(b)(1) that would require submission of the assurance more frequently than at the time of application if the applicant or recipient fails to meet a requirement of the rule, or if OCR or the relevant Department component has reason to suspect or cause to investigate the possibility of such failure. For instance, OCR may have reason to suspect through its investigations or the number of complaints received that a particular recipient is not complying with the Federal conscience and anti-discrimination laws or the rule and consequently asks the recipient to sign an assurance of compliance form offcycle from the normal grants process. To forgo as-needed assurances outside of the application process jeopardizes OCR's and the Department's flexibility to ensure that the Federal financial assistance or other Federal funds that the Department awards are used in a manner compliant with Federal conscience and anti-discrimination laws and this rule.

Comment: The Department received a comment requesting that the certification of compliance contain additional language, such as explicit protections for LGBT patients.

Response: The scope of this rule and the certifications of compliance sought herein are limited to the Federal conscience and anti-discrimination laws. Certifications with respect to other topics or laws not the subject of this rule are outside the scope of this rulemaking.

Comment: The Department received a comment stating that conditioning receipt of Federal financial assistance or Federal funds on receipt of an assurance and certification is unnecessary in light of the proposed enforcement mechanisms provided by § 88.7.

Response: The Department does not agree. This collection of assurances and certifications would facilitate the Department's obligation to ensure that the Federal financial assistance or other Federal funds that the Department awards are used in a manner that complies with Federal conscience and anti-discrimination laws and this rule. The Department is accountable to the American public for protecting the integrity of Federal financial assistance and other Federal funds that the Department awards. The Department's administration of a requirement for a person or entity at the time of application or reapplication to assure and certify compliance with Federal conscience and anti-discrimination laws and the final rule demonstrates that the person or entity was aware of its obligations under those laws and the rule.

In addition, this collection of assurances and certifications would operationalize the obligations of persons and entities to comply with applicable Federal conscience and anti-discrimination laws. As discussed above, the Department has the authority to place terms and conditions with respect to the Federal conscience and anti-discrimination laws in any instrument HHS issues or to which it is a party (*e.g.,* grants, contracts, or other HHS agreements). A Department component extending an award must communicate and incorporate statutory and public policy requirements and obligate the recipient to comply with Federal statues and ''public policy requirements, including . . . those . . . prohibiting discrimination.'' [123] More specifically, the Department component ''must communicate . . . all relevant public policy requirements, including those in general appropriations provisions, and incorporate them either directly or by reference in the terms and conditions of the Federal award.'' [124] To execute this obligation, the Departmental component may require a recipient ''to submit certifications and representations required by Federal statutes, or regulations . . . .'' [125]

Furthermore, the proposed requirements of § 88.4 are consistent with the requirements of other Federal civil rights laws and would bring Federal conscience and anti-discrimination laws into parity with those other civil rights laws. Although instituting an enforcement action against an entity is effective in ensuring that the enforced-against entity is aware of its requirements under the statutes implemented through this rule, the requirement of an assurance and certification of compliance would ensure that such awareness is shared by entities subject to proposed § 88.4 before violations occur and may help prevent them.

Comment: The Department received a comment stating that the requirement that covered entities provide assurances and certifications of compliance could lead to third-party *qui tam* lawsuits parallel to the Department's enforcement actions.

Response: Whether a third-party may bring or prevail in a *qui tam* lawsuit with respect to an assurance or certification required by this rule is a legal question dependent on statutes and precedent governing *qui tam* lawsuits and is beyond the scope of this rulemaking. The Department does not consider the possibility that such laws may apply as a sufficient reason not to require assurance or certification of compliance with Federal conscience and anti-discrimination laws in order to achieve the goals described in this Final Rule for requiring such assurance or certification.

Comment: The Department received a comment stating that the proposed rule is unclear as to whether a person that falls within one of the exempt categories described in § 88.4(c)(1) and (2) remains exempt if such person receives Federal funds under a separate agency or program.

Response: The Department does not agree that the proposed rule is unclear as to whether such a person would remain exempt. Proposed § 88.4(c) states that certain persons or entities shall not be required to comply with paragraphs (a)(1) and (2) of § 88.4 ''provided that such persons or entities are not recipients of Federal financial assistance or other Federal funds from the Department through another instrument, program, or mechanism, other than those set forth in paragraphs (c)(1) through (4) of this paragraph.'' Therefore, a person who would be exempt under one of these provisions, but receives Federal financial assistance or other Federal funds from a non-exempt HHS program, is no longer exempt.

''Federal financial assistance'' as used in the phrase ''Federal financial assistance or other Federal funds from the Department'' should be read to mean such assistance from the Department. Therefore, a person that falls within one of the exempt categories described in § 88.4(c)(1) and (2) remains exempt if such person receives Federal financial assistance from an agency or department other than HHS.

Comment: The Department received a comment stating that the proposed rule is unclear because, while the rule states that it is appropriate to exempt clinicians who are part of State Medicaid programs, such clinicians are not included in the exemptions of § 88.4(c).

[122] U.S. Dep't of Health & Human Serv., HHS Grants Policy Statement, I–31 (Jan. 2007), *https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.*

[123] 45 CFR 75.300(a).

[124] *Id.*

[125] *Id.* sec. 75.208.

Response: The exclusion in § 88.4(c) does not need to explicitly exempt State Medicaid program clinicians because such participants are already excluded from § 88.4's application by virtue of being sub-recipients of the Department, not recipients. States are the direct recipients of Medicaid funding from the Department, and States may offer Medicaid benefits on a fee-for-service (FFS) basis, through managed care plans, or both. Regardless of the model that the States use, clinicians are sub-recipients as this term is used in this rule. Under the fee-for-service model, the State pays the clinicians directly and under the managed care model, a State pays a fee to a managed care plan, which in turn pays the clinician for the services a beneficiary may require that are within the managed care plan's contract with the State to serve Medicaid beneficiaries.[126] The 2008 Rule expressly exempted State Medicaid program clinicians because the certification requirement applied to recipients and sub-recipients;[127] in contrast, the certification requirement in this rule applies to recipients only.[128]

Comment: The Department received a comment stating that, while some pharmacies and pharmacists participate in Medicare Part B, the exemption for health care practitioners in § 88.4(c) does not explicitly include pharmacists and pharmacies, and ''health care practitioners'' may not be understood to include pharmacists or pharmacies.

Response: The Department agrees with the commenter's observation and, accordingly, will finalize § 88.4(c)(1) to explicitly include pharmacists and pharmacies within the exemption if they participate in Medicare Part B and are not otherwise subject to this part.

Comment: The Department received a comment asking that the exemption in § 88.4(c) be expanded to include participants in Medicare Part C as well as Part B.

Response: In contrast to doctors and other health care practitioners who participate in Medicare Part B and are considered recipients under this rule because these providers receive direct payments from the Centers for Medicare & Medicaid Services, Medicare Part C (Medicare Advantage) providers are not recipients, as defined by this rule, but instead are sub-recipients. Under the Medicare Part C program, HHS makes payments to the private plan, which is the recipient for the purpose of Medicare Part C, and the plan pays the provider, which under this rule would be considered a sub-recipient.[129] Therefore, § 88.4(c) does not need to exempt Medicare Part C providers because, as a threshold manner, the assurances and certifications requirement of § 88.4 do not apply to providers participating in Medicare Part C. The same is true of participants in Medicare Part D.[130]

Comment: The Department received a comment asking that the assurance and certification of compliance provisions become effective one year after the final rule is published or provide a one-year safe harbor to entities that make a good faith effort to inform their employees about the Federal conscience and anti-discrimination laws and come into compliance.

Response: Although ultimate responsibility for compliance resides with covered entities, OCR plans to do significant outreach and public education to inform covered entities of their obligations and timelines. Recipients are also free to inform their employees about Federal conscience and anti-discrimination laws through policies and procedures or internal communications efforts, such as by posting notices of rights under Federal conscience and anti-discrimination laws, using the model in appendix A to 45 CFR part 88. Section 88.5 of this rule no longer requires recipients to post notices, but OCR will consider the posting of notices as non-dispositive evidence of compliance if OCR were to investigate the recipients' compliance with Federal conscience and anti-discrimination laws. Because the notice provision is being finalized as a voluntary best practice that serves as non-dispositive evidence of compliance, there is no deadline for posting of notices.

Summary of Regulatory Changes: For the reasons described in the proposed rule[131] and above, and considering the comments received, the Department finalizes § 88.4 with the following changes: A change to paragraph (b)(1), deleting ''applicants or recipients'' and replacing with ''entities'' for accuracy; a change to paragraph (b)(1) to insert ''or any applicants'' and to insert ''application or'' to clarify that new applicants are included; a change to paragraph (b)(1), regarding timing, to clarify that submission of assurance and certifications may be required on a more frequent basis if ''OCR or the relevant Department component has reason to suspect or cause to investigate the possibility of [a] failure'' to meet a requirement of this part; changes to paragraph (b)(6) to clarify that both prior assurances and certifications may be incorporated by reference; a change to the end of paragraph (b)(7) by adding the phrase ''including by referral to the Department of Justice, in coordination with the Department's Office of General Counsel, where appropriate'' as discussed above; a change to paragraph (b)(8) to replace ''remedies'' with ''mechanisms'' for accuracy; and a change to paragraph (c)(1) to include pharmacies and pharmacists in the list of Medicare Part B exclusions.

Notice of Rights Under Federal Conscience and Anti-Discrimination Laws (§ 88.5)

The NPRM proposed requiring the Department and recipients to notify the public, patients, and workforce, which may include students or applicants for employment or training, of their protections under the Federal conscience and anti-discrimination laws and this rule.

For consistency with other notice requirements in civil rights regulations, paragraph (a) of § 88.5 proposed to require the Department and recipients to post the notice provided in Appendix A of the proposed rule within 90 days of the effective date of this part. This proposed notice would advise persons and entities about their rights and the Department's and/or recipients' obligations under Federal conscience and anti-discrimination laws. The notice would provide information about how to file a complaint with OCR. The Department sought comment on whether there are categories of recipients that should be exempted from this requirement to post such notices. The proposed rule did not propose to require sub-recipients to post the notice.

The proposed rule would require all Department components and recipients to use the notice text in appendix A of the proposed rule. The Department invited comment on whether the proposed rule should permit recipients to draft their own notices for which the content meets certain criteria and does not compromise the intent of § 88.5.

Proposed paragraph (b) set forth two categories of locations where the notice

[126] *See, e.g.,* Provider Payment and Delivery Systems, MACPAC, *https://www.macpac.gov/medicaid-101/provider-payment-and-delivery-systems/* (last visited Jan. 29, 2019).

[127] 73 FR at 78101.

[128] *Compare* 2008 Rule, 73 FR at 78098 (requiring sub-recipients to provide the Certification of Compliance set out in the rule as part of the sub-recipient's original agreement with the recipient) *with* § 88.4(a)(1)–(2) *infra* (requiring an applicant or recipient to submit an assurance and certification).

[129] *See Medicare Advantage Program Payment System,* MEDPAC 1 (Oct. 2016), *http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_16_ma_final.pdf* (describing the payment system).

[130] *See id.*

[131] 83 FR 3880, 3896–3897 (stating the reasons for the proposed § 88.4, except for the modifications adopted herein).

would be required to 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. With regard to the physical posting, paragraph (b)(2) would impose readability requirements without identifying prescriptive font-size or other display requirements.

Proposed paragraph (c) would incentivize recipients to display the notice in locations other than their websites and physical establishments. The Department explained that, in the event that the OCR Director, pursuant to the enforcement authority proposed in § 88.7, investigates or initiates a compliance review of a recipient, the OCR Director would consider, as one of many factors with respect to compliance, whether the recipient posted the notice in the documents described in paragraphs (c)(1) through (3), as applicable. Because this part regulates a diverse range of recipients, the Department identified three categories of documents most common across all recipients for proposed listing in paragraph (c). The Department sought comment on the proposed approach of paragraph (c) and on the categories of documents identified in paragraphs (c)(1) through (3).

Finally, paragraph (d) of § 88.5 proposed to permit recipients to combine the text of the notice required in paragraph (a) with other notices under the condition that the recipients retain all of the language provided in Appendix A of the proposed rule in an unaltered state. The Department requested comment on whether the proposed paragraph (d) struck the best balance based on recipients' experiences. The Department received comments on this section, including comments that were general expressions of support or opposition to proposed § 88.5.

Comment: The Department received comments objecting to the burdens of required notices, and stating that none of the Federal conscience and anti-discrimination laws give the Department authority to issue the notice requirements of § 88.5.

Response: The Department has considered these and other comments objecting to the notice requirements of the proposed rule. Each Federal conscience and anti-discrimination law requires the Department and covered entities to comply with its substantive provisions. Notice of rights under those provisions is an important means of ensuring proper compliance. Notices are also commonly used in ensuring compliance with other Federal civil rights protections.

At the same time, the Department appreciates the potential burden of such notices and the fact that they are not explicitly required by statute. In response to comments concerning notice requirements, the Department is finalizing § 88.5 to change the notice provision from a requirement to a voluntary action and to accept self-drafting of notices to provide greater tailoring to individual circumstances.

In investigating complaints and initiating compliance reviews, OCR will consider the extent to which entities post notices, as well as the inclusion of such notices in the type of documents identified in the proposed rule at § 88.5(c), according to the rule's notice provisions as non-dispositive evidence of compliance with the substantive provisions of this rule applicable to such entities. The existence or not of posted or published notices may also be considered in the determination of potential corrective action in cases of violation.

The Department believes that the change of the notice provisions of this rule from a requirement to a voluntary action to be considered in complaint investigations addresses any concerns about the Department's authority to implement mandatory notice provisions. Providing guidance on notices and considering notices with respect to enforcement, including corrective action, are matters concerning the government of the Department and the performance of Department business as authorized by the authorities discussed *supra* at part III.A.

Comment: The Department received a comment stating that, although the commenter approves of the notice proposed in Appendix A of the NPRM, the commenter believes that recipients should be free to draft their own notice if they desire, so long as they clearly state what protections are available under the law. The commenter proposes that permitting recipients to draft their own notice will permit them to tailor the notice to their unique settings and avoid possible unintentional misrepresentations that may arise based on their status. The commenter proposes that any such recipient-drafted notice could be required to state where the text of Appendix A may be found or to provide such text upon request.

Response: The Department agrees that recipients should be permitted to draft their own notices so as to avoid misrepresentations and to tailor their notice to their particular circumstances and is modifying § 88.5 to acknowledge and accept self-drafted notices to provide greater flexibility.

Comment: The Department received a comment stating that recipients should not be permitted to deviate from the text of the proposed notice in Appendix A, because deviations from the text of appendix A could describe Federal conscience and anti-discrimination laws in subtly incorrect manners and the Department would be forced to expend additional resources to determine whether myriad notices are accurate.

Response: While the Department agrees that a fixed notice avoids the concern that a recipient-drafted notice will subtly misstate the protections provided by the rule and mitigates the time and expense of ensuring that self-drafted notices are accurate, the Department is convinced by other commenters that permitting recipients to draft their own notices is preferable, so as to provide greater flexibility and avoid statements that might be false or misleading in the context of, and considering the status of, a particular recipient. To the extent that covered entities misstate statutory protections in the drafting of their own notices, they risk such misstatement being considered by the Department negatively during complaint investigation or compliance reviews.

Comment: The Department received a comment stating that recipients should be permitted to combine this notice with other notices.

Response: Under the proposed § 88.5(d), an entity would be permitted to combine this notice with other notices ''if it retains all of the language provided in appendix A of this part in an unaltered state.'' Because the Department has made the notice provision voluntary and permits recipients to draft their own notices, the requirement that such combination maintain the language of appendix A ''in an unaltered state'' is removed.

Comment: The Department received comments stating that requiring that the notices be posted by April 26, 2018, is unreasonable. The Department also received comments asking that § 88.5 not be required until one year after the final rule is published.

Response: Because the notice provision is being finalized as a voluntary practice that serves as non-dispositive evidence of compliance in investigations and compliance reviews, the notice provision no longer has a timeframe in which such notices must be posted.

Comment: The Department received comments stating that the broad, general language proposed in appendix A could lead a health care provider to believe

that they may violate Federal non-discrimination laws or the Emergency Medical Treatment and Active Labor Act.

Response: The Department disagrees. The broad nature of the proposed language in appendix A specifically avoids implying that providers have a categorical, unconditional right under Federal law to exercise conscientious objections. The notice text is clear that only ''certain health-care related treatments, research, or services'' are covered by the Federal conscience and anti-discrimination laws, and only states that providers ''may,'' in a given circumstance, be protected by the rule. Nothing in the language of the proposed notice states that other Federal laws are waived. The appendix continues to serve as a valid model notice.

Comment: The Department received comments stating that the proposed notice should require mention of an exemption for vaccinations.

Response: As stated above, the Department has changed its approach to the notice provisions, and they are now voluntary and flexible. In addition, with respect to vaccination, this rule provides for enforcement of 42 U.S.C. 1396s(c)(2)(B)(ii), which requires providers of pediatric vaccines funded by Federal medical assistance programs to comply with any State laws relating to any religious or other exemptions, but this rule does not create a new substantive conscience protection concerning vaccination, nor does it require a State to adopt such an accommodation. In investigating a complaint or conducting a compliance review, OCR will consider an entity's voluntary posting of a notice of nondiscrimination as non-dispositive evidence of compliance with the applicable substantive provisions of this part, to the extent such notices are provided according to the provisions of this section and are relevant to the particular investigation or compliance review.

Comment: The Department received a comment stating that the statutes referenced by the proposed notice in appendix A do not apply to health plan employees and, thus, the proposed notice is overly broad.

Response: While the Department disagrees that the statutes referenced by the proposed notice cannot apply to health plan employees, the Department agrees that the proposed appendix A could be misleading for a particular entity, and has modified both § 88.5 to provide greater flexibility as to content and appendix A to provide a more accurate model notice as to the protections provided by the Federal conscience and anti-discrimination laws.

Comment: The Department received a comment stating that if a patient sees the proposed notice, such patient may be less likely to engage in open conversation with the patient's health care provider for fear that services will be denied.

Response: The Department disagrees that a statement of the requirements of certain Federal civil rights laws will discourage patients from engaging in open conversation with their health care providers. First, the overwhelming number of patient-physician interactions do not involve issues that are likely to raise religious or moral considerations. Second, knowing that health care providers are free to work according to their own consciences could encourage patients to engage in open conversation, either by raising the subject where it might not have otherwise been discussed, or because a patient may prefer a health care provider with values consistent with their own. Third, as discussed previously, compliance with the Federal conscience and anti-discrimination laws and this implementing rule would likely increase the diversity of providers and health care professionals, thus providing patients more tailored options and higher quality service on average. Finally, the Department does not believe that, when members of the public are simply informed about Federal laws, they are thereby dissuaded from engaging in conversation with their health care providers.

Comment: The Department received comments stating that the proposed rule was unclear as to who is responsible for posting the notice required by § 88.5.

Response: Paragraph (a) in § 88.5 states that ''the Department and each recipient'' should post the notice text. Because the notice provisions in the rule will now be voluntary, this provision is deleted from § 88.5(a) as finalized. Nevertheless, because the voluntary posting of notices may be considered by the Department in its handling of complaints and compliance reviews, entities specifically subject to this rule (such as certain recipients of Federal funds) would be the appropriate parties for ensuring that such notices are posted if they chose to post them.

Comment: The Department received comments stating that health insurance issuers should not be required to provide the notice to the public.

Response: To the extent the commenters took this position because they did not believe that the protections of the Federal conscience and anti-discrimination laws would apply to health insurance issuers, the Department disagrees with such assumption. The notice provision is being finalized not as a requirement, but as guidance on best practices that the Department will consider in complaint investigation and compliance reviews. Certain Federal conscience and anti-discrimination laws clearly implicate health insurance issuers; accordingly, in investigation of complaints or compliance reviews involving health insurance issuers, the Department may consider whether the issuer has posted such a notice as non-dispositive evidence of compliance with the rule. If a health insurance issuer is subject to provisions of the rule, as at least some will be, notice provided by an insurer to both its employees and the public are appropriate factors to consider as evidence of compliance with this rule.

Comment: The Department received a comment stating that requiring the proposed notice to be displayed in emergency rooms may violate the Emergency Medical Treatment and Active Labor Act because patients who see the notice may leave before they are treated.

Response: The Department disagrees. The regulations enacted under the Emergency Medical Treatment and Active Labor Act at 42 CFR 489.20(q)(1) require that public notices be posted in emergency rooms to inform patients of the requirements of EMTALA. Furthermore, while the Department disagrees that a notice of Federal conscience and anti-discrimination laws would in any way discourage a patient seeking emergency treatment, a patient's voluntary refusal to seek treatment would not be a violation of EMTALA.

Comment: The Department received a comment proposing that, instead of specifying particular locations for the notice to be placed, the rule instead require covered entities to provide the notice using the same means that such entities regularly use to provide important notices.

Response: The Department believes that the proposed rule's specificity with respect to how to place the notice provides appropriate guidance on how to effectively communicate its content to the intended audiences. Because the notice provisions are now voluntary, but the posting of such notices would be considered as positive evidence of compliance, covered entities will have flexibility regarding whether, how, and where they post notices. At the same time, if entities post notices only in contexts or ways where persons to whom the notices are directed are not likely to receive the benefit of the notices, the Department will take that

into consideration in investigations and compliance reviews. The notice provisions under this final rule provide appropriate suggestions for effective placement while still acknowledging that not all circumstances are identical.

Comment: The Department received comments stating that there should be no exceptions to the notice requirement in § 88.5.

Response: The Department appreciates the comments, but has decided not to finalize the notice provision as a requirement. The notice provision is being finalized as a voluntary best practice that the Department will consider in complaint investigation and compliance reviews.

Summary of Regulatory Changes: For the reasons described in the proposed rule [132] and above, and considering the comments received, the Department finalizes § 88.5 with changes so that notices are not required, but will be a voluntary best practice that may demonstrate compliance in any OCR investigation. The rule specifies that OCR may, in investigating complaints and conducting compliance reviews, consider the extent to which covered entities post notices according to the rule's notice provisions as non-dispositive evidence of compliance with substantive provisions of the rule applicable to covered entities. The section also now permits recipients to draft their own version of the notice, or to combine the notice with other non-discrimination notices, to allow greater accuracy, flexibility, and tailoring to their particular circumstances. The Department also changes the section to reflect that, while guidance regarding particular placement of notices remains a factor for compliance consideration purposes, all notice placement provisions may not be applicable or appropriate to all covered entities. The Department also changes the section to remove the requirement that the notice be posted within 90 days of the publishing of the rule, or, with respect to new recipients, within 90 days of becoming a recipient, to reflect that posting of the notice is voluntary and that there is no mandated time frame within which a notice must be posted. The Department also changes the section to include, in paragraphs (b)(3) and (4), ''the Department'' in addition to recipients, for additional clarity. Finally, the Department makes a technical change to relocate the proposed rule's provision regarding the readability of the notice text from paragraph (b)(2) in the proposed rule to paragraph (b)(6) in the final rule.

Compliance Requirements (§ 88.6)

This section of the proposed rule identified specific requirements for compliance with the Federal conscience and anti-discrimination laws. The Department proposed to subject recipients to the imposition of funding restrictions and other appropriate remedies if they or a sub-recipient is found to have violated a Federal conscience and anti-discrimination law. The Department proposed to require recipients, sub-recipients, and agency components to maintain records evidencing compliance with these laws and the proposed rule and to require such entities to cooperate with any OCR compliance review or investigation (including by producing documents or participating in interviews). The proposed rule further would require recipients and sub-recipients to inform any Departmental funding component, and to disclose, on applications for Departmental funding, the existence of any OCR compliance review, investigation, or complaint under the rule. This section also addressed claims in the event a covered entity intimidates or retaliates against those who complain to OCR or participate in or assist in an OCR enforcement action. The Department received comments suggesting improvements to this section, as well as comments generally supporting proposed § 88.6.

Comment: The Department received comments stating that it is unduly burdensome and unnecessary to require recipients to report to the Department funding component all compliance reviews, investigations, and complaints when they occur and to disclose any compliance review, investigation, or complaint for five years prior in any application for new or renewed Federal financial assistance or Departmental funding. Commenters noted that such requirements are burdensome on the covered entities, are unnecessary if an investigation found no violation, and require the covered entity to provide the Department with information that the Department should already have.

Response: The Department agrees that such reporting requirements are unnecessary in situations in which an investigation has found no violation. The Department also agrees that the provision of such reports to funding components of the Department for already awarded Federal financial assistance or Departmental funding is unnecessary because the Office for Civil Rights can notify such funding components at the time such a determination of violation is made. The Department disagrees that such records of violations are unnecessary as to future awards of Federal financial assistance or Departmental funding, because the Department does not maintain records of all such findings in a manner that is generally accessible to funding components across the Department.

Therefore, the Department is revising the reporting requirements under § 88.6 to reduce the burden on covered entities and to eliminate the reporting requirements in situations in which such reports are unnecessary or redundant with actions that will be taken by the Department. The final rule retains the requirement that recipients or sub-recipients subject to a determination by OCR of noncompliance with this part must, in any application for new or renewed Federal financial assistance or Departmental funding following such determination, disclose the determination of noncompliance. The rule also clarifies that applicants must also disclose OCR determinations made against their sub-recipients under previous or existing contracts, grants, or other instruments providing Federal financial assistance. Sub-recipients would only have to disclose findings made against them if they are seeking new or renewed funding as recipients of HHS funds or Federal financial assistance. The final rule shortens the period for reporting from five years to three years.

Comment: The Department received comments stating that none of the Federal conscience and anti-discrimination laws authorize the Department to require record-keeping, conduct compliance reviews, or investigate complaints.

Response: As discussed *supra* at part III.A, various statutes and regulations authorize the Department to issue these regulations. The Department, and entities to which this rule applies, are required by statute to comply with various Federal conscience and anti-discrimination laws. Inherent in Congress's adoption of the statutes that require the recipients of Federal funds from the Department to comply with certain Federal health conscience statutes is the authority of the Department to take measures to ensure compliance. Further, complaint investigation, compliance reviews, and record-keeping are standard measures that the Department employs with respect to the grants and contracts that it issues—to ensure compliance with requirements imposed by Congress with respect to particular programs and on

[132] 83 FR 3880, 3897–98 (stating the reasons for the proposed § 88.5, except for the modifications adopted herein).

recipients of Federal funds, including statutory non-discrimination requirements. Below, the Department discusses in more detail objections to the Department's authority to conduct compliance reviews.

Issuing this rule as finalized provides for the application and imposition of standard Departmental terms, conditions, and procedures to ensure compliance by recipients with statutory non-discrimination requirements, pursuant to the Department's authorities discussed *supra* at part III.A. Those authorities allow, among other things, the imposition of terms and conditions on grant awards, contracts, and other funding instruments, and authorize the Department to require certain information from entities applying for such funds.

Comment: The Department received comments requesting more specificity as to how long records should be maintained, in what form or manner they should be maintained, and what content such records should include.

Response: The Department agrees that greater specificity as to the records that should be maintained, how long such records should be maintained, and in what format such records should be kept is appropriate. Therefore the Department will finalize the rule with modifications specifying that records (1) shall be maintained for a period of three years from the date the record was created, was last in force, or was obtained, by the recipient or sub-recipient; (2) shall contain any information maintained by the recipient or sub-recipient that pertains to discrimination on the basis of religious belief or moral conviction, including any complaints; statements, policies, or notices concerning discrimination on the basis of religious belief or moral conviction; procedures for accommodating employees' or other protected individuals' religious beliefs or moral convictions; and records of requests for such religious or moral accommodation and the recipient or sub-recipient's response to such requests; and (3) may be maintained in any form and manner that affords OCR with reasonable access to them in a timely manner. These modifications are consistent with recordkeeping requirements employed in other civil rights regulations. For example, the Department of Justice imposed three-year record maintenance for self-evaluations [133] required under regulations implementing section 504 of the Rehabilitation Act, and the Department or the Department of Justice imposed similar requirements in regulations under Title II of the Americans with Disabilities Act, the Age Discrimination Act of 1975, and Title IX of the Education Amendments of 1972.[134] And HHS regulations under Title VI, Age Discrimination Act of 1975, and Titles VI and XVI of the Public Health Service Act generally require that a recipient maintain records necessary to determine whether the recipient has complied with the law.[135]

Comment: The Department received a comment requesting that the requirements of § 88.6 not go into effect until at least one year after the publication of the final rule.

Response: The Department believes that covered entities will have sufficient time to begin abiding by the requirements of § 88.6 60 days after the publication of this final rule. To the extent that entities have specific reasons why they cannot comply within that timeframe, the Department will consider exercising enforcement discretion and take those reasons into consideration during any investigation of complaints that may arise.

Comment: The Department received comments requesting that the imposition of funding restrictions or other remedies on recipients based on their sub-recipients' violations of Federal conscience and anti-discrimination laws be made discretionary instead of mandatory because some recipients may have limited control over their sub-recipients.

Response: As with other anti-discrimination regulations OCR enforces, such as the Age Discrimination Act (45 CFR 90), Title IX (45 CFR 86), and Title VI (45 CFR 80), this rule assures that Federal funds channeled from recipients to sub-recipients do not become immune to the protections provided by conscience and associated anti-discrimination laws. The Department, however, agrees that the rule should reflect greater enforcement discretion, and will finalize § 88.6(a) by changing ''shall'' with respect to the imposition of funding restrictions ''and'' other remedies to read ''may'' and ''or,'' respectively.

Summary of Regulatory Changes: For the reasons described in the proposed rule [136] and above, and considering the comments received, the Department finalizes § 88.6 with substantial changes as described above, by making a technical correction to provide OCR with greater enforcement discretion concerning the responsibility of recipients for violations of the rule by sub-recipients, by changing ''shall'' to ''may'' in paragraph (a); by providing greater specificity as to the records covered entities are required to maintain and for how long in paragraphs (b)(1) through (3); by making a technical correction to provide greater clarity on how a covered entity's failure to cooperate may result in an OCR referral to the Department of Justice by inserting ''in coordination with the Department's Office of General Counsel'' in paragraph (c); by making a technical correction, in keeping with the Department's intent for § 88.6 to mirror Title VI enforcement regulations where applicable, to add a provision regarding the time and manner of OCR's access to records, and the applicability of confidentiality and privacy concerns to OCR's access in paragraph (c); by shortening from five years to three years in paragraph (d) the period for disclosing in any application for new or renewed Federal financial assistance or Departmental funding any determination by OCR of noncompliance to reduce the burden on covered entities; by revising reporting requirements in paragraph (d) to reduce the burden on covered entities by eliminating reporting requirements in situations in which such reports are unnecessary or redundant with actions taken by the Department, such as disclosing the existence of complaints, compliance reviews, or investigations in any application for new or renewed Federal financial assistance or Departmental funding; and by making a technical correction at the end of paragraph (d) to clarify that recipients disclose any OCR determinations made against their sub-recipients.

Enforcement Authority (§ 88.7)

This section of the proposed rule reaffirmed the delegation to OCR of the Department's authority to enforce the Federal conscience and anti-discrimination laws, in collaboration with the relevant Department components. The Department also noted that OCR has been expressly delegated the authority to enforce the Church, Coats-Snowe, and Weldon Amendments

[133] *See, e.g.,* ''A public entity shall, within one year of the effective date of this part, evaluate its current services, policies, and practices, and the effects thereof, that do not or may not meet the requirements of this part and, to the extent modification of any such services, policies, and practices is required, the public entity shall proceed to make the necessary modifications.'' 28 CFR 35.105(a).

[134] *See* 45 CFR 84.6(c) and 85.11(c), 28 CFR 35.105(c), 45 CFR 90.43(b), and 45 CFR 86.3(d), respectively.

[135] *See* 45 CFR 80.6(b), 45 CFR 90.42(a) and 91.31, and 42 CFR 124.605(b), respectively.

[136] 83 FR 3880, 3898 (stating the reasons for the proposed § 88.6, except for the modifications adopted herein).

since the 2008 Rule, which was reaffirmed in the 2011 Rule. Enforcement of section 1553 is also expressly delegated to OCR in the ACA. The NPRM provided notice that the Secretary delegated to OCR the authority to enforce all Federal conscience and anti-discrimination laws that were the subject of the proposed rule.

This section also proposed to specify that OCR's enforcement authority would include the authority to handle complaints, perform compliance reviews, investigate, and seek appropriate action (in coordination with the leadership of any relevant HHS component) that the Director deems necessary to remedy the violation of Federal conscience and anti-discrimination laws and the proposed regulation, as allowed by law. The proposed text of § 88.7 of this part would provide OCR discretion in choosing the means of enforcement, from informal resolution to more rigorous enforcement leading to, for example, funding termination, as appropriate to the particular facts, law, and availability of resources.

The Department also proposed to explicitly establish its authority to investigate and handle (a) alleged violations and conduct compliance reviews whether or not a formal complaint has been filed, and (b) ''whistleblower'' complaints, or complaints made on behalf of others, whether or not the particular complainant is a person or entity protected by Federal conscience and anti-discrimination laws.

In this section of the proposed rule, the Department proposed to adopt the enforcement procedures for other civil rights laws, such as Title VI and section 504 of the Rehabilitation Act, for the Federal conscience and anti-discrimination laws. The Department solicited comments on what administrative procedures or opportunities for due process the Department should, as a matter of policy, or must, as a matter of law, provide (1) with respect to the remedial and enforcement measures that the Department may consider imposing or utilizing in response to a failure or threatened failure to comply with Federal conscience and anti-discrimination laws or this part, (2) before the Department may terminate Federal financial assistance or other Federal funds from the Department, or (3) before the Department may implement any or all of the remedial measures identified in § 88.7(i)(3) of the proposed rule. For example, comment was requested on whether the proposed rule should establish notice, hearing, and appeal procedures similar to those established in the Department's regulations implementing Title VI of the Civil Rights Act of 1964, at 45 CFR 80.8–80.10. The Department also requested comment on whether and in what circumstances it would be appropriate to require remedies against a recipient for the violations of a sub-recipient, or against entities' subsidiaries that are found to be in violation of any Federal conscience and anti-discrimination law or the proposed regulation.

The Department received comments on this section, including those generally supporting the proposed § 88.7.

Comment: The Department received comments stating that the Federal conscience and anti-discrimination laws do not provide the Department with the authority to conduct compliance reviews under these statutes or to engage in the investigatory actions provided for in § 88.7. The Department also received a comment stating that conducting a compliance review without having received a complaint is unreasonable.

Response: Inherent in Congress's adoption of the statutes that require the recipients of Federal funds from the Department to comply with certain Federal health conscience statutes is the authority of the Department to take measures to ensure compliance. This is especially true in light of the fact that courts have refused to recognize private rights of action under certain statutes that are the subject of this rule, thus leaving victims of unlawful discrimination with no possible remedy without the Department's intervention. Further, under the various statutes and regulations governing HHS grants, contracts and other programs discussed in part III.A above concerning the authority to issue this rule, the Department has authority to ensure that both it, and covered entities, are spending Federal funds and operating programs consistent with Federal laws applicable to those funds and programs. The Secretary similarly has authority under 5 U.S.C. 301 to prescribe regulations for the government of the Department and the distribution and performance of its business. Providing for Departmental procedures to ensure compliance, including to undertake compliance reviews, falls under such authorities.

As for their reasonableness, compliance reviews are a standard tool for ensuring compliance with Federal nondiscrimination statutes, despite the fact that most Federal nondiscrimination statutes, such as Title VI of the Civil Rights Act of 1964, do not explicitly mention them. Executive Order 12250 directed the Attorney General to implement regulations that addressed investigations and compliance reviews for the Federal nondiscrimination statutes. The order also directed agencies administering Federal nondiscrimination statutes to implement directives, via either policy guidance or regulations, consistent with the Attorney General's regulations. Regulations subsequently promulgated by the Department of Justice regarding coordination of Title VI compliance, pursuant to Executive Order 12250, interpret Title VI as authorizing Federal agencies to conduct compliance reviews for Title VI enforcement. *See, e.g.,* 28 CFR 42.407(c)(1) (''Federal agencies shall establish and maintain an effective program of post-approval compliance reviews regarding approved new applications (*see* 28 CFR 50.3(c) II A), applications for continuation or renewal of assistance (28 CFR 50.3(c) II B) and all other federally assisted programs.'').

Nevertheless, in order to address these concerns, the Department is finalizing § 88.7(c) with certain changes to clarify that OCR may conduct compliance reviews based on information from a complaint or other source that causes OCR to suspect non-compliance by an entity subject to the rule.

Comment: The Department received comments stating that, to provide clarity for covered entities and to ensure fairness of enforcement, potential penalties set forth in the rule should be clear and uniform.

Response: The Department agrees with this comment in part. Potential penalties vary among the Federal conscience and anti-discrimination laws as set by Congress. In addition, to the extent penalties may be imposed involuntarily, regulations such as those that apply to HHS grants, contracts, and CMS programs discussed above provide a well-established process for enforcing compliance with the terms and conditions of grants and contracts and programmatic regulations that require compliance with certain non-discrimination provisions. Consequently, in order to increase the clarity and uniformity of involuntary remedial processes applied through this rule, the Department has concluded that penalties imposed involuntarily under this rule will be imposed through those applicable regulations, such as 45 CFR part 75, or the FAR and HHSAR. This is preferable both to an independent framework mirroring those of Title VI

and section 504 of the Rehabilitation Act, as the Department had proposed, and to a new set of uniform penalties as the commenter may have been proposing. Under this rule, in the event the Department deems that involuntary remedies may be appropriate, OCR will coordinate with the relevant funding component(s) of HHS in pursuing such remedies.

Comment: The Department received a comment stating that conducting a compliance review without having received a complaint is unreasonable.

Response: The Department disagrees. The Department's Office for Civil Rights routinely conducts compliance reviews to ensure covered entities follow the requirements of other Federal civil rights laws, as well as the Health Insurance Portability and Accountability Act of 1996 and its associated regulations.[137] Providing for compliance reviews to ensure that Federal conscience and anti-discrimination laws are not violated brings the Department's ability to enforce such laws into parity with other civil rights laws that the Department enforces.

Comment: The Department received comments stating that proposed § 88.7 does not provide for adequate due process.

Response: The Department agrees in part, and is finalizing the rule to make use of remedial processes under other existing HHS regulations. As clarified herein, where OCR is not able to reach a voluntary resolution of a complaint with a covered entity, involuntary enforcement will occur by the mechanisms established in the Department's existing regulations, such as those that apply to grants, contracts, or CMS programs, with OCR coordinating with the relevant funding component(s) of HHS. In those instances, the due process available under the applicable regulations will be available to covered entities. For example, 45 CFR 75.374 provides for opportunities for grantees to object, obtain hearings, and seek appeals when the Department or a component take a remedy for grantee non-compliance. Consistent with this approach, the language of § 88.7(a) is finalized with changes to clarify that the Director of OCR is authorized to pursue voluntary resolutions of complaints, and that remedial action beyond that will occur through coordination of OCR with funding components, consistent with applicable laws and regulations.

Comment: The Department received a comment stating that the proposed penalties violate the Spending Clause of the Constitution because, for Congress to place a condition on receipt of Federal funds by a State, the condition placed on the State must be unambiguous, and the amount in question cannot be so great that it can be considered coercive to the State's acceptance of the condition.

Response: The Department disagrees. The substantive requirements of laws enforced by this rule were set forth by Congress, and the Department is not aware of any successful Spending Clause challenge to such laws, even though some of those laws have existed for decades. The Department believes the conditions and requirements imposed on the States by the Federal conscience and anti-discrimination laws are unambiguous, and that these rules, in mirroring those requirements, are similarly clear. The Department has provided a clear description of entities to which each such statute applies, and of what is required of each entity in § 88.3 of this rule and elsewhere. Only after a violation has been found should the question of the appropriate remedy available under the law be answered.

It is the consistent policy of the Federal government to presume that statutes passed by Congress and signed by the President are constitutional. Funding remedies in cases of violations under this rule will be applied consistently with the Constitution and relevant case law. The Department's decision to finalize this section to make use of existing remedial mechanisms under longstanding HHS regulations applicable to certain funding instruments, with OCR coordinating with HHS funding components, will also ensure that remedies imposed will be consistent with any constitutional concerns.

Comment: The Department received a comment stating that referral to the Department of Justice for additional enforcement is not provided for in any of the Federal conscience and anti-discrimination laws.

Response: The Department of Justice acts as the Department's representative in court, and the Department routinely refers matters that require litigation on its behalf, or on behalf of the United States, to the Department of Justice including laws enforced by OCR. Furthermore, entities that make assurances or certifications of compliance under § 88.4, or that make other statements or productions to the Department under this part, do so under penalty of 18 U.S.C. 1001 (prohibiting materially false statements regarding an agency matter), violations of which may warrant referral to the Department of Justice. Additionally, the Department of Justice would be the appropriate party to receive referrals of potential violations of 42 U.S.C. 300a–8 which imposes criminal penalties on any officer or employee of the United States, or of any entity that administers federally funded programs (including States), and on any person receiving Federal financial assistance, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance. As a result, the Department finalizes the rule by amending § 88.7(i) (renumbered as § 88.7(h)) to clarify that possible appropriate referrals to the Department of Justice include potential violations of 42 U.S.C. 300a–8 and 18 U.S.C. 1001.

Comment: The Department received comments stating that health care entities should not be subject to the mechanisms in § 88.7 unless a discriminated-against employee had provided prior notice to the entity of the employee's religious beliefs or moral convictions.

Response: While the Department encourages employers and employees to openly discuss religious and moral convictions that may impact which services or tasks the employer may ask of employees, where Federal conscience and anti-discrimination laws do not require prior notice of religious beliefs or moral convictions, neither does this rule. In other situations involving religious accommodations, the Supreme Court has held that notice is not required.[138] Nevertheless, during complaint investigations and compliance reviews, the Department takes into consideration facts such as whether the covered entity knew or should have known about the objection.

Comment: The Department received a comment stating that imposing the penalties described in § 88.7(j)(3) (renumbered as § 88.7(i)(3)) on the basis of a ''threatened failure'' to comport with the Federal conscience and anti-discrimination laws is excessive.

Response: The Department agrees and is removing the phrase ''threatened failure'' from § 88.7(j)(3) (renumbered as § 88.7(i)(3)).

Comment: The Department received a comment stating that § 88.7 threatens all

[137] 45 CFR 160.308.

[138] *See, e.g., EEOC* v. *Abercrombie & Fitch Stores, Inc.,* 135 S. Ct. 2028, 2033 (2015) (stating that importation of a notice requirement would ''add words to the law'' and that a prior request for accommodation ''may make it easier to infer motive, but is not a necessary condition of liability.'').

funding streams for any violation of the Federal conscience and anti-discrimination laws.

Response: The Department disagrees. The only funding streams threatened by a violation of the Federal conscience and anti-discrimination laws are the funding streams that such statutes directly implicate. The Department cannot terminate funding for violation of a Federal conscience or anti-discrimination law unless Congress has applied that law to that funding. Section 88.7 is intended to provide a general description of the range of possible enforcement mechanisms available to the Department, not an exhaustive list of actions to be taken for each violation or prescribed amounts. Termination of funding as a possible remedy is a necessary corollary of Congressional requirements that certain funding not be provided to entities that engage in impermissible discrimination. Nevertheless, OCR commonly investigates complaints under civil rights laws that permit termination of funding on a finding of a violation, and yet OCR only rarely imposes termination of funding as a penalty for such violations. For example, under HIPAA, civil monetary penalties are not uncommon, although they still represent the minority of resolutions to cases where a violation was found to the satisfaction of the Department. In civil rights cases, complaint investigations in which OCR finds a violation are usually resolved by corrective action. What specific remedy is appropriate in the case of a particular violation depends on the facts and circumstances, and OCR does not prejudge those facts in this rule to suggest termination of funding will be either a common or an uncommon outcome. The Department simply observes that, just because the rule provides for termination of funding as a possible corrective action, does not mean that funding, either in whole or in part, will be terminated in all or even most cases. It would be premature and contrary to the history of OCR enforcement to deem this rule as a requirement that OCR terminate all, or even some, funding of all entities found to have committed a violation.

Summary of Regulatory Changes: For the reasons described in the proposed rule [139] and above, and considering the comments received, the Department finalizes § 88.7 by making the changes discussed above, which include clarifying that OCR will serve a coordinating role with other Department components when remedial actions are pursued, and such remedies will be pursued under regulations applicable to relevant funding instruments, rather than under an independent enforcement framework set forth in this rule as had been proposed. Consistent with changes made to the definition of ''discrimination'' regarding the applicability of disparate impact analysis, the Department deletes the phrase ''to overcome the effects of violations of Federal conscience and anti-discrimination laws and this part'' from § 88.7(a)(8). The Department deletes the phrase ''from time to time'' from § 88.7(c) and, in place of the sentence ''OCR may conduct these reviews in the absence of a complaint,'' adds the sentence ''OCR may initiate a compliance review of an entity subject to this part based on information from a complaint or other source that causes OCR to suspect non-compliance by such entity with this part or the laws implemented by this part.'' The Department also adds certain criminal statutes as possible bases of referrals to the Department of Justice under § 88.7(h); and removes the phrase ''threatened failure'' from § 88.7(j)(3) of the proposed rule (renumbered as § 88.7(i)(3) in this final rule). The Department also makes a technical correction, in order to maintain consistency of terminology, to replace the phrase ''cash payments'' with ''Federal financial assistance'' in § 88.7(j)(3)(i) of the proposed rule (renumbered § 88.7(i)(3)(i) in this final rule); makes technical changes to § 88.7(a); adds reference to coordination with the Department's Office of General Counsel to § 88.7(a)(6) and (h); makes a stylistic change to § 88.7(d), including the deletion of ''health care,'' ''associated,'' ''the,'' and ''but not limited to;'' removes proposed § 88.7(e), which discussed destruction of evidence; makes an edit for clarity and readability to relocate the phrase ''in whole or in part'' within paragraph (i)(3)(v); for greater accuracy replaces ''created by Federal law'' with ''under Federal law or this part'' in paragraph (i)(3)(vi); and inserts a new § 88.7(j) to specifically address handling of noncompliance with assurances and certifications, as discussed above.

Relationship to Other Laws § 88.8

This section would clarify the relationship between this part and other Federal, State, and local laws that protect religious freedom and moral convictions. In the proposed rule, the preamble for this section acknowledged that many State laws provide additional conscience protections for providers who have objections to abortion, fertility treatments, sterilization, assisted suicide, and euthanasia, among others. The Department proposed to uphold the maximum protection for the rights of conscience and the broadest prohibition on discrimination provided by Federal, State, or local law, as consistent with the Constitution. Where a State or local law provides as much or greater protection than Federal law for religious freedom and moral convictions, the Department proposed not to construe Federal law to preempt or impair the application of that law, unless expressly provided.

The Department noted that the proposed rule would not relieve OCR of its obligation to enforce other civil rights authorities, such as Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973, and the Americans with Disabilities Act of 1990. The Department affirmed that OCR would enforce all civil rights laws consistent with the Constitution and the statutory language. The Department received comments on this section.

Comment: The Department received comments stating that the proposed rule conflicted with other Federal laws, such as Title X of the Public Health Service Act, that were raised in comments related to other provisions of the proposed rule.

Response: Issues of potential statutory conflict have already been raised by other comments and answered in responses set forth above, so they are not repeated here.

Comment: The Department received comments stating that the proposed rule violates 42 U.S.C. 18114, a section of the ACA that states that, notwithstanding any other provision of ACA, the Secretary shall not promulgate any regulation that creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care, impedes timely access to health care services, interferes with communications regarding a full range of treatment options between the patient and the provider, restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions, violates the principles of informed consent and the ethical standards of health care professionals, or limits the availability of health care treatment for the full duration of a patient's medical needs. Such comments argued that the proposed rule would violate this section by permitting providers to observe their consciences when responding to a patient's request for a particular medical

[139] 83 FR 3880, 3898–3899 (stating the reasons for the proposed § 88.7, except for the modifications adopted herein).

service or treatment, or when determining whether or not to refer for a particular medical service or treatment, instead of requiring providers to comply with such requests by patients.

Response: The Department disagrees. ACA section 1554, 42 U.S.C. 18114, in no way negates the Federal conscience and anti-discrimination laws enforced by this rule. First, section 1554 is limited to regulations promulgated under the ACA. Only a minority of the laws implemented by this rule are set forth in the ACA—most, including for example the Church Amendments, the Coats-Snowe Amendments, and the Weldon Amendment, are not part of the ACA, and therefore regulations implementing those statutes are not affected by section 1554.

Second, it is a basic principle that Congress ''does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.'' *Whitman* v. *Am. Trucking Ass'ns,* 531 U.S. 457, 468 (2001). It is implausible that Congress intended section 1554 to impliedly repeal Federal conscience protections when section 1554 contains no reference to conscience whatsoever—and when, at the same time and in the same legislation, Congress added several new conscience provisions (*e.g.,* ACA sections 1303(b)(1)(A) and (b)(4), 1553), as well as a provision that nothing in the ACA shall be construed to have any effect on Federal laws regarding conscience protection; willingness or refusal to provide abortion; and 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 (*e.g.,* ACA section 1303(c)(2)).

Third, ''it is a commonplace of statutory construction that the specific governs the general,'' *Morales* v. *Trans World Airlines, Inc.,* 504 U.S. 374, 384 (1992). Each Federal conscience and anti-discrimination law enforced by this rule is more specific to each set of circumstances than is section 1554, so that, to the extent there could be a potential conflict between the statutes, the more specific Federal conscience and anti-discrimination laws require that section 1554 not be interpreted to supersede them. For example, to the extent this rule enforces specific provisions of the ACA, such as ACA sections 1303(b)(1)(A) and (b)(4) and 1553, the rule enforces those laws according to their own text. The Department disagrees with the commenter's implication that, in ACA section 1554, 42 U.S.C. 18114, Congress intended to prohibit the enforcement of ACA sections 1303(b)(1)(A) and (b)(4) and 1553 as written. Generally, one part of a statute should not be interpreted to negate many other parts of the same statute, because that would render those parts of the statute meaningless.

Fourth, even assuming that section 1554 applies, it must be construed in harmony with the ACA conscience provisions, as well as the other Federal conscience protections, especially in light of section 1303(c)(2) that nothing in the ACA shall be construed to have any effect on Federal laws regarding conscience protection: There is a presumption that Congress does not silently repeal its own statutes, but it intends multiple statutes to be read without conflict. And this is the manner in which the Department interprets section 1554.

Fifth, again, even assuming that section 1554 applies, this Final Rule does not ''create[ ] any unreasonable barriers to the ability of individuals to obtain appropriate medical care.'' The protections enforced by this rule are duly enacted laws, passed by Congress and signed by the President. Such protections are, by definition, reasonable under 42 U.S.C. 18114. Further, by removing or reducing barriers that discourage health care providers from remaining in the health care industry, this rule promotes diversity and full participation of providers in health care generally and in HHS-funded programs in particular, and enhances the ability of individuals to obtain appropriate medical care. As for the compliance with 42 U.S.C. 18114's provisions concerning timely access to health care services or for full duration of a period of medical need, this rule does not limit a health care provider's ability to provide timely care and appropriate care, and for the reasons just discussed, should result in a greater number of providers and thus more timely and complete care overall. Additionally, as discussed in response to a previous comment above, the Emergency Medical Treatment and Labor Act (EMTALA) would not be displaced by the rule, and requires provision of treatment in certain emergency situations and facilities. As for 42 U.S.C. 18114's provisions concerning informed consent and interference with communications and the ability for doctors and patients to communicate freely, the Department addressed similar concerns in response to several comments above and incorporates such responses here by reference. Moreover, nothing in this rule restricts the doctor-patient relationship or interferes with doctor-patient communications. The underlying statutes enforced by this rule apply, or do not apply, to communications between a patient and provider of their own force, and this final rule does not ''interfere'' in those communications merely by protecting conscience rights established by Congress.

Comment: The Department received comments alleging that the proposed rule conflicts with the Americans with Disabilities Act, 42 U.S.C. 12101 *et seq.,* or the Rehabilitation Act, 29 U.S.C. 701 *et seq.,* because health care providers may exercise their religious beliefs or moral convictions to refuse to treat patients with HIV, or may decline to provide an abortion to a woman with a life-threatening condition.

Response: The Department is unaware of any religious or ethical belief systems that prohibit treatment of persons on the basis of their HIV status. Additionally, the Department disagrees that there is a conflict between the requirements of this rule and the Americans with Disabilities Act or the Rehabilitation Act under the hypotheticals presented. No regulation can, of its own force, supersede statutes enacted by Congress unless such statute is superseded or limited by another act of Congress. This rule merely provides the Department with the means to adequately enforce the Federal conscience and anti-discrimination laws to the extent permissible under the laws of the United States and the Constitution. *See Maher* v. *Roe,* 432 U.S. 464 (1977) (holding that government may favor childbirth over abortion through public funding); *Harris* v. *McRae,* 448 U.S. 917 (1980) (upholding laws limiting Federal funding of abortions).

Comment: The Department received a comment alleging that the proposed rule conflicts with international treaties, such as the International Covenant on Civil and Political Rights (''ICCPR''), which includes a ''right to health,'' and the International Covenant on Economic, Social and Cultural Rights (''ICESCR''), which describes four components of the right to health as availability, accessibility, acceptability and quality.

Response: The Department disagrees that the proposed rule conflicts with the ICCPR. The ICCPR does not include a ''right to health'' as described by the commenter. Instead, the ICCPR includes ''public safety, order, health, or morals'' as a permitted limitation on certain fundamental rights, such as free speech

and religious liberty.[140] When the Senate ratified the ICCPR, however, it did so subject to a declaration ''[t]hat it is the view of the United States that States Party to the Covenant should wherever possible refrain from imposing any restrictions or limitations on the exercise of the rights recognized and protected by the Covenant, even when such restrictions and limitations are permissible under the terms of the Covenant.'' [141] Additionally, the Senate ratified the ICCPR with the understanding that the ICCPR is not self-executing.[142]

The Department also disagrees that the proposed rule conflicts with the ICESCR. First, the description of the ICESCR provided by the commenter is incorrect. The ICESCR simply requires that ''States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.'' [143] Additionally, the United States has not ratified the ICESCR; thus, it is not binding. Nevertheless, because the Department believes, as described elsewhere in this preamble, that this rule will increase access to and quality of health care in America, this rule furthers the goals of the ICESCR.

Comment: The Department received a comment stating that the proposed rule violated the Eighth Amendment to the U.S. Constitution because the proposed rule would reduce access to care in prisons.

Response: The Department disagrees. First, as noted above, the Department believes that this rule will result in greater access to health care or greater options from a wider and more diverse pool of medical professionals. Additionally, the finalized definition of ''discriminate or discrimination'' ensures that a facility that must respect conscience can use alternative staff to accommodate an objector without violating this rule.

Comment: The Department received comments stating that the proposed rule could harm efforts to assist persons with substance use disorder because a health care provider may hold a religious or moral conviction that drug use should be treated as a moral or criminal matter instead of a medical matter.

Response: This rule does not conflict with any Federal statutes that would require the treatment of persons suffering from substance use disorder, because no regulation can, of its own force, supersede statutes enacted by Congress. This rule merely provides the Department with the means to adequately enforce the Federal conscience and anti-discrimination laws to the extent permissible under the laws of the United States and the Constitution. The Department is unaware of any faith community that holds the views identified by the commenter. To the contrary, the Department's experience reveals that many members of the faith community are actively involved and voluntarily play an important role in efforts to help address the opioid crisis and other substance use disorders.

Comment: The Department received comments stating that the proposed rule would violate the Equal Protection Clause of the Constitution by permitting discrimination against women seeking abortion.

Response: The Department disagrees. Nothing in this rule permits the Federal government to discriminate against a person on the basis of such person's membership in a suspect class. Neither the equal protection doctrine nor any other constitutional doctrine negates any of the Federal conscience and anti-discrimination laws pertaining to abortion that this rule enforces. On the contrary, the Supreme Court has upheld laws limiting Federal funding of abortions, even of those deemed to be medically necessary, against equal protection challenges. *See Harris* v. *McRae,* 448 U.S. 917 (1980) (upholding the Hyde Amendment against a challenge under the Equal Protection Clause because the Hyde Amendment is rationally related to the legitimate governmental interest in preserving the life of the unborn); *Maher* v. *Roe,* 432 U.S. 464 (1977) (holding that government may legitimately favor childbirth over abortion through public funding); *Rust* v. *Sullivan,* 500 U.S. 173 (1991) (same). *Roe* v. *Wade* and *Doe* v. *Bolton* both explicitly affirmed the appropriateness of conscience protections,[144] and, therefore, the scope of rights defined by either case cannot be read to conflict with conscience protections relating to abortion. This rule, additionally, furthers the legitimate governmental interest in ensuring a large and diverse pool of health care providers by removing obstacles to persons who are interested in serving as health care providers but might be unwilling to do so for fear of being coerced to violate their religious beliefs or moral convictions.

Comment: The Department received comments stating the proposed rule would violate the Establishment Clause by providing for an affirmative accommodation for religious beliefs that burden a third party.

Response: The Department disagrees that religious accommodations such as those provided by Congress and enforced by this rule violate the Establishment Clause. Congress began enacting laws such as the Church Amendments in 1973, and none of them have been invalidated under the Establishment Clause. As the Supreme Court recognized in *Corporation of Presiding Bishop of the Church of Jesus Christ of Latter-day Saints* v. *Amos,* ''the government may (and sometimes must) accommodate religious practices and . . . it may do so without violating the Establishment Clause.'' 483 U.S. 327, 334 (1987) (quoting *Hobbie* v. *Unemployment Appeals Comm'n of Fla.,* 480 U.S. 136, 144–45 (1987)). As one commenter noted, in *Burwell* v. *Hobby Lobby Stores, Inc.,* 134 S. Ct. 2751, 2781 (2014), the Supreme Court held that the Department's regulation mandating group health plans to cover contraceptives violated the Religious Freedom Restoration Act by failing to provide an exemption for Hobby Lobby to exercise its sincerely held religious beliefs. The Supreme Court also observed that any burden on third parties could be addressed in other ways, including through the establishment of a new governmental program if necessary. The Court held that Hobby Lobby itself did not have to bear a religious burden merely because its religious accommodation may burden a third party.

Furthermore, this rule merely provides for the enforcement of the Federal conscience and anti-discrimination laws as Congress enacted them. These protections are limited to particular programs, particular governmental involvement, and particular funding streams, as Congress determined necessary to ensure that conscience rights are respected and that

[140] *See, e.g.,* International Covenant on Civil and Political Rights arts. 18–19, *adopted* Dec. 19, 1966, 999 U.N.T.S. 171.

[141] Senate Comm. on Foreign Relations, Report on the International Covenant on Civil and Political Rights, S. Exec. Rep. No. 23, 23 (102d Sess. 1992)

[142] *Id.*

[143] International Covenant on Economic, Cultural and Social Rights art. 12, *adopted* Dec. 16, 1966, 993 U.N.T.S. 3. (The ICECSR states that the ''steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; (b) The improvement of all aspects of environmental and industrial hygiene; (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.'' *Id.)*

[144] 410 U.S. at 143–44; 410 U.S. at 197–98.

health care entities with moral or religious objections to certain medical services or certain aspects of health service programs or research activities are not driven from the health care industry.

Comment: The Department received comments stating that the proposed rule will conflict with various State laws and medical standards.

Response: This rule does not establish new Federal law, but provides for the enforcement of laws enacted by Congress. To the extent State or local laws or standards conflict with the Federal laws that are the subject of this rule, the Federal conscience and antidiscrimination laws preempt such laws and standards with respect to funded entities and activities, in accordance with the terms of such Federal laws. With respect to States, States can decline to accept Federal funds that are conditioned on respecting Federal conscience rights and protections.

Summary of Regulatory Changes: For the reasons described in the proposed rule [145] and above, and considering the comments received, the Department finalizes § 88.8 without change, beyond global edits to the rule as a whole.

Rule of Construction § 88.9

This section proposed that the protections for religious freedom and moral conviction for which enforcement mechanisms are provided by this part would be construed broadly and to the maximum extent permitted by law and the Constitution. The Department received comments on this section, including comments in general support of the proposed section.

Comment: The Department received a comment stating that § 88.9 could be more clearly stated as follows: ''This part shall be construed in favor of a broad protection of free exercise of religious beliefs and moral convictions, to the maximum extent permitted by the Constitution and the terms of the Federal conscience protection and associated anti-discrimination statutes.''

Response: The Department agrees that this proposed language is clearer and is modifying § 88.9 to so read, with some stylistic changes to the proposed text, characterizing the Federal laws in question as ''Federal conscience and anti-discrimination laws.''

Summary of Regulatory Changes: For the reasons described in the proposed rule [146] and above, and considering the comments received, the Department finalizes § 88.9 by rephrasing it to add clarity so that it now says, ''This part shall be construed in favor of a broad protection of the free exercise of religious beliefs and of moral convictions, to the maximum extent permitted by the Constitution and the terms of the Federal conscience protection and associated anti-discrimination statutes.''

Severability § 88.10

In § 88.10, the Department proposed a severability provision that would govern the Department's interpretation and implementation of 45 CFR part 88 if any section of part 88 should be held invalid or unenforceable, either facially or as applied. In the event this occurs, the Department proposed that the provision in question be construed in a manner that gives maximum extent to the force of the provision as permitted by law. For instance, a provision held to be unenforceable as applied to a particular circumstance should be construed so as to continue the application of the provision to dissimilar circumstances. Proposed § 88.10 would provide that if the provision is held to be utterly invalid or unenforceable, the provision in question shall be severable from part 88, and the remainder of part 88 should remain in full force and effect to the maximum extent permitted by law. The Department received a comment on this section.

Comment: The Department received a comment stating that a severability clause is unnecessary because, following consideration of public comments to the proposed rule, the Department should be aware of any portions of the rule that are invalid or unenforceable.

Response: The Department does not agree that the severability clause is inappropriate. The Department considers all the provisions of this final rule as being legally supported, has fully considered all comments received, and has made appropriate modifications, additions, and deletions. Nevertheless, as a general matter, severability represents the Department's intention regarding whether the rule should go into effect if parts of it are held invalid or enjoined by a court. The Department deems it appropriate to maintain the severability clause as proposed, so that this rule will remain in place to the maximum extent allowable in the event of adverse court action. In addition, future additions to statutes enforced by this rule could render parts of the rule inapplicable, and it is the Department's intention that such changes will not invalidate parts of the rule that remain statutorily supported.

Summary of Regulatory Changes: For the reasons described in the proposed rule [147] and above, and considering the comments received, the Department finalizes § 88.10 without change.

Appendix A to Part 88—Notice of Rights Under Federal Conscience and Anti-Discrimination Laws

The Department received comments on appendix A to part 88, which were responded to above, with the comments to § 88.5.

Summary of Regulatory Changes: For the reasons described above, and considering the comments received, the Department finalizes appendix A to part 88 to provide a more accurate notice as to the protections provided by the Federal conscience and anti-discrimination laws. For instance, the Department replaces proposed text stating that the entity ''does not'' engage in certain acts with language stating that entity ''complies with'' laws prohibiting certain acts. The Department also modifies the notice text to say that ''You may have the right'' instead of ''You have the right,'' and replaces ''participate in'' with ''perform, assist in the performance of.'' The Department also makes stylistic changes to the heading and certain portions of the body text of the model notice in appendix A.

IV. Regulatory Impact Analysis

A. Introduction and Summary

The Department has examined the impacts of this final rule as required under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354, 5 U.S.C. 601–612), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–04), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), the Assessment of Federal Regulation and Policies on Families (Pub. L. 105–277, sec. 654, 5 U.S.C. 601 (note)), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

This rule revises the regulation that allows OCR to accept and coordinate the handling of complaints alleging violations of the Weldon, Coats-Snowe and Church Amendments, three Federal

[145] 83 FR 3880, 3899.

[146] 83 FR 3880, 3899 (stating the reasons for the proposed § 88.9, except for the modifications adopted herein).

[147] 83 FR 3880, 3899.

laws that collectively protect conscience, prohibit coercion, and require nondiscrimination in certain programs and activities operated by recipients or sub-recipients or that are administered by the Secretary. Specifically, this rule:

(1) Expands the regulation's scope to encompass the full panoply of Federal health-related conscience protection and associated anti-discrimination laws that exist across the Department and that the Secretary has delegated to OCR to handle,

(2) Articulates the scope of enforcement mechanisms available to HHS to address noncompliance with Federal conscience and anti-discrimination laws, and

(3) Requires certain persons and entities covered by this rule to adhere to procedural and administrative requirements that aim to improve compliance with Federal conscience and anti-discrimination laws and to achieve parity with procedural and administrative requirements of other Federal civil rights authorities enforced by OCR.

TABLE 1—ACCOUNTING TABLE OF BENEFITS AND COSTS OF ALL CHANGES

	Present value over 5 years by discount rate (millions of 2016 dollars)		Annualized value over 5 years by discount rate (millions of 2016 dollars)	
	3 Percent	7 Percent	3 Percent	7 Percent
Benefits:				
Quantified Benefits	.....	.....	.....	.....
Non-quantified Benefits: 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.				
Costs:				
Quantified Costs	900.7	731.5	214.9	218.5
Non-quantified Costs: Compliance procedures (recordkeeping and compliance reporting) and seeking of alternative providers of certain objected-to medical services or procedures.				

Analysis of Economic Impacts: Executive Orders 12866 and 13563

HHS has examined the economic implications of this final rule as required by Executive Orders 12866 and 13563. 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 effects; distributive impacts; and equity). The Department estimates that the benefits of this rule, although not always quantifiable or monetized, justify the burdens of the regulatory action.

B. Executive Order 12866

Section 6(3)(C) of Executive Order 12866 requires agencies to prepare a regulatory impact analysis (RIA) for major rules that are significant. Section 3(f) of Executive Order 12866 defines a regulatory action as significant if it is likely to result in a rule that meets one of four conditions: (1) Is economically significant, (2) creates a serious inconsistency or otherwise interferes with an action taken or planned by another agency, (3) materially alters the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of the recipients of these grants and programs, or (4) raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866. A rule is likely to be economically significant where the agency estimates that it will (a) have an annual effect on the economy of $100 million or more in any one year, or (b) adversely and materially affect the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The Department has determined that this rule will have an annual effect on the economy of $100 million or more in one year and, thus, is economically significant. The rule also furthers a presidential priority of protecting conscience and religious freedom. Executive Order 13798, 82 FR 21675 (May 4, 2017).

C. Executive Order 13563

Executive Order 13563 supplements and reaffirms the principles of Executive Order 12866. Section 1(b) of Executive Order 13563 requires agencies to:

- ''propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs,''
- ''tailor its regulations to impose the least burden on society,''
- ''select . . . regulatory approaches that maximize net benefits,''
- ''[as] feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt,'' and
- ''identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior . . . or providing information upon which the public can make choices.''

Executive Order 13563 encourages agencies to promote innovation; avoid creating redundant, inconsistent, or overlapping requirements applicable to already highly regulated industries and sectors; and consider approaches that maintain flexibility and freedom of choice for the public. Finally, Executive Order 13563 requires that agencies use the best reasonably obtainable scientific, technical, and economic information available in evaluating the burdens and benefits of a regulatory action.

The Department considered these objectives and used the best reasonably obtainable technical and economic information to determine that this final rule creates net benefits, is tailored to impose the least burden on society, incentivizes the desired behavior, and maximizes flexibility. This impact analysis also strives to promote transparency in how the Department derived the estimates. To this end, this RIA notes the extent to which key uncertainties in the data and assumptions affect the Department's analytic conclusions.

1. Need for the Rule

(i) Problems That This Rule Seeks To Address

In developing regulatory actions, ''[e]ach agency shall identify the problem that it intends to address (including . . . the failures of private markets or public institutions . . .) as well as assess the significance of the problem.'' E.O. 12866, sec. 1(b)(1). In identifying the problem warranting agency regulatory action, ''[e]ach agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem . . . .'' E.O. 12866, sec. 1(b)(2).

This rule seeks to address two categories of problems: (1) Inadequate enforcement tools to address unlawful discrimination and coercion faced by protected persons, entities, or health care entities, and (2) lack of awareness, and, to the extent there is awareness, confusion, concerning Federal conscience protection obligations and associated anti-discrimination rights, of covered entities and individuals and organizations, respectively, leading to possible violations of law. The array of issues described in *supra* at part I.B (describing the final rule's regulatory history) fall into one or both of these categories.

The first category—inadequate enforcement tools to address unlawful discrimination and coercion—stems from inadequate to non-existent regulatory frameworks to enforce existing Federal conscience and anti-discrimination laws. The absence of adequate Federal governing frameworks to remedy discrimination may have undermined incentives for covered persons and entities to institute proactive measures to protect conscience, prohibit coercion, and promote nondiscrimination. Although some public comments argued that existing law is sufficient to protect conscience and religious freedom, the Department disagrees, given the mutually reinforcing deficiencies at the Federal level, which include:

- An inadequate, minimalistic regulatory scheme set forth in the Department's 2011 Rule that rescinded the comprehensive 2008 Rule, which addressed three of the 25 statutory provisions that are the subject of this rule. *See supra* at part I (describing existing and prior versions of the rule and identifying confusion about the scope and applicability of Federal conscience and anti-discrimination laws);
- An unduly narrow Departmental interpretation of the Weldon Amendment adopted by OCR in connection with the 2011 Rule that limited the scope of prohibited discrimination, contrary to the language that Congress passed, *see supra* at part I.B (addressing confusion caused by OCR sub-regulatory guidance); and
- A lack of strategic coordination across the Department to promote awareness of Federal protections for conscience and religious freedom in health care, and to address the enforcement of Federal conscience and anti-discrimination laws set forth in authorizing statutes of programs conducted or administered by Departmental components. *See supra* at part I.A (identifying additional Federal conscience and anti-discrimination laws).

The second category of problems—lack of awareness and, where there is awareness, confusion concerning Federal conscience protection obligations and associated anti-discrimination rights, of covered entities and individuals and entities, respectively—stems from inadequate information and understanding about such Federal law, leading to possible violations of law. Relevant situations where persons, entities, and health care entities with religious beliefs or moral convictions may be coerced or suffer discrimination include:

- Being required to perform, participate in, pay for, provide coverage for, counsel or refer for abortion, sterilization, euthanasia, or other health services;[148]
- participating in health professional training that pressures students, residents, fellows, etc., to perform, assist in the performance of, refer for, or counsel for, abortion or sterilization;
- being steered away from a career in obstetrics, family medicine, or geriatric medicine, when one has a religious or moral objection, as applicable, to abortion, sterilization, physician-assisted suicide or euthanasia;
- being asked to perform or assist in certain services within the scope of one's employment but contrary to one's religious beliefs or moral convictions.

Comments received in support of the proposed rule demonstrated that persons who are unlawfully coerced to violate their consciences, or otherwise discriminated against because they have acted in accord with their moral convictions or religious beliefs, may experience real harms that are significant and sometimes devastating psychologically, emotionally, and/or financially.[149] This can include loss of jobs, loss of promotion possibilities, ''blackballing'' in the medical community, denial of acceptance into or graduation from a medical school, denial of board certification, stigmatization, shunning by peers, and trauma and stress from forced violations of the Hippocratic Oath. Commenters shared anecdotes of the occurrence and nature of coercion, discriminatory conduct, or other actions potentially in violation of Federal conscience and anti-discrimination laws. Commenters also shared their assessment of the knowledge, or lack thereof, among the general public, health care field, health care insurance industry, and employment law field of the rights and obligations that this rule implements and enforces. Examples follow.

- Numerous commenters shared anecdotes of bias and animus in the health care sector against individuals with religious beliefs or moral convictions with respect to abortion.
- Employees shared that they experienced discrimination based on their objections to prescribing abortifacients or participating in abortion or assisted suicide.
- Commenters stated that many health care professionals' careers are jeopardized because entities are completely unaware or willfully dismissive of applicable Federal law that protects conscience, prohibits coercion, or requires nondiscrimination.
- Students, fellows, and residents shared being forced out of residency programs or fields of medicine because of their beliefs about abortion or contraception.
- Commenters shared that they considered avoiding obstetrics and gynecology programs for fear of discrimination and shared polling data, which the RIA's benefits section describes *infra* at part IV.C.4, documenting discrimination experienced by medical students on the basis of their religious beliefs or moral convictions.
- Commenters expressed concern that States are coercing persons and entities

[148] California, for example, sent a letter to seven insurance companies requiring insurers to include abortion coverage in plans used by persons who objected to such coverage. *See* Letter from California Department of Managed Health Care, *Re: Limitations or Exclusions of Abortion Services* (Aug. 22, 2014). The State of California estimates that at least 28,000 individuals subsequently lost their abortion-free health plans, and multiple churches have challenged California's policy in court. *See Foothill Church* v. *Rouillard,* 2:15–cv–02165–KJM–EFB, 2016 WL 3688422 (E.D. Calif. July 11, 2016); *Skyline Wesleyan Church* v. *California Department of Managed Health Care,* No. 3:16–cv–00501–H–DHB (S.D. Calif. 2016).

[149] *See. e.g.,* Compl. *Cenzon-DeCarlo* v. *Mount Sinai Hosp.,* No: 09–3120 (E.D.N.Y. Jul. 21, 2009) at 15 (''Being forced to assist in this abortion has caused Mrs. DeCarlo extreme emotional, psychological, and spiritual suffering.'') (dismissed on other grounds).

to violate their religious beliefs or moral convictions through laws mandating health coverage for abortion.

• One commenter noted that academic medical institutions are not self-policing compliance with, or educating students on, applicable Federal conscience and anti-discrimination laws.

• Commenters shared barriers to obtaining coverage by Medicare Advantage plans for care provided by RNHCIs.[150] Commenters shared that plans justified the denials of coverage and preauthorization requests because medical professionals did not provide the care (even though by definition, an RNHCI provides nonmedical care).

Some commenters have suggested that the thirty-four complaints that OCR received between November 2016 and January 2018 that allege coercion, violation of conscience, or discrimination do not necessitate this final rule.[151] These commenters misconstrue the reasons for this rule; the increase in complaints received by OCR is one of the many metrics used to demonstrate the importance of this rule. During FY 2018, the most recently completed fiscal year for which data are available, OCR received 343 complaints alleging conscience violations.[152] Some complaints raise issues that affect more than one aggrieved person, entity or health care entity; therefore, although one person may have filed the complaint, the complaint may represent the concerns and objections of all nurses at a hospital, multiple pregnancy care facilities or providers in a State, or entire populations (or subpopulations) of States or communities.

(ii) How the Rule Seeks To Address the Problems

This rule corrects those problems. First, the Department revises 45 CFR part 88 from a minimal regulatory scheme to one comparable to the regulatory schemes implementing other civil rights laws. Such schemes typically include a dozen provisions, addressing a range of conduct. These provisions typically restate the substantive requirements and obligations of the laws and often set forth procedural requirements (*e.g.,* assurances of compliance, recordkeeping of compliance, etc.) to advance compliance with substantive rights and obligations. In addition, the regulatory schemes outline the enforcement procedures to provide regulated entities notice of the enforcement tools available to HHS and the type of remedies HHS may seek. Part 88 in effect as a result of the 2011 Rule, by contrast, was only three sentences long and provided considerably less notice and clarity about the conduct prohibited under Federal law and the enforcement mechanisms available to HHS.

This rule confirms HHS will have the authority to initiate compliance reviews where it believes compliance issues have arisen, conduct investigations, resolve complaints, and supervise and coordinate appropriate action(s) with the relevant Department component(s) to assure compliance. Under this rule, certain persons and entities must maintain records regarding compliance with part 88; cooperate with OCR investigations, compliance reviews, interviews, or other parts of OCR's investigative process; and submit written assurances and certifications of compliance to the Department. These procedural and administrative requirements are similar to those in other civil rights regulations that promote compliance with, and enforcement of, the Federal civil rights laws that the regulations implement. Finally, by expanding the scope of part 88 to cover the 25 statutory conscience and anti-discrimination laws applicable to HHS that are the subject of this rule, the rule supports the Department's strategic coordination with respect to compliance with, and enforcement of, these laws across the Department, as well as providing one location that identifies all of the health care related conscience protections and associated anti-discrimination laws enforced by the Department so that regulated entities have clear knowledge of the applicable conscience requirements.

The investigative and enforcement processes set forth by the rule are vital because other avenues of relief are inadequate or unavailable. The Department solicited comment on whether alternate remedies, such as pursuing litigation, have been sufficient to address discrimination, coercion, or other treatment that the laws that are the subject of this rule prohibit. Many commenters stated that litigation was an inadequate option because several courts have declined to recognize a private right of action, such as under the Coats-Snowe and Church Amendments, and have concluded that persons must rely on OCR's administrative complaint process to secure relief.[153] Some commenters also viewed litigation as unviable given the high economic costs of litigation, which may be against well-funded States or medical providers.

Second, this rule promotes voluntary compliance with laws governing the ability of health care entities to act in accord with their legally protected religious beliefs or moral convictions by ensuring that health care entities are aware of, and understand, Federal conscience and anti-discrimination laws. The rule incentivizes entities to provide notice of rights and obligations under the rule by identifying the provision of notice as non-dispositive evidence of compliance that OCR will consider if an entity is subject to an OCR investigation or compliance review. Entities will be more likely to accommodate conscience and associated anti-discrimination rights if entities understand that they are legally obligated to do so. Entities will also be in a better position to accommodate these rights if they understand these rights are akin to other civil rights protecting people from discrimination on the basis of race, national origin, disability, etc.—rights for which entities already provide notice and are familiar with respecting.

In addition, as described *infra* at part IV.C.3.i, the Department anticipates that a subset of recipients that assure and certify compliance in accordance with § 88.4 will take organization-wide action, such as to update policies and procedures, implement staffing or scheduling practices that respect the exercise of conscience rights under Federal law, or take steps to disseminate the recipient's policies and procedures concerning these laws. Greater transparency of practices through open communication of recipient and sub-recipient policies ''should strengthen relationships between . . . entities and their . . . [workforce members].'' [154]

Protection of religious beliefs and moral convictions serves not only individual rights, but also society as a whole. Protections for conscience help ensure a society free from discrimination and more respectful of personal freedom and fundamental

[150] RNHCIs can participate in Medicare and Medicaid as long as they meet the requisite conditions of coverage and participation. See *supra* at part I.A (summarizing the history of statutory provisions regarding RNHCIs, among other provisions, which this rule implements and enforces). *See also https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/RNHCIs.html.*

[151] *See* 83 FR 3880, 3886 (proposed Jan. 26, 2018) (to be codified at 45 CFR pt. 88) (summarizing the history of OCR enforcement of conscience laws).

[152] Complaint data based on OCR's system of records as of December 20, 2018.

[153] *See, e.g., Vermont All. for Ethical Healthcare, Inc.* v. *Hoser,* 274 F. Supp. 3d 227, 240 (D. Vt. 2017); *Hellwege* v. *Tampa Family Health Centers,* 103 F. Supp. 3d 1303, 1311–12 (M.D. Fla. 2015); Order at 4, *National Institute of Family and Life Advocates, et al.* v. *Rauner,* No. 3:16–cv–50310 (N. D. Ill. July 19, 2017), ECF No. 65. *See also supra* at part II.A (describing the lack of private remedies).

[154] 73 FR 78074, 78074 (2008 Rule).

rights enshrined in the First Amendment and Federal law. The Department shares the anticipation of many commenters who reasoned that the rule will promote a culture of respect for rights of conscience and religious freedom in health care that is currently lacking. The boundaries of protection for conscience may be tested when protections for religious beliefs and moral convictions appear to impose a cost or compete with other public purposes.[155] However, as with other civil rights laws, it is in those cases where fidelity to the law becomes of paramount importance.

2. Affected Persons and Entities

The final rule affects (1) persons and entities already obligated to comply with the Weldon Amendment, Coats-Snowe Amendment, or Church Amendments (or a combination thereof) under the 2008 and 2011 Rules; and (2) persons and entities obligated to comply with at least one of the other Federal statutory provisions that this rule implements.

(i) Scope of Persons and Entities Covered by 45 CFR Part 88 in 2011 Rule

Depending on the operation and applicability of the underlying statutes, the 2011 Rule, *i.e.,* 45 CFR part 88 as currently in effect, extended, and continues to extend, broadly. As explained below, the diversity of entities estimated as covered is due to the applicability of the Church Amendments, which applies to non-governmental (as well as governmental) entities that operate ''any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary''; [156] or receive a grant, contract, loan, or loan guarantee under the Public Health Service (PHS) Act,[157] which contains thirty titles and authorizes dozens of programs, or under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act), or receive an interest subsidy under the DD Act.[158]

(A) The Department

As a result of the 2011 Rule, 45 CFR part 88 applied, and still applies, to the Department because the Weldon and Coats-Snowe Amendments, as well as specific parts of the Church Amendments, apply to the Department.

The Weldon Amendment states that ''[n]one of the funds made available in [the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019] may be made available to a Federal agency or program . . . if such agency [or] program . . . subjects any institutional or individual health care entity to discrimination . . . .'' [159] The Department is a Federal agency that receives substantial funds made available in the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, which are the funds addressed in Weldon.[160] The Department must comply with the Weldon Amendment.

The Coats-Snowe Amendment states that ''[t]he Federal Government . . . may not subject any health care entity to discrimination on the [bases]'' listed in paragraphs (a)(1)–(3) of 42 U.S.C. 238n. The Department, as part of the Federal Government, must comply with the Coats-Snowe Amendment in its operations.

Paragraphs (d) and (c)(2) of the Church Amendments apply to certain programs administered by the Secretary. Paragraph (d) applies to all health service programs or research activities funded in whole or part under programs administered by the Secretary, regardless of the source of funding. Paragraph (c)(2) applies to entities that receive grants or contracts ''for biomedical or behavioral research under any program administered by the Secretary.'' [161] The requirements would, thus, apply to such programs or research activities conducted by, or funded by or through, the Department.

(B) State and Local Governments

As a result of the 2008 and 2011 Rules, 45 CFR part 88 applied, and will continue to apply, to all State and local governments that receive HHS Federal financial assistance by virtue of several statutory provisions. First, the Weldon Amendment applies to State and local governments that receive funds made available in the annual Labor, Health and Human Services, and Education Appropriations Act.[162] Second, the Coats-Snowe Amendment applies to State and local governments that receive Federal financial assistance, including Federal financial assistance from the Department (without restriction to any particular funding stream), ''includ[ing] governmental payments provided as reimbursement for carrying out health-related activities.'' [163] Third, several paragraphs of the Church Amendments apply to State and local governments. Paragraph (b) of the Church Amendments prohibits coercion by a ''public authority,'' and thereby includes States and local governments. Paragraphs (c) and (e) of the Church Amendments apply to State and local governments to the extent that such governments receive funds to implement programs authorized in the public laws cited in such paragraphs. Finally, paragraph (d) of the Church Amendments applies to a State or local government (or a component thereof) to the extent that such State or local government receives funding under any program administered by the Secretary.[164]

State and local governments (such as counties or cities) and instrumentalities of governments (such as State health and human services agencies) receive Federal financial assistance or Federal funds from the Department from a variety of financing streams as recipients or sub-recipients. Examples of programs and activities for which State and local governments (in some cases, not exclusively) receive Federal financial assistance or Federal funds from the Department may include Medicaid and the Children's Health Insurance Program; Title X programs, public health and prevention programs, HIV/AIDS and STD prevention and education, and substance abuse screening; biomedical and behavioral research at State institutions of higher education; services for older Americans; medical assistance to refugees; and adult protection services to combat elder abuse.

[155] *See* Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals,* 49 Ariz. St. L.J. 549, 550–51 (2017) (''[T]he growing acceptance of this 'public utility' model of medicine means in practice that extant Federal and State laws protecting conscience—most of which cover only a limited range of procedures and medical practitioners, lack meaningful enforcement mechanisms, and . . . are inadequate to the task of protecting the right to conscience[] . . .'' (citations omitted)).

[156] 42 U.S.C. 300a–7(d).

[157] 42 U.S.C. 300a–7(c).

[158] 42 U.S.C. 300a–7(e).

[159] *E.g.,* Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Public Law 115–245, Div. B, sec. 507(d), 132 Stat. 2981, 3118 (September 28, 2018).

[160] *Id.*

[161] 42 U.S.C. 300a–7(c)(2) and (d).

[162] *See, e.g.,* Public Law 115–245, Div. B, section 507(d), 132 Stat. 2981, 3118 (''None of the funds made available in [the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019] may be made available to a . . . State or local government[ ] if such . . . government . . . .'').

[163] 42 U.S.C. 238n(a), (c)(1).

[164] *Id.* section 300a–7(d) (''No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services . . . .'').

(C) Persons and Entities

As a result of the 2008 and 2011 Rules, 45 CFR part 88 applied, and still applies, to recipients and sub-recipients that operate ''any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary'' [165]; or receive a grant, contract, loan, or loan guarantee under the Public Health Service (PHS) Act [166] or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act), or receive an interest subsidy under the DD Act.

Examples of recipients and sub-recipients may include:

- Health facilities, including hospitals, federally qualified health centers, community health centers, and mental health clinics;
- Health-related schools and other education entities that provide health professions training for medicine, oral health, behavioral health, geriatric care, nursing, etc.;
- Community-based organizations that provide substance abuse screening, HIV/AIDS prevention and treatment, and domestic violence screening;
- Title X-funded family planning clinics;
- Private non-profit and for-profit agencies that provide medical care to unaccompanied minors;
- Interdisciplinary university centers or public or nonprofit entities associated with universities that receive financial assistance to implement the DD Act [167]; and
- State Councils on Developmental Disabilities [168] and States' Protection and Advocacy Systems that receive funds to implement the DD Act.[169]

Several statutory provisions support this application. First, paragraphs (c)(1) and (2) of the Church Amendments apply to entities that receive a ''grant, contract, loan, or loan guarantee under the [PHS Act],'' or a ''grant or contract for biomedical or behavioral research.'' Second, paragraph (e) of the Church Amendments applies to entities that receive a ''grant, contract, loan, or loan guarantee, or interest subsidy'' under the PHS Act or the DD Act.[170] Third, paragraph (d) of the Church Amendments applies to ''any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services.'' [171] Paragraph (d) of the Church Amendment does not tie the funding source to a particular appropriation, instrument, or authorizing statute, nor does the receipt of funds under Church (d) automatically trigger coverage of all of an entity's operations.

(ii) Persons and Entities Obligated To Comply With Additional Federal Laws That This Rule Implements and Enforces

This rule only affects persons and entities obligated to comply with at least one of the Federal statutory provisions that this rule implements and enforces. There is substantial overlap between persons and entities currenty obligated to comply with 45 CFR part 88, as based on the 2011 Rule and persons and entities subject to at least one of the additional Federal laws that this final rule enforces. This overlap occurs because such persons and entities largely were, and continue to be, subject to 45 CFR part 88 by virtue of the Church Amendments, but also the Weldon Amendment and the Coats-Snowe Amendment, as explained above. Because of this substantial overlap, the Department estimated in the proposed rule that OCR's authority to enforce the following statutory provisions would not add any new persons and entities to the coverage of this rule:

- Provisions protecting health care entities and individuals from discrimination who object to furthering or participating in abortion under Medicare Advantage, *e.g.* Public Law 115–245, Div. B, Tit. II, sec. 209, 132 Stat. 2981, 3090 (2018);
- Provisions of the Affordable Care Act related to assisted suicide (42 U.S.C. 18113), the ACA individual mandate (26 U.S.C. 5000A(d)(2)), and other matters of conscience (42 U.S.C. 18023(c)(2)(A)(i)–(iii), (b)(1)(A) & (b)(4));
- Provisions regarding conscience protections for objections to counseling and referral for certain services in Medicaid or Medicare Advantage (42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B));
- Provisions regarding conscience protections related to the performance of advanced directives (42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406);
- Provisions exempting individuals from compulsory health care or services generally (42 U.S.C. 1396f & 5106i(a)(1)) and under specific programs for hearing screening (42 U.S.C. 280g–1(d)), occupational illness testing (29 U.S.C. 669(a)(5)), vaccination (42 U.S.C. 1396s(c)(2)(B)(ii)), and mental health treatment (42 U.S.C. 290bb–36(f)); and
- Protections for religious nonmedical health care relating to health facility review (42 U.S.C. 1320a–1), peer review (42 U.S.C. 1320c–11), certain health standards (42 U.S.C. 1396a(a)(9)(A)), medical evaluation (42 U.S.C. 1396a(a)(31)), medical licensing review (42 U.S.C. 1396a(a)(33)), and utilization review plan requirements (42 U.S.C. 1396b(i)(4)), and by protecting the exercise of religious nonmedical health care in the Elder Justice Block Grant Program (42 U.S.C. 1397j–1(b)) and in the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106i(a)(2)).

In the proposed rule, the Department estimated that the OCR enforcement of the following Federal statutory provisions could add new persons and entities to the coverage of 45 CFR part 88:

- Global Health Programs for HIV/AIDS Prevention, Treatment, or Care (22 U.S.C. 7631(d)), and
- The Helms, Biden, 1978, and 1985 Amendments, 22 U.S.C. 2151b(f), *e.g.,* Consolidated Appropriations Act, 2019, Public Law 116–6, Div. F, sec. 7018.

However, the proposed rule explained that because paragraph (d) of the Church Amendments does not require that the funding for the health service program or research activity be appropriated to HHS, but only that it be ''funded in whole or part under a program administered by the [HHS] Secretary,'' funding appropriated to other Federal Departments, but awarded by HHS in its administration of certain global health programs would be covered by paragraph (d) of the Church Amendments. Consequently, HHS's

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[165] 42 U.S.C. 300a–7(d).

[166] The PHS Act contains thirty titles and authorizes dozens of programs.

[167] *E.g., https://www.acl.gov/node/466.*

[168] *E.g., https://www.acl.gov/node/110.https://www.acl.gov/sites/default/files/about-acl/2017-12/DDC-2017.pdf.*

[169] *E.g., https://www.acl.gov/sites/default/files/about-acl/2017-06/PADD-2017.pdf.*

[170] *Id.* 300a–7(c)(1)(B) (''No entity which receives a grant, contract, loan, or loan guarantee under the Public Health Service Act . . . .''); 300a–7(e) (''No entity which receives . . . any grant, contract, loan, [or] loan guarantee . . . under the Public Health Service Act . . . or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 may . . . .''). In addition to the PHS Act, paragraphs (c)(1) and (e) of the Church Amendments apply to entities that receive funding under the Community Mental Health Centers Act, 42 U.S.C. 2689 *et seq.* Paragraph (c)(1) of the Church Amendments additionally applies to entities that receive funding under the Developmental Disabilities Services and Facilities Construction Act, 42 U.S.C. 6000 *et seq.* Congress repealed both of these laws. *See* Omnibus Reconciliation Act of 1981, Public Law 97–35, Title IX, sec. 902(e)(2)(B), 95 Stat. 560 (1981); Developmental Disabilities Assistance and Bill of Rights Act of 2000, Public Law 106–402, Title IV, sec. 401(a), 114 Stat. 1737 (2000). Thus, there are no entities receiving funds under programs authorized by these statutes to consider in this RIA.

[171] *Id.* section 300a–7(d) (''No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services . . . .'').

implementation of 22 U.S.C. 2151b(f) and 7631(d) may not expand the scope of persons and entities covered by this part.

(iii) Methodology

The Department quantitatively estimated those persons and entities covered by the final rule by relying primarily on the latest data available from the U.S. Census Bureau's Statistics of U.S. Businesses [172] supplemented with other sources. The Department invited public comment on the proposed rule's methodology and solicited ideas on whether there are other methodologies that the Department could consider to refine the scope of persons and entities affected by this rule. The Department received one comment suggesting that the Department's methodology was flawed for failing to include an estimate of the number of consumers of health care affected, *i.e.,* patients, and thus did not consider consumers of health care in the list of persons and entities shown *infra* at Table 2. The purpose of Table 2 is to identify *regulated entities,* not consumers of health care. An analysis of this rule's impact on persons, entities, and health care entities is included in the rule's analysis of benefits, *infra* at part IV.C.4. The final rule's methods for quantifying the persons and entities impacted are the same methods from the proposed rule, which the Department determined was the most reasonable and reliable approach.[173]

The U.S. Census Bureau's Statistics of U.S. Businesses is based on the North American Industry Classification System (NAICS).[174] The NAICS classifies all economic activity into 20 sectors and breaks that information down into sub-sectors and industries.[175] Essentially, the NAICS groups physical business establishments together based on how similar the locations' processes are for producing goods or services.[176] The NAICS provides information on how many singular physical locations exist for a particular business or industry (called an ''establishment''),[177] how many of those establishments are under common ownership or control of a business organization or entity (called a ''firm''),[178] and the number of people who work in a particular business or industry, among other types of information. For instance, a hospital system that has common ownership and control over multiple hospital facilities is a firm, and each hospital facility is an establishment.

For the vast majority of the recipient and sub-recipient types, the Department assumed that only a portion of the industry captured in the Statistics of U.S. Businesses receives Federal funds to trigger coverage by this rule (*e.g.,* ''Federal financial assistance . . . from the Department or a component of the Department, or who otherwise receives Federal funds directly from the Department or a component of the Department''). For instance, not all physician offices receive FFA or otherwise receive Federal funds as a recipient or sub-recipient. In fact, about 68.9 percent of physician offices accepted new Medicaid patients based on 2013 data from the National Electronic Health Records Survey.[179] Approximately 83.7 percent of physicians accepted new Medicare patients based on the same data.[180] Because OCR interprets the 2011 Rule to apply to physicians receiving reimbursement for Medicare Part B, which is a ''health service program . . . funded in whole or in part under a program administered by the Secretary of Health and Human Services'', the Department assumed that the lower of these two percentages (69 percent) represents the lower-bound of physicians nationwide subject to the 2011 Rule. In the absence of evidence with which to generate a refined upper-bound estimate, the Department assumed that the 2011 Rule covers all physicians nationwide as the upper-bound.

The Department used this same percentage range (69 to 100 percent) in estimating the coverage for other health care industry sector types, such as hospitals and various outpatient care facilities. For the social services and education industries, which generally have principal purposes other than health and patient care, the Department adopted ranges more appropriate for those industries. For the social services industries, the Department adopted a range with 25 percent as the lower-bound and 100 percent as the upper-bound to cover 62.5 percent of the industry on average. In its notice of proposed rulemaking, the Department sought comment on this methodology, but received no comments providing a superior method of generating these estimates.

The Department assumes some portion of the social service industry will be covered by the rule, given the scope of the 2011 Rule and thereby this rule. For instance, entities that carry out social services programs and activities may do so in the context of health service programs or research activities funded in whole or in part under programs administered by the Secretary, or may receive funding through programs administered by the Secretary, as well as by grants or other mechanisms under the PHS Act [181] or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 within the scope of the Church Amendment's application.

To estimate the number of local governments and educational institutions, the Department relied on data from other U.S. Census Bureau statistical programs or available award data available through the HHS Tracking Accountability in Government Grants System (TAGGS).[182] For instance, in estimating the number of counties nationwide, the Department relied on the U.S. Census Bureau's 2010 Census Geographic Entity Tallies by State and Type to identify the total counties and equivalent areas for the U.S., Puerto Rico, the U.S. Territories, and the Island Areas.[183]

As another example, the Department relied on data from TAGGS to derive a lower-bound percentage of colleges and universities that are recipients. (The upper-bound assumes all educational institutions industry-wide are recipients.) Although most colleges and universities receive Federal financial assistance from the U.S. Department of Education, not all universities are recipients of HHS funds; thus, the Department adopted a lower-bound estimate to reflect that assumption.

Using the ''Advanced Search'' function in TAGGS, HHS identified all awards to Junior Colleges, Colleges, and

[172] *https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html.* The Department relied on the data file titled ''U.S. & State, NAICS, detailed employment sizes (U.S., 6-digit and States, NAICS sectors).'' The latest data available is from 2015 that the Bureau made available in September of 2017, and this data relied on the 2012 NAICS codes, *id.,* which are described at *https://www.census.gov/eos/www/naics/2012NAICS/2012_Definition_File.pdf.*

[173] *See* 83 FR 3880, 3907 (describing various sources of data considered and reasons for rejecting other approaches).

[174] *https://www.census.gov/programs-surveys/susb/technical-documentation/methodology.html.*

[175] FAQ 5, *https://www.census.gov/eos/www/naics/faqs/faqs.html#q5.*

[176] FAQ 1, *https://www.census.gov/eos/www/naics/faqs/faqs.html#q1.*

[177] *https://www.census.gov/eos/www/naics/faqs/faqs.html#q2.*

[178] *https://www.census.gov/glossary/#term_Firm.*

[179] Esther Hing, *et al.,* Nat'l Ctr. For Health Statistics, Centers for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Acceptance of New Patients with Public and Private Insurance by Office-Based Physicians: United States, 2013, Data Brief No. 195, 1 (Mar. 2015).

[180] *Id.*

[181] The PHS Act contains thirty titles and authorizes dozens of programs.

[182] *http://taggs.hhs.gov* (last visited Aug. 24, 2017).

[183] *https://www.census.gov/geo/maps-data/data/tallies/all_tallies.html.*

Universities for FY 2016 and de-duplicated the results to obtain a singular list of unique awardees from the Department, which totaled 615. Because these awardees included satellite campuses of college or university systems, the total awardee number was akin to the number of ''establishments'' rather than ''firms'' as those terms are used in the U.S. Census Bureau's Statistics of U.S. Businesses. Similar to how an ''establishment'' is a location of a ''firm'' that has common ownership and control over at least one establishment, a satellite campus is one location of a university system with common ownership and control over multiple campus locations.

To derive an estimate of educational institutions at the ''firm'' level, the Department computed the ratio between firms and establishments from the U.S. Census Bureau's Statistics of U.S. Businesses.[184] This ratio is 51.32 percent (2,457 firms/4,788 establishments). The Department applied that ratio to the total number of Junior Colleges, Colleges, and Universities that received HHS funding as ''establishments'' (0.5132 × 615 awardee establishments) to get an estimate of 316 firms. Despite this method's potential complexity, the Department found it the most reasonable method for estimating the lower-bound number of colleges and universities that are Department recipients.

(iv) Quantitative Estimate of Persons and Entities Covered by This Rule

Table 2 lists each estimated type of recipient and the estimated number of recipients that this final rule covers. Because there is uncertainty as to the universe of actual persons and entities covered, Table 2 captures this uncertainty by reflecting estimated recipients as a range with a lower and an upper-bound. The footnotes detail the assumptions and calculations for each line of the table and assume coverage for 69–100 percent of the industry unless otherwise noted. The Department has made a technical correction to Table 2 to include the number of offices of miscellaneous health practitioners (*e.g.,* clinical pharmacists, dieticians, registered practical or licensed nurses' offices, Christian Science practitioners' offices) who operate private or group practices in their own centers or clinics or in the facilities of others, such as hospitals.[185]

[184] *See* U.S. Census Bureau, Statistics of U.S. Businesses, 2015, NAICS code 611310 (Colleges, Universities, and Professional Schools) (identifying 2,457 firms and 4,788 establishments nationwide).

[185] *See* the industry description for offices of miscellaneous health practitioners, NAICS code 921399, *https://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=621399&search=2012* NAICS Search.

TABLE 2—ESTIMATED NUMBER OF PERSONS AND ENTITIES COVERED BY THIS FINAL RULE

Type	Covered by 45 CFR 88 in 2011 Rule?	Covered by final rule?	Estimate (low)	Estimate (high)
1. State and Territorial Governments[186]	Yes	Yes	58	58
2. Federally recognized Tribes[187]	Yes	Yes	573	573
3. Counties[188]	Yes	Yes	3,234	3,234
Hospitals				
4. General & Medical Surgical Hospitals[189]	Yes	Yes	1,859	2,694
5. Specialty Hospitals (*e.g.,* psychiatric, substance abuse, rehabilitation, cancer, maternity)[190]	Yes	Yes	553	801
Nursing and Residential Care Facilities				
6. Skilled Nursing Facilities[191]	Yes	Yes	6,316	9,153
7. Residential Intellectual and Developmental Disability Facilities[192]	Yes	Yes	4,310	6,246
8. Continuing Care Retirement Communities[193]	Yes	Yes	2,605	3,775
9. Other Residential Care Facilities (*e.g.,* group homes)[194]	Yes	Yes	2,247	3,256
Entities Providing Ambulatory Health Care Services				
10. Entities providing Home Health Care Services[195]	Yes	Yes	15,062	21,829
11. Offices of Physicians (except Mental Health Specialists)[196]	Yes	Yes	115,673	167,642
12. Offices of Physicians (Mental Health Specialists)[197]	Yes	Yes	7,324	10,614
13. Offices of Mental Health Practitioners (except Physicians)[198]	Yes	Yes	14,340	20,782
14. Offices of Dentists[199]	Yes	Yes	86,874	125,904
15. Offices of Chiropractors[200]	Yes	Yes	26,725	38,732
16. Offices of Optometrists[201]	Yes	Yes	13,775	19,964
17. Offices of Physical, Occupational and Speech Therapists, and Audiologists[202]	Yes	Yes	17,623	25,540
18. Offices of Podiatrists[203]	Yes	Yes	5,314	7,701
19. Offices of All Other Misc. Health Practitioners[204]	Yes	Yes	11,502	16,670
20. Family Planning Centers[205]	Yes	Yes	999	1,448
21. Freestanding Ambulatory Surgical and Emergency Centers[206]	Yes	Yes	2,908	4,214
22. HMO Medical Centers[207]	Yes	Yes	78	113
23. Kidney Dialysis Centers[208]	Yes	Yes	305	442
24. Outpatient Mental Health and Substance Abuse Centers[209]	Yes	Yes	3,776	5,472
25. Diagnostic Imaging Centers[210]	Yes	Yes	3,209	4,651
26. Medical Laboratories[211]	Yes	Yes	2,278	3,302
27. Ambulance Services[212]	Yes	Yes	2,185	3,167
28. All Other Outpatient Care Centers (*e.g.,* centers and clinics for pain therapy, community health, and sleep disorders)[213].	Yes	Yes	3,880	5,623
29. Entities Providing All Other Ambulatory Health Care Services (health screening, smoking cessation, hearing testing, blood banks)[214].	Yes	Yes	2,391	3,465
Insurance Carriers				
30. Direct Health and Medical Insurance Carriers[215]	Yes	Yes	607	880
Entities Providing Social Assistance Services				
31. Entities Serving the Elderly and Persons with Disabilities (provision of nonresidential social assistance services to improve quality of life)[216].	Yes	Yes	9,051	36,205
32. Entities Providing Other Individual Family Services (*e.g.,* marriage counseling, crisis intervention centers, suicide crisis centers)[217].	Yes	Yes	5,310	21,240

[186] Assumes coverage of the 50 States, DC, Puerto Rico, 6 U.S. Territories, and the Island Areas.

[187] Assumes all federally recognized Tribes get HHS funds. Indian Health Service, FY 2019 Justification of Estimates for Appropriations Committees CJ–1 (2018), *https://www.ihs.gov/budgetformulation/includes/themes/responsive2017/display_objects/documents/FY2019CongressionalJustification.pdf.*

[188] U.S. Census Bureau, 2010 Census Geographic Entity Tallies by State and Type, *https://www.census.gov/geo/maps-data/data/tallies/all_tallies.html* (total counties and equivalent areas for the U.S., Puerto Rico, the U.S. Territories, and the Island Areas). The Department assumed that every county receives Federal funds as a recipient or a sub-recipient.

[189] U.S. Census Bureau, Statistics of U.S. Businesses, 2015 (released Sept. 2017), *https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html* (nationwide count of firms for NAICS Code 622110).

[190] *Id.* (sum of the nationwide count of firms for NAICS Codes 622210 and 622310).

[191] *Id.* (relying on the nationwide count of firms for NAICS Code 623110).

[192] *Id.* (nationwide count of firms for NAICS Code 623210).

[193] *Id.* (nationwide count of firms for NAICS Code 623311).

[194] *Id.* (nationwide count of firms for NAICS Code 623990).

[195] *Id.* (nationwide count of firms for NAICS Code 621610).

[196] *Id.* (nationwide count of firms for NAICS Code 621111).

[197] *Id.* (nationwide count of firms for NAICS Code 621112).

[198] *Id.* (nationwide count of firms for NAICS Code 621330).

[199] *Id.* (nationwide count of firms for NAICS Code 621210).

[200] *Id.* (nationwide count of firms for NAICS Code 621310).

[201] *Id.* (nationwide count of firms for NAICS Code 621320).

[202] *Id.* (nationwide count of firms for NAICS Code 621340).

[203] *Id.* (nationwide count of firms for NAICS Code 621391).

[204] *Id.* (nationwide count of firms for NAICS Code 621399).

[205] *Id.* (nationwide count of firms for NAICS Code 621410).

[206] *Id.* (nationwide count of firms for NAICS Code 621493).

[207] *Id.* (nationwide count of firms for NAICS Code 621491).

[208] *Id.* (nationwide count of firms for NAICS Code 621492).

[209] *Id.* (nationwide count of firms for NAICS Code 621420).

[210] *Id.* (nationwide count of firms for NAICS Code 621512).

[211] *Id.* (nationwide count of firms for NAICS Code 621511).

[212] *Id.* (nationwide count of firms for NAICS Code 621910).

[213] *Id.* (nationwide count of firms for NAICS Code 621498).

[214] *Id.* (nationwide count of firms for NAICS Code 62199).

TABLE 2—ESTIMATED NUMBER OF PERSONS AND ENTITIES COVERED BY THIS FINAL RULE—Continued

Type	Covered by 45 CFR 88 in 2011 Rule?	Covered by final rule?	Estimate (low)	Estimate (high)
33. Entities Providing Child and Youth Services (*e.g.,* adoption agencies, foster care placement services) [218].	Yes	Yes	2,169	8,674
34. Temporary Shelters (*e.g.,* short term emergency shelters for victims of domestic violence, sexual assault, or child abuse; runaway youth; and families caught in medical crises) [219].	Yes	Yes	805	3,219
35. Emergency and Other Relief Services (*e.g.,* medical relief, resettlement, and counseling to victims of domestic or international disasters or conflicts) [220].	Yes	Yes	169	675
Other Entities				
36. Pharmacies and Drug Stores [221]	Yes	Yes	13,490	19,550
37. Research and Development in Biotechnology [222]	Yes	Yes	2,347	3,402
38. Colleges, Universities, & Professional Schools [223]	Yes	Yes	*316*	*2,457*
Subtotal, subject to part 88 in 2011 Rule			392,236	613,367
39. HHS awarded funds appropriated to the U.S. Dept. of State & USAID [224]	No	Yes	65	130
Subtotal, incremental increase in entities			65	130
TOTAL, estimated entities subject to this rule			392,301	613,497

Approximately 392,236 to 613,367 persons and entities were subject to part 88 in effect based on the 2011 Rule by virtue of the Weldon, Coats-Snowe and Church Amendments. The Department estimated that the number of entities that this final rule covers that are subject to 22 U.S.C. 7631(d) and 2151b(f), but not paragraph (d) of the Church Amendments is small and, possibly, non-existent because paragraph (d) of the Church Amendments does not tie funding to a particular appropriation or financial stream.[225] Consequently, this final rule *may* add 65 to 130 new persons and entities to the coverage of 45 CFR part 88.[226] With this incremental increase, this final rule covers an average of 502,899 entities, which is the mid-point of the low (392,301 entities) and high-end (613,497 entities).

(A) Estimated Persons and Entities Required To Sign an Assurance and Certification of Compliance

Relative to the persons and entities shown in Table 2, a smaller subset is subject to § 88.4, which requires certain recipients to submit an assurance and certification of compliance and exempts others. The Department calculated the subset of persons and entities subject to § 88.4 by (1) removing estimated sub-recipients from the total because § 88.4 applies to recipients, not sub-recipients, and (2) removing the estimated recipients exempted from § 88.4, as identified in § 88.4(c)(1) through (4). *Infra* at Table 3 shows this calculation.

Calculating Estimated Sub-Recipients

The Department sought comment on the policy for § 88.4 to apply to recipients but not sub-recipients, noting that the proposed rule took this approach to reduce the burden on small entities. The Department did not receive comments addressing this question. One commenter, however, raised the question that, if the proposed rule's policy was to exempt clinicians who are part of State Medicaid programs, then the proposed rule did not exclude such clinicians from § 88.4. However, clinicians who receive reimbursement through a State Medicaid program are *sub-recipients* of the Department (*i.e.,* recipients of the State, which is the recipient in relationship to the Department). Under a Medicaid fee-for-service model, the State pays the clinicians directly, and under the managed care model, a State pays a fee to a managed care plan, which in turn pays the clinician for the services a beneficiary may require that are within the managed care plan's contract with the State to serve Medicaid beneficiaries.[227] As sub-recipients, these clinicians that accept Medicaid are not subject to § 88.4, unless they become recipients from HHS Federal financial assistance or other Federal funds from a non-exempt HHS program (*i.e.,* a program not captured in § 88.4(c)(2) through (4)).

In the proposed rule, OCR explained that it had not found a reliable way to calculate the number of sub-recipients of this rule. The Department assumed entities in *supra* at Table 2 were all recipients except for counties, which the Department assumed were sub-recipients for the purpose of this

[215] *Id.* (nationwide count of firms for NAICS Code 524114).

[216] *Id.* (nationwide count of firms for NAICS Code 624120).

[217] *Id.* (nationwide count of firms for NAICS Code 624190).

[218] *Id.* (nationwide count of firms for NAICS Code 624110). As described *supra* at part IV.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

[219] *Id.* (nationwide count of firms for NAICS Code 624221). As described *supra* at part IV.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

[220] *Id.* (nationwide count of firms for NAICS Code 624230). As described *supra* at part IV.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

[221] *Id.* (nationwide count of firms for NAICS Code 44610).

[222] *Id.* (nationwide count of firms for NAICS Code 541711).

[223] *Id.* (nationwide count of firms for NAICS Code 611310). As described *supra* at part IV.C.2.iii (methodology), the Department assumes 13%–100% of institutions of higher-education are covered. *See supra* at XI.C.2.iii for a detailed explanation for how the Department supplemented Statistics of U.S. Businesses data with award data from the Department's Tracking Accountability in Government Grants System.

[224] U.S. Dep't of Health & Human Servs., Tracking Accountability in Government Grants System (TAGGS) *http://taggs.hhs.gov* (last visited Dec. 19, 2017). HHS identified unique awardees for FY 2017 from HHS PEPFAR implementing agencies (CDC, HRSA, SAMHSA, NIH, FDA) to foreign nonprofits, foreign governments, and international organizations and used this number as a lower-bound. Because the Department also receives funds appropriated to USAID through one or more reimbursable agreements, the Department assumed that there could be twice as many recipients and sub-recipients after considering the awardees from these reimbursable agreements and thus multiplied and lower-bound by two.

[225] The text of paragraph (d) states that its protection applies for health service program and research activities ''funded in whole or part under a program administered by the [HHS] Secretary.''

[226] *But see supra* at part IV.C.2.ii (discussing the application of paragraph (d) of the Church Amendments to such grantees).

[227] *See, e.g.,* Provider Payment and Delivery Systems, MACPAC, *https://www.macpac.gov/medicaid-101/provider-payment-and-delivery-systems/* (last visited Jan. 29, 2019).

calculation. The Department received no comments regarding information, data sources, studies, or reports that could assist the Department in improving its approach.

To refine the estimates, the Department reconsidered the proposed rule's blanket assumption that all counties are sub-recipients for purposes of this calculation. Using the ''Advanced Search'' function in TAGGS, the Department identified the total number of county awardees and de-duplicated the results to obtain one list of unique county awardees from the Department for FY 2017. This approach identified 625 counties (19 percent) receiving funding directly from HHS as recipients. Assuming that all counties are HHS recipients or sub-recipients, the remaining of 2,609 counties (81 percent) would be sub-recipients that are not subject to § 88.4's application. This method is a more accurate proxy for estimating the number of sub-recipient counties. If some entities (other than counties) in Table 2 are sub-recipients rather than recipients, then the Department overestimated the scope of entities subject to § 88.4's application that are not exempted.

Calculating Exempted Recipients in § 88.4(c)(1) Through (4)

The Department received no comments regarding the methods used to estimate the scope of exempted recipients under § 88.4(c)(1) through (4). Therefore, the Department maintains the proposed rule's methods.

The Department assumed that all physicians' offices would meet the criteria in § 88.4(c)(1) and subtracted out 255,684 to 370,557 entities, which represents the lower and upper-bounds of all physicians' offices.[228] If some physicians' offices are recipients through an instrument other than Medicare Part B reimbursement, then the Department overestimated the number of physicians' offices exempted due to § 88.4(c)(1). The Department does not have the necessary data to estimate the impact of the final rule's new exemption for pharmacies and pharmacists that receive Medicare Part B because the Department does not know whether such pharmacies or pharmacists exempted under § 88.4(c)(1) are Department recipients (as opposed to sub-recipients) of HHS Federal financial assistance or other Federal funds from a non-exempt HHS program (*i.e.,* a program not captured in § 88.4(c)(2) through (4)).

The Department subtracted out 11,220 to 44,879 persons and entities that meet the criteria in § 88.4(c)(2) and (3) regarding the exemption for recipients of grant programs administered by the Administration for Children and Families or the Administration for Community Living.[229] The exemption applies if the program meets certain regulatory criteria indicating that its purpose is unrelated to health care and certain types of research, does not involve health care providers, and does not involve referral for the provision of health care. The Department reasonably assumed that all persons and entities that provide child and youth services (such as adoption and foster care) would fall into this exemption. The Department also reasonably assumed that all entities providing services for the elderly and persons with disabilities (by providing nonresidential social assistance services to improve quality of life) would fall within this exemption. The Department did not subtract out the entities providing ''Other Individual Family Services'' (*e.g.,* marriage counseling, crisis intervention centers, suicide crisis centers) because there is a significant likelihood of referral for the provision of health care at crisis intervention centers and suicide crisis centers.

The Department subtracted out 230 Tribes and Tribal Organizations for the exemption in § 88.4(c)(4). This number represents the total Tribes and Tribal Organizations that operate contracts under Title I of the ISDEA Act.[230] This final rule revises the requirements for federally recognized Indian tribes, tribal organizations, or urban Indian organizations who are recipients by virtue of grants or cooperative agreements under 42 U.S.C. 290bb–36, removing the requirement that such entities comply with § 88.4. The Department does not have the data necessary to estimate the number of such entities who are recipients of funds via such grants or cooperative agreements that are not already captured within the scope of the exemption in § 88.4(c)(4).

TABLE 3—ESTIMATED RANGE OF RECIPIENTS SUBJECT TO THE ASSURANCE AND CERTIFICATION REQUIREMENTS (§ 88.4)

	Low-end estimate	Upper-bound estimate
Persons or Entities Subject to This Final Rule	392,301	613,497
Sub-Recipients to which § 88.4 Does Not Apply	−2,609	−2,609
Range of Recipients Exempted from § 88.4	*−267,134*	*−415,666*
Total, Recipients Subject to § 88.4	122,558	195,222

(B) Estimated Number of Recipients Incentivized To Provide Voluntarily a Notice of Rights (§ 88.5)

The proposed rule contained a freestanding notice provision with mandatory and discretionary elements. As finalized in this rule, the notice provisions are no longer mandatory. Section 88.5 incentivizes recipients and the Department to provide notice to persons, entities, and health care entities concerning Federal conscience and anti-discrimination laws. The rule intends to accomplish this goal by providing that OCR will consider a recipient's posting of a notice as non-dispositive evidence of compliance with this rule in any investigation or compliance review pursuant to this rule, to the extent such notices are provided according to the provisions of this section and are relevant to the particular investigation or compliance review.

The Department expects that some regulated recipients and Department components will voluntarily post the notice through one of the methods specified. Because recipients are the primary entities responsible for compliance under this rule, the Department assumes that sub-recipients will not be induced by the rule to post a notice on their own accord.

The proposed rule did not permit recipients to modify the pre-written

[228] Sum of rows 11, 12, 14–16, and 18 of Table 2.

[229] Sum of rows 31 and 33 of Table 2.

[230] Indian Health Service, FY 2019 Justification of Estimates for Appropriations Committees CJ–243 (2018), *https://www.ihs.gov/budgetformulation/includes/themes/responsive2017/display_objects/documents/FY2019CongressionalJustification.pdf.*

notice in appendix A. As discussed in the preamble for § 88.5, *supra* at part II.B, public comments asked for flexibility to modify the notice's content as applied to recipients. Paragraph (c) in § 88.5 of the final rule provides greater flexibility by stating that the recipient and the Department should *consider* using the model text provided in appendix A for the notice, but may tailor the content to address the laws that apply to the recipient or Department under the rule and the recipient's or Department's particular circumstances. Accordingly, the Department assumes that some recipients that voluntarily post notices will modify the pre-written notice in appendix A. Recipients that modify the pre-written notice likely will do so at the firm level (*i.e.,* corporate level) rather than the establishment level (*i.e.,* at each facility). For instance, a company with common ownership and control over multiple facilities would modify the notice at its corporate (''firm'') level but would post substantially the same physical notices at each facility (''establishment'') where notices are customarily posted to permit ready observation for members of the workforce or for the public.

The Department estimates that eighteen recipient types, such as medical specialists, elder care providers, and entities providing primarily social services, are likely to modify the pre-written notice as applied to them (in relation to, for example, abortion). The sum of the low-end and high-end estimates of firms associated with these eighteen recipient types is 225,751 (low-end) and 332,707 (high-end), providing an average of 279,229 firms. Given the discretionary nature of the notice provision, the Department adjusts the range of firms downward by 50 percent for the purpose of this calculation to derive the values shown in *infra* at Table 4: 112,876 firms (low-end) and 166,354 firms (high-end) for a mid-point of 139,615 firms likely to modify the pre-written notice in appendix A. To the extent that recipient types other than those listed in Table 4 modify the notice, the Department has underestimated the scope of impact.

TABLE 4—ESTIMATED NUMBER OF FIRMS ASSOCIATED WITH EACH RECIPIENT TYPE LIKELY TO MODIFY THE NOTICE OF RIGHTS IN APPENDIX A (§ 88.5)

Type	Estimate (low)	Estimate (high)
1. Skilled Nursing Facilities	3,158	4,577
2. Residential Intellectual and Developmental Disability Facilities	2,155	3,123
3. Continuing Care Retirement Communities	1,302	1,888
4. Other Residential Care Facilities (*e.g.,* group homes)	1,123	1,628
5. Entities providing Home Health Care Services	7,531	10,915
6. Offices of Physicians, Mental Health Specialists	3,662	5,307
7. Offices of Mental Health Practitioners (except Physicians)	7,170	10,391
8. Offices of Dentists	43,437	62,952
9. Offices of Chiropractors	13,363	19,366
10. Offices of Optometrists	6,888	9,982
11. Offices of Physical, Occupational and Speech Therapists, and Audiologists	8,811	12,770
12. Offices of Podiatrists	2,657	3,851
13. Offices of All Other Miscellaneous Health Practitioners	5,751	8,335
14. Kidney Dialysis Centers	152	221
15. Outpatient Mental Health and Substance Abuse Centers	1,888	2,736
16. Diagnostic Imaging Centers	1,605	2,326
17. Medical Laboratories	1,139	1,651
18. Entities Providing Child and Youth Services (*e.g.,* adoption agencies, foster care placement services)	1,084	4,337
Total, Firms Likely to Modify Pre-Written Notice Text	112,876	166,354

The Department assumes that, for all posting methods, recipients will execute the posting at the establishment level. Using the range of firms subject to this rule as a foundation, the range of establishments associated with those recipients is shown *infra* at in Table 5. Table 5 employs the methodology used for calculating the number of persons and entities shown in Table 2, but uses the U.S. Census Bureau's Statistics of U.S. Businesses data for establishments rather than firms.[231] The footnotes detail the assumptions and calculations for each line and assume 69–100 percent of the industry as covered unless otherwise noted, which parallels the assumptions for Table 2.

Because there is a high degree of uncertainty as to the proportion of recipients that will voluntarily post notices through one or more of the methods specified in § 88.5 in the first year of the rule's implementation, the Department adjusts the range of establishments associated with covered recipients downward by 50 percent for the purpose of this calculation. The values derived from this calculation appear *infra* at in Table 5: 261,735 establishments (low-end) and 408,918 establishments (high-end) for a mid-point of 335,327 establishments. The Department adjusts downward the range of establishments that would voluntarily provide notices of rights in years two through five by 25 percent, relative to year one, to reflect attrition: 196,301 establishments (low-end) and 306,689 establishments (high-end) for a mid-point of 251,495 establishments.

[231] *https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html.* The Department relied on the data file titled ''U.S. & State, NAICS, detailed employment sizes (U.S., 6-digit and States, NAICS sectors).'' The latest data available is from 2015 that the Bureau made available in September of 2017, and this data relied on the 2012 NAICS codes. *Id.*

TABLE 5—NUMBER OF PHYSICAL ESTABLISHMENTS OF EACH RECIPIENT TYPE ESTIMATED TO VOLUNTARILY PROVIDE NOTICE OF RIGHTS IN YEAR 1 (§ 88.5)

Type	Establishments assoc. with covered recipients		Establishments assoc. with covered recipients that would voluntarily post notices in Year 1		
	(Low)	(High)	(Low)	(High)	Mid-point
State and Territorial Governments [232]	58	58	29	29	29
Federally recognized Tribes [233]	573	573	287	287	287
Counties [234]	625	625	313	313	313
General and Medical Surgical Hospitals [235]	3,699	5,361	1,850	2,681	2,265
Specialty Hospitals (*e.g.,* psychiatric, substance abuse, rehabilitation, cancer, maternity) [236]	1,139	1,651	570	826	698
Skilled Nursing Facilities [237]	11,789	17,085	5,894	8,543	7,218
Residential Intellectual & Developmental Disability Facilities [238]	22,611	32,770	11,306	16,385	13,845
Continuing Care Retirement Communities [239]	3,668	5,316	1,834	2,658	2,246
Other Residential Care Facilities (*e.g.,* group homes) [240]	3,627	5,256	1,813	2,628	2,221
Entities providing Home Health Care Services [241]	21,377	30,981	10,688	15,491	13,089
Offices of Physicians (except Mental Health Specialists) [242]	147,817	214,228	73,909	107,114	90,511
Offices of Physicians (Mental Health Specialists) [243]	7,498	10,867	3,749	5,434	4,591
Offices of Mental Health Practitioners (except Physicians) [244]	15,022	21,771	7,511	10,886	9,198
Offices of Dentists [245]	92,895	134,631	46,448	67,316	56,882
Offices of Chiropractors [246]	26,999	39,129	13,500	19,565	16,532
Offices of Optometrists [247]	15,101	21,885	7,550	10,943	9,246
Offices of Physical, Occupational & Speech Therapists, & Audiologists [248]	25,213	36,541	12,607	18,271	15,439
Offices of Podiatrists [249]	5,769	8,361	2,885	4,181	3,533
Offices of All Other Misc. Health Practitioners [250]	12,731	18,450	6,365	9,225	7,795
Family Planning Centers [251]	1,584	2,295	792	1,148	970
Freestanding Ambulatory Surgical & Emergency Ctrs. [252]	4,609	6,679	2,304	3,340	2,822
HMO Medical Centers [253]	560	812	280	406	343
Kidney Dialysis Centers [254]	5,144	7,455	2,572	3,728	3,150
Outpatient Mental Health & Substance Abuse Ctrs. [255]	7,227	10,474	3,614	5,237	4,425
Diagnostic Imaging Centers [256]	4,553	6,598	2,276	3,299	2,788
Medical Laboratories [257]	7,360	10,667	3,680	5,334	4,507

[232] Assumes coverage of the 50 States, DC, Puerto Rico, 6 U.S. Territories, and the Island Areas.

[233] Assumes all federally recognized Tribes get HHS funds. Indian Health Service, FY 2019, Justification of Estimates for Appropriations Committees, CJ–243 (2018), *https://www.ihs.gov/budgetformulation/includes/themes/responsive2017/display_objects/documents/FY2019CongressionalJustification.pdf.*

[234] U.S. Census Bureau, 2010 Census Geographic Entity Tallies by State and Type, *https://www.census.gov/geo/maps-data/data/tallies/all_tallies.html* (total counties and equivalent areas for the U.S., Puerto Rico, the U.S. Territories, and the Island Areas). The values estimate the number of recipient counties and exclude estimated sub-recipients.

[235] U.S. Census Bureau, Statistics of U.S. Businesses, 2015 (released Sept. 2017), *https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html* (nationwide count of firms for NAICS Code 622110).

[236] *Id.* (sum of the nationwide count of firms for NAICS Codes 622210 and 622310).

[237] *Id.* (nationwide count of firms for NAICS Code 623110).

[238] *Id.* (nationwide count of firms for NAICS Code 623210).

[239] *Id.* (nationwide count of firms for NAICS Code 623311).

[240] *Id.* (nationwide count of firms for NAICS Code 623990).

[241] *Id.* (nationwide count of firms for NAICS Code 621610).

[242] *Id.* (nationwide count of firms for NAICS Code 621111).

[243] *Id.* (nationwide count of firms for NAICS Code 621112).

[244] *Id.* (nationwide count of firms for NAICS Code 621330).

[245] *Id.* (nationwide count of firms for NAICS Code 621210).

[246] *Id.* (nationwide count of firms for NAICS Code 621310).

[247] *Id.* (nationwide count of firms for NAICS Code 621320).

[248] *Id.* (nationwide count of firms for NAICS Code 621340).

[249] *Id.* (nationwide count of firms for NAICS Code 621391).

[250] *Id.* (nationwide count of firms for NAICS Code 621399).

[251] *Id.* (nationwide count of firms for NAICS Code 621410).

[252] *Id.* (nationwide count of firms for NAICS Code 621493).

[253] *Id.* (nationwide count of firms for NAICS Code 621491).

[254] *Id.* (nationwide count of firms for NAICS Code 621492).

[255] *Id.* (nationwide count of firms for NAICS Code 621420).

[256] *Id.* (nationwide count of firms for NAICS Code 621512).

[257] *Id.* (nationwide count of firms for NAICS Code 621511).

[258] *Id.* (nationwide count of firms for NAICS Code 621910).

[259] *Id.* (nationwide count of firms for NAICS Code 621498).

[260] *Id.* (nationwide count of firms for NAICS Code 62199).

[261] *Id.* (nationwide count of firms for NAICS Code 524114).

[262] *Id.* (nationwide count of firms for NAICS Code 624120).

[263] *Id.* (nationwide count of firms for NAICS Code 624190).

[264] *Id.* (nationwide count of firms for NAICS Code 624110). As described *supra* at part IV.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

[265] *Id.* (nationwide count of firms for NAICS Code 624221). As described *supra* at part IV.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

[266] *Id.* (nationwide count of firms for NAICS Code 624230). As described *supra* at part IV.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

[267] *Id.* (nationwide count of firms for NAICS Code 44611).

[268] *Id.* (nationwide count of firms for NAICS Code 541711).

[269] *Id.* (nationwide count of firms for NAICS Code 611310). As described *supra* at part IV.C.2.iii (methodology), the Department assumes 13%-100% of institutions of higher-education are covered.

[270] U.S. Dep't of Health & Human Servs., Tracking Accountability in Government Grants System (TAGGS) *http://taggs.hhs.gov* (last visited Dec. 19, 2017).

TABLE 5—NUMBER OF PHYSICAL ESTABLISHMENTS OF EACH RECIPIENT TYPE ESTIMATED TO VOLUNTARILY PROVIDE NOTICE OF RIGHTS IN YEAR 1 (§ 88.5)—Continued

Type	Establishments assoc. with covered recipients		Establishments assoc. with covered recipients that would voluntarily post notices in Year 1		
	(Low)	(High)	(Low)	(High)	Mid-point
Ambulance Services[258]	3,271	4,740	1,635	2,370	2,003
All Other Outpatient Care Centers (*e.g.,* centers & clinics for pain therapy, community health, & sleep disorders)[259]	8,054	11,672	4,027	5,836	4,931
Entities Providing All Other Ambulatory Health Care Services (health screening, smoking cessation, hearing testing, blood banks)[260]	3,670	5,319	1,835	2,660	2,247
Direct Health & Medical Insurance Carriers[261]	3,712	5,379	1,856	2,690	2,273
Entities Serving the Elderly and Persons with Disabilities (provision of nonresidential social assistance services to improve quality of life)[262]	10,475	41,899	5,237	20,950	13,093
Entities providing Other Individual Family Services (*e.g.,* marriage counseling, crisis intervention centers, suicide crisis centers)[263]	7,184	28,736	3,592	14,368	8,980
Entities providing Child & Youth Services (*e.g.,* adoption agencies, foster care placement services)[264]	2,901	11,604	1,451	5,802	3,626
Temporary Shelters (*e.g.,* short-term emergency shelters for victims of domestic violence, sexual assault, or child abuse; runaway youth; and families caught in medical crises)[265]	1,013	4,053	507	2,027	1,267
Emergency & Other Relief Services (*e.g.,* medical relief, resettlement, & counseling to victims of disasters or conflicts)[266]	309	1,236	155	618	386
Pharmacies and Drug Stores[267]	30,450	44,130	15,225	22,065	18,645
Research and Development in Biotechnology[268]	2,505	3,631	1,253	1,816	1,534
Colleges, Universities, & Professional Schools[269]	615	4,788	308	2,394	1,351
HHS awarded funds appropriated to the U.S. Department of State & USAID[270]	65	130	33	65	49
Total	523,470	817,836	261,735	408,918	335,327

3. Estimated Burdens

There are five categories of estimated monetized burdens for this final rule as summarized in Table 6, as well as burdens that cannot be fully monetized. No commenters provided alternate reliable methodologies for monetizing the rule's burden. Potential burdens associated with access to care and health outcomes are discussed *infra* at part IV.C.4.vii.

Several comments argued that the rule would impose costs on entities associated with the increased risk of litigation over incidents of providers' exercise of conscience, both between patients and providers and between individual providers and their employers.

Regading an increase in risk for litigation between individual providers and their employers, the Department agrees with the potential effect these commenters predict: That some entities will change their behavior to come into compliance, or improve compliance, with Federal conscience and anti-discrimination laws. Indeed, the proposed rule's RIA and this RIA estimate the burden associated with such voluntary behavior changes. However, whether entities take such action because of the risk of litigation is too speculative and uncertain for calculation in the RIA. Further, some courts have held that there is no private right of action under the Coats-Snowe and Church Amendments, excluding litigation as a viable alternative for individuals.[271]

Regarding an increase in risk for litigation between patients and providers, the Department agrees that this rule will result in more providers exercising conscientious objections to participating in services requested by patients, and that such objections may give rise to lawsuits by patients. However, the Department is unaware of any reliable basis for estimating the frequency or cost of such lawsuits.

Public comments regarding general burdens are integrated throughout the RIA. Public comments regarding the burden, if any, that may result from secondary effects of this rule, such as the monetary impact of certain health outcomes that may arise from increased conscience protection, are discussed in the rule's analysis of benefits, *infra* at IV.C.4.

[271] *See, e.g., Vermont All. for Ethical Healthcare, Inc.* v. *Hoser,* 274 F. Supp. 3d 227, 240 (D. Vt. 2017); *Hellwege* v. *Tampa Family Health Centers,* 103 F. Supp. 3d 1303, 1311–12 (M.D. Fla. 2015); Order at 4, *National Institute of Family and Life Advocates, et al.* v. *Rauner,* No. 3:16–cv–50310 (N. D. Ill. July 19, 2017), ECF No. 65. *See also supra* at part II.A (describing the lack of private remedies).

[272] The totals in Table 6: Cost Summary of the Final Rule may not appear to add correctly, but that is due to rounding.

TABLE 6—COST SUMMARY OF THE FINAL RULE

(Discounted 3% and 7% in millions) [272]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total (for undiscounted) annualized (for discount'd.)
Familiarization (undiscounted)	$135	$–	$–	$–	$–	$135
Familiarization (3%)	120					120
Familiarization (7%)	103					103
Assurance & Certification (undiscounted)	156	142	142	142	142	724
Assurance & Certification (3%)	138	123	119	116	112	608
Assurance & Certification (7%)	119	101	95	89	83	486
Voluntary Notice (undiscounted)	93	14	14	14	14	150
Voluntary Notice (3%)	83	12	12	11	11	130
Voluntary Notice (7%)	71	10	9	9	8	108
Voluntary Remedial Efforts (undisc.)	7	7	7	7	7	36
Voluntary Remedial Efforts (3%)	6	6	6	6	6	31
Voluntary Remedial Efforts (7%)	6	5	5	5	4	24
OCR Enforcement Costs (undisc.)	3	3	3	3	3	15
OCR Enforcement Costs (3%)	3	3	2	2	2	12
OCR Enforcement Costs (7%)	2	2	2	2	2	10
Total Costs (undiscounted)	394	167	167	167	167	1,061
Total Costs (3%)	350	144	140	135	131	901
Total Costs (7%)	301	119	111	104	97	731

In this impact analysis, the Department calculates labor costs using the mean hourly wage (including benefits and overhead) for a:

- Lawyer at $134.50 per hour ($67.25 per hour × 2),[273]
- Executive at $186.88 ($93.44 per hour x 2),[274]
- Administrative assistant at $38.78 per hour ($19.39 per hour × 2),[275]
- Web developer at $69.38 per hour ($34.69 per hour × 2),[276] and
- Paralegal at $51.84 per hour ($25.92 per hour × 2).[277]

These calculations reflect the Department's standard practice of calculating a fully loaded mean hourly wage (*i.e.,* wage including benefits and overhead) by multiplying the hourly pre-tax wage by two.[278]

(i) Familiarization Burden

The Department estimates a one-time burden for regulated persons and entities to familiarize themselves with the rule. The proposed rule estimated that on average, each person and entity would spend one hour for familiarization. The Department received comments arguing that this estimate fell short of the time needed to accomplish the goal of familiarization. In light of these comments, the Department increased the estimate from one hour to two hours. This increase reflects persons' and entities' familiarization of the rule's requirements and procedures, including the changes from the proposed rule.

The burden is a one-time opportunity cost of staff time (a lawyer) to review the rule. The labor cost is approximately $135.3 million in the first year ($134.50 per hour × 2 hours × 502,899 entities (the average of the low and high-end range in Table 2)) and zero dollars in years two through five. This estimated burden represents the average burden; some persons and entities may spend substantially more time than two hours on familiarization, and others may spend less time.

(ii) Burden Associated With Assurance & Certification (§ 88.4)

As a condition of the approval, renewal, or extension of any Federal financial assistance or Federal funds from the Department, § 88.4 requires every application for Federal financial assistance or Federal funds from the Department to which the rule applies to provide, contain, or be accompanied by an assurance and a certification that the applicant or recipient will comply with applicable Federal conscience and anti-discrimination laws and this rule.

The burden to recipients not exempted from § 88.4 is the opportunity cost of recipient staff time (1) to review the assurance and certification language and the requirements of the Federal conscience and anti-discrimination laws referenced or incorporated, (2) to review recipient-wide policies and procedures or take other actions to self-assess compliance with applicable Federal conscience and anti-discrimination laws, and (3) to implement any actions necessary to come into compliance. *Infra* at Table 7 summarizes these costs.

The Department estimates that each recipient not exempted from § 88.4 will spend an average of 4 hours annually reviewing the assurance and certification language and the Federal conscience protection and associated anti-discrimination laws and the rule. In the 2008 Rule, the Department estimated that it would take 30 minutes to certify compliance with three laws: The Church, Weldon, and Coats-Snowe Amendments.[279] In this rule, there are 22 additional statutory provisions covered. Citations for each law are clearly listed in the rule, the texts of the statutes are easily found online. For many entities, it will be immediately clear when a law that this rule implements and enforces does not apply to those entities.[280] The Department

[273] Bureau of Labor Statistics, Occupational and Employment Statistics, Occupational Employment and Wages, May 2016, *https://www.bls.gov/oes/current/oes_nat.htm* (occupation code 23–1011).

[274] *Id.* (occupation code 11–1011).

[275] *Id.* (occupation code 43–6010).

[276] *Id.* (occupation code 15–11134).

[277] *Id.* (occupation code 23–2011).

[278] "Guidance for Regulatory Impact Analysis," Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, 2016, at 28; *see, e.g.,* 81 FR 31451 (2016) ("We note that one commenter suggested that we use a factor higher than 100% to adjust wages for overhead and benefits. However, the commenter's argument is based on Federal overhead rates for contracts, and not evidence of the resource costs associated with reallocating employee time. As a result, we do not adopt the commenter's recommendation, and we continue to use the Department's standard of 100% for overhead and fringe benefits.").

[279] 73 FR 78072, 78095 (2008 Rule).

[280] For example, provisions applicable to Medicaid recipients would not apply to entities that do not receive Medicaid and, presumably, most entities readily know if they receive Medicaid reimbursements as a result of providing care to Medicaid beneficiaries.

estimates each recipient will take 10 minutes per law on average, yielding an additional 3.5 hours on average to review the applicability of the additional laws that this rule proposes to enforce, for a total burden of 4 hours per recipient, per year, for the first five years. Some recipients may spend considerably less time; others may spend considerably more time.

The labor cost is a function of a lawyer spending 3 hours reviewing the assurance and certification and an executive spending one hour to review and sign, as § 88.4(b)(2) requires a signature by an individual authorized to bind the recipient. The weighted mean hourly wage (including benefits and overhead) is $147.60 per hour.[281] The labor cost is $93.8 million each year for the first five years ($147.60 per hour × 4 hours × 158,890 recipients [282]).

The Department estimates that 79,445 recipients, which is half of recipients required to assure and certify compliance (158,890 recipients/2), will spend 4 hours reviewing policies and procedures or taking other actions to self-assess compliance with applicable Federal conscience and anti-discrimination laws each year for the first five years after publication of the rule. Some entities will spend more time and others will spend less time. The Department reasonably estimates such action because § 88.4(b)(4) states that the submission of an assurance and certification will not relieve a recipient of the obligation to come into compliance prior to or after submission of such assurance or certification. A first step to such actions may be to review organization-wide safeguards (or best practices), such as policies and procedures, that may be, or should be, in place. The labor cost is a function of a lawyer spending 3 hours and an executive spending one hour, which produces the a weighted mean hourly wage of $147.60 per hour. The labor cost for self-assessing compliance is a total of $46.9 million annually for the first five years ($147.60 per hour × 4 hours × 79,445 entities).

The Department estimates that approximately 5 percent of entities (or 16 percent of those subject to § 88.4) will take an organization-wide action to improve compliance in the first year and 0.5 percent of entities (1.6 percent of those subject to § 88.4) will take a similar action annually in years two through five. This percentage equates to 25,145 recipients in year one and 2,514 recipients annually in years two through five. The Department estimates that these recipients would spend 4 hours annually, on average, to take remedial efforts. The Department estimates that recipients will spend an average of 4 hours to update policies and procedures, implement staffing or scheduling practices that respect an exercise of conscience rights under Federal law, or disseminate the recipient's policies and procedures. The labor cost is a function of a lawyer spending 3 hours and an executive spending one hour, which produces a weighted mean hourly wage of $147.60 per hour. The labor cost is $14.8 million in year one ($147.60 per hour × 4 hours × 25,145 entities) and approximately $1.5 million annually for years two through five ($147.60 per hour × 4 hours × 2,514 entities).

If entities were already fully taking steps to be educated on, and comply with, all the laws that are the subject of this rule, there would likely not be any costs within the first five years of publication for remedial efforts associated with a recipient's commitment to assure and certify compliance in § 88.4. However, the fact that there would be such costs is wholly consistent with the Department's stated justifications for the rule (*i.e.,* lack of knowledge of, and compliance with, the laws).

Several commenters expressed concern with the possible burden on health care providers resulting from the requirements to assure and certify compliance with Federal conscience and anti-discrimination laws. In drafting the rule, the Department considered the possible burden on health providers and exempted certain classes of recipients from § 88.4. The impact of the exemption means that, unless such exempted persons or entities are recipients of Federal financial assistance or other Federal funds from the Department through another instrument, program, or mechanism, approximately 70 percent of recipients do not have to comply with the assurance and certification requirement.[283] Given the magnitude of the exemption, § 88.4 does not unduly burden persons and entities subject to the rule. Where the exemption does not apply, the burdens arising from assurances and certifications are fully justified, as they are with every other anti-discrimination law that requires a similar assurance or certification.

Moreover, the Department is committed to ensuring that a health care provider's assurance and certification of compliance with Federal conscience and anti-discrimination laws does not unduly burden small health care providers in their delivery of health care services to the community. As explained in the Paperwork Reduction Act analysis for § 88.4, the Department is leveraging existing grant, contract, and other Departmental forms and government-wide systems, consistent with OMB's government-wide effort to reduce recipient burden.[284]

Finally, the Department has made efforts to reduce the frequency of information collected. Paragraph (b)(6) in § 88.4 allows an applicant or recipient to incorporate the assurances and certification by reference in subsequent applications to the Department or Department component if prior assurances or certifications are initially provided in the same year. This approach is consistent with the HHS Grants Policy Statement.[285] Because recipients file an assurance of compliance form ''for the organization and . . . not . . . for each application,'' a recipient with a signed assurance on file assures through its signature on the award application that it has a signed Form 690 on file.[286]

Paragraph (b)(1) in § 88.4 requires submission more frequently than the time of application if the applicant or recipient fails to meet a requirement of the rule, or OCR or the relevant Department component has reason to suspect or cause to investigate the possibility of such failure. The ability to require assurances outside of the application process permits OCR and the Department to ensure that the Federal financial assistance or other Federal funds that the Department awards are used in a manner compliant with Federal conscience and anti-discrimination laws and the final rule. As this is a new requirement, OCR has

[281] Sum of ($134.50 × .75) and ($186.88 × .25).

[282] This estimate is the average of the low and high-end estimates in *supra* at Table 3. As explained *supra* at part IV.C.2.iv.A, sub-recipients are not subject to this requirement.

[283] The average between the lower-bound (267,134) and upper-bound (415,666) of recipients exempted is 341,400 recipients, which represents 68 percent of the estimated total 500,290 recipients of the rule (which is the result of 502,899 entities minus the estimated 2,609 counties that are estimated for the purposes of this rule as sub-recipients). If fewer recipients are impacted by the exemptions in § 88.4(c)(1) through (4) than estimated, and if such recipients do not receive HHS Federal financial assistance or other Federal funds from a non-exempted HHS program, then the Department overestimated the percent of recipients that do not have to comply with the assurance and certification requirement.

[284] Exec. Office of the President, Memorandum from Mick Mulvaney, Dir., Office of Management & Budget to Heads of Executive Departments and Agencies, Strategies to Reduce Grant Recipient Reporting Burden, at 2 (Sept. 5, 2018), *https://www.whitehouse.gov/wp-content/uploads/2018/09/M-18-24.pdf.*

[285] *See* HHS Grants Policy Statement (Jan. 2007), *https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.*

[286] *Id.* at I–31.

not yet gained the experience to know how many recipients, if any, would be required by OCR or a Department component to sign assurances on an as-needed basis outside of the application process.

TABLE 7—SUMMARY OF ASSURANCE AND CERTIFICATION COSTS

Cost categories	Total costs	
	Year 1	Annually Years 2–5
Review and Sign	$93.8	$93.8
Review Policies & Procedures	46.9	46.9
Update or Disseminate Policies & Procedures	14.8	1.5
Total Costs	155.6	142.2

(iii) Burden Associated With Voluntary Actions To Provide Notices of Rights (§ 88.5)

As explained *supra* at in part IV.C.2.iv.B, the Department assumes that some recipients and Department components will voluntarily post and distribute a notice of rights through one of the methods specified in § 88.5. The expected cost to recipients and the Department is $93.4 million in the first year of the rule's implementation and $14.1 million annually in years two through five. The cost to the Department makes up a miniscule portion of the cost—about 0.04 percent in the first year and 0.10 percent annually in years two through five.

As explained *supra* at part IV.C.2.iv.B, the Department assumes that an estimated 139,615 recipients (the average of the low-end and high-end estimates shown in Table 4) will likely modify the pre-written notice in Appendix A as applied to them. Because the scope of such modifications would likely be limited, the Department estimates that modifying the notice constitutes a minimal opportunity cost of 20 minutes of a lawyer's time for drafting and 10 minutes of an executive's time to provide final approval. For some recipients, modifying the notice will take more of the lawyer's or executive's time; for other recipients, it will take less time. The weighted mean hourly wage (including benefits and overhead) of these two occupations is $151.79 per hour.[287] The one-time labor cost is $10.6 million in the first year ($151.79 per hour × 0.5 hours × 139,615 recipients).

There is uncertainty regarding how many recipients will voluntarily post notices and which method or methods in § 88.5 they will employ. For the purposes of this calculation, the Department erred on the side of overestimating the burden and assumes that recipients likely to provide notice will do so:

- At physical locations,
- On their websites, and
- In two publications, such as a personnel manual or other substantially similar document for members of the recipient's workforce; in an application for membership in the recipient's workforce or for participation in a service, benefit or other program, including for training or study; or in a student handbook or other substantially similar document for students participating in a program for training or study, including for post-graduate interns, residents, and fellows.

One commenter suggested that the final rule should permit the notice requirement to be posted electronically only, and not in paper form. Because the rule does not require recipients to provide notices of rights, recipients are free to provide notice in electronic form only and have such action considered by OCR as non-dispositive evidence of compliance with the substantive provisions of the rule, to the extent such notices are otherwise provided according to § 88.5 and relevant to the particular OCR investigation or compliance review.

For recipients that voluntarily post notices through any of the methods in § 88.5, the Department assumes that the recipients will act by the end of the first year after the rule's implementation. An entity that posts on its website and in a physical location will incur a one-time burden. A recipient that includes an insert in a publication may incur an annual burden represented by the costs of labor, materials (paper and ink for hard-copy publication), and in some cases, postage.

Burden for Voluntary Posting in Physical Locations

The Department estimates that it will take ⅓ of an hour for an administrative assistant to print notice(s) and post them in physical locations of the establishment where notices are customarily posted to permit ready observation. For some establishments, it may take an administrative assistant longer to perform his or her respective functions; for other establishments, it may take less time. As shown in Table 5, 335,327 establishments is the average in the range of estimated establishments associated with covered recipients that would voluntarily post notices in the first year after the rule's publication. The estimated labor cost is $4.3 million (⅓ hour × $38.78 per hour × 335,327 establishments).

A key uncertainty is the total number of locations per establishment where recipients commonly post notices; the per-establishment total will vary based on multiple factors. These factors include the type of recipient, floor plans of the building, the square footage of the common areas, the square footage of the building, the number of floors, the size of the workforce, and the number of ultimate beneficiaries, among other variables. The Department assumes that the average establishment will print and post five notices in physical locations where notices are customarily posted; larger recipients might post more and smaller recipients might post fewer. The Department assumes that the cost of materials (paper and ink) is $0.05 per page. Based on this assumption, the first-year cost to post 5 notices across all establishments would be $83,832 (335,327 establishments × $.05 per page × 5 pages). Because the Department assumes that this cost is a one-time cost during the first year of this rule's implementation, the cost will not recur in years two through five. The total labor and materials costs for 335,327 establishments to post notices in physical locations is $4.4 million ($4.3 million in labor costs and $83,832 for materials) in year one with zero recurring costs.

Burden for Web Posting

To post the notice on the web, the Department estimates that it will take 2 hours for a web developer to execute the design and technical elements for posting. A key uncertainty is whether

[287] Sum of ($134.50 × .67) and ($186.88 × .33).

each recipient maintains separate websites for each facility, and if so, whether those websites are maintained at the corporate (*i.e.,* firm) level or facility (*i.e.,* establishment) level. In the proposed rule, the Department erred on the side of overestimating the burden and assumed that recipients maintained separate websites for each of their facilities at the establishment level. Thus, a web developer at each recipient's physical location would post the notice on the web. For some establishments, it may take web developers longer to perform their respective functions; for other establishments, it may take less time. This labor cost is approximately $46.5 million (2 hours × $69.38 per hour × 335,327 establishments).

If, however, recipients maintain one website at the corporate level for all of their facilities, a web developer at the firm-level, rather than at each establishment, would bear the burden. In contrast to recipients bearing the cost across 335,327 facilities, about 250,145 recipients at the firm-level would each bear this cost, which equals $34.7 million (2 hours × $69.38 per hour × 250,145 firms). Thus, if recipients voluntarily post notices on their websites, and if they do so at their corporate level for all sites including facility-specific websites, recipients would save on average about 25 percent of their labor costs to execute web posting in this manner.

Burden for Posting in Two Publications

The Department did not receive specific comments estimating the annual costs of labor or materials that may be incurred by entities that include notices in relevant publications as set forth in the proposed rule (which remain voluntary under the final rule). Given the key uncertainties in how recipients will disseminate the notices of rights, as explained in subsequent paragraphs, the Department assumes that: (1) Establishments that include notices of rights in publications will most often do so in online publications or in hard-copy publications hand-distributed, where the notice's inclusion results in an additional 100 hard copy notices per establishment per year, and (2) half of the establishments associated with covered recipients voluntarily providing hard-copy notices (*i.e.,* 167,663 establishments in year one and 125,747 establishments annually in years two through five) [288] will distribute the publications via U.S. mail where the weight of the notice incrementally increases the postage costs.

The Department assumes that, within the first year after the rule's publication, each recipient voluntarily posting notices in publications would identify the two publications in which to include the notice, revising the documents or their layouts to include the notice, or otherwise printing an insert to include with hard copies of the publication. A recipient that adds the notice to a publication disseminated only online that is not disseminated in hard copy will incur a one-time labor cost with zero costs for materials. In contrast, recipients that add the notice to a publication disseminated via hard copy may incur the annual cost of materials or incremental postage, or both, as well as the associated labor cost. For instance, a recipient that is unable to add the notice to the back page of an existing publication might add the notice as a separate page to the underlying publication or may print notices annually to include as inserts with the hard-copy publications. A recipient that does so and disseminates the publication via U.S. mail might incur incremental postage costs if the incremental weight of the notice places the total weight of the mailing in the next bracket of postage costs.

These assumptions may differ from recipients' implementation experiences. Some recipients may distribute fewer than 100 hard-copy notices with relevant publications while others will distribute more than 100. Some recipients that mail relevant publications with notices of rights may not experience any incremental postage costs if the total weight of the mailings with notices does not place the mailing in the next postage bracket. Notwithstanding these uncertainties, the Department sets forth the following monetization as its best estimate of the burden based on its assumptions.

The Department assumes an administrative assistant would spend an average of two hours in year one and one hour annually in years two through five to execute the activities except for mailing. The average labor cost, excluding mailing-related labor costs, is $26.0 million in year one ($38.78 per hour × 2 hours × 335,327 establishments) and $9.8 million annually in years two through five ($38.78 per hour × 1 hour × 251,495 establishments).[289] Based on the marginal cost of postage per ounce of $0.15,[290] an annual number of mailings of 100 pages per establishment, average annual labor cost for mailing of $38.78 per hour, and an average number of labor hours per mailing of 0.25 hours, the total costs due to the voluntary mailing of notices are $4.1 million in year one [291] and $3.1 million annually in years two through five.[292] Finally, the annual cost of printed materials for notices (both mailed and hand distributed) is $1.7 million (335,327 establishments × 100 pages × $.05 per page) in year one and $1.3 million annually in years two through five (251,495 establishments × 100 pages × $.05 per page).

In sum, the burden to recipients related to the voluntary posting and distributions of notices that § 88.5 incentivizes is $93.4 million in the first year and $14.1 million annually in years two through five.

Burden to the Federal Government

Federal agencies are encouraged to identify costs and savings to government agencies where significant.[293] The burden of § 88.5 to the Federal government is the cost associated with the Department's components posting the notice voluntarily. Although this burden is not significant, the RIA monetizes the burden for completeness.

The Department uses a framework for estimating its burden that is similar to the framework used to estimate the burden to recipients. For instance, the Department assumes that half of its components will post notices of rights voluntarily in the first year of the rule's publication (*i.e.,* 10 of the 20 HHS Operating and Staff Divisions will post online). Because of attrition in compliance, 75 percent of that number will continue posting annually in certain publications in years two through five. As a proxy for that assumption to enable monetization of the physical posting, the Department assumes that staff at half of 533 physical

[288] Product of 335,327 establishments times 50 percent for year one. Product of 251,495 establishments times 50 percent for years two through five.

[289] Under the final rule, because all the notice provisions are voluntary, the Department assumes that 75% of entities that voluntarily provide notices in year one will continue to do so in out years and there will be lower attrition compared to the estimate provided in the proposed rule.

[290] *See* U.S. Postal Service Postage Rates, *https://www.stamps.com/usps/current-postage-rates/.*

[291] Sum of incremental postage of $2.5 million ($0.15 per mailing × 100 mailings × 167,663 establishments) and incremental labor of $1.6 million ($38.78 per hour × 0.25 hours × 167,663 establishments).

[292] Sum of incremental postage of $1.9 million ($0.15 per mailing × 100 mailings × 125,747 establishments) and incremental labor of $1.2 million ($38.78 per hour × 0.25 hours × 125,747 establishments).

[293] OMB Circular A–4, Regulatory Analysis 37 (2003), *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.*

locations owned or leased by the Department [294] (277 physical locations) would post an average of five hard-copy notices per physical location and would post in certain publications. In years two through five, 75 percent of the 277 locations (207 locations) would post in certain publications. The Department assumes that the duration of the anticipated activities (*e.g.,* downloading, printing, and posting the notice) would take Department staff the same time as it would take recipient staff. Similarly, the Department assumes that half of the physical locations associated with HHS components voluntarily providing hard copy notices (*i.e.,* 138 locations in year one and 104 locations annually in years two through five) [295] will distribute the publications via U.S. mail where the weight of the notice incrementally increases the postage costs.

The methods diverge in how the web posting is implemented (by each HHS Operating and Staff Division but not by each facility owned or leased) and in the average hourly wage rate used: A GS–7 step 5,[296] which, adjusted upward for benefits and overhead, equals $47.44 per hour ($23.72 per hour × 2).[297]

Based on these assumptions, the total labor cost is $5,277 in the first year: ($47.44 per hour × ⅓ hour × 277 locations) + ($47.44 per hour × 2 hours × 10 Departmental components). Cost for materials for the notice is $1,452 dollars [298] in the first year after publication of the final rule and $1,037 annually [299] in years two through five. Finally, the cost associated with the portion of Department locations that mail notices of rights with certain publications is $3,713 in the first year [300] and $2,785 [301] annually in years two through five. In sum, the burden to the Federal government associated with § 88.5 is $36,677 in the first year and $13,660 annually in years two through five.

(iv) Record-Keeping (§ 88.6(b))

Paragraph (b) in § 88.6 of the final rule requires recipients and sub-recipients to maintain records evidencing their compliance with this part. In the proposed rule, the Department did not identify record-keeping as a separate burden because it assumed that recipients and sub-recipients already maintain records in the course of evidencing compliance with the terms and conditions of a Federal award, which would include not only financial management requirements but all applicable Federal laws, including Federal conscience and anti-discrimination laws. The Department requested comment on that assumption. The Department received numerous comments stating that the record-keeping requirements in § 88.6(b) were too vague and requesting clarity on what kinds of records must be maintained. However, the Department received no comments contradicting its assumption that recipients and sub-recipients already follow record-keeping practices that suffice to document compliance with Federal civil rights laws. Therefore, because the Department understands that recipients and sub-recipients must document such compliance in the course of receiving a Federal award,[302] any potential marginal increase in the cost of maintaining records according to the clarity set forth in § 88.6(b) would be *de minimis.*

(v) Reporting a Finding of Noncompliance (§ 88.6(d))

Paragraph (d) in § 88.6 of the proposed rule would have required recipients and sub-recipients to report to the relevant Departmental funding component the existence of an OCR compliance review, investigation, or complaint under 45 CFR part 88 over a five-year period as such incidents arise and in any application for new or renewed Federal financial assistance or Departmental funding. The Department received numerous comments that stated this requirement was too burdensome.

Accordingly, the Department has significantly revised § 88.6(d). Recipients and sub-recipients would no longer have to report a compliance review, investigation, or complaint against them as it arises. Moreover, recipients and sub-recipients would only be required to disclose the existence of a determination by OCR of noncompliance with this rule in any application for new or renewed Federal financial assistance or Departmental funding (rather than reporting compliance reviews, investigations, or complaints). Recipients would be responsible for disclosing any OCR determinations of non-compliance made against their sub-recipients. Finally, the final rule shortens the reporting period from five to three years following an OCR determination of noncompliance.

Given the revisions to § 88.6(d), the Department has revisited its methodology for estimating the costs imposed by § 88.6(d). The Department estimates that the burden is the opportunity cost for recipients and sub-recipients who have had OCR determine that they are noncompliant with this rule to retrieve information from their records systems and enter in the application basic identifying information regarding the determination. The components to monetize this burden include: (1) The time spent for a staff member to execute the reporting functions and that person's fully loaded mean hourly wage, (2) the number of times a recipient or sub-recipient applies for new or renewed funding administered by the Department annually, and (3) the number of recipients and sub-recipients that OCR finds noncompliant with this part annually.

The Department estimates it would take a records custodian at the experience level of a paralegal about 15 minutes to retrieve the relevant information (such as date of the OCR determination of noncompliance and the OCR ''transaction number'' (*i.e.,* case number)) from the recipient's or sub-recipient's records and an administrative assistant 15 minutes to enter the information in the application for Federal financial assistance or other Federal funds from the Department. The mean weighted hourly wage for the paralegal and administrative assistant is

[294] Obtained from U.S. General Services Administration on October 30, 2018 (on file with HHS OCR).

[295] Product of 277 locations times 50 percent for year one. Product of 207 locations times 50 percent for years two through five.

[296] The hourly wage rates of staff are likely to vary from a GS–3 to a GS–11. The Department uses the mid-point GS-level and step and relies on hourly wage rates for the locality salary adjustment for the District of Columbia and surrounding geographic area.

[297] *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DCB_h.pdf.* Executive Order 13771 requires agencies to estimate costs in 2016 dollars.

[298] Sum of costs for materials to post in physical locations (5 pages × $0.05 per page × 277 locations) plus costs for materials to post in certain publications (100 pages × $0.05 per page × 277 locations).

[299] Costs for materials to post in certain publications (100 pages × $0.05 per page × 207 locations).

[300] Sum of incremental postage of $2,074 ($0.15 per mailing × 100 mailings × 138 facilities) and incremental labor of $1,640 ($47.44 per hour × 0.25 hours × 138 facilities).

[301] Sum of incremental postage of $1,555 ($0.15 per mailing × 100 mailings × 104 facilities) and incremental labor of $1,230 ($47.44 per hour × 0.25 hours × 104 facilities).

[302] *See* 45 CFR 75.302 (regarding the sufficiency of an HHS awardee's financial management system, including ''records documenting compliance with Federal statutes, regulations, and the terms and conditions of the Federal award''). *See also id.* section 75.361 (requiring an HHS awardee to maintain records for three years from the date of the final expenditure report or from the date the awardee submits its quarterly or annual financial report).

$45.31.[303] The Department estimates that a recipient would bear this labor cost at the firm level for every award action the recipient applied, including new funding opportunities, supplemental funding, and non-competing continuations, among others.

Because OCR had no publicly available or reliable data source to estimate how many total applications for new or renewed funding in a fiscal year a recipient might make to the Department or its component, actual award data from HHS TAGGS was used as a proxy. The Department considered the number of award actions the Department and its components made to State agencies and State universities in FY 2017 to inform the estimate. Award data in HHS TAGGS for FY 2017 indicated that some State universities receive less than 100 awards per fiscal year and others receive nearly 2,000 awards. Some State agencies receive one or two awards per fiscal year and others receive 80 awards per fiscal year. Consequently, a recipient or sub-recipient found in violation of this part, on the extreme end, would expend $45,310 per year in labor costs at the firm level (2,000 applications per year × $45.31 per hour × 0.5 hours).

The most significant uncertainty for monetizing the burden of § 88.6(d) is the number of recipients and sub-recipients that OCR will determine as noncompliant with this rule. OCR employs a range of fact-finding methods and evaluates each complaint based on the relevant facts, circumstances, and law at issue, which is an approach that this rule codifies in § 88.7(d). OCR is gaining experience in handling the complexity and volume of complaints received alleging violations of the Weldon Amendment, Church Amendment, Coats-Snowe Amendment, and section 1553 of the Affordable Care Act. Most of the statutes that are the subject of the rule have no case law interpreting them. In addition, compared to OCR's experience handling complex cases for other civil rights and health information privacy matters, there is little institutional history of OCR enforcement of the Weldon Amendment, Church Amendments, Coats-Snowe Amendment, and section 1553 of the Affordable Care Act. Indeed, OCR was receiving only approximately 1.25 complaints per year alleging such violations during the eight years preceding the change in Administration. However, during FY 2018, the most recently completed fiscal year for which data are available, OCR received 343 complaints alleging conscience violations.[304] Given this variable posture at this stage of the Department's renewed efforts on conscience and religious freedom, the Department cannot reliably predict the number of OCR determinations of noncompliance to monetize this burden, but estimates that, for those to whom it applies, the related reporting cost is about $45,310 per year per entity with the highest number of applications for HHS funding.

(vi) Voluntary Remedial Efforts

The proposed rule noted that the Department anticipates that some recipients will institute a grievance or similar process to handle internal complaints raised to the recipient's or sub-recipient's attention. The rule does not require such a process, but in HHS OCR's enforcement experience, informal resolution of matters at the recipient or sub-recipient level may effectively resolve a beneficiary's or employee's concern. The Department received no comments regarding the proposed rule's methodology for estimating these costs. The Department anticipates 0.5 percent of entities, or 2,514 entities,[305] would conduct such internal investigations should complaints come to the recipient's or sub-recipient's attention or would undertake remedial efforts to resolve complaints.

The burden is the opportunity cost of staff time to handle internal investigations and take remedial action. Uncertainty exists as to how many hours annually a recipient or sub-recipient would devote to this effort. On average, the Department anticipates entities spending 20 hours annually: 16 hours of a lawyer's time and 4 hours of an executive's time. The weighted mean hourly wage (including benefits and overhead) is $144.98 per hour.[306] The labor cost is $7.3 million ($144.98 per hour × 20 hours × 2,514 entities). Some recipients may spend more than 20 hours on voluntary remedial efforts, and if this is the case, the labor cost will be greater. Other recipients may spend less than 20 hours, and if this is the case, the labor cost will be lower.

(vii) OCR Enforcement and Associated Costs

The Department anticipates a temporary increase in investigation and enforcement costs to OCR over the five years immediately following publication of the final rule. The Department expects this increase from the synergistic impact of persons' increased awareness of rights; increased confidence in the Department's ability and willingness to address those rights through the administrative complaint process; and an increase in the number of Federal conscience and anti-discrimination laws that the rule proposes to enforce. Indeed, since during FY 2018, the most recently completed fiscal year for which data are available, OCR received 343 complaints alleging conscience violations.[307]

The impact of the rule on OCR is the opportunity cost of about 12 FTEs to perform investigative responsibilities and coordinate enforcement with HHS components, as set forth in § 88.7, which is an increase of 7.5 FTEs from the proposed rule's estimate. These responsibilities include receiving and handling complaints, initiating compliance reviews, conducting investigations, coordinating compliance within the Department, and performing other associated activities as part of its program to promote widespread voluntary compliance of Federal conscience and anti-discrimination laws. The Department anticipates that the 12 FTEs consist of a member of the Senior Executive Service, four GS–15 employees, three GS–14 employees, two GS–13 employees, and two GS–12 employees, each paid a mid-level salary for the DC area.[308] The fully loaded labor cost (including benefits and overhead) for those twelve employees is estimated to be $3 million annually. The difference between the proposed rule's estimate for OCR's enforcement costs and this estimate is primarily the result of the increase in the number of FTEs. This increase is informed by OCR's experience since publication of the proposed rule, which has demonstrated that OCR will need to devote greater resources to the area of conscience protections than OCR had anticipated at the time of publication of the proposed

[303] Sum of (0.5 × $38.78 per hour) and (0.5 × $51.84 per hour).

[304] Complaint data based on OCR's system of records as of December 20, 2018.

[305] Product of 0.005 × 502,899 recipients.

[306] Sum of ($67.25 × .80) + ($93.44 × .20) and multiplied by two to adjust upward for overhead and benefits.

[307] Complaint data based on OCR's system of records as of December 20, 2018.

[308] Using the locality salary adjustment for the District of Columbia and surrounding geographic area, the annual salaries adjusted upward for benefits and overhead are as follows: $290,324 for GS–15 step 5 (145,162 × 2); $246,812 for GS–14 step 5 ($123,406 × 2); $208,866 for GS–13 step 5 ($104,433 × 2); and $175,642 for GS–12 step 5 ($87,821 × 2). *See https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/16Tables/html/DCB.aspx*. The mid-level salary adjusted for benefits and overhead for a Senior Executive is $308,275 ($154,138 × 2), which is the average of the minimum and maximum salary for agencies with a certified SES performance appraisal system. *See https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/16Tables/exec/html/ES.aspx*.

rule. This estimate also has been adjusted upwards based on the method of calculating the wages of the FTEs. The proposed rule assumed a fully loaded wage for each of the 4.5 FTEs at $201,000, but the final rule estimates the cost of the 12 FTEs based on various GS levels and therefore relies upon the fully loaded wage using the estimated hourly salaries of employees under the GS schedule.

One commenter stated that the costs associated with OCR's enforcement efforts would double to the extent that both a provider and a patient file a complaint over the same matter. The commenter did not provide an example of a scenario where such ''double filing'' would occur. The Department believes that such scenarios, if they occur at all, would constitute a *de minimis* proportion of complaints received by OCR and would not involve increased or doubled costs, as resources for resolution of the two complaints would be shared through investigation of similar matters.

4. Estimated Benefits

The Department expects this final rule to produce a net increase in access to health care, improve the quality of care that patients receive, and secure societal goods that extend beyond health care. These effects will occur primarily via four mechanisms.

First, this rule is expected to remove barriers to the entry of certain health professionals, and to delay the exit of certain health professionals from the field, by reducing discrimination or coercion that health professionals anticipate or experience. Comments received by the Department demonstrate that a lack of conscience protections diminishes the availability of qualified health care providers. For example, in a survey of providers belonging to faith-based provider organizations, over nine in ten (91 percent) agreed with the statement, ''I would rather stop practicing medicine altogether than be forced to violate my conscience.'' [309]

Second, in supporting a more diverse medical field, the rule will benefit patients by improving doctor-patient relationships and quality of care. Academic literature supports the proposition that prohibiting the exercise of conscience rights in medicine decreases the quality of care that patients receive. As one article noted, ''[I]f physicians do not have loyalty and fidelity to their own core moral beliefs, it is unrealistic to expect them to have loyalty and fidelity to their professional responsibilities.'' [310]

Third, the rule is expected to decrease the harm that providers suffer when they are forced to violate their consciences, with attending improvements to patient health. Scholars have observed that ''[a]bandoning the right to conscience of the medical practitioner not only harms the individual practitioner but also threatens harm to his patients as well—the harms, however paradoxical it might seem, are actually inseparable from one another.'' [311]

Fourth, by providing for OCR investigation and HHS enforcement of Federal conscience and anti-discrimination laws, this final rule is expected to decrease unlawful discrimination, thereby permitting greater personal freedom. The rule will promote protection of religious beliefs and moral convictions, which is a societal good based on fundamental rights. As James Madison, often hailed as the ''father of the Constitution,'' wrote,

> The Religion then of every man must be left to the conviction and conscience of every man; and it is the right of every man to exercise it as these may dictate . . . . It is the duty of every man to render to the Creator such homage, and such only, as he believes to be acceptable to him.[312]

The Department received comments arguing that the proposed rule did not provide a sufficient articulation of the benefits that this rule would create or secure. In addition to analyses provided elsewhere in this preamble where germane, the Department's analysis of the rule's benefits responds to those comments and reflects a review of academic literature on the benefits of conscience protections in health care. The analysis demonstrates that the rule creates and secures significant benefits.

(i) Historical Support for Conscience Protections

The people of the United States of America have valued conscience protections since the country's founding era. Madison said that ''[c]onscience is the most sacred of all property; . . . the exercise of that, being a natural and unalienable right. To guard a man's house as his castle, to pay public and enforce private debts with the most exact faith, can give no title to invade a man's conscience which is more sacred than his castle.'' [313] George Washington wrote, ''Government being, among other purposes, instituted to protect the Persons and Consciences of men from oppression, it certainly is the duty of Rulers, not only to abstain from it themselves, but according to their Stations, to prevent it in others, . . . [and] the Consciencious [sic] scruples of all men should be treated with great delicacy & tenderness.'' [314] Some scholars have argued that the right to conscience was a hallmark of our founding and in fact, ''[p]rotection for individual exercise of rights of conscience was one of the essential purposes for the founding of the United States of America and one of the great motivations for the drafting of the Bill of Rights.'' [315]

(ii) Expected Postive Impact on the Recruitment and Maintenance of Health Care Professionals

Numerous studies and comments show that the failure to protect conscience is a barrier to careers in the health care field.

A 2009 survey found that 82% of responding faith-based health care providers said it was either ''very'' or ''somewhat'' likely that they personally would limit the scope of their practice of medicine if conscience rules were not in place. This was true of 81% of medical professionals who practice in rural areas and 86% who work full-time serving poor and medically-underserved populations . . . 91% agreed, ''I would rather stop practicing medicine

[309] Christian Medical Association & Freedom2Care summary of polls conducted April, 2009 and May, 2011, available at *https://docs.wixstatic.com/ugd/809e70_7ddb46110dde46cb961ef3a678d7e41c.pdf.*

[310] D. White and B. Brody, *Would Accommodating Some Conscientious Objections by Physicians Promote Quality in Medical Care?,* 305 J. Am. Med. Assoc., May 4, 2011, at 1804–1805 (arguing that prohibiting conscience-based refusals ''may negatively influence the type of persons who enter medicine[,] . . . may negatively influence how practicing physicians attend to professional obligation[,] . . . [may cause] higher levels of callousness [by physicians] toward patients[,] . . . [and] may reciprocally diminish physicians' willingness to be sympathetic to and accommodating of patients' diverse moral beliefs'').

[311] Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals,* 49 Ariz. St. L.J. 549, 565 (2017); *see also* J. McCarthy & C. Gastmans (2015). *Moral distress: A review of the argument-based nursing ethics literature,* Nursing Ethics, 22(1), 131–152 (finding a consensus in academic literature that moral distress involves suffering that is psychological, emotional, and physiologic).

[312] James Madison, ''Memorial and Remonstrance Against Religious Assessments'', in 2 The Writings of James Madison 183, 184 (G. Hunt ed. 1901)

[313] James Madison, ''Property'', in The Founders' Constitution, *http://press-pubs.uchicago.edu/founders/documents/v1ch16s23.html.*

[314] Letter from George Washington, to The Society of Quakers (October 13, 1789), *https://founders.archives.gov/documents/Washington/05-04-02-0188.*

[315] Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals,* 49 Ariz. St. L.J. 549, 561 (2017) (citing Lynn Wardle, *Protection of Health-Care Providers' Rights of Conscience in American Law: Present, Past, and Future,* 9 Ave Maria L. Rev. 1, 78 (2010)).

altogether than be forced to violate my conscience.'' [316]

The Department expects this rule to remove barriers to entry into the health care professions and into certain specializations within the health care profession [317] that arise from anticipated or experienced discrimination against such persons' religious beliefs or moral convictions. The Department also expects this rule to delay the exit of certain types of health professionals who are considering leaving the field in order to avoid such coercion or discrimination.[318] Although the rule does not create substantive protections beyond those in existing law, the Department believes that greater awareness and enforcement of those laws will help promote compliance and provide these follow-on effects. The Department has a significant interest in removing unlawful barriers to careers in the health care field.

The American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), which represents 2,500 members and associates,[319] wrote in 2009, ''Like pro-life physicians generally, AAPLOG members overwhelmingly would leave the medical profession—or relocate to a more conscience-friendly jurisdiction—before they would accept coercion to participate or assist in procedures that violate their consciences.'' [320] AAPLOG's members and associates represent 13 percent of OB/GYNs in the United States.[321] Yet, as explained above, the Department has received significant anecdotal evidence of violations of the very conscience laws that Congress has enacted to protect such providers.

Because the rule is expected to remove a barrier to entry into the health care profession, the rule is expected to engender more people to be willing to enter the health care profession. Since there is an unmet need for health care providers in the United States, the Department assumes that an increase in the number of people willing to enter the health care profession (or a certain specialization within the health care profession) will result in an increase in the number of providers. Similarly, a certain proportion of decisions by currently practicing health providers to leave the profession are motivated by coercion or discrimination based on providers' religious beliefs or moral convictions,[322] so the Department anticipates that this rule's protections will decrease such departures from the field. Several commenters agreed anecdotally, stating that without the rule, access to medical care will suffer, because pro-life and faith-based medical providers will leave the profession.

The Department anticipates that this effect will also occur at the macro-scale in the health industry. For example, religiously-operated hospitals or health care systems, being granted greater security to practice medicine consistent with their religious beliefs, may find it worthwhile to hire more providers to serve more people, or to serve new populations (geographic, etc.), and will have a larger pool of medical professionals to choose from. The Department is not aware, however, of data enabling it to quantify any effect the rule may have on increasing the number of health care providers or the possible result of increasing access to care. The Department instead believes it is reasonable to conclude that the rule will increase, or at least not decrease, access to health care providers and services.

Several commenters stated that permitting or honoring conscientious objections, especially objections to referring for a health service, will exacerbate current lack of access to health care caused by the existing shortage of health care providers. This argument appears to not adequately take into account how greater awareness and enforcement of conscience rights will (1) remove a barrier to entry for certain individuals and institutions into the health care field, and (2) encourage individuals and institutions with religious beliefs and moral convictions currently in the health care field that may be thinking about leaving the field to remain, thereby creating net benefits. As described in the analysis below on the effects of this final rule on access to care, commenters who raised the claim that the rule would exacerbate current barriers to accessing health care failed to provide data that the Department believes enables a reliable quantification of the effect of the rule on access to providers and to care. For the reasons explained in this analysis, the Department disagrees with those commenters and believes it is more likely that removing the barriers to entry that may exist due to insufficient enforcement of conscience laws will result in an overall increase in access to care. Again, however, the Department is not aware of data that allows for an estimate of the effect of this rule on access to services.

(iii) Expected Postive Impact on Patient Care by Religious Health Care Professionals and Organizations

Many comments discussed the subject of the management of miscarriages in Catholic hospitals, alleging that Catholic hospitals' adherence to the Ethical and Religious Directives (ERDs), a document that expresses the teaching of the Catholic Church on matters of health care, risks harm to women undergoing a miscarriage. Approximately forty-three public comment submissions (each of which may represent more than one comment per submission) cited the article ''When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals,'' which describes experiences of a handful of physicians across the nation's Catholic health care facilities that adhered to ERDs.[323] The article relays anecdotes and quotes from six physicians out of the thirteen interviewed by the authors. The authors do not state why the article omits quotes from the other seven providers, nor does it highlight anecdotes from positive or neutral experiences with facilities' adherence to ERDs. The authors use the anecdotes and quotes as support for the idea that adherence to ERDs creates actual, potential, or perceived deficiencies in the facilities' management of miscarriagesy Catholic health care facilities. Anecdotal accounts of such a limited nature do not provide the Department with a robust basis for estimating the rule's impact on the management of miscarriages.

Twenty-four public comment submissions (each of which may represent more than one comment per submission) discussed the case of Tamesha Means, who was treated for a miscarriage by a Catholic hospital in

[316] Christian Medical & Dental Association summary of Key Findings on Conscience Rights Polling conducted April, 2009, available at *https://docs.wixstatic.com/ugd/809e70_2f66d15b88a0476e96d3b8e3b3374808.pdf.*

[317] *Id.* (finding that 20% of responding faith-based medical students chose not to pursue a career in obstetrics/gynecology because of perceived coercion and discrimination in that field).

[318] *Id.*

[319] *About Us,* American Association of Pro-Life Obstetricians and Gynecologists, *http://aaplog.org/about-us.*

[320] Letter from Lawrence J. Joseph, on behalf of the American Association of Pro-Life Obstetricians & Gynecologists, to the Office of Public Health & Science, Dep't of Health & Human Servs. 2 (Apr. 9, 2009), *http://downloads.frc.org/EF/EF09D50.pdf.*

[321] Compare i*d., with* Occupational Employment Statistics: Occupational Employment and Wages, May 2017 (March 30, 2018), *https://www.bls.gov/oes/current/oes291064.htm* (calculation assumes all AAPLOG members are OB/GYNs).

[322] Christian Medical Association & Freedom2Care summary of Online Survey of Faith-Based Medical Professionals polls conducted April, 2009 and May, 2011, available at *https://docs.wixstatic.com/ugd/809e70_7ddb46110dde46cb961ef3a678d7e41c.pdf.*

[323] Lori R. Freedman, *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals,* AM. J. PUB. HEALTH (2008), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.*

Michigan, as an example of the harm to patient health caused by the faith-based practices of Catholic hospitals. Ms. Means subsequently brought a lawsuit claiming that the hospital's adherence to the ERDs constituted negligence. Yet the U.S. Court of Appeals for the Sixth Circuit ruled that Ms. Means had not alleged any harm or injury that could sustain her claim. *Means* v. *U.S. Conf. of Catholic Bishops,* No. 15–1779 (6th Cir. 2016).

The rule does not incorporate ERDs, and it does not enforce them. Nothing in the rule requires any individual or institutional provider to abide by any religious belief or moral conviction in his or her practice of medicine, and this rule does not take a position on whether any facility should or should not adhere to ERDs. Instead, the rule provides mechanisms for the enforcement for Federal conscience laws and anti-discrimination statutes, which are very different from ERDs in their text, structure, and legal significance.

Numerous commenters also cited statistics demonstrating that women of color are disproportionately served by Catholic hospitals. These commenters argued that, because ERDs prohibit Catholic hospitals from performing elective abortions, sterilizations, and other procedures that are counter to Catholic beliefs, women of color would be disproportionately harmed by exercises of religious belief protected by the rule.

The question of the ultimate effect of Catholic hospitals' adherence to ERDs on general access to reproductive health care, or access by any particular population, is outside the scope of this rule, but appears to be less settled than many commenters portray it to be. A metastudy in 2019 found a surprising paucity of data on the issue, stating that ''Although many may assume that institutional restrictions cause harm, our current understanding demonstrates that the landscape of provision [of reproductive health care services] is wide-ranging and complex in nature.'' [324] On the subject of miscarriages in particular, another study observed that ''Anecdotal reports have suggested that Catholic hospitals are putting women in danger due to the restrictions on miscarriage management. Contrary to these reports, we find some evidence that Catholic ownership is in fact associated with a *reduction in miscarriages that involve a complication,* suggesting that anecdotal accounts may not be indicative of a widespread pattern.'' [325]

Additionally, Catholic and other religiously affiliated health care providers play a major role in the delivery of health care to residents of the United States, including to underserved or underprivileged communities in particular, and are motivated by their beliefs to serve such communities.[326] As some commenters noted, that role may explain the disproportionately large share of charitable care and service given by religious providers to underserved communities. For example, Ascension, the nation's largest religiously affiliated non-profit health care system, had an annual operating revenue in 2016 that was about one-third the size of the annual operating revenue for Kaiser Permanente, the nation's largest non-profit health care system that is not religiously affiliated.[327] However, both organizations provided approximately $2 billion in care and other benefit programming to underserved communities in 2017.[328]

As the Department discusses above in response to comments, *supra* at part III.A., and as observed in the analysis below on the effects of this final rule on access to care, the Department concludes that the relationship between enforcement of Federal conscience and anti-discrimination laws through this rule and the impact on access to care is more complicated than suggested by commenters who claim this rule will decrease access. The Department believes the rule is just as, or more, likely to result in a net increase access to care because religious or other conscientiously objecting providers are already more likely to serve underserved communities; imposing violations on their conscience may lead to them limiting their practices rather than providing services in violation of their beliefs; and in some underserved communities patients may have a proportionate likelihood to agree with religious providers on controversial services such as abortion. The Department believes that, in passing Federal conscience and anti-discrimination laws, Congress likely intended to protect objecting providers precisely to prevent them from limiting their practices, especially to underserved communities, so as not to exacerbate shortages to those communities.

In light of the demonstrated commitment that religious health care providers have to caring for those for whom it may not always be profitable to care, it likely would harm underprivileged populations if the Department did not provide enforcement mechanisms and certain procedural and administrative requirements, as the alternative status quo risks driving such entities out of underserved communities altogether. Again, however, the Department is not aware of data either in its possession, from commenters, or from the public, that would enable the Department to reliably estimate what the impact of this rule would be on increasing, or allegedly decreasing, access to providers or services. The Department, instead, concludes that enforcing Federal conscience and anti-discrimination laws is an appropriate implementation of Congressional intent, and is more likely overall to lead to net benefits, and possibly to an increase in, health care provider and services access, than to lead to its reduction.

(iv) Expected Reduction in the Moral Distress That Individual Providers Experience

The Department anticipates that this final rule will reduce the incidence of the harm that being forced to violate one's conscience inflicts on providers.

[324] Thorne, et al., *Reproductive Health Care in Catholic Facilities: A Scoping Review,* Obstet. Gynecol. 2019;133:105–15, at 114.

[325] Hill, et al., *Reproductive Health Care in Catholic-Owned Hospitals,* NBER Working Paper No. 23768 (2017), at 4 (emphasis added).

[326] Ascension, RE: Docket HHS–OCR–2018–0002, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (Mar. 27, 2018) (''As the largest non-profit health system in the U.S. and the world's largest Catholic health system, Ascension is committed to delivering compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable. In FY2017, Ascension provided more than $1.8 billion in care of persons living in poverty and other community benefit programs.''); Catholic Health Association, REF: RIN 0945–ZA 03 Protecting Statutory Conscience Rights in Health Care; Delegations of Authority: Proposed Rule, 83 FR 3880, January 26, 2018 (Mar. 27, 2018) (''As a Catholic health ministry, our mission and our ethical standards in health care are rooted in and inseparable from the Catholic Church's teachings about the dignity of each and every human person, created in the image of God. Access to health care is essential to promote and protect the inherent and inalienable worth and dignity of every individual. These values form the basis for our steadfast commitment to the compelling moral implications of our heath care ministry and have driven CHA's long history of insisting on and working for the right of everyone to affordable, accessible health care.'').

[327] *Compare Kaiser Foundation Health Plan and Hospitals Report: 2017 Financial Results,* Kaiser Permanente (Feb. 9, 2018), *https://share.kaiserpermanente.org/article/kaiser-foundation-health-plan-hospitals-report-2017-financial-results/* (last visited Dec. 3, 2018), *with Our One Ascension Journey: Year in Review,* Ascension, *https://ascension.org/about/community-and-investor-relations/year-in-review* (last visited Dec. 3, 2018).

[328] *Facts and Stats,* Ascension, *https://ascension.org/About/Facts-and-Stats* (last visited Dec. 3, 2018); *Thrive: Give Back,* Kaiser Permanente, *https://thrive.kaiserpermanente.org/thrive-together/give-back* (last visited Dec. 3, 2018).

Substantial academic literature documents the existence among health care providers of ''moral distress,'' which is ''a sense of complicity in doing wrong'' and ''a deep anguish that comes from the nature of those circumstances [of the provider's work environment] as systemic, persistently recurrent, and pervasively productive of crises of conscience.'' [329] Moral distress functions as a pressure on providers to leave the health care profession: ''Prolonging these conditions can lead to exhaustion of their resistance resources and cause dissatisfaction with the workplace. Those who continue to work despite these conditions experience stress and burnout along with dissatisfaction.'' [330]

It is difficult to quantify the impact of the psychological trauma that results from moral distress. The strength of the provider's moral objection may vary based on the facts and circumstances of each case, including the service in question.

(v) Expected Patient Benefits From This Rule

To the extent the rule supports a more diverse medical field, the rule would create positive effects for patients. The rule could assist patients in seeking counselors and other health care providers who share their deeply held convictions. Some patients appreciate the ability to speak frankly about their own convictions concerning questions that touch upon life and death and treatment options and preferences with a doctor best suited to provide such treatment. A pro-life woman may seek a pro-life OB/GYN to advise her on decisions relating to her fertility and reproductive choices. Open communication in the doctor-patient relationship will foster better overall care for patients.

The benefit of open and honest communication between a patient and her doctor is difficult to quantify. One study showed that even ''the quality of communication [between the physician and patient] affects outcomes . . . [and] influences how often, and if at all, a patient will return to that same physician.'' [331] But poor communication negatively affects continuity of care and undermines the patient's health goals.[332] When conscience protections are robust, both patients and their physicians can communicate openly and honestly with one another at the outset of their relationship.

Facilitating open communication between providers and their patients also helps to eliminate barriers to care, particularly for people of faith, and especially in migrant communities where culturally competent care matters greatly. Because positions of conscience are often grounded in religious influence, ''[d]enying the aspect of spirituality and religion for some . . . patients can act as a barrier. These influences can greatly affect the well-being of people. They were reported to be an essential element in the lives of certain migrant women which enabled them to face life with a sense of equality.'' [333] It is important for patients seeking care to feel assured that their religious beliefs and their moral convictions will be honored. This will ensure that they feel they are being treated fairly.[334] And for some, being able to find health care providers that share the same moral convictions can be a source of personal healing.

As mentioned above, academic literature supports the proposition that prohibiting the exercise of conscience rights in medicine may decrease the quality of care that patients receive.[335] Commentary on the concept of moral distress among providers also expresses concern over how a degraded moral culture in health care can jeopardize patients' health.[336] As one review of literature on moral distress in nursing found, ''There is also a general consensus among the reviews that [moral distress] arises from a number of different sources, and that it (mostly) impacts negatively on nurses' personal and professional lives and, ultimately, harms patients.'' [337] Similarly, allowance for the exercise of conscience rights may promote ethical behavior by providers more broadly,[338] preserve a preferable model of health care practice,[339] and improve the doctor-patient relationship.[340]

[329] Christy A. Rentmeester, *Moral Damage to Health Care Professionals and Trainees: Legalism and Other Consequences for Patients and Colleagues,* Journal of Medicine and Philosophy, 33: 27–43, 2008, p. 37 (elaborating that ''[M]oral distress is a sense of complicity in doing wrong. This sense of complicity does not come from uncertainty about what is right but from the experience that one's power to resist participation in doing wrong is severely restricted by one's work environment and from *the experience that resisting participation in doing wrong exposes one to harm. Moral distress is generated in the health care work environment when a practitioner is aware that he is acting other than how he is motivated to act, but he believes that he cannot act as he is motivated to act without suffering some morally significant harm* . . . A number of situations can generate moral distress. Broad systemic changes in the recent past in health care—in how health care institutions are organized, how health care is financed, and how health care resources are managed, for example—have de facto demanded that individual practitioners adjust to being treated more like laborers than autonomous professionals and less like trusted fiduciaries than like employees with suspicious conflicts of interest.'') (emphasis added).

[330] Borhani et al., *The relationship between moral distress, professional stress, and intent to stay in the nursing profession,* J. Med. Ethics Hist. Med. 2014; 7: 3.

[331] Fallon E. Chipidza, *et al., Impact of the Doctor-Patient Relationship,* 17(5) The Primary Care Companion for CNS Disorders (2015), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4732308/.*

[332] *Id.*

[333] Emmanuel Scheppers, *et al., Potential Barriers to the Use of Health Services Among Ethnic Minorities: A Review,* 23 Family Practice 325, 343 (2006), *https://academic.oup.com/fampra/article/23/3/325/475515.*

[334] *Id.*

[335] Stephen J. Genuis and Chris Lipp, *Ethical Diversity and the Role of Conscience in Clinical Medicine,* 2013 Int'l. J. Fam. Med. 587541(2013), 4–5 (arguing that ''if successive physicians lose individual liberty of conscience and are morally compromised because of authoritarian dictates, the end result [may] be a diminishing of collective professionalism and physician morale, leading to inadequate patient care.'').

[336] Josh Hyatt, *Recognizing Moral Disengagement and Its Impact on Patient Safety,* J. of Nursing Regulation, 7:4, 18 (''Perhaps, patients experience the most significant and dangerous consequences of moral distress and moral disengagement . . . As health care providers reduce their communications with patients, patients may feel less safe and less satisfied with their medical experiences, and their clinical progress may be hindered. Further, if health care providers avoid patients or distance themselves from patients emotionally, they minimize their ability to advocate for their patients' welfare. Providers' emotional transition can also manifest as frustration toward patients, which may impair the quality of care. If health care providers do not fulfill their commitments or perform at a mediocre level, patient care can become inadequate or inappropriate . . . Lower quality of care leads to several costs for the patient. Patients may have to stay longer in the hospital or may miss care. Patient autonomy may also be threatened, and patients can be more likely to be coerced into pursuing therapeutic options they would otherwise decide against. Care can then become less patient centered and more paternalistic, a structure associated with worse health outcomes.'' (citations omitted)).

[337] J. McCarthy & C. Gastmans (2015). *Moral distress: A review of the argument-based nursing ethics literature,* Nursing Ethics, 22(1), 150.

[338] White and Brody, *supra* at note 120; Stephen J. Genuis and Chris Lipp, *Ethical Diversity and the Role of Conscience in Clinical Medicine,* 2013 Int'l. J. Fam. Med. 587541 (2013), 5 (''Compromise of personal moral integrity, of any kind or nature, will inevitably lead to an erosion of ethical behavior—a prospect not conducive to the optimal provision of healthcare.'').

[339] Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals,* 49 Ariz. St. L.J. 549, 565–66 (2017) (''[T]he 'public utility' model of medicine is not only a 'challenge [to] a conscientious physician's integrity as a physician,' it also 'depreciates his expertise, reduces his discretionary latitude in decisionmaking, and makes him a technical instrument of another person's wishes,' thereby 'subvert[ing] the healing purpose for which medicine is intended in the first place.' The myopic view of medicine that views a medical practitioner as a mere service provider 'can redound to the patient's harm by undermining the physician's moral obligation to provide sound advice and sound practice and to avoid medically useless or futile treatments.' '' (citations omitted)).

[340] Genuis & Lipp, at 5 (arguing that ''[freedom of conscience] promotes open, transparent physician-patient relationships and engenders patient advocacy . . . It is unlikely that individual patients or society would support a situation in which

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As noted above, the Department assumes that this rule will increase the overall number of providers because (1) it will reduce barriers to entry into the health care field (and reduce pressure to leave the field) for individuals and organizations with religious beliefs or moral convictions, and (2) there exists an unmet demand for more providers. If the Department is incorrect in assuming that the rule will increase the overall number of providers—*i.e.,* if health care employers and medical training programs do not increase their hiring rates and the size of their programs, respectively, despite an increase in applicants—then the rule will increase the quality of the average provider, because the increase in the pool of available professionals will result in the selection of better providers overall. An increase in the quality of providers will increase the quality of care that patients receive. The Department is not, however, aware of data that provides a basis for quantifying these effects.

(vi) Expected Societal Benefits From This Rule

The rule will also yield lasting societal benefits. The rule mitigates current misunderstanding about what conduct the Federal government is legally able to support and fund, and educates individuals about their Federal conscience rights. By requiring certifications and assurances (with some exemptions), this rule provides a mechanism by which regulated entities will learn about—and, thus, be more likely to comply with—Federal conscience and anti-discrimination laws. The rule also provides a centralized office within the Department for individuals and institutions to file complaints with the Department when such individuals and institutions believe that their rights have been infringed. The Department expects that, as a result of this rule, more individuals, having been apprised of those rights, will assert them. The combination of these mechanisms will contribute to the general public's knowledge and appreciation of the foundational nature of these rights, as well as the protections afforded by Federal law.

Fostering respect for the existing Federal conscience and anti-discrimination laws also fosters lawfulness more generally. As one author stated,

> [L]aw and conscience are deeply intertwined. . . . But the phenomenon of conscience isn't important only to legal experts. Just as conscience helps explain why people follow legal rules, it helps explain why people follow other types of rules as well, such as employers' rules for employees, parents' rules for children, and schools' and universities' rules for students. It may also help explain why people adhere to difficult-to-enforce ethical rules and to the sorts of cultural rules (''social norms'') that make communal life bearable. . . . Twenty-first century Americans still enjoy a remarkably cooperative, law-abiding culture.[341]

Because fostering conscience in individuals—and compliance with Federal conscience laws—contribute to a more lawful and virtuous society, governments and their subdivisions have a significant interest in encouraging expressions of, and fidelity to, conscience.

> Forcing religious believers to violate their consciences involves harms that go beyond these individuals and their communities. When an individual is forced to act in ways that they view as deeply wrong, indeed as prohibited by the ultimate power responsible for everything that exists, moral habits essential for democratic citizenship are undermined.[342]

Governments also have an interest in ensuring the implementation and enforcement of existing laws, as part of the greater virtue of the rule of law.

It is difficult to monetize the benefits of respect for conscience to the individual and society as a whole, but they are clearly significant. As the Supreme Court has said:

> Both morals and sound policy require that the state should not violate the conscience of the individual. All our history gives confirmation to the view that liberty of conscience has a moral and social value which makes it worthy of preservation at the hands of the state. So deep in its significance and vital, indeed, is it to the integrity of man's moral and spiritual nature that nothing short of the self-preservation of the state should warrant its violation; and it may well be questioned whether the state which preserves its life by a settled policy of violation of the conscience of the individual will not in fact ultimately lose it by the process.[343]

To protect the rights of conscience is to protect personal and interpersonal goods that permit peaceful and fulfilling lives.[344]

(vii) Analysis of Expected Effects of This Final Rule on Access to Care

The Department solicited information on costs that may arise as secondary effects of this rule, such as those associated with changes in health outcomes arising from increased protection of conscience for health care providers, as well as information about whether the existence or expansion of rights to exercise religious beliefs or moral convictions in health care improves or worsens patient outcomes and access to health care. The Department also requested comment on the related question of whether this final rule would result in unjustified limitations on access to health care.

The questions of access to care and of health outcomes are largely interdependent; access to care matters because of its effects on health outcomes, and the discussion in the public comments on health outcomes in the context of this rule were typically framed as a consequence of changes in access to care. Many comments the Department received argued that the rule would decrease access to care and harm patient health outcomes, and most such comments focused on the potential that providers would decline to perform a particular service for a patient.

Generally, however, instead of attempting to answer the difficult question of how this rule would affect access to care and health outcomes, and how to quantify those effects, such comments argued that significant discrimination against some segments of the population in health care exists and is *per se* proof that the rule would result in harm. The comments made this argument without establishing a causal relationship between this rule and how it would affect health care access, and without providing any data the Department believes enables a reliable quantification of the effect of the rule on access to providers and to care.

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physicians were being coerced to hide their convictions, making decisions they felt were morally wrong or unethical, or failing to act in what they perceived to be their patients' best interests''); Christian Medical Association & Freedom2Care summary of polls conducted April, 2009 and May, 2011, available at *https://docs.wixstatic.com/ugd/809e70_7ddb46110dde46cb961ef3a678d7e41c.pdf* (''77% of American adults surveyed said it is either 'very' or 'somewhat' important to them that 'that healthcare professionals in the U.S. are not forced to participate in procedures or practices to which they have moral objections;' '' ''88% of American adults surveyed said it is either 'very' or 'somewhat' important to them that they share a similar set of morals as their doctors, nurses, and other healthcare providers''). Comments received by the Department supported the finding that patients prefer providers who share their general belief system.

[341] Lynn Stout, *Cultivating Conscience: How Good Laws Make Good People* 17 (2011).

[342] Kathleen A. Brady, *The Disappearance of Religion from Debates about Religious Accommodation,* 20 Lewis & Clark L. Rev. 1093, 1110 (2017).

[343] *United States* v. *Seeger,* 380 U.S. 163, 169 (1965) quoting Harlan Fisk Stone, *The Conscientious Objector,* 21 Col. Univ. Q. 253, 269 (1919).

[344] Christopher C. Lund, *Religion Is Special Enough,* 103 Va. L. Rev. 481, 504 (2017) (''Freedom of moral conscience, it turns out, serves many of the same values served by freedom of religion—among other things, it can serve to ameliorate psychological distress, reduce civil strife, and preserve individual identity.'').

Other comments focused on whether health disparities exist among demographics that tend to utilize health services that may be the subject of conscientious objections protected by this final rule, but again without establishing a causal link between the provisions of this rule and the predicted or speculated effects.

Many comments observed that various demographic groups—women, LGBT people, immigrants and refugees, people of color, people living with HIV/AIDS, people with language barriers, people living in poverty, people with disabilities, and people living in rural areas—already face barriers to access to care and therefore would be disproportionately harmed by any additional barriers to access to care. The Department does not dispute that people in such demographic categories face health care disparities of various forms. The Department does disagree, however, with these comments' conclusions that the rule will create any negative effect on access to care that cannot be otherwise addressed, or that is not outweighed by gains in overall public health, overall access to care due to the removal of barriers for providers, or the benefits of compliance with the law and respect for conscience and religious freedom. In fact, as the Department discusses *supra* at part IV.C.4.iii and *infra,* the Department expects the rule to specifically benefit underserved populations.

A common sentiment expressed in comments was that conscience protections for providers are only appropriate to the extent they do not interfere with, impose upon, or in any way result in others feeling harmed. This type of objection is not accepted for any other anti-discrimination law. For example, the Fair Housing Act and the Americans with Disabilities Act, under certain circumstances, require building and apartment owners to incur costs to ensure that facilities are accessible to persons with disabilities. These statutes impose costs, but Congress and several Presidents have deemed it important to remove barriers to full participation in economic and social life for persons with disabilities. Similarly, America has since the founding recognized that Free Speech results in harm and hurt feelings (sometimes extraordinarily so) for many Americans, yet it is deemed a price worth paying. Conscience protection should be not be a special exception to the principle that fundamental rights do not depend on there being zero conflicts or disagreements in their exercise.

In any event, the objections based on potential (often temporary) lack of access to particular procedures as a result of enforcement of the law are really objections to policy decisions made by the people's representatives in Congress in enacting the Federal conscience and anti-discrimination laws in the first place, rather than to this rule's mechanisms for implementing and enforcing those laws.

An analysis of any change in access to care caused by this final rule is not the same as an analysis of the total impact of the exercise of religious belief and moral conviction on access to care. Nor is it the same as estimating the total impact of discrimination against women, LGBT individuals, or individuals in any other population demographic on access to care. Rather, the question involves isolating the impact of the exercises of religious belief or moral conviction attributable to this final rule specifically, over and above whatever impact is attributable to the pre-existing base rate of exercise of religious belief or moral conviction.

Different types of harm can result from denial of a particular procedure based on an exercise of such belief or conviction. First, the patient's health might be harmed if an alternative is not readily found, depending on the condition. Second, there may be search costs for finding an alternative. Third, the patient may experience distress associated with not receiving a procedure he or she seeks. These three potential harms, however, would also be applicable for denials of care based on, for example, inability to pay the requested amount. Fourth, there may be a harm resulting from a conscientious objection to referring for a health service, distinct from the harm of the initial objection to performing the service. Fifth, some commentators allege others in the community to which the patient belongs may be less willing to seek medical care.

On the other hand, it is important not to assume that every patient who wants a particular service is offended by a provider's unwillingness to provide that service, or wishes that the provider would do so against his or her religious beliefs or moral convictions. Some persons, out of respect for the beliefs of providers, may want a service but not take any offense, nor deem it any burden on themselves, for the provider to not provide that service to them. Some patients may even value the health care provider's willingness to obey his or her conscience, because the patient feels that provider can be trusted to act with integrity in other matters as well. The Department does not believe it is appropriate to assume that all patients who want a particular service also want to force unwilling providers to provide it in violation of their consciences.

Lastly, numerous comments focused on the potential for a patient to feel insulted or emotionally distressed because of a perception that a provider, in declining for reasons of religious belief or moral conviction to perform an objected-to service or procedure, is expressing disapprobation of the patient, especially regarding his or her personal identity or personal conceptions of morality. Although the Department does not understand such conscientious objections to be necessarily intended to convey such disapprobation, the Department recognizes that, in some circumstances, some patients do experience emotional distress as a consequence of providers' exercise of religious beliefs or moral convictions. However, Congress, in considering the statutes enforced by this rule, did not establish balancing tests that weigh such emotional distress against the right to abide by one's conscience.

On the other side of the equation, those who suffer discrimination on the basis of their religious beliefs or moral convictions, or those coerced to violate those convictions, may themselves experience emotional distress, as well as economic harms such as job loss or rejection from admission into a training program.

There appears to be no empirical data on how previous legislative or regulatory actions to protect conscience rights have affected access to care or health outcomes. In fact, studies have specifically found that there is insufficient evidence to conclude that conscience protections have negative effects on access to care.[345]

Many commenters reasoned that, despite this lack of empirical evidence, the rule would cause an increase in denials of care. For example, one comment cited various statistics on the rates of discrimination against LGBT individuals, but those statistics were general in nature and did not assist the

[345] *See* Chavkin et al., *Conscientious objection and refusal to provide reproductive healthcare: A White Paper examining prevalence, health consequences, and policy responses,* 123 Int'l J. Gynecol. & Obstet. 3 (2013), S41–S56 (''[I]t is difficult to disentangle the impact of conscientious objection when it is one of many barriers to reproductive healthcare. . . . [C]onscientious objection to reproductive health care has yet to be rigorously studied.''); K. Morrell & W. Chavkin, *Conscientious objection to abortion and reproductive healthcare: a review of recent literature and implications for adolescents,* 27 Curr. Opin. Obstet. Gynecol. 5 (2015), 333–338 (''[T]he degree to which conscientious objection has compromised sexual and reproductive healthcare for adolescents is unknown.'').

Department in estimating what degree may be attributable to the lawful exercise of religious beliefs or moral convictions. The comment also identified numerous health disparities between LGBT individuals and non-LGBT individuals, but did not explain the extent to which such disparities are the product of the lawful exercise of religious beliefs or moral convictions. The comment then concluded that ''discrimination and related health disparities facing the LGBT population stand to worsen if health care providers are authorized to refuse to serve LGBT people.''

The same comment attached an amicus brief that cited two studies on how State laws affect health disparities among LGBT populations—one study on States that either did not include sexual orientation as a protected category in its hate crimes statute or did not prohibit employment discrimination on the basis of sexual orientation, and another on States that had constitutional amendments banning gay marriage on the ballot in 2004 and 2005. Neither study provides a reliable basis for inferring an answer to the questions at issue here.

Another comment cited to a 2018 report on anecdotal experiences of discrimination among LGBT individuals in eight States where laws had been passed to protect religious freedom. The report itself includes a citation to one study finding that awareness of legislation prohibiting discrimination on the basis of sexual orientation is associated with a decrease in the rate of such discrimination in interpersonal employment contexts. While analogous, such a finding is not the same as a finding that the awareness of legislation protecting conscience rights increases the rates of discriminatory conduct by people with religious beliefs or moral convictions. The report provides anecdotal accounts of discrimination from LGBT residents of those States. However, the report does not attempt to determine if the laws passed by those States played any causal role in the discrimination experienced by the respondents, *e.g.,* via comparison to LGBT individuals' experiences in States where no such laws had been passed.

Multiple comments provided lists of various incidents in which providers declined to participate in a service or procedure to which they had a religious or moral objection. Such lists offer no suitable data for estimating the impact of this rule.

No comment attempted a detailed description of the actual impact expected from the rule on access to care, health outcomes, and associated concerns.

The Department attempted to quantify the impact of this rule on access to care but determined that there is not enough reliable data, and that the analysis was subject to too many confounding variables, for the Department to arrive at a useful estimate. For instance, the Department is not aware of a source for data on the percentages of providers who have religious beliefs or moral convictions against each particular service or procedure that is the subject of this rule.[346]

Likewise, the Department is not aware of data on the actual rate of providers' exercise of conscientious objections to performing such services or procedures. Some providers who have a religious or moral objection to performing a service or procedure may nonetheless perform it for one reason or another, such as fear of legal reprisal. Others may respond to pressure to violate their consciences by limiting their practices, rather than providing the service to which they object. Commenters who contend the rule will reduce access to care seem to assume all providers with conscientious objections that are not being honored are providing those services anyway, so that the rule will reduce their provision of those services. The Department does not believe that assumption is correct. The Department considered methods for estimating the increase in the rate of such exercise of conscientious objections that may occur as a result of this rule, but determined that no reliable method was available. The Department likewise considered whether providers who, for reasons of religious beliefs or moral convictions, have left the practice of medicine or limited their scope of practice may reenter the field or resume their previous scope of practice, given the rule's expanded enforcement of protections for religious beliefs or moral convictions. If providers who limited their practices because of threats to their consciences expand them because of this rule, those would not be instances of a reduction in the provision of services to which they object, but of an increase in other services. However, the Department was unable to find reliable data on this question, and concluded that no useful quantitative estimate of this impact was feasible.

The impact on health outcomes from the exercise of conscientious objections to particular services and procedures also resisted a useful quantitative estimate. Without data—to inform an estimate of the quantity of such objections that would be attributable this rule, the number of those objections that led to providers offering services to which they object rather than limiting their practices, the number of persons who left or did not enter certain fields or practices altogether because conscience laws were insufficiently enforced, the market effect of providers expanding or moving into different areas because conscience laws are enforced, and the overall resulting availability of access, both to objected-to services and to other health care overall—the Department lacks the predicate for estimating the impact on health outcomes of any change in the availability of services. The analysis on this point is also generally subject to the same confounding factors discussed below regarding the impact of conscientious objections to providing referrals.

The Department expects any decreases in access to care to be outweighed by significant overall increases in access generated by this rule. If the laws that are the subject of this rule are not enforced, many of the exact same people who would face a burden from a denial of access to a particular procedure from a particular doctor or provider would face the potential of receiving no health care at all from that doctor or provider because such providers may limit, or leave, their practices if unable to comply with their religious beliefs or moral convictions. The absence or departure of those providers from the health field does not clearly lead to any increase in other providers who are willing to offer services that are the subject of Federal conscience and anti-discrimination laws, but is more likely to simply diminish the overall availability of health care services. The burden of not being able to receive any health care clearly outweighs the burden of not being able to receive a particular treatment.

For example, after the Department proposed in 2009 to rescind the 2008

[346] For instance, even in the case of abortion, for which some data on the rates of providers' objections actually exists, those rates vary significantly based on the facts and circumstances of the scenario presented, confounding an attempt to produce a single measure of providers' rate of objection to abortion in general. *See* Harris, *et al., Obstetrician-Gynecologists' Objections to and Willingness to Help Patients Obtain an Abortion* 118 OBSTETRICS & GYNECOLOGY 905 (2011) (''These data suggest that ob-gyns also consider contextual factors, including risk of physical harm to the woman by continuing pregnancy (breast cancer, cardiopulmonary disease), the circumstances of the sexual encounter that resulted in pregnancy (rape), the impact abortion may have on pregnancy outcome (selective reduction), the potential for fetal anomaly (diabetes), and the duration of pregnancy (second versus first trimester) . . . Among ob-gyns, support for abortion varies widely depending on the context in which abortion is sought and physician characteristics.'').

rule providing conscience protections for providers, a survey found that 81 percent of faith-based health care professionals working in rural areas and 86 percent of faith-based health care professionals working full-time in service to underserved communities said that they were either ''very'' or ''somewhat'' likely to limit the scope of their practice if the 2008 rule was rescinded.[347] For such providers who did not in fact limit their scope of practice, this rule will help to prevent future situations in which they feel forced to do so. For those who did, this rule provides protections that may induce them to resume their previous scope of practice. In this sense the Department believes the rule will both preserve and expand access to health care generally.

Furthermore, as one academic article observed, ''[P]atients choose not merely particular services, but particular kinds of professionals.'' [348] As noted earlier in this section, a survey of patients found that 88 percent would prefer that their providers share their moral beliefs.[349] Another survey conducted by a former Chair of Bioethics of the National Institutes of Health Clinical Center ''reinforces the existence of patient preference for physicians with shared values . . . [finding] that nearly one-fifth of [cancer] patients surveyed 'thought they would change physicians if their physician told them he or she 'had provided euthansia [sic] or assisted suicide' for other patients.' '' [350] The Department, accordingly, expects this rule, through its recognition of the ''fundamental necessity of conscience protections to ensuring patient access'' for ''patients who want access to physicians of conscience,'' to result in an increase in access to care.[351]

The Effect of the Rule's Protection of Refusals To Refer for Services

As with the analysis in the above factors, there exists some baseline rate of exercise of conscientious objection to referring for a service to which the provider morally objects. A significant percentage of providers believe that they are not obligated to refer for a service to which they morally object.[352] It is reasonable to assume that the rates of exercise of the right not to refer will increase under the rule, but it is difficult to determine by how much. It is likewise difficult to estimate what part of the baseline instances of conscientious objection manifest themselves in providers providing the referrals in violation of their objections, instead of limiting their practices so as to avoid the conflict.

First, it is unclear how many providers understand their existing right to decline to refer, whether grounded in ethics or the law, to be coextensive with the freedom that the rule reflects. For example, a provider who objects to performing sterilizations may feel ethically obligated to inform a patient where vasectomies are locally available—an act that the rule may allow the provider to abstain from—but may not feel obligated to provide the patient any further information about how to obtain that procedure. Research suggests that providers may often draw such a distinction.[353]

It is also difficult to estimate what actual impact the increase in refusals to refer would have. One confounding factor is that the practical effect of a provider's exercise of conscientious objection to providing a referral may vary greatly depending on the particular facts and circumstances of the case. Public knowledge of the availability of certain medical services may be extensive or minimal depending on the procedure. For instance, any pregnant woman is almost certainly aware of the existence and purpose of abortion, and the extensive efforts of pro-choice groups to facilitate women's access to abortion make information about how to obtain an abortion relatively easy to find.[354] So the effect of a provider's refusal to refer for an abortion is mitigated by the patient's own knowledge and the widespread availability of information about abortion access on the internet and elsewhere.

The Change in the Number of Patients Who Delay or Forgo Health Care for Fear of Being Denied a Health Service

As numerous public comments demonstrate, certain minority groups already experience significant health care disparities. Commenters state that negative health outcomes from some demographics are due to fear of discrimination leading to avoidance of seeking health care. However, the Department is not aware of any data establishing what, if any, part of this avoidance phenomenon is attributable to the exercise of conscientious objections protected by this rule or by implementation of the enforcement mechanisms of this rule.

Other Comments on Access to Care

Many of the comments that claimed that the rule would result in more frequent denials of service to patients also argued that the rule is unnecessary because there is no current problem with health care providers being coerced into violating their consciences. These arguments are contradictory. If, under the final rule, a provider exercises a right protected by the rule to decline to perform a service that he had been performing prior to this rule, his previous performances of the service would likely have been contrary to his conscience.

Many commenters observed that, in rural areas, if a provider were to decline on religious or moral grounds to provide a particular service or procedure, there may not be alternative providers within a feasible distance of the patient. The Department does not dispute that patients in rural areas are more likely than patients in urban areas to suffer adverse health outcomes as a result of being denied care. That is why enforcement of Federal conscience and anti-discrimination laws to prevent health care providers from being unlawfully driven out of business,

[347] Christian Medical Association & Freedom2Care summary of polls conducted April, 2009 and May, 2011, *available at https://docs.wixstatic.com/ugd/809e70_7ddb46110dde46cb961ef3a678d7e41c.pdf.*

[348] M. Bowman & C. Schandevel, *The Harmony between Professional Conscience Rights and Patients' Right of Access,* 6 Phoenix L. Rev. 31 (2012) at 56 (''First, a patient who chooses a pro-life physician is not merely choosing a physician who does not do something. She is choosing a physician who affirmatively practices medicine according to principles that unconditionally value human life, whether in the context of the preborn, the born, the disabled, or the terminally ill . . . Second, patients seek physicians not only for discrete services, but even more so for relationships of trust.'')

[349] Christian Medical Association & Freedom2Care summary of polls conducted April, 2009 and May, 2011, available at *https://docs.wixstatic.com/ugd/809e70_7ddb46110dde46cb961ef3a678d7e41c.pdf* (''88% of American adults surveyed said it is either 'very' or 'somewhat' important to them that they share a similar set of morals as their doctors, nurses, and other healthcare providers'').

[350] Bowman & Schandevel, citing Ezekiel J. Emanuel et al., *Euthanasia and Physician-Assisted Suicide: Attitudes and Experiences of Oncology Patients,* Oncologists, and the Public, 347 Lancet 1805, 1808 (1996).

[351] *Id.* at 36.

[352] Combs et al., *Conscientious refusals to refer: findings from a national physician survey,* J. Med. Ethics 2011;37:397–401, 399 (''[43%] of physicians in this present study . . . did not agree that physicians are obligated to make referrals that they believe are immoral.'').

[353] Farr A. Curlin M.D., et al., Religion, Conscience, and Controversial Clinical Practices, NEW ENG. J. MED. 593–600, 593 (2007) available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2867473/* (finding that some providers will inform patients of options but not refer for such options) (''Most [providers] also believe that physicians are obligated to present all options (86%) and to refer the patient to another clinician who does not object to the requested procedure (71%)'').

[354] *See, e.g., https://prochoice.org/think-youre-pregnant/find-a-provider/* (first result for Google search of phrase ''find abortion clinic near me'' performed 10/17/18).

especially in rural areas, is of paramount importance. Instead of a decrease in access to a particular procedure from a particular doctor or provider, the residents of a rural area would face the potential of receiving no health care at all from that doctor or provider because such providers may leave the practice if unable to practice medicine according to their religious beliefs or moral convictions. In addition, as discussed in response to comments *supra* at part III.A., some polls show populations in rural communities may be more likely to agree with providers in objecting to certain procedures encompassed by Federal conscience and anti-discrimination laws. This implies that the demand for such services may not exist (or be as great) in such communities, partially offsetting the impact of a higher number of conscientious objections that may be effectuated because of the rule. Persons in urban areas, in contrast, may feel less effect from an increase in conscientious objections because of the relatively greater availability of alternative providers as compared to rural areas.

One commenter noted that individuals whose health insurance does not provide financially adequate coverage for a large enough number of providers may similarly face a lack of alternative providers in the event one provider exercises a conscientious objection to a desired service. The Department regards its analysis herein regarding rural areas to be applicable to such situations as well.

Just as the consequences of denials of care may in some cases be magnified in rural areas, so too may be the consequences of forcing a rural health care provider to violate her conscience. First, the provider may limit her practice or exit the field, harming health care access in a significant way. Second, if the provider continues to practice, the stress of having to violate her conscience may detract from the quality of care the provider delivers to her patients in general, who have no alternative provider.

Additionally, if a provider is in an area where the majority of the population shares the provider's belief system, and if the provider leaves the area due to inability to exercise protected beliefs, many in the community may lose the ability to have a provider with values they share, thus negatively impacting the delivery of health care and the doctor-patient relationship.

5. Analysis of Regulatory Alternatives

The Department carefully considered alternatives to this final rule. The Department determined that no alternative could achieve appropriately robust enforcement of, and respect for, Federal conscience and anti-discrimination laws without unduly burdening covered persons and entities subject to those laws and this rule. The following alternatives represent the major approaches the Department considered, including how burden reduction was a consideration in constructing this rule.

The Department considered preserving the status quo by maintaining 45 CFR part 88 without change from the 2011 Rule. Under this approach, the Department would largely defer to the States to enforce their respective conscience laws or to enact new laws to fill gaps in the landscape of Federal and State conscience protection and associated anti-discrimination rights and their enforcement, continue with the current inadequate enforcement scheme, and provide no meaningful enforcement of the conscience and associated anti-discrimination laws that were not part of the 2011 Rule. The Department received comments advocating this approach since, in commenters' views, State law, in conjunction with Federal law, already provides adequate accommodation of religious beliefs. Furthermore, some commenters stated that the stringent protections for conscience established by the statutes implemented by this rule are in tension with State nondiscrimination laws, State pharmaceutical dispensing laws, and State immunization laws that offer employers greater leeway in handling situations in which an employee asserts a conscientious objection.[355] As stated elsewhere in response to similar comments, the Department disagrees with these arguments. As described above and further in the rule's Federalism analysis, to eliminate or reduce any tension between this rule's application of Federal statutes and State law, the final rule narrows the scope of the definitions of ''discrimination'' and ''referral'' in § 88.2.

The Department also disagrees that maintaining the status quo is preferable to this rule. Deference to States would perpetuate the current circumstances necessitating Federal regulation, which include (1) inadequate to non-existent Federal government frameworks to enforce Federal conscience and anti-discrimination laws and (2) inadequate information and understanding about the obligations of regulated persons and entities and the rights of persons, entities, and health care entities under the Federal conscience and anti-discrimination laws. State action cannot correct these deficiencies at the Federal level. Furthermore, the Department could not, in good faith, choose to rely on States to promote conscience protection policies, knowing that some States have adopted laws that are inconsistent with, or have otherwise expressed indifference towards, the rights protected by the laws that part 88 (as written in the 2011 Rule) implements—the Weldon, Church, and Coats-Snowe Amendments.[356]

Additionally, as noted more extensively in the preamble's summary of regulatory history, *supra* at part I, many commenters have pointed out the mutually reinforcing inadequate circumstances of the status quo contribute to the critical need for this final rule, including a conspicuously minimalistic regulatory scheme (compared to regulations implementing other civil rights laws OCR enforces); a lack of recognition by courts of a private right of action under certain Federal conscience and anti-discrimination laws; [357] and hostility to conscience protections in some portion of the population and in certain State and local governments. Maintaining the status quo leaves a gap where HHS has a responsibility to coordinate compliance with, and enforcement of, Federal conscience protection and anti-discrimination laws but does not have the regulatory scheme to accomplish that goal. The Department consequently promulgates this final rule to eliminate that gap.

The Department considered maintaining the status quo, but dramatically increasing its outreach. Numerous commenters asserted the strong need for outreach to combat bias and animus in the health care sector against individuals with religious beliefs or moral convictions, to raise awareness of the conscience rights of individuals, entities, and health care entities, and to clarify the legal obligations of regulated persons and entities. Commenters suggested a range

[355] These comments paralleled the concerns, described *supra* at part III.B, raised by commenters who argued that this rule conflicts with other Federal statutes like Title VII of the Civil Rights Act of 1964.

[356] *See supra* at part II.A (discussing laws and policies that some States have adopted).

[357] *See, e.g., Cenzon-DeCarlo* v. *Mount Sinai Hospital,* 626 F.3d 695 (2d Cir. 2010); *Hellwege* v. *Tampa Family Health Centers,* 103 F. Supp. 3d 1303 (M.D. Fla. 2015); *National Institute of Family and Life Advocates, et al.* v. *Rauner,* No. 3:16–cv–50310, at 4 (N.D. Ill. July 19, 2017).

of ideas, including that the Department publish educational materials for academic medical institutions to educate students about their protected conscience rights and the obligation of regulated entities to comply with Federal conscience and anti-discrimination laws; that HHS partner with State institutions regulating health professions; and that HHS create an advisory team with diverse members to develop a plan for extensive outreach to combat ignorance about Federal conscience and anti-discrimination laws.

The Department remains committed to robust outreach. Outreach has tremendous benefits to clarify legal obligations, raise awareness of OCR, and elevate awareness of the importance of conscience protections generally. The Department, however, agrees with one commenter who noted that, although outreach is important, it is insufficient without an enforceable rule to uphold the substantive protections under Federal law. As with every other civil rights law, outreach without adequate enforcement mechanisms is not enough to ensure appropriate compliance.

The Department considered a regulatory scheme that was more prescriptive than this rule by requiring all recipients and sub-recipients to establish policies and procedures for accommodating workforce members who objected to certain services based on moral convictions or religious beliefs; to address certain substantive elements in their policies and procedures; and to require the dissemination of information to workforce members about Federal conscience and anti-discrimination laws, this rule, or the recipient's and sub-recipient's policies and procedures. The burden under this option across 502,899 entities (the mid-point of the range shown in supra at Table 2) is the labor of a lawyer's time (3 hours) and an executive's time (1 hour). Using the mean hourly wages for these occupations adjusted upward for benefits and overhead, the annual average burden would be $297 million.[358]

The Department rejected this alternative, but estimates *supra* at part IV.C.3.ii that five percent of entities in year one and 0.5 percent of entities annually in years two through five would voluntarily update policies and procedures or disseminate them to staff as a by-product of assuring and certifying compliance with Federal conscience and anti-discrimination laws and this rule.

As discussed above, the Department considered requiring recipients to post notices of nondiscrimination in various physical locations and online, but has chosen to make the notice provisions voluntary, in part to reduce burden. The final rule allows recipients and sub-recipients flexibility to decide what measures will best ensure compliance with Federal conscience and anti-discrimination laws and this rule, while providing for vigorous enforcement in cases of violation. Recipients and sub-recipients are better positioned to decide whether organization-wide action is necessary, and if so, what extent, content, and manner of that action is appropriate to ensure compliance. This approach allows recipients and sub-recipients to tailor appropriate organization-wide action based on their type, the populations they serve, their size, the scope of their workforce members likely to exercise protected rights under the Federal conscience and anti-discrimination laws and this rule, and other relevant considerations. This rule, therefore, permits recipient employers to establish their own policies and procedures for how they will handle individuals' objections to certain procedures, such as abortion, sterilization, or assisted suicide, and recognizes the availability of appropriate accommodation procedures. In addition, this rule permits recipient employers who do have institution-wide objections to performing certain procedures, such as sterilization, but that do not object to referring for such procedures, to establish referral systems with nearby institutions that do not have objections to such procedures to facilitate the delivery of the services or programs.

D. Executive Order 13771

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' The Department believes that this final rule is a significant regulatory action as defined by section 3(f) of Executive Order 12866. This rule is also considered a regulatory action under Executive Order 13771. Excluding any negative externalities attributed to this rule in the form of health outcomes or other effects not compensated by positive health or other externalities from protecting conscience rights, the Department estimates that this rule will generate $148.2 million in annualized costs at a 7 percent discount rate, discounted relative to year 2016, over a perpetual time horizon.

One commenter argued that the final rule violates Executive Order 13771 because it imposes costs but does not identify what other burdens imposed by other regulations are being eliminated. Although each agency must identify offsetting deregulatory actions for each new regulatory burden, OMB does not interpret Executive Order 13771 to require each regulation that imposes costs to cite the particular deregulatory actions that offset that particular burden.[359]

E. Regulatory Flexibility Act

HHS has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612). 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.

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

[358] Product of weighted mean hourly wage of $147.60 per hour × 4 hours × 502,899 entities.

[359] Office of Management & Budget, Guidance Implementing Executive Order 13771, Titled Reducing Regulation and Controlling Regulatory Costs, at 16 (Apr. 5, 2017), *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf* (stating in the answer to question 37 that ''[w]hile each **Federal Register** notice should identify whether the regulation is an E.O. 13771 regulatory action, there is no need to discuss specific offsetting E.O. 13771 deregulatory actions within the same **Federal Register** entry.'').

industry.[360] 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, thus, affect small entities, this rule's per-entity effects are relatively small. The Department estimates that this rule would impose an average cost of $778 per entity in the first year of compliance [361] and about $325.30 per year in years two through five.[362] Furthermore, these 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 those required to have a significant impact on a substantial number of small entities, within the meaning of the RFA.

Furthermore, the rule attempts to minimize costs imposed on small entities. For example, the assurance and certification requirements in § 88.4 contain exceptions to relieve many small entities of the requirement to submit an assurance and certification. Approximately 70 percent of recipients are exempted from the assurance and certification requirement, assuming that those exempted do not receive HHS funding through a non-exempt program.[363] Given the magnitude and type of entities granted the exception, § 88.4 should not be understood as unduly burdening small entities subject to the rule.

The Department has further committed to leveraging existing grant, contract, and other Departmental forms where possible to implement § 88.4, rather than create additional, separate forms for recipients to sign. Similarly, § 88.5 no longer requires recipients to provide notices of conscience rights, but incentivizes recipients to voluntarily provide such notices. In light of this determination, the Secretary certifies that this rule will not result in a significant impact on a substantial number of small entities.

F. Unfunded Mandates Reform Act

The Department similarly concludes that the requirements of the Unfunded Mandates Reform Act of 1995 are not triggered by this final rule. Section 202(a) of that Act requires the Department to prepare a written statement, including an assessment of anticipated costs and benefits, before issuing ''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 $150 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. As discussed in this RIA, this rule will not result in an expenditure in any year that meets or exceeds that amount with regard to State, local, or tribal governments, but will exceed that amount with regard to the private sector. An in-depth analysis of the rule with respect to State and local governments specifically appears in the following section of this RIA regarding Executive Order 13132 (Federalism).

G. Executive Order 13132—Federalism; Executive Order 13175—Impact on Tribal Entities

Federalism

The Secretary has determined that this final rule comports with Executive Order 13132.[364] Executive Order 13132 aims to ''guarantee the division of governmental responsibilities between the national government and the States that was intended by the Framers of the Constitution . . . [and] ensure that the principles of federalism . . . guide the executive departments and agencies in the formulation and implementation of policies.'' [365] 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.

Under the Supremacy and Spending Clauses of the Constitution, States and their political subdivisions are subject to Acts of Congress,[366] and Federal conscience and anti-discrimination laws are no exception. This rule holds States and local governments accountable for compliance with these laws by setting forth mechanisms for OCR investigation and HHS enforcement related to those requirements. The rule does not change the substantive conscience protections or anti-discrimination requirements of these statutes.

The Department received comments arguing that the enforcement of this rule through § 88.7 could infringe on State sovereignty, in violation of the limits of the Spending Clause power afforded by the U.S. Constitution to Congress. The Federal government presumes the constitutionality of statutes that Congress enacts. Congress has exercised the broad authority afforded to it under the Spending Clause to attach clear conditions on Federal funds to secure conscience protection and associated anti-discrimination rights. In cases of violation of the Federal conscience and anti-discrimination laws, the Department intends to interpret and apply the remedies that § 88.7 sets forth in a manner consistent with the particular Federal law(s) at issue and the U.S. Constitution, and, as discussed in response to earlier comments, will comply with relevant Supreme Court precedents concerning federalism.[367]

Some commenters argued that the rule implicates the requirements of Executive Order 13132 and unconstitutionally impedes the ability of States to exercise power in areas traditionally reserved to them, such as health, safety, and welfare. Commenters also raised concerns that the rule may inhibit States from implementing their own conscience protections. The Department disagrees with these concerns. The Department promulgates this rule under longstanding Federal laws that leave ample room for State activity. States are free to enact their own conscience protection and anti-discrimination laws that consider their own respective needs, populations, and prerogatives. Indeed, all fifty States have some protections in place for conscientious objectors to certain health or medical services and several provisions of this rule explicitly apply to reinforce and respect State conscience protections.[368] States are

[360] U.S. Small Business Administration, Table of Small Business Size Standards Marched to North American Industry Classification System Codes (Oct. 1, 2017), *https://www.sba.gov/sites/default/files/files/Size_Standards_Table_2017.pdf* (identifying the size standards by NAICS code for the health care and social service industries).

[361] Result of $391.5 million in first year costs to non-HHS entities divided by 502,899 entities.

[362] Result of $163.6 million annually to non-HHS entities in years two through five divided by 502,899 entities.

[363] The average between the lower-bound (267,134) and upper-bound (415,666) of recipients exempted is 341,400 recipients, which represents 68 percent of the estimated total 500,290 recipients of the rule (excluding the estimated 2,609 counties that for the purpose of this rule are estimated to be sub-recipients).

[364] E.O. 13132, 64 FR 43255 (Aug. 4, 1999).

[365] *Id.*

[366] *Id.* section 2(d).

[367] *See supra* at part III.B (section-by-section analysis for § 88.7) and part I.B (this regulation's history) for further discussion of this matter.

[368] *See* Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare*

free to experiment with various approaches to promote respect of, and tolerance for, the exercise of conscience rights, and this final rule respects that prerogative. States are also free to reject Federal funding if they object to conditions required by any of the laws that are the subject of this rule.

Section 88.8 of the rule makes clear that the rule is not intended to interfere with the operation of State law. For State laws equally or more protective of religious freedom and moral convictions than this rule, § 88.8 of this rule states that nothing in the rule ''shall be construed to preempt'' such State or local law. Section 88.8 also declares that nothing in the rule ''shall be construed to narrow the meaning or application of any State . . . law protecting free exercise of religious beliefs or moral convictions.''

Some statutes that the rule implements, such as 42 U.S.C. 1396s(c)(2)(B)(ii), *require* providers to comply ''with applicable State law, including any law relating to any religious or other exemption'' as a condition of participation in the program that the statute authorizes (in this example, the Federal pediatric vaccine program). Other laws that this rule implements, such as 42 U.S.C. 280g–1(d), clarify that Federal assistance for newborn and infant hearing screening programs do not preempt or prohibit any State law protections for parents to assert religious objections to such screenings. Similarly, 42 U.S.C. 1396f clarifies that nothing requires 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.

This rule's requirements and prohibitions do not impose substantial direct effects on States and their political subdivisions, modify the relationship between the Federal government and the States, or alter the distribution of power and responsibilities among the various levels of government.[369]

Some commenters argued that this rule, or the statutes that the rule implements, conflict with State and local laws regarding student and health provider immunizations, mandated provision of abortion coverage, employer protections, counseling related to assisted suicide, or employers being able to accommodate objectors with alternative arrangements. These comments paralleled the concerns already addressed above. In short, the Department finalizes the rule to recognize forms of accommodation and to eliminate or reduce such tension between applicable statutes or between this final rule and State laws. Accordingly, the final rule narrows the scope of the definitions of ''discrimination'' and ''referral'' in § 88.2.

The impact of § 88.4 is minimal in terms of the added labor costs for State and local government staff to assure and certify compliance.[370] Additionally, the rule relies on enforcement mechanisms already available to HHS for grants and other forms of financial assistance.

In light of the above, the rule cannot be properly understood to impose substantial direct effects on States or their political subdivisions, their relationship with the Federal Government, or the distribution of power among the various levels of government.

One comment noted that it ''does not threaten principles of federalism [to] requir[e] respect for constitutionally-protected conscience rights as a condition of receiving Federal funds.'' The Department agrees. The Department has not identified any Federal laws or jurisprudence that indicates that merely implementing and enforcing Federal laws as written violates constitutional principles of federalism.

Impact on Tribal Entities

One comment stated that the Department would be required to engage in tribal consultation regarding the rule as required under Executive Order 13175. However, because the final rule removes the requirement in the proposed § 88.3(p)(1)(iii) that certain federally recognized Indian tribes or tribal organizations and urban Indian organizations comply with sections 88.4 and 88.6 of the rule, the Department believes that the rule does not have tribal implications as defined in Executive Order 13175, and that tribal consultation regarding the rule was, therefore, not necessary.

H. Congressional Review Act

The Congressional Review Act defines a ''major rule'' as ''any rule that the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget finds has resulted in or is likely to result in—(A) an annual effect on the economy of $100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.'' 5 U.S.C. 804(2). Based on the analysis of this final rule under Executive Order 12866, the Office of Management and Budget has determined that this rule is a major rule for purposes of the Congressional Review Act.

I. Assessment of Federal Regulation and Policies on Families

In the proposed rule, the Department included a discussion of section 654 of the Treasury and General Government Appropriations Act of 1999, Public Law 105–277, sec. 654, 112 Stat. 2681 (1998) as amended by Public Law 108–271, sec. 654, 118 Stat. 814 (2004), which required Federal departments and agencies to determine whether a policy or regulation could affect family well-being. These provisions are codified as a ''note'' to 5 U.S.C. 601. Because Congress did not renew these requirements in the most recent appropriations act applicable to the Department,[371] the Department believes it is not obligated to conduct an analysis of potential impact on family well-being before finalizing regulations. Additionally, OMB Circular A–4 does not require such an analysis. Nevertheless, out of an abundance of caution, the Department conducts such an analysis below.

Section 601 (note) of 5 U.S.C. required agencies to assess whether a regulatory action (1) impacts the stability or safety of the family, particularly in terms of marital commitment; (2) impacts the authority of parents in the education, nurture, and supervision of their children; (3) helps the family perform its functions; (4) affects disposable income or poverty of families and children; (5) if the regulatory action which financially impacts families, is justified; (6) may be carried out by State or local government or by the family; and (7) establishes a policy concerning the relationship between the behavior

Professionals, 49 Ariz. St. L.J. 549, 575–76, 587–600 (2017) (summarizing State laws).

[369] E.O. 13132, section 1(a). Executive Order 13132 requires an agency to meet certain requirements when it promulgates a rule with ''policies that have federalism implications.'' *Id.* sections 2–3, 6(b)–(c) (identifying federalism principles, policymaking criteria, and consultation requirements).

[370] *See supra* at part IV.C.2.vi of this RIA estimating the rule's burden.

[371] Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Public Law 115–245, 132 Stat. 2981 (2018).

and personal responsibility of youth and the norms of society.

The Department received comments stating that it did not adequately assess the impact on families in the proposed rule and reached an incorrect conclusion in determining that it is unlikely that this rule will negatively impact factors (1)–(4), with respect to the stability of the family, parental authority, or the disposable income or poverty of families and children. Other comments referenced concerns about how delays or refusals in treatment or in the transmission of information could affect factor (5): The emotional and financial well-being of families. The Department did not receive comments addressing factors (6) or (7). In response to these comments, the Department notes that these concerns do not constitute an impact on the well-being of the family within the meaning of 5 U.S.C. 601 (note) and that, in any event, the objections are to the underlying statutes that are the subject of the rule, not the mechanisms provided by the rule itself. With regard to factor (5), the prospect of a person losing their job, thus affecting the emotional and financial well-being of their family, is greater if conscience laws are not enforced as people of faith and moral conviction risk being driven out of the health care field as discussed above. Further discussion on the impact of this rule on patients and individuals can be found in part IV.C.4 (Estimated Benefits).

As the Department noted in the proposed rule, the action taken in this rule cannot be carried out by State or local governments or by the family on their own (factor (6)) because the rule pertains to enforcement of certain Federal laws. Additionally, by protecting parents' ability to assert conscience rights on behalf of their children, the rule clearly enhances parental authority under factor (2). None of the rule's provisions impact factors (1), (3)–(5), or (7) to the degree contemplated by 5 U.S.C. 601 (note). Accordingly, this rule will not negatively affect family well-being within the meaning of 5 U.S.C. 601 (note) in the event such provisions apply.

J. Paperwork Reduction Act

This final rule requires new collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Congress enacted the Paperwork Reduction Act of 1995 to ''maximize the practical utility and public benefit of the information created, collected, disclosed, 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). As defined in 5 CFR 1320.3(c), ''collection of information'' comprises reporting, record-keeping, monitoring, posting, labeling, and other similar actions. The Department sought comments regarding the burden estimates and the information collections generally. Some comments are discussed *supra* at part IV.C.3.ii–vi and others discussed in the following sections. The collections of information required by this final rule relate to §§ 88.4 (Assurance and Certification), 88.5 (Voluntary Posting of Notice of Rights), and 88.6(d) (Compliance Requirements).

1. Information Collection for § 88.4 (Assurance and Certification)

(i) Summary of the Collection of Information

This final rule requires each recipient (or applicant to become a recipient), with limited exceptions, to assure and certify compliance with Federal conscience and anti-discrimination laws. Specifically, § 88.4(a)(1) and (2) requires each recipient or applicant to include in its application for Federal funds, or accompany its application with, an assurance and a certification that it will operate applicable projects or programs in compliance with applicable Federal conscience and anti-discrimination laws and this rule.

Operationalizing the Assurance of Compliance Requirement

To operationalize the requirement in § 88.4(a)(1) for a recipient or applicant to sign an assurance of compliance, the Department is seeking clearance under the PRA to update the HHS–690 form, which is entitled ''Assurance of Compliance'' [372] and is described in the section-by-section analysis of the preamble for § 88.4. The new language that the Department is adding to the HHS–690 form identifies the major Federal conscience and anti-discrimination laws by their popular titles and their U.S. Code provisions (if codified) and directs the reader to OCR's Conscience and Religious Freedom web page for a full listing of the laws.

Operationalizing the Certification of Compliance Requirement

In response to public comments that encouraged the Department to use existing forms, the Department explored operationalizing the certification of compliance requirement in § 88.4(a)(2) by updating the HHS form 5161–1, but this form is only used by two HHS components rather than by all or most HHS operating or staff divisions. The Department also explored updating the Assurances for Non-Construction Programs (SF–424B), which, despite its name, enables the authorized representative of the applicant to certify up to nineteen paragraphs of agency and program-specific laws and regulations, such as housing, environmental, and labor laws and regulations.[373] Pursuant to an OMB directive, ''[e]ffective January 1, 2019, the SF–424B will become optional and agencies shall make plans to phase out use in Funding Opportunity Announcements.'' [374] Given this directive, the Department did not further explore updating the SF–424B.

The Department is seeking PRA clearance to operationalize the certification of compliance requirement during calendar year 2019 through the existing signature block of the government-wide Application for Federal Assistance (SF–424) [375] or, for research or related grants, through the Application for Federal Assistance for Research and Related (R&R) Series (SF–424 R&R).[376] The signature block for both applications contains the following statement:

> By signing this application, I certify (1) to the statements contained in the list of certifications ** and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances ** and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001).

** The list of certifications and assurances, or an internet site where you may obtain this list, is contained in the announcement or agency specific instructions.

In calendar year 2020 and the outyears, the Department is seeking PRA

[372] U.S. Dep't of Health & Human Servs., Assurance of Compliance, HHS 690, *https://www.hhs.gov/sites/default/files/hhs-690.pdf.*

[373] Assurances for Non-Construction Programs, SF–424B, (OMB #4040–0007) *https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf* (last visited Apr. 11, 2019).

[374] Exec. Office of the President, Memorandum from Mick Mulvaney, Dir., Office of Management & Budget to Heads of Executive Departments and Agencies, Strategies to Reduce Grant Recipient Reporting Burden, at 2 (Sept. 5, 2018), *https://www.whitehouse.gov/wp-content/uploads/2018/09/M-18-24.pdf.*

[375] Application for Financial Assistance, SF–424, (OMB # 4040–0004), *https://apply07.grants.gov/apply/forms/sample/SF424_2_1-V2.1.pdf* (last visited Apr. 11, 2019).

[376] Application for Financial Assistance, SF–424 (R&R), (OMB # 4040–0001), *https://apply07.grants.gov/apply/forms/sample/RR_SF424_2_0-V2.0.pdf* (last visited Apr. 11, 2019).

clearance to operationalize the certification of compliance requirement through the government-wide System for Award Management (SAM) [377] because this system, pursuant to an OMB directive, ''will become the central repository for common government-wide certifications and representations required of Federal grants recipients.'' [378] The certifications and representations through SAM replace the government-wide assurances contained in the Assurances for Non-Construction Programs (SF–424B).[379]

In submitting the general certifications and representations through SAM,[380] the authorized representative certifies to several statements, two of which the Department interprets as operationalizing § 88.4(b).[381] First, the authorized representative certifies that it ''[w]ill comply with U.S. statutory and public policy requirements which prohibit discrimination, including but not limited to[]'' certain Federal civil rights statutes.[382] The Federal conscience and anti-discrimination laws are not listed because the general certifications and representations identified in SAM are government-wide, rather than agency or multi-agency specific. However, the Department construes the non-exhaustive list as incorporating the Federal conscience and anti-discrimination laws, as applicable, that the final rule implements.

Another statement conveys that the authorized representative certifies that it ''[w]ill comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies government financial assistance awards and any financial assistance project covered by this certification document.'' [383] The Department construes this catch-all statement as incorporating the Federal conscience and anti-discrimination laws, as applicable, and the final rule.

(ii) Need for Information

Requiring certain recipients and applicants to assure and certify compliance serves two purposes. First, through the act of reading and reviewing the statutory requirements to which recipients or applicants assure and certify compliance, recipients would be apprised of their obligations under the applicable Federal conscience and anti-discrimination laws and this rule. Second, a recipient's or applicant's awareness of its obligations would increase the likelihood that it would comply with such laws and, consequently, afford entities and individuals protection of their conscience rights and protection from coercion or discrimination.

In the proposed rule, the Department requested comment on whether the collection of information is necessary for the proper performance of the Department's functions to enforce Federal laws on which Federal funding is conditioned. At least one commenter encouraged the Department to add the assurance and certification requirements in § 88.4 because of the ''surge in harassment and coercion of medical providers of faith.'' Other commenters stated that assurance and certification was unnecessary because recipients already must certify compliance with Federal law upon the receipt of Federal funds.

This collection of information facilitates the Department's obligation to ensure that the Federal financial assistance or other Federal funds that the Department awards are used in a manner compliant with Federal conscience and anti-discrimination laws and the final rule. The Department's administration of a requirement for an entity at the time of application or reapplication to assure and certify compliance with Federal conscience and anti-discrimination laws and the final rule demonstrates that the person or entity was aware of its obligations under those laws and the rule.

In addition, HHS has the authority to place terms and conditions consistent with those statutes in any instrument HHS issues or to which it is a party (*e.g.,* grants, contracts or other HHS instruments). A Department component extending an award must communicate and incorporate statutory and public policy requirements and obligate the recipient to comply with Federal statues and ''public policy requirements, including . . . those . . . prohibiting discrimination.'' [384] More specifically, the Department component ''must communicate . . . all relevant public policy requirements, including those in general appropriations provisions, and incorporate them either directly or by reference in the terms and conditions of the Federal award.'' [385] The Departmental component may require a recipient ''to submit certifications and representations required by Federal statutes, or regulations . . .'' [386]

(iii) Use of Information

The Department and its components awarding Federal funds and OCR will use the signed assurance and certification as documentation of (1) a recipient's or applicant's awareness of its obligations under the Federal conscience and anti-discrimination laws and this rule, and (2) a recipient's or applicant's binding agreement to abide by such obligations. This use would most likely occur during an OCR investigation of the recipient's compliance with Federal conscience and anti-discrimination laws and this rule, and as part of an entity's record keeping obligations under this rule.

(iv) Description of the Respondents

The respondents are applicants or recipients for Federal financial assistance or Federal funds from the Department as set forth in § 88.3, which identifies the applicability of this rule for each of the underlying statutes that would be implemented and enforced. Respondents include hospitals, research institutions, health professions training programs, qualified health plan issuers, Health Insurance Marketplaces, home health agencies, community mental health centers, and skilled nursing facilities.

(v) Number of Respondents

The Department estimates the number of respondents at 158,890 persons or

[377] U.S. Gen. Servs. Admin., System for Award Management, *Home, https://www.sam.gov/SAM/pages/public/index.jsf* (last visited Apr. 11, 2019).

[378] Exec. Office of the President, Memorandum from Mick Mulvaney, Dir., Office of Management & Budget to Heads of Executive Departments and Agencies, Strategies to Reduce Grant Recipient Reporting Burden, at 2 (Sept. 5, 2018), *https://www.whitehouse.gov/wp-content/uploads/2018/09/M-18-24.pdf.*

[379] *See id.* (''[R]egistration in SAM is required for eligibility for a Federal award and registration must be updated annually . . . . Federal agencies will use SAM information to comply with award requirements and avoid increased burden and costs of separate requests for such information, unless the recipient fails to meet a Federal award requirement, or there is a need to make updates to their SAM registration for other purposes.'').

[380] U.S. Gen. Servs. Admin., System for Award Management, SAM Release Notes Build 2019–02–01, at 3 (Feb. 2, 2019), *https://www.sam.gov/SAM/transcript/SAM_Release_Notes_2019_02_01.pdf* (describing under ''enhancements'' that SAM has ''a new government-wide Financial Assistance Representations and Certifications module within the SAM entity management registration'' and ''[a]ll non-federal registrants in SAM will be required to certify to the new Financial Assistance Reps & Certs as part of their registration'').

[381] The certifications and representations are not publicly available until an individual creates an account. The list of certifications and representations were obtained from staff at *Grants.gov* on March 19, 2019, and are on file with OCR.

[382] Financial Assistance General Certifications and Representations, at 2, para. 9 (on file with OCR).

[383] Financial Assistance General Certifications and Representations, at 1, para. 7 (on file with OCR).

[384] 45 CFR 75.300(a).

[385] *Id.*

[386] *Id.* at § 75.208.

entities, which is the average between the low (122,558) and high (195,222) estimates of entities required to sign an assurance or a certification. These figures appear *supra* at Table 3, part IV.C.2.iv.A. Respondents are a subset of the recipients because § 88.4(c)(1) through (4) excludes certain categories of recipients. The rule excludes physicians, as defined in 42 U.S.C. 1395x(r), physician offices, other health care practitioners or pharmacists who are recipients in the form of reimbursements for services provided to beneficiaries under Medicare Part B. *See* § 88.4(c)(1). The rule also exempts recipients of certain grant programs administered by the Administration for Children and Families or the Administration for Community Living when the program's purpose is unrelated to health care and certain types of research, does not involve health care providers, and does not involve any significant likelihood of referral for the provision of health care. *See* § 88.4(c)(2) and (3). Finally, this final rule excludes Indian Tribes and Tribal Organizations when contracting with the Indian Health Service under the Indian Self-Determination and Education Assistance Act. *See* § 88.4(c)(4).

(vi) Burden of Response

The Paperwork Reduction Act burden is the opportunity cost of recipient staff time to review the assurance and certification language as well as the requirements of the underlying Federal conscience and anti-discrimination laws referenced or incorporated. The methods that the Department uses are outlined *supra* at part IV.C.3.ii, and the mean hourly wage is adjusted downward to exclude benefits and overhead.

The labor cost is a function of a lawyer spending 3 hours reviewing the assurance and certification and an executive spending one hour to review and sign, as § 88.4(b)(2) requires a signature by an individual authorized to bind the recipient. The weighted mean hourly wage (not including benefits and overhead) of these two occupations is $73.80 per hour.[387] The labor cost is $46.9 million each year ($73.80 per hour × 4 hours × 158,890 entities).[388]

The Department asked for public comment on the information collection under § 88.4. Several specific questions that the Department posed received no comments:

- Whether the exception for Indian Tribes and tribal Organizations in proposed 45 CFR 88.4(c)(vi) avoids ''tribal implications'' and does not ''impose substantial direct compliance costs on Indian Tribal governments'' as stated in Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, sec. 5(b) (Nov. 9, 2000);
- Whether assuring compliance with the Federal conscience protection and associated anti-discrimination statutes would constitute a burden exempt from the Paperwork Reduction Act as a usual and customary business practice incurred by recipients during the ordinary course of business;
- How the quality, utility, and clarity of the information to be collected may be enhanced; and
- How the manner of compliance with the assurance and certification requirements could be improved, including through use of automated collection techniques or other forms of information technology.

The Department received public comments expressing concern with the possible burden on health care providers resulting from § 88.4, which is discussed *supra* at part IV.C.3.ii. In addition, as explained in the summary of this Paperwork Reduction Act analysis, the Department is leveraging existing grant, contract, and other Departmental forms and government-wide systems, consistent with OMB's government-wide effort to reduce recipient burden.[389]

2. *Information Collection for § 88.5 (Notice)*

(i) Summary of the Collection of Information

Under this rule as finalized, § 88.5 does not mandate the provision of notice, but rather incentivizes recipients and Department components to provide notice concerning Federal conscience and anti-discrimination laws. The rule intends to accomplish this goal by considering a recipient's or a Department component's posting of the notice as non-dispositive evidence of compliance with the rule when OCR investigates or initiates a compliance review of a recipient or Department component. If recipients voluntarily provide notice to implement § 88.5, recipients are encouraged to use the pre-written notice in appendix A. The recipient is otherwise free to draft its own notices tailored to its specific circumstances and applicable laws under the rule.

(ii) Need for Information

The Department incentivizes recipients and Department components to provide notice of rights because notice serves three primary purposes. First, individuals become apprised of their rights under applicable Federal conscience and anti-discrimination laws, including the right to file a complaint with HHS OCR. Second, an individual's awareness of his or her rights increases the likelihood that the individual will exercise those rights. Third, recipients and their managers and employees will be more likely to be reminded, and be made aware, of their own obligations under these laws.

(iii) Use of Information

Individuals, entities, and health care entities will use the information to increase their awareness of their rights and file complaints with OCR if they believe their rights have been violated. Entities required to comply will have an increased likelihood of understanding their obligations to thus act accordingly to fulfill them. During OCR investigation or compliance review of a recipient, OCR will consider as non-dispositive evidence of compliance whether and how the recipient posted a notice according to § 88.5.

(iv) Description of the Respondents

The respondents are recipients as defined in this rule at § 88.2. Respondents include, but are not limited to, States, hospitals, research institutions, and skilled nursing facilities.

(v) Number of Respondents

The number of respondents is estimated at 335,327 recipients at the establishment-level in year one and 75 percent of that amount in years two through five (*i.e.,* 251,495 establishments). This estimate represents the average between the lower and upper-bound estimates of how many recipient establishments will voluntarily post notices through one of more of the methods in § 88.5 in years one and annually in years two through five. A subset of respondents, about 139,615 recipients at the firm level, will likely modify the pre-written notice in appendix A.

(vi) Burden of Response

Even though the notice provision of the final rule is entirely voluntary, the Department expects that some segment

[387] Sum of ($67.25 × .75) and ($93.44 × .25).

[388] This total differs from the burden in the RIA because a fully-loaded wage that is adjusted upwards for benefits and overhead must be used in the RIA.

[389] Exec. Office of the President, Memorandum from Mick Mulvaney, Dir., Office of Management & Budget to Heads of Executive Departments and Agencies, Strategies to Reduce Grant Recipient Reporting Burden, at 2 (Sept. 5, 2018), *https://www.whitehouse.gov/wp-content/uploads/2018/09/M-18-24.pdf.*

of the recipients and Department components that this rule regulates will choose to post the notice through one of the methods specified. The burden is mix of labor, materials, and in some cases, postage costs. The methods and assumptions that the Department uses are outlined *supra* at part IV.C.3.iii, and the mean hourly wage is adjusted downward to exclude benefits and overhead. Unlike the burden estimated in the RIA of the rule, the PRA burden associated with § 88.5 excludes the costs of posting the notice for those entities that post it verbatim because the Department is supplying the language for the notice for the purpose of disclosure to the public, under 5 CFR 1320.3(c)(2).

Assuming that 139,615 recipients at the firm level alter the text of the notice in appendix A, these recipients will, on average, bear a minimal opportunity cost of ⅓ hour of a lawyer's time for drafting and ten minutes of an executive's time to provide final sign-off. The weighted mean hourly wage (excluding benefits and overhead) of these two occupations is $75.89 per hour. The one-time labor cost is $5.3 million in the first year ($75.89 per hour × 0.5 hours × 139,615 recipients).

The assumptions regarding the timing of providing notices of rights and the various uncertainties inherent in the implementation of § 88.5 described in detail in the RIA *supra* at part IV.C.3.iii apply to this analysis, too, such as the number of locations where notices are customarily posted, and the length of time it may take an administrative assistant or web developer to perform their respective functions.

(vii) Burden for Voluntary Posting in Physical Locations

The Department estimates that it will take ⅓ of an hour for an administrative assistant to print notice(s) and post them in physical locations of the establishment where notices are customarily posted. The 139,615 recipients at the firm level estimated to alter the notice are associated with 180,331 establishments. Assuming that about 180,331 facilities at the establishment level choose voluntarily to post notices in physical locations, the estimated labor cost is $1.2 million (⅓ hour × $19.39 per hour × 180,331 establishments).[390] The cost to post 5 notices across all establishments would be $45,083 (180,331 establishments × $.05 per page (paper and ink) × 5 pages). The total labor and materials costs associated with voluntary posting in physical locations by 180,331 establishments is $1.2 million ($1.2 million in labor costs and $45,083 for materials) in the first year of implementation with zero recurring costs.

One commenter raised concerns with the notice requirement being overly broad because it would require a multi-State health care entity to post notices at every location where workforce notices are customarily posted to permit ready observation, even if the particular location had no connection to the funding or activity giving rise to the obligation to post the notice. The final rule's modification of the notice from mandatory to voluntary should resolve this concern. Additionally, the rule provides for posting in locations as ''applicable and appropriate.''

One commenter expressed concern that the Department's estimate of time that an administrative assistant would spend to post the notice did not take into account the multiple facilities owned by a corporate entity. The estimates for the Paperwork Reduction Act and in the RIA, however, do take this into account because the Department multiplied the per facility labor and materials costs by the number of facilities (*i.e.,* establishments) over which a corporate entity (*i.e.,* firm) exercises common ownership and control.

(viii) Burden for Voluntary Web Posting

To post the notice on the web, the Department estimates that it will take 2 hours for a web developer at each recipient's physical location to execute the design and technical elements for posting. This labor cost is approximately $12.5 million (2 hours × $34.69 per hour × 180,337 establishments) in the first year of implementation with zero recurring costs.[391]

(ix) Burden for Voluntary Posting in Two Publications

The Department assumes that, within the first year after the rule's publication, each recipient voluntarily posting notices in publications would identify two publications in which to include the notice, revising the document or its layout to include the notice, or otherwise printing an insert to include with hard copies of the publication.[392] Acknowledging the uncertainties outlined *supra* at part IV.C.3.iii, the Department estimates the annual costs of labor, material, and postage according to the following assumptions. The Department assumes that (1) establishments that include notices of rights in publications will most often do so in online publications or in hard-copy publications hand-distributed, where the notice's inclusion results in an additional 100 hard copy notices per establishment per year, and (2) half of the establishments associated with covered recipients voluntarily providing hard copy notices (*i.e.,* 90,166 establishments in year one and 67,624 establishments annually in years two through five)[393] will mail the publications for which the weight of the notice incrementally increases the postage costs. These assumptions may differ from the actual experience of recipients' implementation, as described *supra* at part IV.C.3.iii.

Using the model, hourly estimates, and other assumptions described *supra* at part IV.C.3.iii, the average labor cost, excluding mailing-related labor costs, resulting from including notices in relevant publications is $7.0 million in year one ($19.39 per hour × 2 hours × 180,331 establishments) and $2.6 million annually in years two through five ($19.39 per hour × 1 hour × 135,249 establishments).[394] Based on the marginal cost of postage per ounce of $0.15,[395] an annual number of mailings of 100 pages per establishment, average annual labor cost for mailing of $19.39 per hour, and an average number of labor hours per mailing of 0.25 hours, the total costs due to the voluntary mailing of notices is $1.8 million[396] in year one and $1.3 million[397] annually in years two through five.[398] Finally, the

[390] This total differs from the burden in the RIA because a fully loaded wage that is adjusted upwards for benefits and overhead must be used.

[391] This total differs from the estimate of the burden in the RIA because the RIA uses a fully loaded wage rate (*i.e.,* including benefits and overhead) not employed here.

[392] Under the final rule, because all the notice provisions are voluntary, the Department assumes that 75% of entities that voluntarily provide notices in year one will continue to do so in out years and there will be lower attrition compared to the estimate provided in the proposed rule.

[393] Product of 180,331 establishments times 50 percent for year one. Product of 135,249 establishments times 50 percent for years two through five.

[394] These totals differ from the estimate of the burden in the RIA because the RIA uses a fully loaded wage rate (*i.e.,* including benefits and overhead) not employed here.

[395] *See* U.S. Postal Service Postage Rates, *https://www.stamps.com/usps/current-postage-rates/.*

[396] Sum of incremental postage of $1.4 million ($0.15 per mailing × 100 mailings × 90,166 establishments) and incremental labor of $437,078 ($19.39 per hour × 0.25 hours × 90,166 establishments).

[397] Sum of incremental postage of $1.0 million ($0.15 per mailing × 100 mailings × 67,624 establishments) and incremental labor of $327,809 ($19.39 per hour × 0.25 hours × 67,624 establishments).

[398] This total differs from the estimate of the burden in the RIA because the RIA uses a fully

Continued

annual cost of printed materials for notices (both mailed and hand distributed) is $0.9 million (180,331 establishments × 100 pages × $.05 per page) in year one and $676,243 annually in years two through five (135,249 establishments × 100 pages × $.05 per page).

In sum, the total expected cost of activities related to the voluntary posting and distributions of notices that § 88.5 incentivizes is $28.7 million in the first year and $4.6 million annually in years two through five.

(x) Burden to the Federal Government

Unlike the burden estimated in the RIA of the rule, the PRA burden to the Department associated with § 88.5 excludes the costs of posting the notice for those HHS components that post it verbatim because the Department is supplying the language of the notice for the purpose of disclosure to the public, under 5 CFR 1320.3(c)(2). Because the Department components will likely post the notice from Appendix A verbatim, all costs to the Department under the PRA for § 88.5 are excluded.

The remaining issue raised by commenters is whether the rule requires translation of the notice into non-English languages. Under the conscience protection and associated anti-discrimination laws and this rule, translation or posting of translated notices is not independently required. However, recipients subject to this rule may also have independent obligations to provide language assistance services and meaningful access to individuals with limited English proficiency when abiding by the prohibition of national origin discrimination in Federal civil rights laws that OCR enforces.[399]

The Department asked for public comment on the following issues and received no comments:

- Whether the proposed collection of information is necessary for the proper performance of the Department's functions to enforce Federal laws on which Federal funding is conditioned, including whether the information will have practical utility;
- Whether the public had feedback on the assumptions that formed the basis of the cost estimates for the notice provision; and
- How the manner of compliance with the notice provision could be improved, including through the use of automated collection techniques or other forms of information technology.

3. Compliance Procedures (§ 88.6(d))

(i) Summary of the Collection of Information

Paragraph 88.6(d) requires any recipient or sub-recipient that is subject to a determination by OCR of noncompliance with this part concerning Federal conscience and anti-discrimination laws to report this fact in any application for new or renewed Federal financial assistance or Departmental funding in the three years following the determination of noncompliance. This includes a requirement that recipients disclose any OCR determinations made against their sub-recipients.

(ii) Need for Information

The information alerts applicable Departmental components of OCR's determination of noncompliance on the part of the recipient or sub-recipient, to ensure appropriate coordination within the Department during OCR's enforcement of Federal conscience and anti-discrimination laws, and to inform funding decision-making.

(iii) Use of Information

This requirement puts the Departmental component on notice of OCR's determination of noncompliance to inform a component's decision whether to approve, renew, or modify Federal funding to the recipient. This requirement also facilitates coordination between the component and OCR on the status of the recipient or sub-recipient's compliance status.

(iv) Description of the Respondents

The respondents are recipients and sub-recipients that HHS OCR has found noncompliant with this final rule.

(v) Number of Respondents

As explained, *supra* at part IV.C.3.v, the Department cannot predict the number of entities that OCR will find noncompliant with the rule.

(vi) Burden of Response

The Department estimates it would take a records custodian at the experience level of a paralegal about 15 minutes to retrieve the relevant information (such as date of the violation finding and the OCR ''transaction number'' (*e.g.,* case number)) from the recipient's or sub-recipient's records and an administrative assistant 15 minutes to enter the information on the application. Based on the methods and assumptions *supra* at part IV.C.3.v, the Department assumes that a recipient, at the highest end, would submit 2,000 applications each year for new funding opportunities, supplemental funding, and non-competing continuations, among others. The mean weighted hourly wage for the paralegal and administrative assistant is $22.66, which excludes benefits and overhead. Each recipient or sub-recipient found in violation of the rule would expend on the highest end, $22,655 per year in labor costs at the firm level ($22.66 per hour × 2,000 applications × 0.5 hours).[400]

Commenters stated that the version of this requirement in the proposed rule was redundant and duplicative. The Department agrees. The final rule and this information collection has been modified substantially to require recipients and sub-recipients to notify the Departmental components from which the recipient or sub-recipient receives Federal funds in the three years following a determination of noncompliance with Federal conscience and anti-discrimination laws and this final rule by OCR.

List of Subjects in 45 CFR Part 88

Abortion, Adult education, Advanced directives, Assisted suicide, Authority delegations, Childbirth, Civil rights, Coercion, Colleges and universities, Community facilities, Contracts, Educational facilities, Employment, Euthanasia, Family planning, Federal-State relations, Government contracts, Government employees, Grant programs-health, Grants administration, Health care, Health facilities, Health insurance, Health professions, Hospitals, Immunization, Indian Tribes, Insurance, Insurance companies, Laboratories, Manpower training programs, Maternal and child health, Medicaid, Medical and dental schools, Medical research, Medicare, Mental health programs, Mercy killing, Moral convictions, Nondiscrimination, Nursing homes, Nursing schools, Occupational safety and health, Occupational training, Physicians, Prescription drugs, Public assistance programs, Public awareness, Public health, Religious discrimination, Religious beliefs, Religious liberties, Religious nonmedical health care institutions, Reporting and recordkeeping requirements, Rights of conscience, Scholarships and fellowships, Schools, Scientists, State and local governments, Sterilization,

loaded wage rate (*i.e.,* including benefits and overhead) not employed here.

[399] *E.g.,* 42 U.S.C. 2000d (Title VI of the Civil Rights Act of 1964); 45 CFR part 80 (HHS implementing regulations); Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 FR 47311, 47313 (Aug. 8, 2003).

[400] This total differs from the burden in the RIA because a fully loaded wage that is adjusted upwards for benefits and overhead must be used.

Students, Technical assistance, Tribal Organizations.

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

PART 88—PROTECTING STATUTORY CONSCIENCE RIGHTS IN HEALTH CARE; DELEGATIONS OF AUTHORITY

Authority: 42 U.S.C. 300a–7 (the Church Amendments); 42 U.S.C. 238n (Coats-Snowe Amendment); the Weldon Amendment (*e.g.,* Pub. L. 115–245, Div. B, sec. 507(d)); 42 U.S.C. 18113 (Section 1553 of the Affordable Care Act); Medicare Advantage (*e.g.,* Pub. L. 115–245, Div. B, sec. 209); the Helms, Biden, 1978, and 1985 Amendments, 22 U.S.C. 2151b(f) (*e.g.,* Pub. L. 116–6, Div. F, sec. 7018); 22 U.S.C. 7631(d); 29 U.S.C. 669(a)(5); 42 U.S.C. 300gg–92; 42 U.S.C. 1302(a); 42 U.S.C. 18041(a) (Section 1321 of the Affordable Care Act); 42 U.S.C. 18081 (Section 1411 of the Affordable Care Act); 42 U.S.C. 18023 (Section 1303 of the Affordable Care Act); 26 U.S.C. 5000A(d)(2); 42 U.S.C. 18031; 42 U.S.C. 280g–1(d); 42 U.S.C. 290bb–36(f); 42 U.S.C. 1315; 42 U.S.C. 1315a; 42 U.S.C. 1320a–1; 42 U.S.C. 1320c–11; 42 U.S.C. 1395cc(f); 42 U.S.C. 1395i–3; 42 U.S.C. 1395i–5; 42 U.S.C. 1395w–22(j)(3)(B); 42 U.S.C. 1395w–26; 42 U.S.C. 1395w–27; 42 U.S.C. 1395x; 42 U.S.C. 1396a; 42 U.S.C. 1396a(w)(3); 42 U.S.C. 1396f; 42 U.S.C. 1396r; 42 U.S.C. 1396s(c)(2)(B)(ii); 42 U.S.C. 1396u–2(b)(3)(B); 42 U.S.C. 1397j–1(b); 42 U.S.C. 5106i(a); 42 U.S.C. 14406; 5 U.S.C. 301; 40 U.S.C. 121(c); 42 U.S.C. 263a(f)(1)(E); 45 CFR parts 75 and 96; 48 CFR chapter 1; 48 CFR parts 300 thru 370; 2 CFR part 376.

§ 88.1 Purpose.

The purpose of this part is to provide for the implementation and enforcement of the Federal conscience and anti-discrimination laws listed in § 88.3. Such laws, for example, protect the rights of individuals, entities, and health care entities to refuse to perform, assist in the performance of, or undergo certain health care services or research activities to which they may object for religious, moral, ethical, or other reasons. Such laws also protect patients from being subjected to certain health care or services over their conscientious objection. Consistent with their objective to protect the conscience and associated anti-discrimination rights of individuals, entities, and health care entities, the statutory provisions and the regulatory provisions contained in this part are to be interpreted and implemented broadly to effectuate their protective purposes.

§ 88.2 Definitions.

For the purposes of this part:

Assist in the performance means to take an action that has a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program or research activity undertaken by or with another person or entity. This may include counseling, referral, training, or otherwise making arrangements for the procedure or a part of a health service program or research activity, depending on whether aid is provided by such actions.

Department means the Department of Health and Human Services and any component thereof.

Discriminate or *discrimination* includes, as applicable to, and to the extent permitted by, the applicable statute:

(1) To withhold, reduce, exclude from, terminate, restrict, or make unavailable or deny any grant, contract, subcontract, cooperative agreement, loan, license, certification, accreditation, employment, title, or other similar instrument, position, or status;

(2) To withhold, reduce, exclude from, terminate, restrict, or make unavailable or deny any benefit or privilege or impose any penalty; or

(3) To utilize any criterion, method of administration, or site selection, including the enactment, application, or enforcement of laws, regulations, policies, or procedures directly or through contractual or other arrangements, that subjects individuals or entities protected under this part to any adverse treatment with respect to individuals, entities, or conduct protected under this part on grounds prohibited under an applicable statute encompassed by this part.

(4) Notwithstanding paragraphs (1) through (3) of this definition, an entity subject to any prohibition in this part shall not be regarded as having engaged in discrimination against a protected entity where the entity offers and the protected entity voluntarily accepts an effective accommodation for the exercise of such protected entity's protected conduct, religious beliefs, or moral convictions. In determining whether any entity has engaged in discriminatory action with respect to any complaint or compliance review under this part, OCR will take into account the degree to which an entity had implemented policies to provide effective accommodations for the exercise of protected conduct, religious beliefs, or moral convictions under this part and whether or not the entity took any adverse action against a protected entity on the basis of protected conduct, beliefs, or convictions before the provision of any accommodation.

(5) Notwithstanding paragraphs (1) through (3) of this definition, an entity subject to any prohibition in this part may require a protected entity to inform it of objections to performing, referring for, participating in, or assisting in the performance of specific procedures, programs, research, counseling, or treatments, but only to the extent that there is a reasonable likelihood that the protected entity may be asked in good faith to perform, refer for, participate in, or assist in the performance of, any act or conduct just described. Such inquiry may only occur after the hiring of, contracting with, or awarding of a grant or benefit to a protected entity, and once per calendar year thereafter, unless supported by a persuasive justification.

(6) The taking of steps by an entity subject to prohibitions in this part to use alternate staff or methods to provide or further any objected-to conduct identified in paragraph (5) of this definition would not, by itself, constitute discrimination or a prohibited referral, if such entity does not require any additional action by, or does not take any adverse action against, the objecting protected entity (including individuals or health care entities), and if such methods do not exclude protected entities from fields of practice on the basis of their protected objections. Entities subject to prohibitions in this part may also inform the public of the availability of alternate staff or methods to provide or further the objected-to conduct, but such entity may not do so in a manner that constitutes adverse or retaliatory action against an objecting entity.

Entity means a ''person'' as defined in 1 U.S.C. 1; the Department; a State, political subdivision of any State, instrumentality of any State or political subdivision thereof; any public agency, public institution, public organization, or other public entity in any State or political subdivision of any State; or, as applicable, a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).

Federal financial assistance includes:

(1) Grants and loans of Federal funds;

(2) The grant or loan of Federal property and interests in property;

(3) The detail of Federal personnel;

(4) The sale or lease of, and the permission to use (on other than a casual or transient basis), Federal property or any interest in such property without consideration or at a nominal consideration, or at a consideration which is reduced for the purpose of assisting the recipient or in recognition of the public interest to be served by such sale or lease to the recipient; and

(5) Any agreement or other contract between the Federal government and a recipient that has as one of its purposes the provision of a subsidy to the recipient.

Health care entity includes:

(1) For purposes of the Coats-Snowe Amendment (42 U.S.C. 238n) and the subsections of this part implementing that law (§ 88.3(b)), an individual physician or other health care professional, including a pharmacist; health care personnel; a participant in a program of training in the health professions; an applicant for training or study in the health professions; a post-graduate physician training program; a hospital; a medical laboratory; an entity engaging in biomedical or behavioral research; a pharmacy; or any other health care provider or health care facility. As applicable, components of State or local governments may be health care entities under the Coats-Snowe Amendment; and

(2) For purposes of the Weldon Amendment (*e.g.,* Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, and Continuing Appropriations Act, 2019, Pub. L. 115–245, Div. B., sec. 507(d), 132 Stat. 2981, 3118 (Sept. 28, 2018)), Patient Protection and Affordable Care Act section 1553 (42 U.S.C. 18113), and to sections of this part implementing those laws (§ 88.3(c) and (e)), an individual physician or other health care professional, including a pharmacist; health care personnel; a participant in a program of training in the health professions; an applicant for training or study in the health professions; a post-graduate physician training program; a hospital; a medical laboratory; an entity engaging in biomedical or behavioral research; a pharmacy; a provider-sponsored organization; a health maintenance organization; a health insurance issuer; a health insurance plan (including group or individual plans); a plan sponsor or third-party administrator; or any other kind of health care organization, facility, or plan. As applicable, components of State or local governments may be health care entities under the Weldon Amendment and Patient Protection and Affordable Care Act section 1553.

Health service program includes the provision or administration of any health or health-related services or research activities, health benefits, health or health-related insurance coverage, health studies, or any other service related to health or wellness, whether directly; through payments, grants, contracts, or other instruments; through insurance; or otherwise.

Instrument is the means by which Federal funds are conveyed to a recipient and includes grants, cooperative agreements, contracts, grants under a contract, memoranda of understanding, loans, loan guarantees, stipends, and any other funding or employment instrument or contract.

OCR means the Office for Civil Rights of the Department of Health and Human Services.

Recipient means any State, political subdivision of any State, instrumentality of any State or political subdivision thereof, and any person or any public or private agency, institution, organization, or other entity in any State, including any successor, assign, or transferee thereof, to whom Federal financial assistance is extended directly from the Department or a component of the Department, or who otherwise receives Federal funds directly from the Department or a component of the Department, but such term does not include any ultimate beneficiary. The term may include a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).

Referral or *refer for* includes the provision of information in oral, written, or electronic form (including names, addresses, phone numbers, email or web addresses, directions, instructions, descriptions, or other information resources), where the purpose or reasonably foreseeable outcome of provision of the information is to assist a person in receiving funding or financing for, training in, obtaining, or performing a particular health care service, program, activity, or procedure.

State includes, in addition to the several States, the District of Columbia. For those provisions related to or relying upon the Public Health Service Act, the term ''State'' includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands. For those provisions related to or relying upon the Social Security Act, such as Medicaid or the Children's Health Insurance Program, the term ''State'' shall be defined in accordance with the definition of ''State'' found at 42 U.S.C. 1301.

Sub-recipient means any State, political subdivision of any State, instrumentality of any State or political subdivision thereof, or any person or any public or private agency, institution, organization, or other entity in any State, including any successor, assign, or transferee thereof, to whom there is a pass-through of Federal financial assistance or Federal funds from the Department through a recipient or another sub-recipient, but such term does not include any ultimate beneficiary. The term may include a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).

Workforce means employees, volunteers, trainees, contractors, and other persons whose conduct, in the performance of work for an entity or health care entity, is under the direct control of such entity or health care entity, whether or not they are paid by the entity or health care entity, as well as health care providers holding privileges with the entity or health care entity.

§ 88.3 Applicable requirements and prohibitions.

(a) *The Church Amendments, 42 U.S.C. 300a–7*—(1) *Applicability.* (i) The Department is required to comply with paragraphs (a)(2)(i) through (vii) of this section and § 88.6 of this part.

(ii) Any State or local government or subdivision thereof and any other public entity is required to comply with paragraphs (a)(2)(i) through (iii) of this section.

(iii) Any entity that receives a grant, contract, loan, or loan guarantee under the Public Health Service Act (42 U.S.C. 201 *et seq.*) after June 18, 1973, is required to comply with paragraph (a)(2)(iv) of this section and §§ 88.4 and 88.6 of this part.

(iv) Any entity that receives a grant or contract for biomedical or behavioral research under any program administered by the Secretary of Health and Human Services after July 12, 1974, is required to comply with paragraph (a)(2)(v) of this section and §§ 88.4 and 88.6 of this part.

(v) The Department and any entity that receives funds for any health

service program or research activity under any program administered by the Secretary of Health and Human Services is required to comply with paragraph (a)(2)(vi) of this section and §§ 88.4 and 88.6 of this part.

(vi) Any entity that receives, after September 29, 1979, any grant, contract, loan, loan guarantee, or interest subsidy under the Public Health Service Act or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 [42 U.S.C. 15001 *et seq.*] is required to comply with paragraph (a)(2)(vii) of this section and §§ 88.4 and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Pursuant to 42 U.S.C. 300a–7(b)(1), the receipt of a grant, contract, loan, or loan guarantee under the Public Health Service Act by any individual does not authorize entities to which this paragraph (a)(2)(i) applies to require such individual to perform or assist in the performance of any sterilization procedure or abortion if his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions.

(ii) Pursuant to 42 U.S.C. 300a–7(b)(2)(A), the receipt of a grant, contract, loan, or loan guarantee under the Public Health Service Act by any recipient does not authorize entities to which this paragraph (a)(2)(ii) applies to require such recipient to make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the recipient on the basis of religious beliefs or moral convictions.

(iii) Pursuant to 42 U.S.C. 300a–7(b)(2)(B), the receipt of a grant, contract, loan, or loan guarantee under the Public Health Service Act by any recipient does not authorize entities to which this paragraph (a)(2)(iii) applies to require such recipient to provide personnel for the performance or assistance in the performance of any sterilization procedure or abortion if the performance or assistance in the performance of such procedure or abortion by such personnel would be contrary to the religious beliefs or moral convictions of such personnel.

(iv) Pursuant to 42 U.S.C. 300a–7(c)(1), entities to which this paragraph (a)(2)(iv) applies shall not discriminate against any physician or other health care personnel in employment, promotion, termination of employment, or extension of staff or other privileges because such physician or other health care personnel performed or assisted in the performance of a lawful sterilization procedure or abortion, because he refused to perform or assist in the performance of a lawful sterilization procedure or abortion on the grounds that his performance or assistance in the performance of such 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.

(v) Pursuant to 42 U.S.C. 300a–7(c)(2), entities to which this paragraph (a)(2)(v) applies shall not discriminate against any physician or other health care personnel in employment, promotion, termination of employment, or extension of staff or other privileges because such physician or other health care personnel 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.

(vi) Pursuant to 42 U.S.C. 300a–7(d), entities to which this paragraph (a)(2)(vi) applies shall not require any individual to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if the individual's performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions.

(vii) Pursuant to 42 U.S.C. 300a–7(e), entities to which this paragraph (a)(2)(vii) applies shall not deny admission to or otherwise discriminate 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.

(b) *The Coats-Snowe Amendment (Section 245 of the Public Health Service Act), 42 U.S.C. 238n*—(1) *Applicability.* (i) The Department is required to comply with paragraphs (b)(2)(i) through (ii) of this section and § 88.6 of this part.

(ii) Any State or local government or subdivision thereof that receives Federal financial assistance, including Federal payments provided as reimbursement for carrying out health-related activities, is required to comply with paragraphs (b)(2)(i) through (ii) of this section and §§ 88.4 and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Pursuant to 42 U.S.C. 238n(a)(1), (2), and (3), entities to which this paragraph (b)(2)(i) applies shall not subject any health care entity to discrimination on the basis that the health care entity—

(A) 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;

(B) Refuses to make arrangements for any of the activities specified in (b)(2)(i)(A); or

(C) 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.

(ii) Pursuant to 42 U.S.C. 238n(b), entities to which this paragraph (b)(2)(ii) applies shall not, for the purposes of granting a legal status to a health care entity (including a license or certificate), or providing such entity with financial assistance, services, or benefits, fail to deem accredited any postgraduate physician training program that would be accredited but for the accrediting agency's reliance upon accreditation standards that require an entity to perform an induced abortion or that require an entity to require, provide, or refer for training in the performance of induced abortions or make arrangements for such training, regardless of whether such standards provide exceptions or exemptions. Entities to which this paragraph (b)(2)(ii) applies and which are involved in such matters shall formulate such regulations or other mechanisms, or enter into such agreements with accrediting agencies, as are necessary to comply with this paragraph.

(c) *Weldon Amendment (See, e.g., Pub. L. 115–245, Div. B, sec. 507(d))*—(1) *Applicability.* (i) The Department and its programs, while operating under an appropriations act that contains the Weldon Amendment, are required to comply with paragraph (c)(2) of this section and § 88.6 of this part.

(ii) Any State or local government that receives funds under an appropriations act for the Department that contains the Weldon Amendment is required to

comply with paragraph (c)(2) of this section and §§ 88.4 and 88.6 of this part.

(2) *Prohibition.* The entities to which this paragraph (c)(2) applies shall not subject 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, abortion.

(d) *Medicare Advantage (See, e.g., Pub. L. 115–245, Div. B, sec. 209)*—(1) *Applicability.* The Department, while operating under an appropriations act that contains a provision with respect to the Medicare Advantage program as set forth by Public Law 115–245, Div. B, sec. 209, is required to comply with paragraph (d)(2) of this section and § 88.6 of this part.

(2) *Prohibition.* The entities to which this paragraph (d)(2) applies shall not deny participation in the Medicare Advantage program to an otherwise eligible entity (including a Provider Sponsored Organization) because that entity informs the Secretary that it will not provide, pay for, provide coverage of, or provide referrals for abortions.

(e) *Section 1553 of the Affordable Care Act, 42 U.S.C. 18113*—(1) *Applicability.* (i) The Department is required to comply with paragraph (e)(2) of this section and § 88.6 of this part.

(ii) Any State or local government that receives Federal financial assistance under the Patient Protection and Affordable Care Act (or under an amendment made by the Patient Protection and Affordable Care Act) is required to comply with paragraph (e)(2) of this section and §§ 88.4 and 88.6 of this part.

(iii) Any health care provider that receives Federal financial assistance under the Patient Protection and Affordable Care Act (or under an amendment made by the Patient Protection and Affordable Care Act) is required to comply with paragraph (e)(2) of this section and §§ 88.4 and 88.6 of this part.

(iv) Any health plan created under the Patient Protection and Affordable Care Act (or under an amendment made by the Patient Protection and Affordable Care Act) is required to comply with paragraph (e)(2) of this section and §§ 88.4 and 88.6 of this part.

(2) *Prohibition.* The entities to which this paragraph (e)(2) applies shall 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. Nothing in this paragraph shall be construed to apply to, or to affect, any limitation relating to:

(i) The withholding or withdrawing of medical treatment or medical care;

(ii) The withholding or withdrawing of nutrition or hydration;

(iii) Abortion; or

(iv) The use of an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as such item, good, benefit, or service is not also furnished for the purpose of causing, or the purpose of assisting in causing, death, for any reason.

(f) *Section 1303 of the Affordable Care Act, 42 U.S.C. 18023*—(1) *Applicability.* (i) The Department is required to comply with paragraph (f)(2)(i) of this section and § 88.6 of this part.

(ii) Qualified health plans, as defined under 42 U.S.C. 18021, offered through any Exchange created under the Patient Protection and Affordable Care Act, are required to comply with paragraphs (f)(2)(i) and (ii) of this section and §§ 88.4 and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Pursuant to 42 U.S.C. 18023(b)(1)(A)(i), entities to which this paragraph (f)(2)(i) applies shall not construe anything in Title I of the Patient Protection and Affordable Care Act (or any amendment made by Title I of the Patient Protection and Affordable Care Act) to require a qualified health plan to provide coverage of abortion or abortion-related services as described in 42 U.S.C. 18023(b)(1)(B)(i) or (ii) as part of its essential health benefits for any plan year.

(ii) Pursuant to 42 U.S.C. 18023(b)(4), entities to which this paragraph (f)(2)(ii) applies shall not discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.

(g) *Section 1411 of the Affordable Care Act, 42 U.S.C. 18081*—(1) *Applicability.* The Department shall comply with paragraph (g)(2) of this section and § 88.6 of this part.

(2) *Requirement.* The Department shall provide a certification documenting a religious exemption from the individual responsibility requirement and penalty under the Patient Protection and Affordable Care Act and shall coordinate with State Health Benefit Exchanges in the implementing of the certification requirements of 42 U.S.C. 18031(d)(4)(H)(ii) where applicable to:

(i) Any applicant for such a certificate for any month who provides information demonstrating that the applicant:

(A) Is an adherent of religious tenets or teachings by reason of which he is conscientiously opposed to acceptance of the benefits of any private or public insurance which makes payments in the event of death, disability, old-age, or retirement or makes payments toward the cost of, or provides services for, medical care (including the benefits of any insurance system established by the Social Security Act), or

(B) Is an adherent of religious tenets or teachings that are not described in paragraph (g)(2)(i)(A) of this section, who relies solely on a religious method of healing, and for whom the acceptance of medical health services would be inconsistent with the religious beliefs of the individual, and the application for the certificate includes an attestation that the individual has not received medical health services during the preceding taxable year.

(*1*) For purposes of this paragraph (g)(2)(i)(B), ''medical health services'' does not include routine dental, vision and hearing services, midwifery services, vaccinations, necessary medical services provided to children, services required by law or by a third party, and such other services as the Secretary may provide in implementing section 1311(d)(4)(H) of the Patient Protection and Affordable Care Act;

and

(ii) Any applicant for such a certificate for any month who provides information demonstrating that the applicant is a member of a ''health care sharing ministry,'' as defined in 26 U.S.C. 5000A(d)(2)(B)(ii), for the month.

(h) *Counseling and referral provisions of 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B)*—(1) *Applicability.* (i) The Department is required to comply with paragraphs (h)(2)(i) and (ii) of this section and § 88.6 of this part.

(ii) Any State agency that administers a Medicaid program is required to comply with paragraph (h)(2)(ii) of this section and §§ 88.4 and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Pursuant to 42 U.S.C. 1395w–22(j)(3)(B), entities to which this paragraph (h)(2)(i) applies shall not construe 42 U.S.C. 1395w–22(j)(3)(A) or 42 CFR 422.206(a) to require a Medicare Advantage organization to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization offering the plan:

(A) Objects to the provision of such service on moral or religious grounds, and

(B) In the manner and through the written instrumentalities such organization deems appropriate, makes

available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization adopts a change in policy regarding such a counseling or referral service.

(ii) Pursuant to 42 U.S.C. 1396u–2(b)(3)(B), entities to which this paragraph (h)(2)(ii) applies shall not construe 42 U.S.C. 1396u–2(b)(3)(A) or 42 CFR 438.102(a)(1) to require a Medicaid managed care organization to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization:

(A) Objects to the provision of such service on moral or religious grounds, and

(B) In the manner and through the written instrumentalities such organization deems appropriate, makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization adopts a change in policy regarding such a counseling or referral service.

(i) *Advance Directives, 42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406*—(1) *Applicability.* (i) The Department is required to comply with paragraph (i)(2) of this section and § 88.6 of this part with respect to the Medicare and Medicaid programs.

(ii) Any State agency that administers a Medicaid program is required to comply with paragraph (i)(2) of this section and §§ 88.4 and 88.6 of this part with respect to its Medicaid program.

(2) *Prohibitions.* The entities to which this paragraph (i)(2) applies shall not:

(i) Construe 42 U.S.C. 1395cc(f) or 1396a(w)(3) to require any provider or organization, or any employee of such a provider or organization, to inform or counsel any individual regarding any right to obtain an item or service furnished for the purpose of causing, or the purpose of assisting in causing, the death of the individual, such as by assisted suicide, euthanasia, or mercy killing; or to apply to or affect any requirement with respect to a portion of an advance directive that directs the purposeful causing of, or the purposeful assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing; or

(ii) Construe 42 U.S.C. 1396a to prohibit the application of a State law which allows for an objection on the basis of conscience for any health care provider or any agent of such provider which as a matter of conscience cannot implement an advance directive.

(j) *Global Health Programs, 22 U.S.C. 7631(d)*—(1) *Applicability.* (i) The Department is required to comply with paragraph (j)(2) of this section and § 88.6 of this part.

(ii) Any entity that is authorized by statute, regulation, or agreement to obligate Federal financial assistance under section 104A of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2), under Chapter 83 of Title 22 of the U.S. Code or under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, to the extent such Federal financial assistance is administered by the Secretary, is required to comply with paragraph (j)(2) of this section and §§ 88.4 and 88.6 of this part.

(2) *Prohibitions.* The entities to which this paragraph (j)(2) applies shall not:

(i) Require an organization, including a faith-based organization, that is otherwise eligible to receive assistance under section 104A of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2), under Chapter 83 of Title 22 of the U.S. Code, or under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, to the extent such assistance is administered by the Secretary, for HIV/AIDS prevention, treatment, or care to, as a condition of such assistance:

(A) Endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or

(B) 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.

(ii) Discriminate against an organization, including a faith-based organization, that is otherwise eligible to receive assistance under section 104A of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2), under Chapter 83 of Title 22 of the U.S. Code, or under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, to the extent such assistance is administered by the Secretary, for HIV/AIDS prevention, treatment, or care, in the solicitation or issuance of grants, contracts, or cooperative agreements under such provisions of law for refusing to meet any requirement described in paragraph (j)(2)(i) of this section.

(k) *The Helms, Biden, 1978, and 1985 Amendments, 22 U.S.C. 2151b(f); see, e.g., Consolidated Appropriations Act, 2019, Public Law 116–6, Div. F, sec. 7018*—(1) *Applicability.* (i) The Department is required to comply with paragraph (k)(2)(i) of this section and § 88.6 of this part.

(ii) Any entity that is authorized by statute, regulation, or agreement to obligate or expend Federal financial assistance under part I of the Foreign Assistance Act of 1961, as amended (22 U.S.C. 2151b–2), to the extent administered by the Secretary, is required to comply with paragraph (k)(2)(i) of this section and §§ 88.4 and 88.6 of this part.

(iii) Any entity that receives Federal financial assistance under part I of the Foreign Assistance Act of 1961, as amended (22 U.S.C. 2151b–2), to the extent administered by the Secretary, is required to comply with paragraph (k)(2)(ii) of this section and §§ 88.4 and 88.6 of this part.

(2) *Prohibitions.* (i) The entities to which this paragraph (k)(2)(i) applies shall not:

(A) Permit Federal financial assistance identified in paragraph (k)(1)(ii) of this section to be used in a manner that would violate provisions in paragraphs (k)(2)(ii)(A)(*1*) through (*5*) of this section related to abortions and involuntary sterilizations.

(B) Obligate or expend Federal financial assistance under an appropriations act that contains the 1985 Amendment and identified in paragraph (k)(1)(ii) of this section for any country or organization if the President certifies that the use of these funds by any such country or organization would violate provisions in paragraphs (k)(2)(ii)(A)(*1*) through (*5*) of this section related to abortions and involuntary sterilizations.

(ii) The entities to which this paragraph (k)(2)(ii) applies shall not:

(A) Use such Federal financial assistance identified in paragraph (k)(1)(iii) of this section to:

(*1*) Pay for the performance of abortions as a method of family planning;

(*2*) Motivate or coerce any person to practice abortions;

(*3*) Pay for the performance of involuntary sterilizations as a method of family planning;

(*4*) Coerce or provide any financial incentive to any person to undergo sterilizations; or

(*5*) Pay for any biomedical research that relates in whole or in part, to methods of, or the performance of, abortions or involuntary sterilization as a means of family planning.

(B) Obligate or expend Federal financial assistance under an appropriations act that contains the 1985 Amendment and identified in paragraph (k)(1)(iii) of this section for

any country or organization if the President certifies that the use of these funds by any such country or organization would violate provisions in paragraphs (k)(2)(ii)(A)(*1*) through (*5*) of this section related to abortions and involuntary sterilizations.

(l) *Newborn and Infant Hearing Loss Screening, 42 U.S.C. 280g–1(d)*—(1) *Applicability.* The Department is required to comply with paragraph (l)(2) of this section and § 88.6 of this part.

(2) *Requirement.* The Department shall not construe 42 U.S.C. 280g–1 to preempt or prohibit any State law that does not require the screening for hearing loss of children of parents who object to the screening on the grounds that it conflicts with the parents' religious beliefs.

(m) *Medical Screening, Examination, Diagnosis, Treatment, or Other Health Care or Services, 42 U.S.C. 1396f*—(1) *Applicability.* The Department is required to comply with paragraph (m)(2) of this section and § 88.6 of this part.

(2) *Requirements and prohibitions.* The Department shall not construe anything in 42 U.S.C. 1396 *et seq.* to require a State agency that administers a State Medicaid Plan to compel any person to undergo any medical screening, examination, diagnosis, or treatment or to accept any other health care or services provided under such plan for any purpose (other than for the purpose of discovering and preventing the spread of infection or contagious disease or for the purpose of protecting environmental health), if such person objects (or, in case such person is a child, his parent or guardian objects) thereto on religious grounds.

(n) *Occupational Illness Examinations and Tests, 29 U.S.C. 669(a)(5)*—(1) *Applicability.* (i) The Department is required to comply with paragraph (n)(2) of this section and § 88.6 of this part.

(ii) Any recipient of grants or contracts under 29 U.S.C. 669, to the extent administered by the Secretary, is required to comply with paragraph (n)(2) of this section and §§ 88.4 and 88.6 of this part.

(2) *Requirements.* Entities to which this paragraph (n)(2) applies shall not deem any provision of 29 U.S.C. 651 *et seq.* to authorize or require medical examination, immunization, or treatment, as provided under 29 U.S.C. 669, for those who object thereto on religious grounds, except where such is necessary for the protection of the health or safety of others.

(o) *Vaccination, 42 U.S.C. 1396s(c)(2)(B)(ii)*—(1) *Applicability.* (i) The Department is required to comply with paragraph (o)(2) of this section and § 88.6 of this part.

(ii) Any State agency that administers a pediatric vaccine distribution program under 42 U.S.C. 1396s is required to comply with paragraph (o)(2) of this section and §§ 88.4 and 88.6 of this part.

(2) *Requirement.* The entities to which this paragraph (o)(2) applies shall ensure that, under any State-administered pediatric vaccine distribution program under 42 U.S.C. 1396s, the provider agreement executed by any program-registered provider, as defined under 42 U.S.C. 1396s(c)(1), includes the requirement that the program-registered provider will provide pediatric vaccines in compliance with all applicable State law relating to any religious or other exemption. Such State law may include State statutory, regulatory, or constitutional protections for conscience and religious freedom, where applicable.

(p) *Specific Assessment, Prevention and Treatment Services, 42 U.S.C. 290bb–36(f), 5106i(a)*—(1) *Applicability.* (i) The Department is required to comply with paragraphs (p)(2)(i) through (iii) of this section and § 88.6 of this part.

(ii) Any State, political subdivision, public organization, private nonprofit organization, institution of higher education, or tribal organization actively involved with the State-sponsored statewide or tribal youth suicide early intervention and prevention strategy, designated by a State to develop or direct the State-sponsored Statewide youth suicide early intervention and prevention strategy under 42 U.S.C. 290bb–36 and that receives a grant or cooperative agreement thereunder, is required to comply with paragraph (p)(2)(iii) of this section and §§ 88.4 and 88.6 of this part.

(iii) Any federally recognized Indian tribe or tribal organization (as defined in the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5301 *et seq.*)) or an urban Indian organization (as defined in the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*)) that is actively involved in the development and continuation of a tribal youth suicide early intervention and prevention strategy under 42 U.S.C. 290bb–36 and that receives a grant or cooperative agreement thereunder is required to comply with paragraph (p)(2)(iii) of this section.

(iv) Any entity that receives funds under 42 U.S.C. chapter 67, subchapters I or III is required to comply with paragraphs (p)(2)(i) and (ii) of this section and §§ 88.4 and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Entities to which this paragraph (p)(2)(i) applies shall not construe the receipt of funds under or anything in 42 U.S.C. chapter 67, subchapters I or III as establishing any Federal requirement that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of the parent or legal guardian.

(ii) Entities to which this paragraph (p)(2)(ii) applies shall not construe the receipt of funds under or anything in 42 U.S.C. chapter 67, subchapters I or III as requiring a State to find, or prohibiting a State from finding, 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 the religious beliefs of the parent or legal guardian.

(iii) Entities to which this paragraph (p)(2)(iii) applies shall not construe anything in 42 U.S.C. 290bb–36 to require suicide assessment, early intervention, or treatment services for youth whose parents or legal guardians object based on the parents' or legal guardians' religious beliefs or moral objections.

(q) *Religious nonmedical health care, 42 U.S.C. 1320a–1(h), 1320c–11, 1395i–5, 1395x(e), 1395x(y)(1), 1396a(a), and 1397j–1(b)*—(1) *Applicability.* (i) The Department is required to comply with paragraphs (q)(2)(i) through (iv) of this section and § 88.6 of this part.

(ii) Any State agency that makes an agreement with the Secretary pursuant to 42 U.S.C. 1320a–1(b) is required to comply with paragraph (q)(2)(i) of this section and §§ 88.4 and 88.6 of this part.

(iii) Any entity receiving Federal financial assistance from participating in Medicare is required to comply with paragraphs (q)(2)(ii) of this section and §§ 88.4 and 88.6 of this part.

(iv) Any entity, including a State, receiving Federal financial assistance from participating in Medicaid, including any entity receiving Federal financial assistance through CHIP that is used to expand Medicaid, is required to comply with paragraphs (q)(2)(iii) of this section and §§ 88.4 and 88.6 of this part.

(v) Any entity, including a State or local government or subdivision thereof, receiving Federal financial assistance under subtitle B of Title XX of the Social Security Act (42 U.S.C. 1397j–1397m–5) is required to comply with paragraph (q)(2)(iv) of this section and §§ 88.4 and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) The entities to which this paragraph (q)(2)(i) applies shall not apply the provisions of 42 U.S.C. 1320a–1 to a

religious nonmedical health care institution as defined in 42 U.S.C. 1395x(ss)(1).

(ii) With respect to a religious nonmedical health care institution as defined in 42 U.S.C. 1395x(ss)(1), the entities to which this paragraph (q)(2)(ii) applies shall not:

(A) Fail or refuse to make a payment under part A of subchapter XVIII of chapter 7 of Title 42 of the U.S. Code for inpatient hospital services, post-hospital extended care services, or home health services furnished to an individual by a religious nonmedical health care institution that is a hospital as defined in 42 U.S.C. 1395x(e), a skilled nursing facility as defined in 42 U.S.C. 1395x(y), or a home health agency as defined in 42 U.S.C. 1395x(aaa), respectively, if the condition under 42 U.S.C. 1395i–5(a)(2) is satisfied and an individual makes an election pursuant to 1395i–5(b) that:

(*1*) Such individual is conscientiously opposed to acceptance of medical care or treatment other than medical care or treatment (including medical and other health services) that is:

(*i*) Received involuntarily, or

(*ii*) Required under Federal or State law or law of a political subdivision of a State; and

(*2*) Acceptance of such medical treatment would be inconsistent with such individual's sincere religious beliefs, or

(B) In administering 42 U.S.C. 1395i–5 or 1395x(ss)(1):

(*1*) Require any patient of a religious nonmedical health care institution to undergo medical screening, examination, diagnosis, prognosis, or treatment or to accept any other medical health care service, if such patient (or legal representative of the patient) objects to such service on religious grounds, or

(*2*) Subject a religious nonmedical health care institution or its personnel to any medical supervision, regulation, or control, insofar as such supervision, regulation, or control would be contrary to the religious beliefs observed by the institution or such personnel, or

(C) Subject religious nonmedical health care institution to the provisions of part B of subchapter XI of Chapter 7 of Title 42 of the U.S. Code.

(iii) Pursuant to 42 U.S.C. 1396a(a), the entities to which this paragraph (q)(2)(iii) applies shall not fail or refuse to exempt a religious nonmedical health care institution from the Medicaid requirements to:

(A) Meet State standards described in 42 U.S.C. 1396a(a)(9)(A);

(B) Be evaluated under 42 U.S.C. 1396a(a)(33), on the appropriateness and quality of care and services;

(C) Undergo a regular program, under 42 U.S.C. 1396(a)(31), of independent professional review, including medical evaluation, of services in an intermediate care facility for persons with mental disabilities; and

(D) Meet the requirements of 42 U.S.C. 1396(b)(i)(4) to establish a utilization review plan consistent with, or superior to, the utilization review plan criteria under 42 U.S.C. 1395x(k) for Medicare.

(iv) Pursuant to 42 U.S.C. 1397j–1(b), the entities to which this paragraph (q)(2)(iv) applies shall not construe subtitle B of Title XX of the Social Security Act (42 U.S.C. 1397j–1397m–5) to interfere with or abridge an elder's right to practice his or her religion through reliance on prayer alone for healing when this choice:

(A) Is contemporaneously expressed, either orally or in writing, with respect to a specific illness or injury which the elder has at the time of the decision by an elder who is competent at the time of the decision;

(B) Is previously set forth in a living will, health care proxy, or other advance directive document that is validly executed and applied under State law; or

(C) May be unambiguously deduced from the elder's life history.

§ 88.4 Assurance and certification of compliance requirements.

(a) *In general*—(1) *Assurance.* Except for an application or recipient to which paragraph (c) of this section applies, every application for Federal financial assistance or Federal funds from the Department to which § 88.3 of this part applies shall, as a condition of the approval, renewal, or extension of any Federal financial assistance or Federal funds from the Department pursuant to the application, provide, contain, or be accompanied by an assurance that the applicant or recipient will comply with applicable Federal conscience and anti-discrimination laws and this part.

(2) *Certification.* Except for an application or recipient to which paragraph (c) of this section applies, every application for Federal financial assistance or Federal funds from the Department to which § 88.3 of this part applies, shall, as a condition of the approval, renewal, or extension of any Federal financial assistance or Federal funds from the Department pursuant to the application, provide, contain, or be accompanied by, a certification that the applicant or recipient will comply with applicable Federal conscience and anti-discrimination laws and this part.

(b) *Specific requirements*—(1) *Timing.* Entities who are already recipients as of the effective date of this part or any applicants shall submit the assurance required in paragraph (a)(1) of this section and the certification required in paragraph (a)(2) of this section as a condition of any application or reapplication for funds to which this part applies, through any instrument or as a condition of an amendment or modification of the instrument that extends the term of such instrument or adds additional funds to it. Submission may be required more frequently if:

(i) The applicant or recipient fails to meet a requirement of this part, or

(ii) OCR or the relevant Department component has reason to suspect or cause to investigate the possibility of such failure.

(2) *Form and manner.* Applicants or recipients shall submit the assurance required in paragraph (a)(1) of this section and the certification required in paragraph (a)(2) of this section in the form and manner that OCR, in coordination with the relevant Department component, specifies, or shall submit them in a separate writing signed by the applicant's or recipient's officer or other person authorized to bind the applicant or recipient.

(3) *Duration of obligation.* The assurance required in paragraph (a)(1) of this section and the certification required in paragraph (a)(2) of this section will obligate the recipient for the period during which the Department extends Federal financial assistance or Federal funds from the Department to a recipient.

(4) *Compliance requirement.* Submission of an assurance or certification required under this section will not relieve a recipient of the obligation to take and complete any action necessary to come into compliance with Federal conscience and anti-discrimination laws and this part prior to, at the time of, or subsequent to, the submission of such assurance or certification.

(5) *Condition of continued receipt.* Provision of a compliant assurance and certification shall constitute a condition of continued receipt of Federal financial assistance or Federal funds from the Department and is binding upon the applicant or recipient, its successors, assigns, or transferees for the period during which such Federal financial assistance or Federal funds from the Department are provided.

(6) *Assurances and certifications in applications.* An applicant or recipient may incorporate the assurances and

certifications by reference in subsequent applications to the Department or Department component if prior assurances or certifications are initially provided in the same fiscal or calendar year, as applicable.

(7) *Enforcement of assurances and certifications.* The Department, Department components, and OCR shall have the right to seek enforcement of the assurances and certifications required in this section.

(8) *Remedies for failure to make assurances and certifications.* If an applicant or recipient fails or refuses to furnish an assurance or certification required under this section, OCR, in coordination with the relevant Department component, may effect compliance by any of the mechanisms provided in § 88.7.

(c) *Exceptions.* The following persons or entities shall not be required to comply with paragraphs (a)(1) and (2) of this section, provided that such persons or entities are not recipients of Federal financial assistance or other Federal funds from the Department through another instrument, program, or mechanism, other than those set forth in paragraphs (c)(1) through (4) of this section:

(1) A physician, as defined in 42 U.S.C. 1395x(r), physician office, pharmacist, pharmacy, or other health care practitioner participating in Part B of the Medicare program;

(2) A recipient of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration for Children and Families, the purpose of which is either solely financial assistance unrelated to health care or which is otherwise unrelated to health care provision, and which, in addition, does not involve—

(i) Medical or behavioral research;

(ii) Health care providers; or

(iii) Any significant likelihood of referral for the provision of health care;

(3) A recipient of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration on Community Living, the purpose of which is either solely financial assistance unrelated to health care or which is otherwise unrelated to health care provision, and which, in addition, does not involve—

(i) Medical or behavioral research;

(ii) Health care providers; or

(iii) Any significant likelihood of referral for the provision of health care.

(4) Indian Tribes and Tribal Organizations when contracting with the Indian Health Service under the Indian Self-Determination and Education Assistance Act.

§ 88.5 Notice of rights under Federal conscience and anti-discrimination laws.

(a) *In general.* In investigating a complaint or conducting a compliance review, OCR will consider an entity's voluntary posting of a notice of nondiscrimination as non-dispositive evidence of compliance with the applicable substantive provisions of this part, to the extent such notices are provided according to the provisions of this section and are relevant to the particular investigation or compliance review.

(b) *Placement of the notice text.* In evaluating the Department's or a recipient's compliance with this part, OCR will take into account whether, as applicable and appropriate, the Department or recipient has provided the notice under this section:

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

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

(3) In a personnel manual or other substantially similar document for members of the Department or recipient's workforce;

(4) In applications to the Department or recipient for inclusion in the workforce or for participation in a service, benefit, or other program, including for training or study; and

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

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

(c) *Content of the notice text.* The recipient and 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 laws that apply to it under this rule.

(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 non-discrimination notices).

§ 88.6 Compliance requirements.

(a) *In general.* The Department and each recipient has primary responsibility to ensure that it is in compliance with Federal conscience and anti-discrimination laws and this part, and shall take steps to eliminate any violations of the Federal conscience and anti-discrimination laws and this part. If a sub-recipient is found to have violated the Federal conscience and anti-discrimination laws, the recipient from whom the sub-recipient received funds may be subject to the imposition of funding restrictions or any appropriate remedies available under this part, depending on the facts and circumstances.

(b) *Records and information.* The Department, each recipient, and each sub-recipient shall maintain complete and accurate records evidencing compliance with Federal conscience and anti-discrimination laws and this part, and afford OCR, upon request, reasonable access to such records and information in a timely manner and to the extent OCR finds necessary to determine compliance with the Federal conscience and anti-discrimination laws and this part. Such records:

(1) Shall be maintained for a period of three years from the date the record was created or obtained by the recipient or sub-recipient;

(2) Shall contain any information maintained by the recipient or sub-recipient that pertains to discrimination on the basis of religious belief or moral conviction, including, without limitation, any complaints; statements, policies, or notices concerning discrimination on the basis of religious belief or moral conviction; procedures for accommodating employees' or other protected individuals' religious beliefs or moral convictions; and records of requests for such religious or moral accommodation and the recipient or sub-recipient's response to such requests; and

(3) May be maintained in any form and manner that affords OCR with reasonable access to them in a timely manner.

(c) *Cooperation.* The Department, each recipient, and each sub-recipient shall cooperate with any compliance review, investigation, interview, or other part of OCR's enforcement process, which may include production of documents, participation in interviews, response to data requests, and making available of premises for inspection where relevant. Failure to cooperate may result in an OCR referral to the Department of Justice, in coordination with the Department's Office of the General Counsel, for

further enforcement in Federal court or otherwise. Each recipient or sub-recipient shall permit access by OCR during normal business hours to such of its books, records, accounts, and other sources of information, as well as its facilities, as may be pertinent to ascertain compliance with this part. Asserted considerations of privacy or confidentiality may not operate to bar OCR from evaluating or seeking to enforce compliance with this part. Information of a confidential nature obtained in connection with compliance reviews, investigations, or other enforcement activities shall not be disclosed except as required in formal enforcement proceedings or as otherwise required by law.

(d) *Reporting requirement.* If a recipient or sub-recipient is subject to a determination by OCR of noncompliance with this part, the recipient or sub-recipient must, in any application for new or renewed Federal financial assistance or Departmental funding in the three years following such determination, disclose the existence of the determination of noncompliance. This includes a requirement that recipients disclose any OCR determinations made against their sub-recipients.

(e) *Intimidating or retaliatory acts prohibited.* Neither the Department nor any recipient or sub-recipient shall intimidate, threaten, coerce, or discriminate against any entity for the purpose of interfering with any right or privilege under the Federal conscience and anti-discrimination laws or this part, or because such entity has made a complaint or participated in any manner in an investigation or review under the Federal conscience and anti-discrimination laws or this part.

§ 88.7 Enforcement authority.

(a) *In general.* OCR has been delegated the authority to facilitate and coordinate the Department's enforcement of the Federal conscience and anti-discrimination laws, which includes the authority to:

(1) Receive and handle complaints;

(2) Initiate compliance reviews;

(3) Conduct investigations;

(4) Coordinate compliance within the Department;

(5) Seek voluntary resolutions of complaints;

(6) In coordination with the relevant component or components of the Department and the Office of the General Counsel, make enforcement referrals to the Department of Justice;

(7) In coordination with the relevant Departmental funding component, utilize existing regulations for involuntary enforcement, such as those that apply to grants, contracts, or CMS programs; and

(8) 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.

(b) *Complaints.* Any entity, whether individually, as a member of a class, on behalf of others, or on behalf of an entity, may file a complaint with OCR alleging any potential violation of Federal conscience and anti-discrimination laws or this part. 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 conscience and anti-discrimination laws or this part have been potentially violated.

(c) *Compliance reviews.* OCR may conduct compliance reviews or use other similar procedures as necessary to permit OCR to investigate and review the practices of the Department, Department components, recipients, and sub-recipients to determine whether they are complying with Federal conscience and anti-discrimination laws and this part. OCR may initiate a compliance review of an entity subject to this part based on information from a complaint or other source that causes OCR to suspect non-compliance by such entity with this part or the laws implemented by this part.

(d) *Investigations.* OCR shall make a prompt investigation, whenever a compliance review, report, complaint, or any other information found by OCR indicates a threatened, potential, or actual failure to comply with Federal conscience and anti-discrimination laws or this part. The investigation should include, where appropriate, 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 shall 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.

(e) *Failure to respond.* Absent good cause, the failure of an entity that is subject to this part to respond to a request for information or to a data or document request within 45 days of OCR's request shall constitute a violation of this part.

(f) *Related administrative or judicial proceeding.* Consistent with other applicable Federal laws, testimony and other evidence obtained in an investigation or compliance review conducted under this part may be used by the Department for, and offered into evidence in, any administrative or judicial proceeding related to this part.

(g) *Supervision and coordination.* If as a result of an investigation, compliance review, or other enforcement activity, OCR determines that a Department component appears to be in noncompliance with its responsibilities under Federal conscience and anti-discrimination laws or this part, OCR will undertake appropriate action with the component to assure compliance. In the event that OCR and the Department component are unable to agree on a resolution of any particular matter, the matter shall be submitted to the Secretary for resolution. OCR may from time to time request the assistance of officials of the Department in carrying out responsibilities in connection with the enforcement of Federal conscience and anti-discrimination laws and this part, including the achievement of effective coordination and maximum uniformity within the Department.

(h) *Referral to the Department of Justice.* If as a result of an investigation, compliance review, or other enforcement activity, OCR determines that a recipient or sub-recipient is not in compliance with the Federal conscience and anti-discrimination laws or this part, OCR may, in coordination with the relevant Department component and the Office of the General Counsel, make referrals to the Department of Justice, for further enforcement in Federal court or otherwise. OCR may also make referrals to the Department of Justice, in coordination with the Office of the General Counsel, concerning potential violations of 18 U.S.C. 1001 or 42 U.S.C. 300a–8 for enforcement or other appropriate action.

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

(2) If an investigation or compliance review indicates a failure to comply with Federal conscience and anti-discrimination laws or this part, OCR will so inform the relevant parties and the matter will be resolved by informal means whenever possible. Attempts to resolve matters informally shall not preclude OCR from simultaneously

pursuing any action described in paragraphs (a)(5) through (7) of this section.

(3) If OCR determines that there is a failure to comply with Federal conscience and anti-discrimination laws or this part, compliance with these laws and this part may be effected by the following actions, taken in coordination with the relevant Department component, and pursuant to statutes and regulations which govern the administration of contracts (*e.g.,* Federal Acquisition Regulation), grants (*e.g.,* 45 CFR part 75) and CMS funding arrangements (*e.g.,* the Social Security Act):

(i) Temporarily withholding Federal financial assistance or other Federal funds, in whole or in part, pending correction of the deficiency;

(ii) Denying use of Federal financial assistance or other Federal funds from the Department, including any applicable matching credit, in whole or in part;

(iii) Wholly or partly suspending award activities;

(iv) Terminating Federal financial assistance or other Federal funds from the Department, in whole or in part;

(v) Denying or withholding, in whole or in part, new Federal financial assistance or other Federal funds from the Department administered by or through the Secretary for which an application or approval is required, including renewal or continuation of existing programs or activities or authorization of new activities;

(vi) In coordination with the Office of the General Counsel, referring the matter to the Attorney General for proceedings to enforce any rights of the United States, or obligations of the recipient or sub-recipient, under Federal law or this part; and

(vii) Taking any other remedies that may be legally available.

(j) *Noncompliance with § 88.4.* If a recipient of Federal financial assistance or applicant therefor fails or refuses to furnish an assurance or certification required under § 88.4 or otherwise fails or refuses to comply with a requirement imposed by or pursuant to that section, OCR, in coordination with the relevant Department component, may effect compliance by any of the remedies provided in paragraph (i) of this section. The Department shall not be required to provide assistance in such a case during the pendency of the administrative proceedings brought under such paragraph.

§ 88.8 Relationship to other laws.

Nothing in this part shall be construed to preempt any Federal, State, or local law that is equally or more protective of religious freedom and moral convictions. Nothing in this part shall be construed to narrow the meaning or application of any State or Federal law protecting free exercise of religious beliefs or moral convictions.

§ 88.9 Rule of construction.

This part shall be construed in favor of a broad protection of the free exercise of religious beliefs and moral convictions, to the maximum extent permitted by the Constitution and the terms of the Federal conscience and anti-discrimination laws.

§ 88.10 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 Anti-Discrimination Laws

[Name of recipient, the Department, or Department component] complies with applicable Federal conscience and anti-discrimination laws prohibiting exclusion, adverse treatment, coercion, or other discrimination against individuals or entities on the basis of their religious beliefs or moral convictions. You may have the right under Federal law to decline to perform, assist in the performance of, refer for, undergo, or pay for certain health care-related treatments, research, or services (such as abortion or assisted suicide, among others) that violate your conscience, religious beliefs, or moral convictions.

If you believe that [Name of recipient, the Department, or Department component] has failed to accommodate your conscientious, religious, or moral objection, or has discriminated against you on those grounds, you can file a conscience and religious freedom 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://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 and anti-discrimination laws are available at *http://www.hhs.gov/conscience.*

Dated: May 2, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–09667 Filed 5–20–19; 8:45 am]

BILLING CODE 4153–01–P

EXHIBIT B

TO: Interested Parties

FROM: Kellyanne Conway, President & CEO
the polling company™, inc./WomanTrend

DATE: April 8, 2009

RE: Key Findings on Conscience Rights Polling

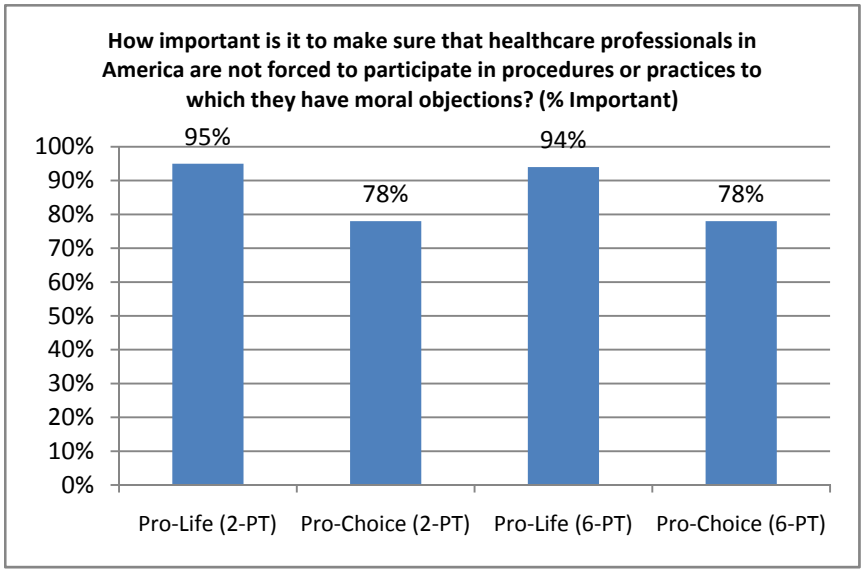
On behalf of the Christian Medical & Dental Association (CMDA), the polling company™, inc./ WomanTrend *conducted a nationwide survey of 800 American adults and an online survey of members of faith-based medical organizations. Full statements of methodology can be found at the conclusion of this document.*

Americans of All Demographic Characteristics and Political Stripes Seek a Shared a Set of Values with their Healthcare Providers.

Fully 88% of American adults surveyed said it is either "very" or "somewhat" important to them that they enjoy a similar set of morals as their doctors, nurses, and other healthcare providers. Intensity was strong, as 63% described this as "very" important while at the other end of the spectrum, just 6% said it is "not at all important," a ratio of more than 10-to-1.

Healthcare Providers' Conscience Protections Viewed as an Inalienable Right

A sizable 87% of American adults surveyed believed it is important to ***"make sure that healthcare professionals in America are not forced to participate in procedures and practices to which they have moral objections."*** Support for this protection garnered considerable intensity as well, with 65% of respondents considering it very essential. Majorities of men, women, and adults of all ages, races, regions, and political affiliations considered it critical to defend the rights of healthcare providers to refuse to perform certain procedures on moral grounds. Also joining with these majorities were 95% of respondents who self-identified as "pro-life," 78% who considered themselves "pro-choice," 94% who voted for Senator McCain in November 2008 and 80% who cast a ballot for (now) President Obama.



Americans Oppose The *Principle* of Forcing Healthcare Providers to Act Against Their Consciences...

A majority (57%) of American adults opposed regulations ***"that require medical professionals to perform or provide procedures to which they have moral or ethical objections."*** In contrast, 38% favored such rules. The potency of opposition was twice that of the supporters: 40% strongly objected to the laws while just 19% strongly backed them. Politically, a majority of conservative Republicans (69%), moderate Republicans (69%), and conservative Democrats (59%), as well as the plurality of liberal/moderate Democrats (49%), joining together to reject policies to that require doctors and nurses to act against their personal moral code or value set.

…Support Laws That Protect Them From Doing So…
Without any names or political parties being mentioned, respondents were provided with a short description of the new conscience protection law and its recent inception: ***"Just two months ago, a federal law known as 'conscience protection' went into effect after reports of doctors being discriminated against for declining to perform abortions. It protects doctors and other medical professionals who work at institutions that receive federal money from performing medical procedures to which they object on moral or religious grounds."***

After hearing this short description, support for this new law outpaced opposition by a margin of more than 2-to-1 (63% vs. 28%). Intensity favored the law, with 42% strongly backing it and 19% strongly rejecting it. Endorsements for the rule spanned demographic and political spectra, with majorities in all cohorts offering their support. **In fact, even 56% of adults who said they voted for President Obama last fall and 60% of respondents who self-identified as "pro-choice" said they favor this two-month old conscience protection rule.**

… And Oppose Any Efforts to Remove Such Laws.
Next, respondents were asked to react to the proposed rescission of the conscience protection law: *"Earlier this month, officials from the U.S. Department of Health and Human Services introduced a rule change that would effectively eliminate the two-month-old conscience protection. This could mean that doctors and other medical professionals could be coerced to participate in medical procedures to which they object on moral or religious grounds."*

Opposition to revocation of the conscience protection law outpaced support by a margin of more than 2-to-1 (62% vs. 30%). As was the case in the previous question, intensity favored retention of the law (44% strongly opposing rescission versus 17% strongly supporting it). Again, there was consistent demographic alignment, as a majority of men, women, and adults of all ages, races, incomes, regions, and geographic types stood together to reject removal of the law. And, there was cohesiveness across political lines, as 52% of self-identified Democrats, 67% of self-identified Independents, and 73% of self-identified Republicans, as well as 50% of liberals, 65% of moderates, and 69% of conservatives also opposed nullification. A narrow majority (53%) of people who considered themselves to be "pro-choice" opposed rescission. Notably, a small number (7%) were ambivalent or undecided, saying they did not know or lacked the information to render an opinion one way or the other.

Rescission of Conscience Protection Viewed by a Majority as Government Insinuating Itself into the Patient-Physician Relationship.
When asked whether rescission of the rule and a resulting forced participation of doctors in abortions is a sign of more, less, or the right amount of government involvement in medicine, the majority (58%) said it exemplified excessive participation. Just 18% thought it reflected the ideal role and 11% believed it was still too minimal.

The Political Currency Calculus: Voters Will Punish Politicians Who Fail to Defend Healthcare Providers' Rights to Refuse to Violate Their Conscience in the Name of Medicine.
Finally, when asked how they would view their Member of Congress if he or she voted ***against*** conscience protection rights, 54% indicated they would be less likely to back their United States Representative. In fact, 36% said they would be *much less likely*, a figure three times greater than the 11% who said they would be *much more likely*. Furthermore, 43% of respondents who said they voted for President Obama indicated that they would be less inclined to back a Member of Congress if he or she opposed conscience protection rights.

Rescission of Conscience Protections May be a Priority for Obama Administration, but not for his Constituents.
When presented with a list of 13 areas for the sitting Congress and current President to address and allowed to select multiple answers, only 10% of American adults preferred that Washington devote its time and energy to abortion policy. In fact, the issue of abortion was ranked 9th out of 13 among the issues offered to survey respondents. Moreover, adults desirous of action on abortion policy were six times more likely to be "pro-life" than "pro-choice" (19% vs. 3%). In contrast, no less than 68% of any demographic or political cohort studied said that President Obama and Congressional leaders should focus on the economy and jobs.

Real Effects Likely to Be Felt in Medical Community If Doctors Forced to Act Against Their Moral and Ethical Codes
In the survey of 2,865 members of faith-based organizations, doctors and other medical professionals voiced their concerns that serious consequences could occur if doctors are forced to participate in or perform practices to which they have moral or ethical objections. Nearly three-quarters (74%) believed that elimination of the conscience protection could result in "fewer doctors practicing medicine," 66% predicted "decreased access to healthcare providers, services, and/or facilities for patients in low-income areas," 64% surmised "decreased access to healthcare providers, services, and/or facilities for patients in rural areas," and 58% hypothesized "fewer hospitals providing services."

When asked how rescission of the conscience rule would affect them personally, fully 82% said it was either "very" or "somewhat" likely that they personally would limit the scope of their practice of medicine. This was true of 81% of medical professionals who practice mainly in rural areas and 86% who work full-time in serving poor and medically-underserved populations.

Conscience Protection Rule Fundamental and Necessary in the Medical Profession, According to Members of the Christian Medical & Dental Association, the Catholic Medical Association, and the Christian Pharmacists Fellowship International
Fully 97% of members who participated in the survey supported the two-month-old conscience protection clause and 96% objected to rescission of the rule.

The Department of Health and Human Services has asked whether the objectives of the conscience protection law can be achieved "through non-regulatory means, such as outreach and education." Nearly nine-in-ten (87%) members surveyed – those who are on the ground, in hospitals and clinics across the country – felt "outreach and education" alone were insufficient to accomplish the goal.

Ninety-two percent declared the codification of conscience protection to be necessary (83% "very" and 9% "somewhat") based on their knowledge of "discrimination in healthcare on the basis of conscience, religious, and moral values." Many respondents held this opinion due in part to their own personal experience. When asked to assess their educational experiences:

- 39% have "experience pressure from or discrimination by faculty or administrators based on [their] moral, ethical, or religious beliefs"
- 33% have "considered not pursuing a career in a particular medical specialty because of attitudes prevalent in that specialty that is not considered tolerant of [their] moral, ethical or religious beliefs."
- 23% have "experienced discrimination during the medical school or residency application and interview process because of [their] moral, ethical or religious beliefs."

And, when asked to assess their professional experiences:

- 32% have "been pressured to refer a patient for a procedure to which [they] had moral, ethical, or religious objections
- 26% have "been pressured to write a prescription for a medication to which [they] had moral, ethical, or religious objections
- 17% have "been pressured to participate in training for a procedure to which [they] had moral, ethical, or religious objections."
- 12% have "been pressured to perform a procedure to which you had moral, ethical, or religious objections."

STATEMENT OF METHODOLOGY

Nationwide Survey of Adults:
On behalf of the **Christian Medical & Dental Association,** the polling company™, inc./ WomanTrend conducted a nationwide survey of 800 American Adults (18+). The survey contained one screener question, 10 substantive questions, and 13 demographic inquiries. All substantive questions were closed-ended in nature.

The survey was fielded March 23-25, 2009 at a Computer-Assisted Telephone Interviewing (CATI) facility using live callers. The sample was drawn utilizing Random Digit Dial, a computer dialing technique that ensures that every household in the nation with a landline telephone has an equal chance of being called. Each respondent was screened to ensure he or she was 18 years of age.

Sampling controls were used to ensure that a proportional and representative number of people were interviewed from such demographic groups as age, race and ethnicity, and region according to the most recent figures available from the U.S. Census Bureau and voter registration and turnout figures. After data collection, weighting was used to ensure that the sample reflected the current population. This is a common and industry-accepted practice. Age, race, and gender were allowed four points of flexibility in pre-set quotas while three points of flexibility was permitted on region.

The overall margin of error for the survey is ± 3.5% at a 95% confidence interval, meaning that in 19 out of 20 cases, the data obtained would not differ by any more than 3.5 percentage points in either direction if the survey were repeated multiple times employing this methodology and sampling method. Margins of error for subgroups are higher.

Online Survey of Members of Faith-Based Medical Organizations:
On behalf of the **Christian Medical & Dental Association,** the polling company™, inc./ WomanTrend conducted an online survey of members of faith-based organizations. The Catholic Medical Association and Christian Pharmacists Fellowship International also invited their members to participate.

The survey was fielded March 31, 2009 to April 3, 2009 and was completed by 2,865 members of the Christian Medical and Dental Association (CMDA), 400 members of the Catholic Medical Association (CMA), 69 members of the Fellowship of Christian Physicians Assistants, 206 members of the Christian Pharmacists Fellowship International, and 8 members of Nurses Christian Fellowship. Respondents were allowed to select membership in multiple organizations.

Each respondent was provided with a unique hyperlink to take the survey, allowing no member to take the survey more than once and prohibiting respondents from passing the link to another individual after completing the survey.

This survey is intended to demonstrate the views and opinions of members surveyed. It is not intended to be representative of the entire medical profession nor of the entire membership rosters of these organizations. Respondents who participated in the survey were self-selecting.

EXHIBIT C

May 2011: National poll shows majority support healthcare conscience rights, conscience law

Highlights of *the polling company, inc*. Phone Survey of the American Public

On May 3, 2011, the Christian Medical Association and the Freedom2Care coalition released the results of a nationwide, scientific poll conducted April 29-May 1, 2011 by the polling company™, inc./ WomanTrend. Survey of 1000 American Adults, Field Dates: April 29-May 1, 2011, Margin of Error=±3.1.

1. **77%** of American adults surveyed said it is either "very" or "somewhat" important to them that "that healthcare professionals in the U.S. are **not forced to participate** in procedures or practices to which they have **moral objections**." **16%** said it is not important.

ALL		*PRO-CHOICE* (n=465)	*PRO-LIFE* (n=461)
77%	Total **important** (net)	68%	85%
52%	Very important	42%	64%
25%	Somewhat important	26%	21%
16%	Total **not important** (net)	24%	8%
8%	Not too important	11%	5%
8%	Not at all important	13%	3%
8%	Do not know/depends	8%	6%
1%	Refused	*	

2. **50%** of American adults surveyed "strongly" or "somewhat" support "a **law** under which federal agencies and other government bodies that receive federal funds could **not discriminate** against hospitals and health care professionals who **decline to participate in abortions**." **35%** opposed.

ALL		*PRO-CHOICE* (n=465)	*PRO-LIFE* (n=461)
50%	Total **support** (net)	45%	58%
29%	Strongly support	20%	40%
21%	Somewhat support	25%	18%
35%	Total **oppose** (net)	43%	32%
14%	Somewhat oppose	20%	10%
21%	Strongly oppose	23%	22%
7%	It depends/need more info.	7%	5%
7%	Do not know	6%	5%
1%	Refused	1%	1%

April, 2009: Two National Polls[1] Reveal Broad Support for Conscience Rights in Health Care

Highlights of *the polling company, inc.* Phone Survey of the American Public

39% Democrat • 33% Republican • 22% Independent

1. **88%** of American adults surveyed said it is either "very" or "somewhat" **important to them that they share a similar set of morals as their doctors**, nurses, and other healthcare providers.
2. **87%** of American adults surveyed believed it is important to "make sure that healthcare professionals in America are **not forced to participate** in procedures and practices to which they have moral objections."
3. Support for the conscience protection regulation (rule finalized Dec. 2008):
   - **63% support conscience protection regulation**
   - 28% oppose conscience protection regulation
4. Support for Obama administration proposal to eliminate the new conscience protection regulation:
   - 30% support Obama administration proposal
   - **62% oppose Obama administration proposal**
5. Likelihood of voting for current Member of Congress who supported eliminating the conscience rule:
   - 25% more likely to vote for Member who supported eliminating rule
   - **54% less likely to vote for Member who supported eliminating rule**
6. "In 2004 the Hyde-Weldon Amendment was passed. It ruled that taxpayer funds must not be used by governments and government-funded programs to discriminate against hospitals, health insurance plans, and healthcare professionals who decline to participate in abortions. Do you support or oppose this law?"
   - **58% support Hyde-Weldon Amendment**
   - 31% oppose Hyde-Weldon Amendment

Highlights of Online Survey of Faith-Based Professionals

2,865 faith-based healthcare professionals

1. **Over nine of ten** (91%) faith-based physicians agreed, "I would **rather stop practicing medicine** altogether than be forced to violate my conscience."
2. **32%** of faith-based healthcare professionals report having "been **pressured to refer a patient** for a procedure to which [they] had moral, ethical, or religious objections."
3. **39%** of faith-based healthcare professionals have "experienced pressure from or **discrimination by faculty** or administrators based on [their] moral, ethical, or religious beliefs"
4. **20%** of faith-based medical students say they are "**not pursuing a career in Obstetrics or Gynecology**" because of perceived discrimination and coercion in that field.

[1] Results of both 2009 surveys released April 8. On behalf of the Christian Medical Association, the polling companyTM, inc./ WomanTrend conducted a nationwide survey of 800 American adults. Field Dates: March 23 -25, 2009. The overall margin of error for the survey is ± 3.5% at a 95% confidence interval. The polling companyTM, inc./ WomanTrend also conducted an online survey of members of faith-based organizations, fielded March 31, 2009 to April 3, 2009. It was completed by 2,298 members of the Christian Medical Association, 400 members of the Catholic Medical Association, 69 members of the Fellowship of Christian Physicians Assistants, 206 members of the Christian Pharmacists Fellowship International, and 8 members of Nurses Christian Fellowship. http://www.freedom2care.org/learn/page/surveys

April 2009 Phone Survey of the American Public

Americans of all characteristics and politics seek shared values with healthcare professionals.

Fully 88% of American adults surveyed said it is either "very" or "somewhat" important to them that they enjoy a similar set of morals as their doctors, nurses, and other healthcare providers. Intensity was strong, as 63% described this as "very" important while at the other end of the spectrum, just 6% said it is "not at all important," a ratio of more than 10-to-1.

Voters will punish politicians who fail to defend healthcare providers' conscience rights.

Finally, when asked how they would view their Member of Congress if he or she voted against conscience protection rights, 54% indicated they would be less likely to back their United States Representative. In fact, 36% said they would be much less likely, a figure three times greater than the 11 % who said they would be much more likely. Furthermore, 43% of respondents who said they voted for President Obama indicated that they would be less inclined to back a Member of Congress if he or she opposed conscience protection rights.

Healthcare providers' conscience protections are viewed as an inalienable right.

A sizable 87% of American adults surveyed believed it is important to "make sure that healthcare professionals in America are not forced to participate in procedures and practices to which they have moral objections." 65% of respondents considered it very essential. Also joining with these majorities were 95% of respondents who self-identified as "pro-life," 78% who considered themselves "pro-choice," 94% who voted for Senator McCain in November 2008 and 80% who cast a ballot for (now) President Obama.

Americans oppose forcing healthcare providers to act against their consciences...

A majority (57%) of American adults opposed regulations "that require medical professionals to perform or provide procedures to which they have moral or ethical objections." In contrast, 38% favored such rules. A full 40% strongly objected to the rules while just 19% strongly backed them. A majority of conservative Republicans (69%), moderate Republicans (69%), and conservative Democrats (59%), as well as the plurality of liberal/moderate Democrats (49%), joining together to reject policies to that require doctors and nurses to act against their personal moral code or value set.

...Support laws that protect them from doing so...

Without any names or political parties being mentioned, support for the new conscience protection rule outpaced opposition by a margin of more than 2-to-1 (63% vs. 28%). Intensity favored the rule, with 42% strongly backing it and 19% strongly rejecting it. Endorsements for the rule spanned demographic and political spectra, with majorities in all cohorts offering their support. In fact, even 56% of adults who said they voted for President Obama last fall and 60% of respondents who self-identified as "pro-choice" said they favor this two-month old conscience protection rule.

... And oppose any efforts to remove such rules.

Opposition to revocation of the conscience protection rule outpaced support by a margin of more than 2- to-1 (62% vs. 30%). Intensity favored retention of the rule (44% strongly opposing rescission versus 17% strongly supporting it). There was consistent demographic alignment and cohesiveness across political lines, as 52% of self-identified Democrats, 67% of self-identified Independents, and 73% of self- identified Republicans, as well as 50% of liberals, 65% of moderates, and 69% of conservatives also opposed nullification. A narrow majority (53%) of people who considered themselves to be "pro-choice" opposed rescission. Notably, a small number

(7%) were ambivalent or undecided, saying they did not know or lacked the information to render an opinion one way or the other.

Online Survey of Faith-Based Medical Professionals

1. Medical access will suffer if doctors are forced to act against their moral and ethical codes.

In the survey of 2,865 members of faith-based organizations, doctors and other medical professionals voiced their concerns that serious consequences could occur if doctors are forced to participate in or perform practices to which they have moral or ethical objections. Nearly three-quarters (74%) believed that elimination of the conscience protection could result in "fewer doctors practicing medicine," 66% predicted "decreased access to healthcare providers, services, and/or facilities for patients in low-income areas," 64% surmised "decreased access to healthcare providers, services, and/or facilities for patients in rural areas," and 58% hypothesized "fewer hospitals providing services."

Asked how rescission of the rule would affect them personally, 82% said it was either "very" or "somewhat" likely that they personally would limit the scope of their practice of medicine. This was true of 81% of medical professionals who practice in rural areas and 86% who work full-time serving poor and medically-underserved populations.

The conscience protection rule is fundamental and necessary in the medical profession.

Fully 97% of members who participated in the survey supported the two-month-old conscience protection clause and 96% objected to rescission of the rule. 91% of physicians agreed, "I would rather stop practicing medicine altogether than be forced to violate my conscience." The Department of Health and Human Services has asked whether the objectives of the conscience protection rule can be achieved "through non-regulatory means, such as outreach and education." Nearly nine-in-ten (87%) members surveyed – those who are on the ground, in hospitals and clinics across the country – felt "outreach and education" alone were insufficient to accomplish the goal. Ninety-two percent declared the codification of conscience protection to be necessary (83% "very" and 9% "somewhat") based on their knowledge of "discrimination in healthcare on the basis of conscience, religious, and moral values."

Discrimination is widespread in education and professional practice.

Asked to assess their educational experiences:

- 39% have "experienced pressure from or discrimination by faculty or administrators based on [their] moral, ethical, or religious beliefs"
- 33% have "considered not pursuing a career in a particular medical specialty because of attitudes prevalent in that specialty that is not considered tolerant of [their] moral, ethical or religious beliefs."
- 23% have "experienced discrimination during the medical school or residency application and interview process because of [their] moral, ethical or religious beliefs."

Asked to assess their professional experiences:

- 32% have "been pressured to refer a patient for a procedure to which [they] had moral, ethical, or religious objections."
- 26% have "been pressured to write a prescription for a medication to which [they] had moral, ethical, or religious objections."
- 17% have "been pressured to participate in training for a procedure to which [they] had moral, ethical, or religious objections."
- 12% have "been pressured to perform a procedure to which [they] had moral, ethical, or religious objections."

Discrimination is forcing faith-based medical students to shun careers in Obstetrics and Gynecology.

- 20% of students surveyed agreed with the statement, "I am **not pursuing a career in Obstetrics or Gynecology** mainly because I do not want to be forced to compromise my moral, ethical, or religious beliefs by being required to perform or participate in certain procedures or provide certain medications."
- **96%** of medical students support (90% "Strongly Support") the conscience protection regulation.
- 32% of medical students say they "have experienced pressure from or **discrimination by faculty** or administrators based on your moral, ethical, or religious beliefs."

EXHIBIT D

CMDA Ethics Statement

Healthcare Right of Conscience

Respect for conscientiously held beliefs of individuals and for individual differences is an essential part of our free society. The right of choice is foundational in our healthcare process, and it applies to both healthcare professionals and patients alike. Issues of conscience arise when some aspect of medical care is in conflict with the personal beliefs and values of the patient or the healthcare professional. CMDA believes that in such circumstances the Rights of Conscience have priority.

PATIENT'S RIGHT OF CONSCIENCE:

- The right of competent patients on the basis of conscience to refuse treatment, even when such refusal would likely bring harm to themselves, should be respected.
- The right of competent patients on the basis of conscience to refuse treatment, when such refusal would likely threaten the health and/or life of others, should be resisted and should become a matter of public interest and responsibility.
- The right of a healthcare surrogate on the basis of conscience to refuse treatment, thereby threatening the health and/or life of another, should be resisted and should become a matter of public interest and responsibility.

THE HEALTHCARE PROFESSIONAL'S RIGHT OF CONSCIENCE:

- All healthcare professionals have the right to refuse to participate in situations or procedures that they believe to be morally wrong and/or harmful to the patient or others. In such circumstances, healthcare professionals have an obligation to ensure that the patient's records are transferred to the healthcare professional of the patient's choice.

THE HEALTHCARE INSTITUTION'S RIGHT OF CONSCIENCE:

- Healthcare institutions have the right to refuse to provide services that are contrary to their foundational beliefs.
- Healthcare institutions have the obligation to disclose the services they would refuse to give.
- Healthcare institutions should not lose public funding as a result of exercising their right of conscience.

HEALTHCARE EDUCATION RIGHT OF CONSCIENCE:

- Institutions, educators and trainees should be allowed to refuse to participate in policies and procedures that they deem morally objectionable without threat of reprisal.
- Healthcare professionals at all levels should seek to learn about and understand policies and procedures that they deem morally objectionable..
- No organization or governing body should mandate participation in policies or procedures that violate conscience.

CMDA Ethics Statement

CMDA believes Christian healthcare professionals in our society should give dual service* to a Holy God and the humanity He created and sustains. We believe the Christian healthcare professional's conscience should be informed by available evidence and Scripture. We believe obedience to conscience is obligatory for all Christians.

See statement on Moral Complicity with Evil.

Approved by the House of Representatives
Passed with 53 approvals; 2 abstentions.
June 11, 2004. San Antonio, Texas.

EXHIBIT E

City and County of San Francisco
Mark Farrell
Mayor

San Francisco Department of Public Health
Barbara A. Garcia, MPA
Director of Health

Secretary Alex Azar
The U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Department of Health and Human Services Proposed Rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," Docket ID No. HHS-OCR-2018-0002 (RIN 0945-ZA03)

Dear Secretary Azar,

Thank you for the opportunity to submit comments on "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," Department of Health and Human Services (HHS) proposed rule RIN0945-ZA03, Docket ID No. HHS-OCR-2018-0002. **The San Francisco Department of Public Health (SFDPH) strongly opposes this proposed rule and requests that it be withdrawn.** In support of our position, we offer the information below based on our experience as a safety net provider of direct health services to thousands of insured and uninsured residents of San Francisco, including those most socially and medically vulnerable.

SFDPH, through the San Francisco Health Network (SFHN), provides San Francisco's only complete care system and includes primary care, dental care, emergency and trauma treatment, medical and surgical specialties, diagnostic testing, skilled nursing and rehabilitation, behavioral health services and jail health services. The mission of SFDPH is to protect and promote the health of all San Franciscans. SFDPH is dedicated to reducing health disparities and providing inclusive care to all patients. SFDPH provides this care though its top-rated programs, fifteen primary care community clinics, and hospitals, including Zuckerberg San Francisco General Hospital and Trauma Center (ZSFG). For example, Zuckerberg San Francisco General alone delivers over one thousand babies a year, has been at the forefront of HIV/AIDS care from the beginning of the AIDS crisis, and provides gender-confirmation surgeries to transgender patients.

Zuckerberg San Francisco General cares for approximately one in eight San Franciscans a year, regardless of their ability to pay. As the City's safety net hospital, Zuckerberg San Francisco General provides the highest-quality services, including to many patients covered through Medi-Cal (California's Medicare program). It provides life-saving emergency care as the only level one trauma center in San Francisco, serving a region of more than 1.5 million people. With the busiest emergency room in San Francisco, Zuckerberg San Francisco General receives one-third of all ambulances in the City, and treats nearly four

thousand patients with traumatic injuries, annually. Many of Zuckerberg San Francisco General's programs focus on providing life-saving care in emergency situations.

As a safety net provider, SFDPH is extremely concerned by the proposed rule. HHS recently created the Division of Conscience and Religious Freedom with the purpose of protecting health care workers who refuse to treat patients on the basis of religious and moral objections. This new division and the proposed rule threaten the health of our patients, and are likely to have a particular negative impact on low-income people, women, and the LGBTQ community.

The proposed rule compromises patient care, undermines the oaths sworn to by medical and healthcare professionals, is unnecessary, and is practically unworkable.

First, the proposed rule provides no benefits and imposes only burdens on patients. It fails to take into account the very real costs it imposes on patients' rights to access care, and to do so without being subjected to discrimination. Prioritizing religious freedom over the provision of care allows discrimination and threatens the lives of patients, including women and the LGBTQ community. The proposed rule would undermine San Francisco's long-standing efforts to advance women's health and reproductive rights, prevent domestic violence, address sexual assault and human trafficking, and promote the health and well-being of women and the LGBTQ community through access to health promotion and health care services. The proposed rule threatens patients' constitutional right to access reproductive healthcare services, including abortions. This proposed rule would also exacerbate already enormous deficiencies in health care access among transgender and gender non-conforming individuals. Nearly a quarter of transgender people already report avoiding seeking medical care for fear of being mistreated.[1] This rule could further dissuade transgender people from seeking even the most routine services. The breadth of the rule is such that it is impossible to fully predict how the rule could impact patients—even access to basic care that on its face has no discernable connection to religious observance, such as dental care, could be threatened. Further, it would disproportionately place low-income San Franciscans at risk and threaten San Francisco's ability to provide necessary healthcare services to its residents most in need. The proposed rule completely fails to take into account the very real costs it imposes on patients' rights to access care, and to do so without being subjected to discrimination.

Second, the proposed rule elevates a right of conscience above all other ethical considerations. The proposed rule is in direct violation of the Hippocratic Oath, in which doctors swear to do no harm and to treat the ill to the best of their ability. Its definition of "refer" is so broad that it could potentially prevent SFDPH from ensuring that if one health care provider were unwilling to give certain care, another provider would be able to provide it without delay. When a patient seeks care from one of SFHN's clinics or hospitals, both the patient and SFDPH need to know that the patient is receiving all medically-necessary care.

Third, existing laws and regulations ensure that patients receive the essential health services they need, while adequately protecting the rights of conscience of healthcare workers. Patients have the right to access high-quality, inclusive and comprehensive care without encountering discrimination, and current

[1] Sandy E. James et al., The Report of the U.S. Transgender Survey 98 (2016), www.ustranssurvey.org/report.

law ensures that access while also allowing accommodations for healthcare workers' religious beliefs. SFDPH is not aware of any employee request for a religious accommodation that it has been unable to provide under existing laws and regulations. Current law is perfectly adequate, and there is no need for the proposed rule.

Lastly, the proposed rule is unworkable in many other respects. In addition to ignoring the needs of patients, the proposed rule fails to account for how a health care organization could legally administer it. The proposed rule ignores competing obligations imposed on SFHN by other statutes such as the Emergency Medical Treatment and Active Labor Act and California's Unruh Civil Rights Act. It also ignores SFDPH's contractual obligations to its employees; the proposed rule could create problems with the fair administration of labor contracts between employees asserting conscience rights and those who do not.

The rule also appears to create administrative obstacles to providing employees with religious accommodations. The current draft lacks a requirement that workers seeking to assert a right of conscience inform their organization of their request, and therefore could deny the organization an opportunity to provide the worker with an accommodation. Moreover, the proposed definition of "discrimination" is so broad that even if a worker did request an accommodation, the very act of providing one could be considered discriminatory. If an employee failed to request an accommodation in advance of being presented with a patient who has an immediate need for care, the proposed rule creates a very real risk that the patient could be denied legally required or medically necessary care. Patient care is SFDPH's first and primary priority, but it is worth noting that in addition to harming a patient, such a situation could also potentially expose SFDPH to liability for violations of other laws and for malpractice.

For these reasons, we respectfully request HHS withdraw the Proposed Rule from consideration.

Sincerely,

Barbara A. Garcia

Director of Health
San Francisco Department of Public Health

EXHIBIT F

National Institute for Reproductive Health

March 23, 2018

VIA ELECTRONIC SUBMISSION

Secretary Alex Azar
U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Attention: Comments on RIN 0945-ZA03 – Proposed Rule Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar,

The National Institute for Reproductive Health (NIRH) believes a health care provider's personal beliefs should never determine the care a patient receives. That is why we strongly oppose the Department of Health and Human Services' (the "Department") proposed rule ("Proposed Rule"), which seeks to permit discrimination in all aspects of health care.[1]

The Proposed Rule seeks to unlawfully expand refusals to provide care by attempting to allow individuals and health care entities who receive federal funding to refuse to provide *any* part of a health service or program. In addition, the Proposed Rule unlawfully attempts to create new refusals seemingly out of thin air. Such expansions exceed the Department's authority; violate the Constitution; undermine the ability of states to protect their citizens; undermine critical HHS programs like Title X; interfere with the provider-patient relationship; and threaten the health and well-being of people across the country and around the world.

By issuing the Proposed Rule and creating a new division within the Office of Civil Rights ("OCR") – the new "Conscience and Religious Freedom Division" – the Department seeks to inappropriately use OCR's limited resources in order to affirmatively allow institutions, insurance companies, and almost anyone involved in patient care to use their personal beliefs to deny people the care they need. For these reasons the National Institute for Reproductive Health calls on the Department and OCR to withdraw the Proposed Rule in its entirety.

[1] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (proposed Jan. 26, 2018) (*to be codified at* 45 C.F.R. pt. 88) [*hereinafter* Rule].

National Institute for Reproductive Health

The Proposed Rule Unlawfully Exceeds the Department's Authority by Impermissibly Expanding Religious Refusals to Provide Care

The Proposed Rule attempts to expand the reach not only of existing harmful refusal of care laws but also to create new refusals of care where none were intended.

a. The Proposed Rule Seeks to Allow the Refusal of any Health Service Based on Personal Belief

The Proposed Rule will exacerbate health inequities by expanding the ability to refuse critical services, including abortion and transition-related care. Specifically, the Department and OCR are attempting to require a broad swath of entities to allow individuals to refuse "*any* lawful health service or activity based on religious beliefs or moral convictions (emphasis added)."[2] Read in conjunction with the rest of the Proposed Rule, it is clear this is intended to allow any entity involved in a patient's care—from a hospital board of directors to the receptionist that schedules procedures—to use their personal beliefs to determine a patient's access to care.

b. The Proposed Rule Unlawfully Expands Already Harmful Abortion/Sterilization Refusal of Care Laws

Already existing refusal of care laws are used across the country to deny patients the care they need.[3] The Proposed Rule attempts to expand these laws in numerous ways that are directly contrary to the stated purpose of the existing laws. For example, one provision of the Church Amendments allows individuals who work for or with entities receiving grants or contracts for biomedical or behavioral research entities to refuse to participate in "any lawful health services or research activity" based on religious beliefs or moral convictions specifically related to the service or research activity to which they object.[4] But the Proposed Rule attempts to broaden this provision to allow individuals to refuse to perform aspects of their jobs based on a mere reference to a religious or moral belief regardless of whether it relates to the specific biomedical or behavioral service or research activity they are working on.[5] Such an attempted expansion goes beyond what the statute enacted by Congress allows. Furthermore, the Proposed Rule would expansively apply other provisions of the Church Amendments to, among other things,

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[2] *See id.* at 12.
[3] *See, e.g., Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Catherine Weiss, et al., *Religious Refusals and Reproductive* Rights, AM. CIVIL LIBERTIES UNION (2002), https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report; Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf; Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[4] The Church Amendments, 42 U.S.C. § 300a-7 (2018).
[5] *See* Rule *supra* note 1, at 185.

National Institute for Reproductive Health

individuals working under global health programs funded by the Department thereby allowing global health providers and entities to refuse individuals the care they need contrary to the very purpose of such programs.

Similarly, the Proposed Rule defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. For example, the definition of "assist in the performance" greatly expands the types of services that can be refused to include merely "making arrangements for the procedure" no matter how tangential.[6] This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees, can now assert a new right to refuse. The Proposed Rule's definition of "referral" similarly goes beyond any understanding of the term, allowing refusals to provide any information, including location or funding, that could help an individual to get the care they need.[7]

Furthermore, the Proposed Rule's new and unwarranted expanded definitions often exceed, or are not in accordance with, existing definitions contained within the statutes the Proposed Rule seeks to enforce. Specifically, under the Coats and Weldon Amendments "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in the delivery of health care.[8] The Proposed Rule attempts to combine separate definitions of "health care entity" found in different statutes and applicable in different circumstances into one broad term.[9] Such an attempt to expand the meaning of a statutory term Congress already took the time to define not only fosters confusion, but goes directly against congressional intent. By expressly defining the term "health care entity" Congress implicitly rejected the inclusion of the other terms the Department now attempts to insert.[10]

When these impermissibly broad definitions are combined with the expansive interpretations of the underlying statutes, they work together to further expand refusals of care to allow more individuals and entities to refuse to provide access to health care. For example, one way the Weldon Amendment is expanded under the Proposed Rule is through the definition of "discrimination."[11] In particular, the Proposed Rule defines "discrimination" against a health care entity broadly to include a number of activities, including denying a grant or employment as well as an unspecified catch-all phrase "any activity reasonably regarded as discrimination."[12] In

[6] *Id.* at 180.
[7] *Id.* at 183.
[8] The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018).
[9] *See* Rule *supra* note 1, at 182.
[10] The doctrine of expression unius est exclusion alterius (the expression of one thing implies the exclusion of others) as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.
[11] *See* Rule *supra* note 1, at 180.
[12] *Id.*

National Institute for Reproductive Health

a Proposed Rule that seeks to protect those who want to discriminate, this broad definition is nonsensical and inappropriate. Further such a vague and inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements, thereby fostering confusion.

The Proposed Rule Carries Severe Consequences for Patients and will Exacerbate Already Existing Inequities

a. Refusals of Care Make it Difficult for Many Individuals to Access the Care They Need

Across the country refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need.[13] One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care.[14] Another woman experiencing pregnancy loss was denied care for ten days at a religiously affiliated hospital outside Chicago, Illinois.[15] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[16] Another patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic hospital provider refused to give her the procedure.[17] Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options.[18]

[13] *See, e.g.*, *supra* note 3.
[14] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[15] *See* Julia Kaye, et al., *Health Care* Denied, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.
[16] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 29 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[17] *See The Patient Should Come First: Refusals to Provide Reproductive Health Care*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/05/Refusals-FS.pdf; Sandhya Somashekhar, *A Pregnant Woman Wanted her Tubes Tied. Her Catholic Hospital Said No.*, WASH. POST (Sept. 13, 2015), https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2_story.html?utm_term=.8c022b364b75.
[18] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 27 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

National Institute for Reproductive Health

b. Refusals of Care are Especially Dangerous for Those Already Facing Barriers to Care

Refusals of care based on personal beliefs already make it difficult for many individuals to access health care and have real consequences for those denied the care they need because of a provider or hospital's religious beliefs. When women and families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another location, refusals bar access to necessary care.[19] This is especially true for immigrant patients who often lack access to transportation and may have to travel great distances to get the care they need.[20] In rural areas there may be no other sources of health and life preserving medical care.[21] In developing countries where many health systems are weak, health care options and supplies are often unavailable.[22] When these individuals encounter refusals of care, they may have nowhere else to go.

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that women of color in many states disproportionately receive their care at Catholic hospitals. In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals.[23] These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provides guidance on a wide range of hospital matters, including reproductive health care and can keep providers from offering the standard of care.[24] Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women were delayed care or transferred to other facilities at great risk to their health.[25] The reach of this type of

[19] In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. *Women's Health Insurance* Coverage, KAISER FAMILY FOUND. 1, 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage.
[20] Athena Tapales et al., *The Sexual and Reproductive Health of Foreign-Born Women in the United States*, CONTRACEPTION 8, 16 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf; Nat'l Latina Inst. For Reproductive Health & Ctr. For Reproductive Rights, *Nuestra Voz, Nuestra Salud, Nuestro Texas: the Fight for Women's Reproductive Health in the Rio Grande Valley* 1, 7 (2013), http://www.nuestrotexas.org/pdf/NT-spread.pdf.
[21] Since 2010, eighty-three rural hospitals have closed. *See Rural Hospital Closures: January 2010 – Present*, THE CECIL G. SHEPS CTR FOR HEALTH SERVS. RES. (2018), http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.
[22] *See* Nurith Aizenman, *Health Care Costs Push a Staggering Number of People into Extreme Poverty*, NPR (Dec. 14, 2017), https://www.npr.org/sections/goatsandsoda/2017/12/14/569893722/health-care-costs-push-a-staggering-number-of-people-into-extreme-poverty; *Tracking Universal Health Coverage: 2017 Global Monitoring Report*, WORLD HEALTH ORG. & THE WORLD BANK (2017), http://documents.worldbank.org/curated/en/640121513095868125/pdf/122029-WP-REVISED-PUBLIC.pdf.
[23] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 12 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[24] *See id.* at 10-13.
[25] Lori R. Freedman, *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.

National Institute for Reproductive Health

religious refusal of care is growing with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.[26]

In addition, in many of the countries where the Department implements global AIDS programs, many of the patients served already face numerous barriers to care, including a broad and harmful refusal provision contained within the statute governing such programs.[27]

c. In Proposing this Rule, the Agency has Abandoned its Legal Obligations to Adequately Account for Harm to Patients

By expanding refusals of care the Proposed Rule will exacerbate the barriers to health care services patients need. It is evident that the harm caused by this Proposed Rule will fall hardest on those most in need of care by allowing individuals and health care entities to use their personal beliefs to dictate patient care. The Department should remember, under Executive Order 13563, an agency may only propose regulations where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on society."[28] The Proposed Rule plainly fails on both counts. Although the Proposed Rule attempts to quantify the costs of compliance, it completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs.[29]

Moreover, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant religious exemptions and, in fact, bars granting an exemption when it would detrimentally affect any third party.[30] Because the Proposed Rule would cause substantial harm, including to patients, it would violate the Establishment Clause.[31]

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[26] *See, e.g.*, *Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.

[27] *See The Mexico City Policy: An Explainer*, KAISER FAMILY FOUND. (June 1, 2017), https://www.kff.org/global-health-policy/fact-sheet/mexico-city-policy-explainer/.

[28] Improving Regulation and Regulatory Review, Executive Order 13563 (Jan. 18, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review.

[29] *See* Rule *supra* note 1, at 94-177.

[30] U.S. Const. amend. I; *Cutter v. Wilkinson*. 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment Clause, courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985)); *see also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).

[31] Respecting religious exercise may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *See Burwell v. Hobby Lobby*, 134 S. Ct. at 2787. When considering

National Institute for Reproductive Health

The Proposed Rule Will Undermine Critical Federal Health Programs, including Title X

The Proposed Rule would seemingly allow health care entities to receive grants and contracts under HHS-funded programs or other federal health programs, such as Title X, the only domestic family planning program, while refusing to provide key services required by those programs.[32] For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[33] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[34] Under the Proposed Rule, the Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such funds are generally conditioned.[35] The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the subrecipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.[36] When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objectives. Every year millions of low-income, including under-insured, and uninsured individuals, rely on Title X clinics to access services they otherwise might not be able to afford.[37]

The Proposed Rule Will Carry Severe Consequences for Providers and Undermine the Provider-Patient Relationship

Existing refusals of care based on personal beliefs already undermine open communication between providers and patients, interfere with providers' ability to provide care according to medical standards, and ignore the reality that many providers want to provide comprehensive care. Hospital systems across the country use religious beliefs to prevent their employees from

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whether the birth control coverage requirement was the least restrictive means in Hobby Lobby, the Court considered that the accommodation offered by the government ensured that affected employees "have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing coverage." *See id.* at 2759. In other words, the effect of the accommodation on women would be "precisely zero." *Id.* at 2760.

[32] *See* Rule *supra* note 1, at 180-181, 183. *See also Title X Family Planning*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (2018), https://www.hhs.gov/opa/title-x-family-planning/index.html; *Title X an Introduction to the Nation's Family Planning Program*, NAT'L FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOC. (2017) (*hereinafter* NFPRHA), https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf.

[33] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).

[34] *See* What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).

[35] *See, e.g.*, Rule *supra* note 1, at 180-185.

[36] *See* NFPRHA *supra* note 34.

[37] *See id.*

National Institute for Reproductive Health

treating patients regardless of the professional, ethical, or moral convictions of these providers.[38] The Proposed Rule would exacerbate these problems by emboldening health care entities and institutions, including foreign and international organizations, to bind the hands of providers and attempt to limit the types of care they can provide.

The Proposed Rule threatens informed consent, a necessary principle of patient-centered decision-making intended to help balance the power dynamics between health providers and patients and ensure patient-centered decision-making.[39] Informed consent requires providers disclose relevant and medically accurate information about treatment choices and alternatives so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.[40] By allowing providers, including hospital and health care institutions, to refuse to provide patients with information, the Proposed Rule makes it impossible for patients to have full information regarding treatment options. While the Department claims the Proposed Rule improves communication between patients and providers, in truth it will deter open, honest conversations that are vital to ensuring that a patient can control their medical circumstances.[41]

The Proposed Rule also disregards standards of care established by the medical community by allowing providers to opt out of providing medical care. Medical practice guidelines and standards of care establish the boundaries of medical services that patients can expect to receive and that providers should be expected to deliver. Yet, the Proposed Rule seeks to allow providers and institutions to ignore the standards of care, particularly surrounding reproductive and sexual health. Information, counseling, referral and provision of contraceptive and abortion services are part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer.[42] Individuals seeking reproductive health care, regardless of their reasons for needing these services, should be treated with dignity and respect. Allowing providers to flout established medical guidelines and deny medically accurate,

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[38] *See* Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

[39] *See* TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); CHARLES LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).

[40] *See id.*

[41] *See* Rule *supra* note 1, at 150-151.

[42] For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care. Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant. AM. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE § 114-15, S117 (2017), available at http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf. The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival. AM. ACAD. OF PEDIATRICS & AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).

National Institute for Reproductive Health

evidence-based care to patients harms them and impairs their ability to make the health care decision that is right for them.

In addition, the Proposed Rule ignores the many providers with deeply held moral convictions that affirmatively motivate them to provide patients with health care, including abortion, transition-related care, and end-of-life care. Moreover, the Proposed Rule fails to acknowledge the Church Amendments' protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[43] No health care professional should face discrimination from their employer because they treated or provided information to a patient seeking an abortion.

The Department is Abdicating its Responsibility to Patients

The Proposed Rule exceeds OCR's authority by abandoning OCR's mission to address health disparities and discrimination that harms patients.[44] Instead, the Proposed Rule appropriates language from civil rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the Proposed Rule creates a regulatory scheme that is not only nonsensical but is affirmatively harmful. For example, the notice and certification of compliance and assurance requirements simply do not make sense when applied to the laws the Proposed Rule seeks to enforce.[45] They will place a significant and burdensome requirement on health care providers and impose unique challenges for those working in other countries by taking resources away from patient care without adding any benefit.

The Department, including OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities.[46] If finalized, however, the Proposed Rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care,

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[43] *See* The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).

[44] *OCR's Mission and Vision*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html ("The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

[45] *See* Rule *supra* note 1, at 203-214.

[46] As one of its first official acts in 1967, the Office of Equal Health Opportunity undertook the massive effort of inspecting 3,000 hospitals to ensure they were complying with Title VI's prohibition against discrimination on the basis of race, color, or national origin. 42. U.S.C. § 2000d (1964). After this auspicious start, the Office of Equal Health Opportunity which would eventually become OCR would go on to ensure that health programs and activities it regulated complied with key anti-discrimination laws including Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (1973), Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 (1972), the Age Discrimination Act of 1976, 42 U.S.C. § 6101 (1976), and Section 1557 of the Affordable Care Act, 42 U.S.C. §18116 (2010), among others. Through robust enforcement of these laws, OCR has worked to reduce discrimination in health care.

National Institute for Reproductive Health

and eliminate health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.[47]

Nevertheless, there is still work to be done, and the Proposed Rule seeks to divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color.[48] And these disparities do not occur in isolation. Black women, for example, are three to four times more likely than white women to die during or after childbirth.[49] Further, the disparity in maternal mortality is growing rather than decreasing,[50] which in part may be due to the reality that women have long been the subject of discrimination in health care and the resulting health disparities. For example, women's pain is routinely undertreated and often dismissed.[51] And due to gender biases and disparities in research, doctors often offer women less aggressive treatment, or even no treatment, for conditions such as heart disease.[52] Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[53] Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a doctor or other health care

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[47] *See, e.g.*, *Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html; *Protecting the Civil Rights and Health Information Privacy Rights of People Living with HIV/AIDS*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html; *National Origin Discrimination*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/index.html; *Health Disparities*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

[48] *See* Skinner et al., *Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans*, NAT'L INSTIT. OF HEALTH 1 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf.

[49] *See* Nina Martin, *Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why*, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why.

[50] *See id.*

[51] *See, e.g.*, Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29:1 J. OF L., MED., & ETHICS 13, 13-27 (2001).

[52] *See, e.g.*, Judith H. Lichtman et al., *Symptom Recognition and Healthcare Experiences of Young Women with Acute Myocardial Infarction*, 10 J. of the Am. Heart Ass'n 1 (2015).

[53] *See, e.g.*, *When Health Care Isn't Caring*, LAMBDA LEGAL 5 (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring_1.pdf. A survey examining discrimination against LGBTQ people in health care more than half of respondents reported that they have experienced at least one of the following types of discrimination in care: being refused needed care; health care professionals refusing to touch them or using excessive precautions; health care professionals using harsh or abusive language; being blamed for their health care status; or health care professionals being physically rough or abusive.

provider had refused to see them because of their actual or perceived sexual orientation or gender identity in the year before the survey.[54]

OCR must work to address these disparities, yet the Proposed Rule seeks to prioritize the expansion of existing religious refusal laws beyond their statutory requirements and create new religious exemptions where none had previously existed rather than using already limited resources to protect patient access to health care. The Proposed Rule will harm patient care and is antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality.[55]

The Proposed Rule Conflicts with Other Existing Federal Law

The Proposed Rule generates chaos through its failure to account for existing laws that conflict with the refusals to care it would create.

For example, the Proposed Rule makes no mention of Title VII,[56] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[57] With respect to religion, Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.[58] For decades, Title VII has established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal obligations. The Proposed Rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[59]

Furthermore, the language in the Proposed Rule would seem to put health care entities in the position of being forced to hire people who intend to refuse to perform essential elements of a position even though Title VII would not require such an "accommodation." For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health

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[54] *See* Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NAT'L GAY AND LESBIAN TASK FORCE & NAT'L CTR. FOR TRANSGENDER EQUALITY, http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.
[55] *See supra* note 46.
[56] 42 U.S.C. § 2000e-2 (1964).
[57] *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.
[58] *See id.*
[59] Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), *available at* https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html.

National Institute for Reproductive Health

center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the applicant refuses to provide non-directive options counseling even though the employer would not be required to do so under Title VII.[60] It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

In addition, the Proposed Rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility.[61] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[62] Because the Proposed Rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

The Proposed Rule Will Make It Harder for States to Protect their Residents

The Proposed Rule will have a chilling effect on the enforcement of and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. The preamble of the Proposed Rule discusses at length state laws that the Department finds objectionable, such as state laws that require anti-abortion counseling centers to provide information about where reproductive health care services can be obtained or whether facilities have licensed medical staff, as well as state laws that require health insurance plans to cover abortion.[63] Moreover, the Proposed Rule invites states to further expand refusals of care by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.[64]

[60] *See* Rule *supra* note 1, at 180-181.
[61] 42 U.S.C. § 1295dd(a)-(c) (2003).
[62] In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. *See, e.g.*, *Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220, 228 (3rd Cir. 2000); In In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); *Nonsen v. Medical Staffing Network, Inc.* 2006 WL 1529664 (W.D. Wis.); *Grant v. Fairview Hosp.*, 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); *Barris v. County of Los Angeles*, 972 P.2d 966, 972 (Cal. 1999).
[63] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.
[64] *See id.*

National Institute for Reproductive Health

Conclusion

The Proposed Rule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The Proposed Rule is discriminatory, violates multiple federal statutes and the Constitution, ignores congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons, the National Institute for Reproductive Health calls on the Department to withdraw the Proposed Rule in its entirety. If you have any questions, please do not hesitate to contact Rose MacKenzie at rmackenzie@nirhealth.org or 646-520-3519.

Sincerely,

Andrea Miller
President
National Institute for Reproductive Health
& National Institute for Reproductive Health Action Fund

EXHIBIT G

WASHINGTON
LEGISLATIVE OFFICE

March 27, 2018

Department of Health and Human Services
Office for Civil Rights
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TREASURER

Re: Proposed New 45 CFR Part 88 Regarding Refusals of Medical Care

The American Civil Liberties Union ("ACLU") submits these comments on the proposed rule published at 83 FR 3880 (January 26, 2018), RIN 0945-ZA03, with the title "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (the "Proposed Rule" or "Rule").

For nearly 100 years, the ACLU has been our nation's guardian of liberty, working in courts, legislatures, and communities to defend and preserve the individual rights and liberties that the Constitution and the laws of the United States. With more than 2 million members, activists, and supporters, the ACLU is a nationwide organization that fights tirelessly in all 50 states, Puerto Rico, and Washington, D.C. for the principle that every individual's rights must be protected equally under the law, regardless of race, religion, gender, sexual orientation, gender identity or expression, disability, national origin, or record of arrest or conviction.

In Congress and in the courts, we have long supported strong protections for religious freedom. Likewise, we have participated in nearly every critical case concerning reproductive rights to reach the Supreme Court and advocated for policies that promote access to reproductive health care. The ACLU is also a leader in the fight against discrimination on behalf of those who historically have been denied their rights, including people of color, LGBT (lesbian, gay, bisexual, and transgender) people, women, and people with disabilities. Because of its profound respect for and experience defending religious liberty, reproductive rights, and principles of non-discrimination, the ACLU is particularly well positioned to comment on the Proposed Rule. We steadfastly protect the right to religious freedom. But the right to religious freedom does not include a right to harm others as this Proposed Rule contemplates. And, indeed, when the Bush Administration adopted similar rules, the ACLU challenged them in court. *See National Family Planning & Reproductive Health*

Association, Inc. v. Leavitt, *consolidated in* Case No. 3:09-cv-00054-RNC (D. Conn. 2009).[1]

The Proposed Rule grants health care providers unprecedented license to refuse to provide information and health care to patients and puts faith before patients' health. The Rule thus contravenes the core mission of the Department of Health and Human Services [the "Department"] to protect and advance the health of all. The Department's failure even to mention the impact of the rule on patients is clear evidence of its misplaced priorities. The Rule also flies in the face of the longstanding history of the Department to further our nation's health by addressing discrimination in health care, aiming instead to foster discrimination.

Tellingly, the Department justifies the Rule by citing as the "problem" cases in which patients sought remedies after being denied health care—to the detriment of their health and often for discriminatory reasons. *See* 83 FR 3888-89 & n.36. The problem, however, is not that patients want care, but that health care providers denied vital, even life-saving, medical care, discriminated, and imposed their religious doctrine to the detriment of patients' health. Tamesha Means, for example, should not have been turned away from the hospital where she sought urgent care even once, let alone three times, without even being provided with the information that her own life could be in jeopardy if she did not obtain emergency abortion care for her miscarriage.[2] Rebecca Chamorro should not have been required to undergo the additional stress, health risks, and cost of two surgical procedures, rather than a single one, when her doctor was ready, willing, and able to perform a standard postpartum tubal ligation.[3] Evan Minton's scheduled hysterectomy should not have been canceled on the eve of that procedure, despite his doctor's willingness to proceed with that routine operation, because the hospital became aware he was transgender.[4] These refusals, not the patients seeking justice, are the problem. Yet these are the types of refusals the Department seeks to make more commonplace with this Rule. 83 FR 3888-89 & n.36.

Moreover, if the Department is to adhere to its mission and to address discrimination, its focus should not be on expanding a purported right of institutions to refuse to provide care because of beliefs, but on eliminating the discrimination that continues to devastate communities in this country. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color.[5] Black women, for example, are three to four times more likely than white women to die during or after childbirth.[6] Women have long been the subject of discrimination in

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[1] That lawsuit was ultimately dismissed when the Obama Administration rescinded virtually all of the regulations. *See* 74 FR 10207, 75 FR 9968, 76 FR 9968, *infra* n.16.

[2] *See* Health Care Denied 9-10 (May 2016), *available at* https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied.

[3] *See id.* at 18.

[4] *See* Verified Complaint, *Minton v. Dignity Health*, Case No. 17-558259 (Calif. Super. Ct. April 19, 2017).

[5] *See* Skinner et al., *Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans*, NAT'L INSTIT. OF HEALTH 1 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf.

[6] *See* Nina Martin, *Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why*, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why.

health care and the resulting health disparities.[7] And due to gender biases and disparities in research, doctors offer women less aggressive treatment, or even no treatment, for conditions such as heart disease.[8] Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[9] Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a doctor or other health care provider had refused to see them because of that aspect of their identity in the year before the survey.[10] The Department should be working to end, not foster, discrimination in health care.[11]

In the comments below, the ACLU details some of the specific ways in which the Proposed Rule exceeds the Department's authority and in so doing causes significant harm to patients.[12] The non-exhaustive examples of serious flaws in the Rule include:

- The Proposed Rule utterly fails to consider the harmful impact it would have on patients' access to health care.

- The Department lacks *any* legislative rule-making authority under the Church Amendments, 42 U.S.C. § 300a-7, the Coats-Snowe Amendment, 42 U.S.C. § 238n, and the Weldon Amendment, Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, Div. H, Tit. V, § 507(d) (collectively, the "Amendments"), the primary statutory authority for the Rule, and thus it cannot adopt these proposed force-of-law requirements to expand those Amendments.

- The Rule tries to expand the plain language Congress used in the Amendments and over a dozen other laws referenced by this rulemaking (collectively, the "Refusal Statutes"), proposing definitions that distort the ordinary meaning of words and otherwise impermissibly stretching these narrow provisions.

- The Rule's impact is not limited to individual health care providers; it attempts to greatly expand the Refusal Statutes to enable more institutions—e.g., hospitals,

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[7] *See, e.g.*, Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29:1 J. OF L., MED., & ETHICS 13, 13-27 (2001).

[8] *See, e.g.*, Judith H. Lichtman et al., *Symptom Recognition and Healthcare Experiences of Young Women with Acute Myocardial Infarction*, 10 J. of the Am. Heart Ass'n 1 (2015).

[9] *See, e.g.*, *When Health Care Isn't Caring*, LAMBDA LEGAL 5 (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring_1.pdf.

[10] *See* Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NAT'L GAY AND LESBIAN TASK FORCE & NAT'L CTR. FOR TRANSGENDER EQUALITY, http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.

[11] The Department's Office of Civil Rights ("OCR") has a long history of combating discrimination, protecting patient access to care, and eliminating health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.

[12] Although these ACLU comments primarily focus on examples of the Proposed Rule's flaws and harms with reference to the Church, Coats and Weldon Amendments, virtually all of the problems identified in this letter extend to the Rule's similar, unfounded extension of the over a dozen other provisions encompassed within the Rule.

clinics, and other corporate entities—to deny care, even in emergency situations, and even when individual providers at the institutions have no objection to providing the care.

- The Rule is entirely unnecessary as health care providers are already shielded by Title VII's religion protections, and addressed by the Refusal Statutes, and there is no evidence that existing mechanisms are insufficient to ensure compliance with those Refusal Statutes.

- The Rule purports to seek a "society free from discrimination," but repeatedly *invites expanded discrimination – through refusals of care* – against women, LGBT patients, and other members of historically-mistreated groups.

- Likewise, the Rule purports to advance "open and honest communication," yet it *empowers providers to withhold information* from patients about their medical condition and treatment options in contravention of legal and ethical requirements and principles of informed consent.

Because the Proposed Rule harms patient health, encourages discrimination, and exceeds the Department's rulemaking authority, it should be withdrawn. If the Department refuses to do so, it must, at a minimum, revise the Proposed Rule so that it comes into alignment with the statutory provisions it purports to implement, makes clear that it is not intended to conflict with other state and federal laws that protect patients, and mitigates the harm to patients' health and well-being.

I. The Proposed Rule Fails Even to Mention Its Impact on Patients, While Inviting More Refusals of Care That Would Fall Disproportionately on Low-Income People and Other Marginalized Groups.

The Department's mission is "to enhance and protect the health and well-being of all Americans. [It] fulfill[s] that mission by providing for effective health and human services and fostering advances in medicine, public health, and social services."[13] The Department administers more than 100 programs, which aim to "protect the health of all Americans and provide essential human services, especially for those who are least able to help themselves."[14]

It is thus extraordinary that this Notice of Proposed Rulemaking ("NPRM") is devoted solely to increasing the ability of health care entities and professionals to refuse to provide health care information and services to patients. Nowhere in the 50 pages that the NPRM spans in the Federal Register does it discuss the impact that refusals to provide information and denials of care have on patient health and well-being. In fact, patients are not even mentioned in the discussion of "affected persons and entities." 83 FR 3904. And in the Proposed Rule's flawed attempt at a cost-benefit analysis, the Department devotes a mere three paragraphs to the Rule's purported effects on patient-provider communication—and none at all to the direct harms suffered by those who are denied information and care. 83 FR 3916-17.

[13] *See* https://www.hhs.gov/about/index.html.
[14] *See* https://www.hhs.gov/programs/index.html.

But this failure to address the obvious consequences of giving federally-subsidized providers *carte blanche* to decide whom to treat or not treat based on religious or moral convictions—or indeed, based on any reasoning or none at all[15]—does not mean the harm does not exist. Indeed, the harms would be substantial. For example, as set forth in more detail below, the Proposed Rule:

- Appears to provide immunities for health care institutions and professionals who refuse to provide complete information to patients about their condition and treatment options;

- Would result in patients being denied, or delayed in getting, health care to the extent the Rule requires health care facilities to employ people who refuse to perform core functions of their jobs;

- Purports to create new "exemptions," that would leave patients who rely on federally-subsidized health care programs, such as Title X family planning services, unable to obtain services those programs are required by law to provide;

- Creates confusion about whether hospitals can refuse to provide, and bar its staff from providing, emergency care to pregnant women who are suffering miscarriages or otherwise need emergent abortion care; and

- Invites health care providers to discriminate against individuals based on who they are by, for example, refusing to provide otherwise available services to a patient for the sole reason that the patient is transgender.

These harms will fall most heavily on historically disadvantaged groups and those with limited economic resources. As the ACLU's own cases and requests for assistance reflect, women, LGBT individuals, and members of other groups who continue to struggle for equality are those who most often experience refusals of care. The Proposed Rule's unauthorized expansion of the Refusal Statutes will only exacerbate these disparities.

Likewise, people with low and moderate incomes will suffer most acutely under the Proposed Rule. The Refusal Statutes, and therefore the expansive Proposed Rule, are tied to federal funding. Individuals with limited income are more likely to rely on health care that is in some manner tied to federal funding and are therefore more likely to be subject to the refusals to provide care and information sanctioned by the Proposed Rule. Thus, for example, if a health care entity that, under the Proposed Rule, is now able to obtain a government contract to provide Title X family planning services despite its unwillingness to provide the required services, low-income individuals in the area are likely to have few, if any, other options for the care.

[15] Although the NPRM highlights religious freedom and rights of conscience, a number of the Refusal Statutes – and the proposed expansions of those in the Rule – do not turn on the existence of any religious or moral justification. The Proposed Rule would empower not only those acting based on the basis of belief, but others acting, for example, out of bare animus toward a patient's desired care or any aspect of their identity.

Not only will this result in the outright denial of care to the detriment of patients' health, it will also impose serious economic consequences that the Proposed Rule fails to take into account. For example, the denial of care can result not only in greater health care costs, but also in lost wages (and in some cases loss of employment), increased transportation costs and increased child care costs. For women, immigrant patients, and rural patients, these snowballing effects can be particularly acute. Yet, remarkably, the Proposed Rule finds no effect at all on the "disposable income or poverty of families and children" from expanding denials of health care. 83 FR 3919. Contrary to the Department's conclusions, this Rule would impose new costs on and create new pressures for many families, especially those with the least economic means.

Rather than seek to expand patient protections, the Proposed Rule appears to launch a direct attack on existing federal legal protections that prevent or remedy discrimination against patients. *See, e.g., infra* Part IV. The Rule raises equal concern with regard to its intended effect on state laws that aim to enhance patient protection and address discrimination. The Preamble devotes extensive discussion to "Recently Enacted State and Local health care laws" that have triggered some litigation by "conscientious objectors," 83 FR 3888, characterizing those disputes as part of the rationale for the Rule.[16] But this rulemaking provides no clarity as to preservation of other legal protections and repeatedly evidences an intent to cut back on, for example, important equality safeguards for patients. At the very least, this will create severe confusion, creating competing and contradictory requirements, and in so doing put critical federal funding for vital care at risk. At worst, it targets vulnerable patients for increased refusals of care and the harms described above.

Because it is contrary to the very mission of the Department, attempts to license widespread denials of care and harm to patients, and fosters discrimination, the Proposed Rule should be withdrawn.

II. The Department Lacks the Authority to Promulgate the Proposed Rule.

Not only does the Rule undermine patient's health, it is unauthorized. For example, the Department does not possess *any* legislative rulemaking powers under the Church, Coats-Snowe or Weldon Amendments – the Amendments that form the bases for the bulk of the Rule – and thus it lacks the authority to promulgate this Rule with respect to those statutes.

"It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). With this Proposed Rule, the Department clearly seeks to adopt legislative rules that will impose force-of-law, substantive requirements and compliance procedures that must be followed by covered entities. But there is no authority delegated by Church, Coats-Snowe or Weldon to undertake such rulemaking. Indeed, in prior litigation, the Department itself emphasized that "[i]n the first place, it is not clear that the Weldon Amendment can be said to delegate regulatory authority to the Executive Branch at all." Br. of

[16] *See also* 83 FR 3889 (seeking to "clarify" that conscience protections "supersede conflicting provisions of State law"; pointing to state requirements, for example, that insurers include abortion coverage in health plans as illustrations of "the need for greater clarity concerning the scope and operation" of federal rights of refusal).

Defs. at 35, *National Family Planning and Reproductive Health Association v. Gonzales*, 391 F. Supp. 2d 200 (D.D.C. 2005), *available at* 2004 WL 3633834; *see also* 76 FR 9971, 9975 (discussing that the Amendments do not provide for promulgation of regulations).

None of the Amendments includes, or references, *any* explicit delegation of regulatory authority. *Compare, e.g.*, 42 U.S.C. § 2000d-1 (expressly directing all relevant federal agencies to issue "rules, regulations, or orders of general applicability" to achieve the objectives of Title VI). Nor is there any implicit delegation of legislative rulemaking authority for these provisions. As underscored by the decades that Church, Coats-Snowe and Weldon have applied without any legislative rulemaking supplementing their content, those enactments do not give the Department the power to issue force-of-law rules under them, as the Department is now – expansively – trying to do.[17] For this reason alone, the Department cannot properly proceed to adopt the Proposed Rule or any similar variation of it.

III. The Rule Proposes Numerous Expansive Definitions That Defy the Meaning of the Statutory Terms and Would Fuel Confusion, Misinformation, and Denials of Care.

Even if the Department had the necessary rulemaking authority (which it does not), the Proposed Rule's broad definition of certain terms and expansions of the Refusal Statutes' reach would far exceed any conceivable authority. An agency cannot use rulemaking to extend the scope of a statute. *See City of Arlington, Tex. v. F.C.C.*, 569 U.S. 290, 297 (2013) (agency must stay within the bounds of the statute under which it acts). Yet that is what this Rule does, through numerous proposed "definitions," including, among others, those proposed for "assist in the performance," "referral or refer for," and "discrimination."

Indeed, it is telling that the Rule's Preamble devotes four pages in the Federal Register to trying to justify its over-reaching definitions, but does not attempt to describe the Rule's proposed substantive requirements at all. Instead, the Preamble claims that the substantive requirements are simply "taken from the relevant statutory language." 83 FD 3895. But that assertion is belied by, *inter alia*, the Department's proposed expansion and re-writing of those statutes through impermissible re-definition of numerous statutory terms and other sleights of hand. Any rule-making of this kind needs to attempt to explain not only the definitions of words, but how those definitions and the Rule's substantive requirements come together to regulate conduct, which the Department utterly fails to do.

For example, the Department proposes to define "assist in the performance" of an abortion or sterilization to include not only assistance *in the performance* of those actual procedures—the ordinary meaning of the phrase—but also participation in any other activity

[17] Although the Bush Administration promulgated similar rules in December 2008, those rules did not take full effect before their reconsideration and rescission commenced. The eventual replacement regulation, which became final in 2011 and remains in force today, consists of just two provisions describing solely that OCR is designated to receive complaints under the Amendments. The Department promulgated that rule under 5 U.S.C. § 301, the Department's "housekeeping" authority for adopting regulations limited to the conduct of its own affairs. Section 301 does not authorize the promulgation of substantive regulatory requirements like those in the Proposed Rule. *See* 76 FR 9975-76. Moreover, that we here highlight the lack of regulatory rule-making authority under Section 301 and under the Amendments should not be read to imply that any such authority exists under the other Refusal Statutes referenced in this NPRM; the Proposed Rule does not specify *any* authority for legislative rulemaking.

with "an articulable connection to a procedure[.]" 83 FR 8892, 3923. Through this expanded definition, the Department explicitly aims to include activities beyond "direct involvement with a procedure" and to provide "broad protection"—despite the statutory references limited to "assist[ance] in the performance of" an abortion or sterilization procedure itself. *Id.*; *cf. e.g.*, 42 U.S.C. § 300a-7(c)(1).

This would mean, for example, that simply admitting patients to a health care facility, filing their charts, transporting them from one part of the facility to another, or even taking their temperature could conceivably be considered "assist[ing] in the performance" of an abortion or sterilization, as any of those activities could have an "articulable connection" to the procedure. As described more fully below, *see infra* Part VI, the Proposed Rule would even sanction the withholding of basic information about abortion or sterilization on the grounds that "assist[ing] in the performance" of a procedure "includes but is not limited to counseling, referral, training, and other arrangements for the procedure." 83 FD 3892, 3923.

But the term "assist in the performance" does not have the virtually limitless meaning the Department proposes ascribing to it. The Department has no basis for declaring that Congress meant anything beyond actually "assist[ing] in the performance of" the specified procedure—given that it used that phrase, 42 U.S.C. § 300a-7(c)(1). There is no basis for the Department to interpret that term to mean any activity with any connection that can merely be articulated, regardless of how attenuated the claimed connection, how distant in time, or how non-procedure-specific the activity.

Likewise, the Proposed Rule's definition of "referral or refer for" impermissibly goes beyond the statutory language and congressional intent. The Rule declares that "referral or refer for" means "the provision of *any* information … by any method … pertaining to a health care service, activity, or procedure … that could provide *any assistance* in a person obtaining, assisting, … financing, or performing" it, where the entity (including a person) doing so "sincerely understands" the service, activity, or procedure to be a "possible outcome[.]" 83 FR 3894, 3924 (emphasis added). This expansive definition could have dire consequences for patients. For example, a hospital that prohibits its doctors from even discussing abortion as a treatment option for certain serious medical conditions could attempt to claim that the Rule protects this withholding of critical information because the hospital "sincerely understands" the provision of this information to the patient may assist the patient in obtaining an abortion.[18]

But by providing a green light for the refusal to provide information that patients need to make informed decisions about their medical care, the Proposed Rule not only violates basic medical ethics, but also far exceeds congressional intent. A referral, as used in common parlance and the underlying statutes, has a far more limited meaning than providing *any* information that *could* provide *any assistance whatsoever* to a person who may ultimately decide to obtain, assist, finance, or perform a given procedure sometime in the future. The meaning of "referral or refer for" in the health care context is to *direct* a patient elsewhere for care. *See* Merriam-Webster, https://www.merriam-webster.com/dictionary/referral ("referral" is "the process of directing or redirecting (as a medical case or a patient) to an appropriate specialist or agency for definitive

[18] As explained in Part VI(B), *infra*, the Proposed Rule's overbroad interpretation of the phrase "make arrangements for," 83 FR 3895, compounds the problems with the unjustified definition of referral.

treatment"); Medicare.gov, *Glossary: Referral*, https://www.medicare.gov/glossary/r.html (defining referral as "[a] written order from your primary care doctor for you to see a specialist or get certain medical services"); HealthCare.gov, *Glossary: Referral*, https://www.healthcare.gov/glossary/referral/ (same); Ctrs. for Medicare & Medicaid Services Website, *Glossary: Referral*, https://www.cms.gov/apps/glossary/default.asp?Letter=R&Language ("Generally, a referral is defined as an actual document obtained from a provider in order for the beneficiary to receive additional services."); *id.* (a referral is a "written OK from your primary care doctor for you to see a specialist or get certain services").

In addition, the Proposed Rule's definition appears to include a subjective element not present in any of the referenced statutes or in the ordinary meaning of "referral": Under the Rule, an entity's "sincere understanding" determines whether or not a referral has occurred. 83 FR 3924; *see also* 83 FR 3894 n.46 (claiming that a "referral constitutes moral cooperation with a conscientiously objected activity"). The Proposed Rule states that it is attempting to provide "broad protection for entities unwilling to be complicit in" certain services, 83 FR 3895, but transforming "refer for" into a much looser, subjective notion of being "complicit in" is a significant departure from the actual statutory language of the Refusal Statutes and plainly exceeds the Department's authority.

These expansive definitions are all the more troubling to the extent the Proposed Rule's definition of "discrimination" purports to provide unlimited immunity for institutions or employees who refuse to perform essential care. The Rule apparently attempts to provide unlimited immunity for institutions that receive some federal funds to deny abortion care, to block coverage for such care, or to stop patients' access to information, no matter what the patients' circumstances or the mandates of state or federal law. Likewise, the definition appears aimed at providing immunity for employees who refuse to perform central parts of their job, regardless of the impact on the ability of a health care entity to provide appropriate care to its patients. This expansion of "discrimination" would apparently treat virtually any adverse action—including government enforcement of a patient non-discrimination or access-to-care law—against a health care facility or individual as *per se* discrimination. Indeed, the definition of discrimination appears designed to provide a tool to stop enforcement of state laws providing more protection of patients, particularly those seeking abortion care. But "discrimination" does not mean any negative action, and instead requires an assessment of context and justification, with the claimant showing unequal treatment on prohibited grounds under the operative circumstances. [19] *See infra* Parts IV-V.

While this comment letter does not attempt to detail all of the unfounded definitional expansions included in the Proposed Rule, other examples abound. *See e.g.*, 83 FR 3893

[19] The Rule should not be expanded even further by an unfounded "disparate impact" concept that has no place in implementing these narrowly-targeted Refusal Statutes. While the Proposed Rule does not explain its proffered "disparate impact" concept, such a concept might empower the Department, for example, to forbid *any* enforcement of a general state government policy that is contrary to a particular institution's religious dictates, or of a neutral employment rule that is contrary to some employees' beliefs (rather than accepting that an employer's obligations are at most reasonable accommodation of particular employees, if possible without undue hardship, *see infra* Part IV).

(proposing to define "health care entity" to include those employers and others who sponsor health plans but "are *not* primarily in the business of health care") (emphasis added), 3894 (proposing to define "workforce" to include volunteers and contractors, despite those individuals' independence from any corporate or public entities employing workers), 3894 (erroneously expanding definition of "health service program"), 3923-24.[20] The Department has no authority to expand the Refusal Statutes in this way, and these irrational definitions that are contrary to both the Refusal Statutes and congressional intent should be explicitly rejected.

IV. The Proposed Rule Threatens to Upend the Appropriate Balance Struck by Long-Standing Federal Laws.

A. The Proposed Rule Ignores the Careful Balance Title VII Strikes Between Protecting Employees' Religious Beliefs and Ensuring Patients Can Obtain the Health Care They Need.

The Proposed Rule is not only unauthorized and harmful to patients, it is also unnecessary as federal law already amply protects individuals' religious freedom—freedom the ACLU has fought to protect throughout its nearly 100-year history.

For example, for more than four decades, Title VII has required employers to make reasonable accommodations for current and prospective employers' religious beliefs so long as doing so does not pose an "undue hardship" to the employer. 42 U.S.C. §§ 2000e(j), 2000e-2(a).[21] An "undue hardship" occurs under Title VII when the accommodation poses a "more than *de minimis* cost" or burden on the employer's business. *Trans World Airlines, Inc. v. Hardison*, 432 U.S. 63, 84 (1977); EEOC Guidelines, 29 C.F.R. § 1605.2(e)(1). Thus, Title VII—while protecting employees' freedom of religion—establishes an essential balance. It recognizes that an employer cannot subject an employee to less favorable treatment solely because of that employee's religion and that generally an employer must accommodate an employee's religious practices. However, it does not require accommodation when the employee objects to performing core job functions, particularly to the extent those objections harm patients, depart from standards of care, or otherwise constitute an undue hardship. *Id.*; *see also Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703 (1985). This careful balance between the needs of employees, patients, and employers is critical to ensuring that health care employers are able to provide quality health care.

Despite this long-standing balance, nowhere does the Proposed Rule mention these basic legal standards or the need to ensure patient needs are met. Instead, by presenting a seemingly unqualified definition of what constitutes "discrimination," 83 FR 3923-24, the Department

[20] Moreover, the Proposed Rule not only re-defines words and phrases from the Refusal Statutes, but also adds words. For example, Section 1303 of the Patient Protection and Affordable Care Act ("ACA"), 42 U.S.C. § 18023(b)(1)(A)(i), refers to "abortion services"; the Proposed Rule expands that to "abortion or abortion-related services," without defining what that added term – found nowhere in the statute – purports to cover. 83 FR 3926; *see also, e.g.*, 83 FR 3924 (defining "health program or activity" without any apparent use of phrase in a Refusal Statute though it is used to protect patients in Section 1557 of the ACA).

[21] For purposes of Title VII, religion includes not only theistic beliefs, but also non-theistic "moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views." Equal Employment Opportunity Commission ("EEOC") Guidelines, 29 C.F.R. §1605.1.

appears to attempt to provide complete immunity for religious refusals in the workplace, no matter how significantly those refusals undermine patient care, informed consent, or the essential work of health care institutions. Indeed, the Rule is explicit in seeking an unlimited ability to "be[] free not to act contrary to one's beliefs," regardless of the harm it causes others. 83 FR 3892. This definition thus raises real concerns that the Proposed Rule could be invoked by employees or job applicants who refuse to perform core elements of the job. For example, job applicants may attempt to claim that a family planning provider is required to hire them as pregnancy options counselors even though they refuse to provide any information about the option of abortion and even where the provision of such information is required by the provider's federal funding.

However, neither the Refusals Statutes, nor any other federal law, permits such an unprecedented re-definition of "discrimination." When Congress prohibited discrimination in certain Refusal Statutes, it did not *sub silentio* create an absolute right to a job even if the employee refuses to perform essential job functions, as that has never been the meaning, legal or otherwise, of "discrimination." *See, e.g.*, *McDonnell Douglas Corp. v. Green*, 411 U.S. 793, 802 (1973) (employment discrimination claim requires proof that employee was qualified for the position, and employer may articulate a legitimate, non-discriminatory job-related reason to defeat such a claim). Such an unfounded definitional shift for "discrimination" improperly expands narrow congressional enactments and attempts to reinterpret federal laws, all long construed to be harmonious, to instead be conflicting and contradictory. It turns the Department's mission on its head. If the Department does not withdraw the entire Rule, it should explicitly limit its reach and attempt to clarify how Title VII's balance can continue to have full force and effect in the workplace.

B. Rather than Ensuring Patients Can Get Care in an Emergency, the Proposed Rule Describes the Obligation to Provide Critical Care as Part of the "Problem."

The Proposed Rule puts patients at risk by ignoring the federal Emergency Medical Treatment and Labor Act ("EMTALA") and hospitals' obligations to care for patients in an emergency. As Congress has recognized, a refusal to treat patients facing an emergency puts their health and, in some cases, their lives at serious risk. Through EMTALA, Congress has required hospitals with an emergency room to provide stabilizing treatment to any individual experiencing an emergency medical condition or to provide a medically beneficial transfer. 42 U.S.C. § 1395dd(a)-(c).

The Refusal Statutes do not override the requirements of EMTALA or similar state laws that require health care providers to provide abortion care to a patient facing an emergency. *See, e.g.*, *California v. U.S.*, Civ. No. 05-00328, 2008 WL 744840, at *4 (N.D. Cal. March 18, 2008) (rejecting notion "[t]hat enforcing [a state law requiring emergency departments to provide emergency care] or the EMTALA to require medical treatment for emergency medical conditions would be considered 'discrimination' under the Weldon Amendment"). Indeed, after a challenge to the Weldon Amendment was filed on the ground that it could inhibit the enforcement of statutes requiring hospitals to provide emergency abortion care, Representative

Weldon emphasized that his amendment did not disturb EMTALA's requirement that critical-care facilities provide appropriate treatment to women in need of emergency abortions.[22]

It is particularly troubling, therefore, to have the Department include the long-standing legal and ethical obligation to provide emergency care to patients in the Rule's Preamble as *justification* for expanding the Refusal Statutes – in other words, as justification to *relieve* hospitals or hospital personnel of any obligation, for example, to perform an emergency abortion when a patient is in the midst of a miscarriage, or even to "refer" a patient whose health is deteriorating for an emergency abortion. 83 FR 3888, 3894. But the ethical imperative is the opposite: "In an emergency in which referral is not possible or might negatively affect a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections." 83 FR 3888 (quoting American Congress of Obstetricians and Gynecologists ("ACOG") ethics opinion and describing it as part of the problem the Proposed rule is meant to address).

Tragically, such concerns are far from hypothetical. As noted above, Tamesha Means was turned away from critical care three times, exposing her to serious risk and putting her life in jeopardy, and in the midst of being discharged the third time, was finally helped only when she started to deliver. Another miscarrying patient collapsed at home and almost bled to death after being turned away three different times from the only hospital in her community which refused to provide her the emergency abortion she needed.[23] Refusals such as these disproportionately affect women of color who are more likely than other women to receive their care at Catholic hospitals, which follow directives that can keep providers from following standards of care and governing law.[24]

The Proposed Rule suggests that hospitals that fail to provide patients like these with appropriate emergency care should be given a free pass. Any such license to refuse patients emergency treatment, including emergency abortions, however, would not only violate EMTALA, but also the legal, professional, and ethical principles governing access to health care in this country. For that reason, if not withdrawn in its entirety, the Proposed Rule should, as one of many necessary limitations, clarify that it does not disturb health care providers' obligations to provide appropriate care in an emergency.

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[22] *See* 151 Cong. Rec. H176-02 (Jan. 25, 2005) (statement of Rep. Weldon) ("The Hyde-Weldon Amendment is simple. It prevents federal funding when courts and other government agencies force or require physicians, clinics, and hospitals and health insurers to participate in *elective* abortions.") (emphasis added); *id.* (Weldon Amendment "ensures that in situations where a mother's life is in danger a health care provider must act to protect a mother's life"); *id.* (discussing that the Weldon Amendment does not affect a health care facility's obligations under EMTALA). Nor were the other Refusal Statutes intended to affect the provision of emergency care. *See*, e.g., 142 Cong. Rec. S2268-01, S2269 (March 19, 1996) (statement of Senator Coats in support of his Amendment) ("a resident needs not to have [previously] performed an abortion … to have mastered the procedure to protect the health of the mother if necessary"); *id.* at S2270 (statement of Senator Coats) ("[T]he similarities between the procedure which [residents] are trained for, which is the D&C procedure, and the procedures for performing an abortion are essentially the same and, therefore, [residents] have the expertise necessary, as learned in those training procedures, should the occasion occur and an emergency occur to perform an abortion.").

[23] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[24] *Id.* at 12 (2018).

C. The Proposed Rule Fosters Discrimination.

The Proposed Rule also puts patients at risk by ignoring the federal Patient Protection and Affordable Care Act ("ACA"), which explicitly confers on patients the right to receive nondiscriminatory health care in any health program or activity that receives federal funding. 42 U.S.C. § 18116. Incorporating the prohibited grounds for discrimination described in other federal civil rights laws, the ACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability. *Id.* at § 18116(a).

The Refusal Statutes must be read to coexist with the nondiscrimination requirements of the ACA and similar state nondiscrimination laws. If a nondiscrimination requirement has any meaning in the healthcare context, it must mean that patients cannot be refused care simply because of their race, color, national origin, sex, age, or disability. And as courts have recognized, the prohibition on sex discrimination under the federal civil rights statutes should be interpreted to prohibit discrimination against transgender people. *See Whitaker by Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1049-50 (7th Cir. 2017) (discrimination against transgender students violates Title IX, which is the basis for the ACA's prohibition on sex discrimination); *see also EEOC v. R.G. & G.R. Funeral Homes, Inc.*, __ F.3d __, 2018 WL 1177669 at *5-12 (6th Cir. Mar. 7, 2018) (Title VII); *Glenn v. Brumby*, 663 F.3d 1312, 1316-19 (11th Cir. 2011) (Title VII); *Rosa v. Park W. Bank & Tr. Co.*, 214 F.3d 213, 215-16 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schwenk v. Hartford*, 204 F.3d 1187, 1201-03 (9th Cir. 2000) (Gender Motivated Violence Act).

Notwithstanding these protections, as well as explicit statutory protections from discrimination based on gender identity and sexual orientation in many states, the Proposed Rule invites providers to discriminate against LGBT patients, particularly transgender people. The Department includes as a *justification* for expanding the Refusals Statutes a California lawsuit—*Minton v. Dignity Health*—in which a transgender patient is suing under the state nondiscrimination law, alleging that he was denied care a religiously-affiliated hospital routinely provided to other patients, simply because he is transgender. 83 FR 3888-89 & n.36. The Proposed Rule thus suggests that discrimination against a patient simply because he is transgender is permissible—in violation not only of California's nondiscrimination law, but also of the ACA. For that reason, if not withdrawn in its entirety, the Proposed Rule should, as one of many necessary limitations, clarify that it does not disturb health care providers' obligations to provide nondiscriminatory care.

D. The Proposed Rule Creates Confusion That Threatens to Deprive Title X Clients of Services That the Underlying Statutes and Regulations Require.

Finally, the Proposed Rule threatens to undermine the Title X program, which for more than four decades has provided a safety net upon which millions of low-income, under-insured, and uninsured individuals rely each year for family planning essential to their health and the promise of equality. For example, Congress requires that all pregnancy counseling within the Title X program be neutral and "nondirective." *See, e.g.*, Pub. L. No. 115-31 at 521. The Department's own regulations also require that pregnant women receive "neutral, factual

information" and "referral[s] upon request" for prenatal care and delivery, adoption, and/or abortion. 42 C.F.R. § 59.5(a)(5). Yet the Proposed Rule's unauthorized expansion of the Weldon Amendment, *see infra* Part V(C), creates confusion about whether health care entities that refuse to provide non-directive options counseling (which includes discussion of abortion) and abortion referrals may seek to claim an exemption from these requirements and therefore a right to participate in the Title X program despite their refusal to provide the services to which Title X clients are entitled. The Department cannot promulgate a rule that conflicts with federal law in this manner and if it is not withdrawn, the Department should make explicit that it does not provide an exemption to the Title X requirements.

* * *

None of the Refusal Statutes was intended or designed to disrupt the balance between existing federal laws—such as Title VII, EMTALA, Title X and also later-in-time statutes, such as Section 1557 of the ACA—or to create categorical and limitless rights to refuse to provide basic health care, referrals, and even information. Thus, even if the Department had the authority to promulgate the Proposed Rule (which it does not), the Proposed Rule is so untethered to congressional language and intent that it must be withdrawn or substantially modified.

V. The Rule Attempts Impermissibly Transform the Referenced Statutes Into Shields for Inadequate or Discriminatory Care.

The Proposed Rule not only distorts the definitions of words in the statutes, but also alters their substantive provisions in other ways to attempt to expand the ability of entities and individuals to deny care in contravention of legal and ethical requirements and to the severe detriment of patients. Some of these additional statutory expansions, are highlighted below.

A. Examples of Impermissible Church Amendment Expansions.

Subsection (b) of the Church Amendments, for example, specifies only that the receipt of Public Health Service Act funding *in and of itself* does not permit a court or other public authority to require that an individual perform or assist in the performance of abortion or sterilization, or require that an entity provide facilities or personnel for such performance. *See, e.g.*, 42 U.S.C. 300a-7(b) ("The receipt of any grant, contract or loan guarantee under the Public Health Service Act . . . by any individual does not authorize any court or any public official or other public authority to require . . . such individual to perform or assist in the performance of any sterilization procedure or abortion if [doing so] would be contrary to his religious beliefs or moral convictions."). The Proposed Rule, however, attempts to transform that limited prohibition – that receipt of certain federal funds alone does not create an obligation to provide abortions or sterilizations – into an across-the-board shield that forbids any public entity from determining that *any* source of law requires that the entities provide these services. 83 FR 3924-25. If the Rule is not withdrawn, the Department should modify the Rule so that it does not exceed the statute.

Similarly, the Proposed Rule apparently aims to vastly expand the prohibitions contained in subsection (d) of the Church Amendments in a manner that is contrary to the legislative language, the statutory scheme, and congressional intent. Congress enacted Subsection (d) of the Church Amendment in 1974 as part of Public Law 93-348, a law that addressed biomedical and behavioral research, and appended that new Subsection (d) to the pre-existing subsections of Church from 1973, which all are codified within 42 U.S.C. § 300a-7: the "Sterilization or Abortion" section within the code subchapter that relates to "Population Research and Voluntary Family Planning Programs."

Despite this explicit and narrow context for Subsection (d), the Proposed Rule attempts to transform this Subsection into a much more general prohibition that would apply to *any* programs or services administered by the Department, and that would assertedly prevent any entity that receives federal funding through those programs or services from requiring individuals to perform or assistance in the performance of *any* actions contrary to their religious beliefs or moral convictions. *See* 83 FR 3894, 3906, 3925. This erroneous expansion of Church (d) could prevent health care institutions from ensuring that their employees provide appropriate care and information: It would purportedly prevent taking action against members of their workforce who refuse to provide any information or care that they "sincerely understand" may have an "articulable connection" to some eventual procedure to which they object, no matter what medical ethics, their job requirements, Title VII or laws directly protecting patient access to care may require.

The ACLU is particularly concerned that the Proposed Rule's erroneous expansion of Church (d) could be used to deny services because of the identity of the individual seeking help. To name a few of the many possibilities that could result from the Proposed Rule's emboldening of personal-belief-based care denials:

- A nurse could deny access to reproductive services to members of same-sex or inter-racial couples, because her religious beliefs condemn them;
- A physician could refuse to provide treatment for sexually transmitted infections to unmarried individuals, because of her opposition to non-marital sex;
- Administrative employees could refuse to process referrals or insurance claims, just as health care professionals could deny care itself, because they object to recognizing transgender individuals' identity and medical needs.

This inappropriately expanded conception of Church Subsection (d) conflicts with statutory language, the anti-discrimination protections of Section 1557 of the ACA, the requirements of EMTALA, and the balance established by Title VII, and otherwise manifestly overreaches in a number of respects. Instead, the Department should clarify that the Church Amendments are limited to what the statute provides and Congress intended.

B. Examples of Impermissible Coats-Snowe Amendment Expansions.

The Proposed Rule similarly stretches the Coats-Snowe Amendment beyond its language and Congress' clear intent. In 1996, Congress adopted the Coats-Snowe Amendment, entitled "Abortion-related-discrimination in governmental activities regarding training and licensing of physicians," in response to a decision by the Accrediting Council for Graduate Medical Education to require obstetrician-gynecologist residency programs to provide abortion training. The Proposed Rule, however, entirely omits that context.

Rather than being confined to training and licensing activities as the statute is, the Proposed Rule purports to give all manner of health care entities, including insurance companies and hospitals, a broad right to refuse to provide abortion and abortion-related care. In addition, the Rule's expansion of the terms "referral" and "make arrangements for" extends the Coats-Snowe Amendment to shield any conduct that would provide "any information … by any method … that could provide *any assistance* in a person obtaining, assisting, … financing, or performing" an abortion or that "render[s] aid to anyone else reasonably likely" to make such an abortion referral. 83 FR 3894-95, 3924 (emphasis added). This expansive interpretation not only goes far beyond congressional intent and the terms of the statute, it also could have extremely detrimental effects on patient health. For example, it would apparently shield, against any state or federal government penalties, a women's health center that required any obstetrician-gynecologist practicing there who diagnosed a pregnant patient as having a serious uterine health condition to refuse even to provide her with the name of an appropriate specialist, because that person "is reasonably likely" to provide the patient with information about abortion.

Again, if the Proposed Rule is not withdrawn, it should be pared back and clarified so as to be faithful to both the statutory text and congressional intent.

C. Examples of Impermissible Weldon Amendment Expansions.

The Department attempts the same sort of improper regulatory expansion of the Weldon Amendment, which is not a permanent statutory provision but a rider that Congress has attached to the Labor, Health and Human Services and Education Appropriations Act annually since 2004. As written, the Weldon Amendment is no more than a bar on particular appropriated funds flowing to federal agencies or programs, or state or local government, if any of those government institutions discriminate on the basis that a health care entity does not provide, pay for, provide coverage of, or refer for abortion. But the Proposed Rule attempts to vastly increase the Amendment's reach in multiple ways. First, the Proposed Rule explicitly extends the reach of the Weldon Amendment beyond the appropriations act to which it is attached, by stating that it also applies to any entity that receives any other "funds through a program administered by the Secretary," which would include, for example, Medicaid. 83 FR 3925. Second, although the terms of the Amendment itself bind only federal agencies and programs and state and local governments, the Rule expands Weldon's reach to also proscribe the behavior of any person, corporation, or public or private agency that receives any of this newly enlarged category of funds. *Id.*

The Rule then provides that no one of this greatly expanded universe of parties may subject any institutional or individual health care entity[25] to discrimination for refusal to provide, pay for, provide coverage for, or refer for abortions. Such unauthorized expansions of limited appropriations language seem designed to encourage broad and harmful denials of care. For example, under the expanded definitions contained in the Proposed Rule, an employer, even one with no religious or moral objection to abortion, may attempt to claim that it has a right to deny its employees' insurance coverage for abortion irrespective of state law. Or a private health care network that receives Medicaid reimbursement could face employees asserting not only the ability to refuse to participate in certain abortion-related care, but also to remain in their positions without repercussions. This is not implementation of the Weldon Amendment; this is a new scheme. If the Rule is not withdrawn, the Department should modify the Rule so that it does not exceed the statute.[26]

VI. The Proposed Rule Appears Intended to Provide a Shield for Health Care Providers Who Fail to Provide Complete Information to Patients in Violation of Both Medical Ethics and Federal Law.

The Proposed Rule also appears to allow providers to let their own personal preferences distort provider-patient communications and deprive patients of critical health care information about their condition and treatment options. The Proposed Rule's Preamble suggests the Rule will improve physician-patient communication because it will purportedly "assist patients in seeking counselors and other health-care providers who share their deepest held convictions." 83 FR 3916-17. But patients are already free to inquire about their providers' views and providers must already honor patients' own expressions of faith and decisions based on that faith. *Cf. id.* Allowing *providers* to decide what information to share—or not share—with patients, as the Rule would do, regardless of the requirements of informed consent and professional ethics would gravely harm trust and open communication in health care.

As the American Medical Association's Code of Medical Ethics ("AMA Code") explains, the relationship between patient and physician "gives rise to physicians' ethical responsibility to place patients' welfare about the physician's own self-interest[.]" AMA Code § 1.1.1. Even in instances where a provider opposes a particular course of action based on belief, the AMA states that the provider must "[u]phold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects." *Id.* § 1.1.7(e). Similarly, ACOG emphasizes that "the primary duty" is to the patient, and that without exception "health care providers must impart accurate and unbiased information so that patients can make informed decisions about their health care." ACOG Committee Opinion No. 385, Recommendations 1-2 (Nov. 2007) (Reaffirmed 2016). Therefore, under well-established principles of informed consent and medical ethics, health care providers must provide patients with all of the information they need to make their own decisions; providers

[25] Although the Weldon Amendment itself defines "health care entity" to include individual health care professionals or "any other kind of health care facility, organization or plan," the Proposed Rule's definitions, as discussed above, try to further extend "health care entity" to also encompass companies or associations whose primary purpose is *not* health care, but who happen to sponsor a health care plan. This appears to reach employers.

[26] Moreover, for any promulgated Rule, the Department must explain its practical operation in detail, so that any affected public or private actors can ascertain the Department's meaning.

may not allow their own religious or moral beliefs to dictate whether patients receive full information about their condition, the risks and benefits of any procedure or treatment, and any available alternatives.

By erroneously expanding the meaning of "assist in the performance of," "refer for" and "make arrangements for," as described above, however, the Proposed Rule purports to allow health care providers to refuse to provide basic information to patients in ways that were never contemplated by the underlying statutes. As described above, these broad definitions may be used to immunize the denial of basic information about a patient's condition as well as her treatment options. Protecting health care professionals when they withhold this vital information from patients violates fundamental legal and ethical principles, deprives patients of the ability to make informed decisions and leads to negligent care. If the Department moves forward with the Proposed Rule, it should modify it to make clear that it does not subvert basic principles of medical ethics and does not protect withholding information from a patient about her condition or treatment options.

VII. The Rule Would Violate the Establishment Clause Because It Authorizes Health Care Providers to Impose their Faith on their Patients, to the Detriment of Patient Health.

The Proposed Rule imposes the significant harms on patients identified above in service of institutional and individual religious objectors. It purports to mandate that their religious choices take precedence over the health care needs of patients. But the First Amendment forbids government action that favors the free exercise of religion to the point of forcing unwilling third parties to bear the burdens and costs of someone else's faith. As the Supreme Court has emphasized, "[t]he principle that government may accommodate the free exercise of religion does not supersede the fundamental limitation imposed by the Establishment Clause." *Lee v. Weisman*, 505 U.S. 577, 587 (1992); *accord Bd. of Educ. of Kiryas Joel Village School Dist. v. Grumet*, 512 U.S. 687, 706 (1994) ("accommodation is not a principle without limits").

Because the Rule attempts to license serious patient harms in the name of shielding others' religious conduct, it is incompatible with our longstanding constitutional commitment to separation of church and state. *See Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 708-10 (1985) (rejecting, as Establishment Clause violation, law that freed religious workers from Sabbath duties, because the law imposed substantial harms on other employees); *see also Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 14, 18 n.8 (1989) (plurality opinion) (invalidating sales tax exemption for religious periodicals, in part because the exemption "burden[e]d nonbeneficiaries markedly" by increasing their tax bills). The Department should withdraw the Rule to avoid its violation of the Establishment Clause.

VIII. The Proposed Enforcement Scheme Is Excessive and Fails to Adequately Protect the Due Process and Other Rights of Grantees.

As explained above, the Refusal Statutes carve out specific, narrow exemptions that are only relevant and applicable to certain entities and individuals in certain circumstances. Even with its unfounded expansion of the referenced Refusal Statutes, the Department forecasts only

10-50 complaint investigations or compliance reviews arising under the Refusal Statutes each year, all concerning objections to providing certain health care. 83 FR 3915, 3922. As such, these statutes are quite unlike the various provisions of the Civil Rights Act of 1964, or other civil rights or anti-discrimination statutes that provide broad protection against discrimination to the public or across a wide range of society. Despite these differences, the Proposed Rule claims to model its compliance and enforcement mechanisms on those broad "civil rights laws, such as Title VI and Section 504 of the Rehabilitation Act." 83 FR 3896, 3898. Yet, the Rule's enforcement provisions exceed the ones in place for civil rights laws and, notably, this proposed rulemaking does not anywhere reference basic constitutional limits or specify important due process protections against overzealous enforcement. Taken together, these provisions are ripe for abuse.

The following provisions, which are not an exhaustive list of the serious enforcement scheme issues, appear particularly problematic:

- Funded entities must disclose any complaints or compliance reviews under the Refusal Statutes or Rule from the last five years in any funding application or renewal request, even if the complaint did not warrant an investigation or the investigation or review closed with no finding of any violation, 83 FR 3930;

- The Rule permits onerous remedies for a "failure or threatened failure to comply," including withholding or terminating funding or referral to the Attorney General for "enforcement in federal court or otherwise" without waiting for any attempts at voluntary compliance or resolution through informal means, 83 FR 8330-31;

- The Rule allows the Department to employ the full array of punishments against funding recipients for infractions by sub-recipients, no matter how independent those sub-recipients' actions and no matter how vigorous the recipients' compliance efforts;[27]

- The Rule creates violations for failure to satisfy *any* information requests, and grants access to "complete records," providing especially expansive access with more stringent enforcement than in the Department's Title VI regulations, without any reference to the Fourth Amendment protections developed under Title VI and other similar laws, 83 FR 3829-30; and

- The Rule's enforcement scheme also appears to lack the robust administrative review process, including proceedings before a hearing officer and required findings on the

[27] As proposed subsection 88.6(a) provides, if a sub-recipient violation is found, the recipient "from whom the sub-recipient received funds shall be subject to the imposition of funding restrictions and other appropriate remedies available under this part." 83 FR 3930. This language lacks clarity as to whether imposing a penalty is mandatory or an option, but regardless, not every violation by a sub-recipient should open the recipient to the possibility of sanctions. Moreover, fund termination under the Proposed Rule does not appear to be restricted by the "pinpointing" concept that applies under Title VI, which ensures against vindictive, broad funding terminations and excessive harms to program beneficiaries. Neither this proposed subsection nor the other new enforcement provisions should be added to Part 88, but if they are, subsection 88.6(a) should, like the Proposed Rule's other unfounded enforcement expansions, be clarified and much more strictly limited.

> record, that must precede any suspension or termination of federal funding under, for example, Title VI's enforcement regulations. *See* 45 C.F.R. Part 81. If the Rule is not withdrawn, the Department should make clear that those same rigorous protections apply here.

In addition, while claiming such vast, unauthorized enforcement powers, the Department also repeatedly states that it proposes to uphold "the maximum protection" for the rights of conscience and "the broadest prohibition on" actions against any providers acting to follow their own beliefs. 83 FR 3899, 3931. This combination of a pre-ordained inclination in favor of refusers and excessive enforcement powers further threatens to undermine federal health programs by harming funding recipients who are serving patients well.

If the Rule is not withdrawn, it should be modified in accordance with these comments to ensure that providers of health care are not subjected to unduly broad inquiries or investigations, unfairly penalized, or deprived of due process, all to the detriment of focusing on care for their patients.

IX. The Department Has Not Shown the Need for Expanded Enforcement Authority and Requirements, Uses Faulty Regulatory Impact Analyses, and Proposes a Rule That Will Only Add Compliance Burdens and Significant Costs to Health Care.

Finally, the Department itself estimates hundreds of millions of dollars in cost, almost all imposed on entities providing health care, to undertake the elaborate compliance and enforcement actions the Rule contemplates. But the Proposed Rule's regulatory impact analysis severely underestimates the cost and other burdens it would impose. At virtually every step of its purported tallying of costs, the Department grossly underestimates the time that a covered institution's lawyers, management and employees will have to spend to attempt to understand the Rule, interpret its interplay with other legal and ethical requirements, train staff, modify manuals and procedures, certify and assure compliance, and monitor the institution's actions on an ongoing basis. For example, the Rule considers a single hour by a single lawyer enough for covered entities to "familiarize themselves with the content of the proposed rule and its requirements." 83 FR 3912. It allocates 10 minutes per Refusal Statute, for the roughly two dozen laws referenced, for an entity to execute the assurance and certification of compliance—thus allocating no time for actually reviewing an entity's records or operations in order to do so. 83 FR 3913. Similarly, the impact analysis mentions the time necessary to disclose investigations or compliance reviews, but not the much more significant amount of time needed to respond to and cooperate in those processes. Moreover, the Department does not factor into cost *at all* the cost to the institution when employees refuse to perform care or provide information, or the costs to the refused patients, who must seek help elsewhere and suffer harms to their health.

In estimating benefits, the analysis does not demonstrate barriers to entry for health professionals, or exits from the health profession that are occurring, nor does it substantiate the contention that the medical field does not already include professionals with a wide diversity of religious and other beliefs. As discussed above, it claims benefits to provider-patient

communication and relationships that are non-existent. The Proposed Rule offers no evidence that either greater protection for refusals or expanded enforcement mechanisms are needed.

The Department's prior rulemaking, which emphasized outreach and enforcement, remains in effect and makes clear that OCR has sufficient enforcement authority, consistent with the specific governing statutes, to address any meritorious complaints or other violations. 45 C.F.R. Part 88; 76 FR 9968. In fact, the Department itself estimates that, even with adoption of the Proposed Rule, it would initiate only 10-50 OCR investigations or compliance reviews per year. Since 2008, the number of Refusal Statute complaints per year has averaged 1.25, with 34 complaints filed in the recent November 2016 to mid-January 2018 period.[28] The Proposed Rule contemplates an enormous outlay of funds to implement an elaborate and unnecessary enforcement system that will only divert resources away from enforcing patients' civil rights protections and the provision of high-quality health care to those who need it most.

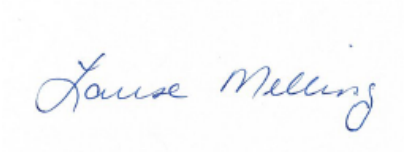
Thus, the Rule's analysis of economic impacts, including under Executive Orders 12866 and 13563, is seriously flawed and fails to demonstrate that any benefits of the Proposed Rule justify its enormous costs, many of which go unacknowledged. In addition, the Secretary proposes to falsely "certify that this rule will not result in a significant impact on a substantial number of small entities." 83 FR 3918. Small health care entities will have to bear the same regulatory analysis and ongoing compliance costs as larger entities, will face the same loss of employee time and effort from religious and other refusals, and yet have fewer resources and other employees to fall back on. While some small entities may be relieved of routinely certifying their compliance in writing, that compliance is still required – and the compliance itself imposes the much more significant cost and interference with its operations. Similarly, the Secretary erroneously "proposes to certify that this proposed rule … will not negatively affect family well-being," 83 FR 3919, when expanded refusals of medical information and health care by federally funded providers would significantly affect the stability, disposable income, and well-being of low-income families.

The Rule's regulatory impact analyses utterly fail to support its adoption. This expansive rulemaking exceeds any statutory authority and overwhelms any need, and would leave health care institutions, patients, and their families suffering.

* * *

For all these reasons, the Department should withdraw the Proposed Rule.

Sincerely,



Louise Melling
Deputy Legal Director

Faiz Shakir
National Political Director

[28] For context, in FY 2017, OCR received a total of 30,166 complaints under all of the federal statutes it enforces.

EXHIBIT H

March 27, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Public Comment in Response to the Proposed Regulation, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

To Whom it May Concern:

I am writing on behalf of Community Catalyst in response to the request for public comment on the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26.[1]

Community Catalyst is a national non-profit advocacy organization dedicated to quality affordable health care for all. Since 1997, Community Catalyst has been working to build the consumer and community leadership required to transform the American health system. With the belief that this transformation will happen when consumers are fully engaged and have an organized voice, Community Catalyst works in partnership with national, state and local consumer organizations, policymakers and foundations, providing leadership and support to change the health care system so it serves everyone - especially vulnerable members of society.

This proposed regulation would exacerbate the challenges that many patients -- especially women, LGBTQ people, people of color, immigrants and low-income people -- already face in getting the health care they need in a timely manner and at an affordable cost. The rule would expose vulnerable patients to increased discrimination and denials of medically-indicated care by broadening religious health care provider exemptions beyond the existing limited circumstances allowed by law. Moreover, while protecting health providers who deny care, the rule would provide *no protections for patients who are being denied care – even in emergencies*. As drafted, the rule would not even require that patients be informed of all their potential treatment options and referred to alternative providers of needed care.

[1] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (proposed Jan. 26, 2018) (*to be codified at* 45 C.F.R. pt. 88) [*hereinafter* Rule].

Indeed, this proposal runs in the opposite direction of everything the American health system is striving to achieve in the pursuit of "patient-centered care." We urge the administration to put patients first, and withdraw the proposed regulation because of the serious problems enumerated below.

1. The rule improperly seeks to expand on existing religious refusal exemptions to potentially allow denial of any health care service based on a provider's personal beliefs or religious doctrine.

Existing refusal of care laws (such as for abortion and sterilization services) are already being used across the country to deny patients the care they need.[2] The proposed rule attempts to expand on these laws in numerous ways that are directly contrary to the stated purpose of the existing laws. Specifically, the Department and its Office for Civil Rights (OCR) are attempting to require a broad swath of entities to allow individuals to refuse "*any* lawful health service or activity based on religious beliefs or moral convictions (emphasis added)."[3]

This expansive interpretation could lead to provider denials based on personal beliefs that are biased and discriminatory, such as objections to providing care to people who are transgender or in same-sex relationships. We are aware of cases in which this type of unjust denial of care has occurred, such as a California physician's denial of donor insemination to a lesbian couple, even though the doctor routinely provided the same service to heterosexual couples. [4]

We are also concerned about potential enabling of care denials by providers based on their non-scientific personal beliefs about other types of health services. For example, certain religiously-affiliated hospitals and individual clinicians have refused to provide rape victims with emergency contraception to prevent pregnancy[5] based on the belief that it can cause an abortion, even though there is no scientific evidence that this is the case. Providers could conceivably be motivated by the proposed rule to object to administering vaccinations or refuse to prescribe or dispense Pre-exposure Profylaxis (PrEP) medication to help gay men reduce the risk of HIV transmission through unprotected sex.

2. The rule would protect refusals by anyone who would be "assisting in the performance of" a health care service to which they object, not just clinicians.

The rule seeks to protect refusals by any "member of the workforce" of a health care institution whose actions have an "articulable connection to a procedure, health services or health service program, or research activity." The rule includes examples such as "counseling, referral, training and other arrangements for the procedure, health service or research activity."

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[2] *See, e.g.*, *Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Uttley, L., et al, *Miscarriage of Medicine,* MergerWatch and the ACLU (2013), https://www.aclu.org/report/miscarriage-medicine.

[3] *See* Rule *supra* note 1, at 12.

[4] Hardaway, Lisa, *Settlement Reached in Case of Lambda Legal Lesbian Client Denied Infertility Treatment by Christian Fundamentalist Doctors,* Lambda Legal, September 29, 2009, accessed at https://www.lambdalegal.org/news/ca_20090929_settlement-reached.

[5] Erdely, Sabrina, *Doctors' beliefs can hinder patient care*, SELF magazine, June 22, 2007, accessed at http://www.nbcnews.com/id/19190916/print/1/displaymode/1098/

An expansive interpretation of "assist in the performance of" thus *could conceivably allow an ambulance driver to refuse to transport a patient to the hospital for care he/she finds objectionable*. It could mean a hospital admissions clerk could refuse to check a patient in for treatment the clerk finds objectionable or a technician could refuse to prepare surgical instruments for use in a service.

On an institutional level, the right to refuse to "assist in the performance of" a service could mean a religiously-affiliated hospital or clinic could deny care, and *then also refuse to provide a patient with a referral or transfer to a willing provider* of the needed service. Indeed, the proposed rule's definition of "referral" goes beyond any common understanding of the term, allowing refusals to provide *any information,* including location of an alternative provider, that could help people get care they need.[6]

The proposed rule thus could be read as allowing health providers to refuse to inform patients of all potential treatment options. A 2010 publication of the National Health Law Program, "Health Care Refusals: Undermining Quality of Care for Women," noted that "refusal clauses and institutional restrictions can operate to deprive patients of the complete and accurate information necessary to give informed consent."[7]

3. The rule does not address how a patient's needs would be met in an emergency situation.

There have been reported instances in which pregnant women suffering medical emergencies – including premature rupture of membranes (PPROM) and ectopic pregnancies[8] -- have gone to hospital emergency departments and been denied prompt, medically-indicated care because of institutional religious restrictions.[9] This lack of protections for patients is especially problematic in regions of the country, such as rural areas, where there may be no other nearby hospital to which a patient could easily go without assistance and careful medical monitoring enroute.[10]

The proposed rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person

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[6] *See* Rule *supra* note 1, at 183.

[7] The NHeLP publication noted (at page 21) that the Ethical and Religious Directives for Catholic Healthcare Services, which govern care at Catholic hospitals, limit the information a patient can be given about treatment alternatives to those considered "morally legitimate" within Catholic religious teachings. (Directive No. 26).

[8] Foster, AM, and Smith, DA, *Do religious restrictions influence ectopic pregnancy management? A national qualitative study*, Jacob Institute for Women's Health, Women's Health Issues, 2011 Mar-Apri; 21(2): 104-9, accessed at https://www.ncbi.nlm.nih.gov/pubmed/21353977

[9] Stein, Rob, *Religious hospitals' restrictions sparking conflicts, scrutiny,* The Washington Post, January 3, 2011, accessed at https://www.washingtonpost.com/health-environment-science/religious-hospitals-restrictions-sparking-conflicts-scrutiny/2011/01/03/ABVVxmD_story.html?utm_term=.cc34abcbb928

[10] For example, a 2016 study found there were 46 Catholic-affiliated hospitals that were the federally-designated "sole community providers" of hospital care for their geographic regions. Women needing reproductive health services that are prohibited by Catholic health restrictions would have no other easily accessible choice of hospital care. Uttley, L., and Khaikin, C., *Growth of Catholic Hospitals and Health Systems,* MergerWatch, 2016, accessed at www.MergerWatch.org

to another facility.[11] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[12] Because the proposed rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

4. **Health care institutions would be required to notify employees that they have the right to refuse to provide care, *but would not be required to notify patients about the types of care they will not be able to receive at that hospital, pharmacy, clinic or doctor's office*.**

The rule sets forth extensive requirements for health care institutions, such as hospitals, to notify employees about their refusal rights, including how to file a discrimination complaint with OCR. The rule requires posting of such notices on the employer's website and in prescribed physical locations within the employer's building. The rule also sets forth the expectation that OCR would investigate or do compliance reviews of whether health care institutions are following the posting rule.[13]

By contrast, the rule contains no requirement that patients be notified of institutional restrictions on provision of certain types of care. Such notification is essential because research has found that patients often are unaware of service restrictions at religiously-sponsored health care institutions. [14]

5. The rule conflicts with other existing federal laws, including the Title VII framework for accommodation of employee's religious beliefs.

The Proposed Rule generates chaos through its failure to account for existing laws that conflict with the refusals of care it would create. For example, the proposed rule makes no mention of Title VII,[15] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[16] Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.[17] For decades, Title VII has

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[11] 42 U.S.C. § 1295dd(a)-(c) (2003).

[12] In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. *See, e.g.*, *Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220, 228 (3rd Cir. 2000); *In re Baby K*, 16 F.3d 590, 597 (4th Cir. 1994); *Nonsen v. Medical Staffing Network, Inc.* 2006 WL 1529664 (W.D. Wis.); *Grant v. Fairview Hosp.*, 2004 WL 326694, *93 Fair Empl. Prac. Cas.* (BNA) 685 (D. Minn. 2006); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); *Barris v. County of Los Angeles*, 972 P.2d 966, 972 (Cal. 1999).

[13] The notice requirement is spelled out in section 88.5 of the proposed rule.

[14] *See*, for example, Freedman, Lori R., Luciana E. Hebert, Molly F. Battistelli, and Debra B. Stulberg, *Religious hospital policies on reproductive care: what do patients want to know?* American Journal of Obstetrics & Gynecology 218, no. 2 (2018): 251-e1, accessed here: http://www.ajog.org/article/S0002-9378(17)32444-4/fulltext; also Guiahi, Maryam, Jeanelle Sheeder, and Stephanie Teal, *Are women aware of religious restrictions on reproductive health at Catholic hospitals? A survey of women's expectations and preferences for family planning care*, Contraception and Stulberg, D., et all, accessed here: http://www.contraceptionjournal.org/article/S0010-7824(14)00358-8/fulltext; *Do women know when their hospital is Catholic and how this affects their care? Restrictions in Catholic Hospitals (PARRCH) national survey*, Contraception, Volume 96, Issue 4, 268-269,accessed here: http://www.contraceptionjournal.org/article/S0010-7824(17)30235-4/fulltext; a

[15] 42 U.S.C. § 2000e-2 (1964).

[16] *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.

[17] *See id.*

established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal obligations. The proposed rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[18]

Furthermore, the language in the proposed rule would seem to put health care entities in the position of being forced to hire people who intend to refuse to perform essential elements of a position, even though Title VII would not require such an "accommodation." For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the applicant refuses to provide non-directive options counseling, even though the employer would not be required to do so under Title VII.[19] It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

6. There is no provision protecting the rights of health care providers with religious or moral convictions to *provide* (not deny) services their patients need.

The proposed rule ignores those providers with deeply held moral convictions that motivate them to provide patients with health care, including abortion, transition-related care and end-of-life care. The rule fails to acknowledge the Church Amendment's protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[20]

Doctors are, in effect, forced to abandon their patients when they are prevented by health care institutions from providing a service they believe is medically-indicated. This was the case for a doctor in Sierra Vista, Arizona, who was prevented from helping end a patient's wanted, but doomed, pregnancy after she suffered premature rupture of membranes. The patient had to be sent to the nearest non-objecting hospital, which was 80 miles away, far from her family and friends. The physician described the experience as "a very gut wrenching thing to put the staff through and the patient, obviously."[21]

7. The proposed rule carries severe consequences for patients and would exacerbate existing inequities.

a. *Refusals of care make it difficult for many individuals to access the care they need*

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[18] Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), *available at* https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html.
[19] *See* Rule *supra* note 1, at 180-181.
[20] *See* The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).
[21] Uttley, L, et all, *Miscarriage of Medicine,* MergerWatch and the ACLU (2013), p. 16, https://www.aclu.org/report/miscarriage-medicine.

Across the country, refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need.[22] One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care.[23] Another woman experiencing pregnancy loss was denied care for 10 days at a religiously affiliated hospital outside Chicago, Illinois.[24] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[25] A patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic hospital provider refused to give her the procedure.[26] Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options.[27]

b. *Refusals of care are especially dangerous for those already facing barriers to care*

Refusals of care based on personal beliefs already make it difficult for many individuals to obtain health care and have real consequences for those denied the care they need because of a clinician's or hospital's religious beliefs. When women and families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another location, refusals bar access to necessary care.[28] This is especially true for immigrant patients who often lack access to transportation and may have to travel great distances to get the care they need.[29] In rural areas there may be no other sources of health and life preserving medical care.[30] When these individuals encounter refusals of care, they may have nowhere else to go.

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[22] *See, e.g.*, *supra* note 2.

[23] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[24] *See* Julia Kaye, et al., *Health Care* Denied, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

[25] *See* Kira Shepherd, et al., *supra* note 23, at 29..

[26] *See The Patient Should Come First: Refusals to Provide Reproductive Health Care*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/05/Refusals-FS.pdf; Sandhya Somashekhar, *A Pregnant Woman Wanted her Tubes Tied. Her Catholic Hospital Said No.*, WASH. POST (Sept. 13, 2015), https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2_story.html?utm_term=.8c022b364b75.

[27] *See* Kira Shepherd, et al., *supra* note 23, at 27.

[28] In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. *Women's Health Insurance* Coverage, KAISER FAMILY FOUND. 1, 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage.

[29] Athena Tapales et al., *The Sexual and Reproductive Health of Foreign-Born Women in the United States*, CONTRACEPTION 8, 16 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf; Nat'l Latina Inst. For Reproductive Health & Ctr. For Reproductive Rights, *Nuestra Voz, Nuestra Salud, Nuestro Texas: the Fight for Women's Reproductive Health in the Rio Grande Valley* 1, 7 (2013), http://www.nuestrotexas.org/pdf/NT-spread.pdf.

[30] Since 2010, eighty-three rural hospitals have closed. *See Rural Hospital Closures: January 2010 – Present*, THE CECIL G. SHEPS CTR FOR HEALTH SERVS. RES. (2018), http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that In 19 states, women of color are more likely than white women to give birth in Catholic hospitals.[31] Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provide guidance on a wide range of hospital matters, including reproductive health care, and can keep providers from offering the standard of care.[32] Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women were delayed care or transferred to other facilities at great risk to their health.[33] The reach of this type of religious refusal of care is growing with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.[34]

We concur with the comments submitted by the National Health Law Program (NHeLP) that the regulations fail to consider the impact of refusals on persons suffering from substance use disorders. Rather than promoting the evidence-based standard of care, the rule could allow practitioners to refuse to provide, or even recommend, Medication Assisted Treatment (MAT) and other evidence-based interventions due simply to a personal objection.

Stigma associated with drug use stands in the way of saving lives.[35] America's prevailing cultural consciousness -- after decades of treating the disease of addiction as largely a criminal justice and not the public health issue it is -- generally perceives drug use as a moral failing and drug users as less deserving of care. For example, a needle exchange program designed to protect injection drug users from contracting blood borne illnesses such as HIV, Hepatitis C, and bacterial endocarditis was shut down in October 2017 by the Lawrence County, Indiana County Commission due to their moral objection to drug use, despite overwhelming evidence that these programs are effective at reducing harm and do not increase drug use.[36] One commissioner even quoted the Bible as he voted to shut it down. Use of MAT to reverse overdose has been decried as "enabling these people" to go on to overdose again.[37]

In this frame of mind, only total abstinence is seen as successful treatment for substance use disorders, usually as a result of a 12-step or faith-based program, even though evidence for 12-step

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[31] *See* Kira Shepherd, et al., *supra* note 23, at 12.
[32] *See id.* at 10-13.
[33] Lori R. Freedman, *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.
[34] *See, e.g.*, *Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.
[35] Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance*, 13 J. HEALTH CARE L. & POL'Y 49, 56 (2010); German Lopez, *There's a highly successful treatment for opioid addiction. But stigma is holding it back.*, https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone.
[36] German Lopez, *An Indiana county just halted a lifesaving needle exchange program, citing the Bible,* VOX, Oct. 20, 2017, https://www.vox.com/policy-and-politics/2017/10/20/16507902/indiana-lawrence-county-needle-exchange.
[37] Tim Craig & Nicole Lewis, *As opioid overdoses exact a higher price, communities ponder who should be saved*, WASH. POST, Jul. 15, 2017, https://www.washingtonpost.com/world/as-opioid-overdoses-exact-a-higher-price-communities-ponder-who-should-be-saved/2017/07/15/1ea91890-67f3-11e7-8eb5-cbccc2e7bfbf_story.html?utm_term=.4184c42f806c.

programs is weak. The White House's own opioid commission found that "negative attitudes regarding MAT appeared to be related to negative judgments about drug users in general and heroin users in particular."[38]

People with substance use disorders already suffer due to stigma and have a difficult time finding appropriate care. This rule, which allows misinformation and personal feelings to get in the way of science and lifesaving treatment, would not help achieve the goals of the administration; it could instead trigger countless numbers of deaths.

By expanding refusals of care, the proposed rule will exacerbate the barriers to health care services patients need. It is evident that the harm caused by this proposed rule will fall hardest on those most in need of care. The Department should remember, under Executive Order 13563, an agency may only propose regulations where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on society."[39] The proposed rule plainly fails on both counts. Although the proposed rule attempts to quantify the costs of compliance, it completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs.[40] Moreover, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant religious exemptions and, in fact, bars granting an exemption when it would detrimentally affect any third party.[41] Because the proposed rule would cause substantial harm, including to patients, it would violate the Establishment Clause.[42]

8. The Department is abdicating its responsibility to patients

The proposed rule exceeds OCR's authority by abandoning OCR's mission to address health disparities and discrimination that harms patients.[43] Instead, the proposed rule appropriates language from civil

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[38] Report of the President's Commission on Combating Drug Addiction and the Opioid Crisis, Nov. 1, 2017, https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf

[39] *Improving Regulation and Regulatory Review*, Executive Order 13563 (Jan. 18, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review.

[40] *See* Rule *supra* note 1, at 94-177.

[41] U.S. Const. amend. I; *Cutter v. Wilkinson*. 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment Clause, courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985)); *see also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).

[42] Respecting religious exercise may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *See Burwell v. Hobby Lobby*, 134 S. Ct. at 2787. When considering whether the birth control coverage requirement was the least restrictive means in Hobby Lobby, the Court considered that the accommodation offered by the government ensured that affected employees "have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing coverage." *See id.* at 2759. In other words, the effect of the accommodation on women would be "precisely zero." *Id.* at 2760.

[43] *OCR's Mission and Vision*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html ("The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS

rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the proposed rule creates a regulatory scheme that is not only nonsensical but is affirmatively harmful. For example, the notice and certification of compliance and assurance requirements simply do not make sense when applied to the laws the proposed rule seeks to enforce.[44]

The Department, including OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities.[45] If finalized, however, the proposed rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care, and eliminate health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.[46]

Nevertheless, there is still work to be done, and the proposed rule seeks to divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color.[47] Black women are three to four times more likely than white women to die during or after childbirth.[48] According to a recent report, doctors often fail to inform Black women of the full range of reproductive health options regarding labor or delivery, possibly due to stereotypes about Black women's sexuality and reproduction.[49] Young Black women said they felt they were shamed by

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programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

[44] *See* Rule *supra* note 1, at 203-214.

[45] As one of its first official acts in 1967, the Office of Equal Health Opportunity undertook the massive effort of inspecting 3,000 hospitals to ensure they were complying with Title VI's prohibition against discrimination on the basis of race, color, or national origin. 42. U.S.C. § 2000d (1964). After this auspicious start, the Office of Equal Health Opportunity which would eventually become OCR would go on to ensure that health programs and activities it regulated complied with key anti-discrimination laws including Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (1973), Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 (1972), the Age Discrimination Act of 1976, 42 U.S.C. § 6101 (1976), and Section 1557 of the Affordable Care Act, 42 U.S.C. §18116 (2010), among others. Through robust enforcement of these laws, OCR has worked to reduce discrimination in health care.

[46] *See, e.g., Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html; *Protecting the Civil Rights and Health Information Privacy Rights of People Living with HIV/AIDS*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html; *National Origin Discrimination*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/index.html; *Health Disparities*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

[47] *See* Skinner et al., *Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans*, NAT'L INSTIT. OF HEALTH 1 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf.

[48] *See* Nina Martin, *Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why*, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why.

[49] CTR. FOR REPROD. RIGHTS, NAT'L LATINA INST. FOR REPROD. HEALTH & SISTERSONG WOMEN OF COLOR REPROD. JUSTICE COLLECTIVE, *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care* 20-22 (2014), *available at*

providers when seeking sexual health information and contraceptive care, due to their age and in some instances, sexual orientation.[50]

Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[51] Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a health care provider had refused to see them because of their actual or perceived sexual orientation or gender identity in the year before the survey.[52]

As NHelP's comments note, many people with disabilities receive home and community-based services (HCBS), including residential and day services, from religiously-affiliated providers. Historically, people with disabilities who rely on these services have sometimes faced discrimination, exclusion and a loss of autonomy due to provider objections. Group homes have, for example, refused to allow residents with intellectual disabilities who were married to live together in the group home.[53] Individuals with HIV – a recognized disability under the Americans with Disabilities Act (ADA) – have repeatedly encountered providers who deny services, necessary medications and other treatments citing religious and moral objections. One man with HIV was refused care by six nursing homes before his family was finally forced to relocate him to a nursing home 80 miles away.[54] Given these and other experiences, the extremely broad proposed language at 45 C.F.R. § 88.3(a)(2)(vi) that would allow any individual or entity with an "articulable connection" to a service, referral, or counseling described in the relevant statutory language to deny assistance due to a moral or religious objection is extremely alarming and could seriously compromise the health, autonomy and well-being of people with disabilities.

OCR must work to address these disparities, yet the proposed rule seeks to prioritize the expansion of existing religious refusal laws beyond their statutory requirements and create new religious exemptions where none had previously existed rather than using already limited resources to protect patient access to health care. The proposed rule will harm patient care and is antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality.[55]

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https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD_Shadow_US_6.30.14_Web.pdf [hereinafter *Reproductive Injustice*]; IN OUR OWN VOICE: NAT'L BLACK WOMEN'S REPROD. JUSTICE AGENDA, *The State of Black Women & Reproductive Justice* 32-33 (2017), *available at* http://blackrj.org/wp-content/uploads/2017/06/FINAL-InOurVoices_Report_final.pdf.

[50] *Reproductive Injustice*, *supra* note 10, at 16-17.

[51] *See, e.g.*, *When Health Care Isn't Caring*, LAMBDA LEGAL 5 (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring_1.pdf.

[52] *See* Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NAT'L GAY AND LESBIAN TASK FORCE & NAT'L CTR. FOR TRANSGENDER EQUALITY, http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.

[53] See *Forziano v. Independent Grp. Home Living Prog.*, No. 13-cv-00370 (E.D.N.Y. Mar. 26, 2014) (dismissing lawsuit against group homes, including a religiously affiliated group home, that refused to allow married couple with intellectual disabilities live together). Recent regulations have reinforced protections to ensure available choice of roommates and guests. 42 C.F.R. §§ 441.301(c)(4)(vi)(B) & (D).

[54] NAT'L WOMEN'S LAW CTR., *Fact Sheet: Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS,* (May 2014), *available at* https://nwlc.org/wp-content/uploads/2015/08/lgbt_refusals_factsheet_05-09-14.pdf.

[55] *See supra* note 42.

9. The proposed rule will make it harder for states to protect their residents

The proposed rule will have a chilling effect on the enforcement of and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. The preamble of the proposed rule discusses at length state laws that the Department finds objectionable, such as state laws that require anti-abortion counseling centers to provide information about where reproductive health care services can be obtained or whether facilities have licensed medical staff, as well as state laws that require health insurance plans to cover abortion.[56] Moreover, the proposed rule invites states to further expand refusals of care by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.[57]

10. The proposed rule will undermine critical federal health programs, including Title X

The proposed rule would seemingly allow health care entities to receive grants and contracts under HHS-funded programs or other federal health programs, such as Title X, the only domestic family planning program, while refusing to provide key services required by those programs.[58] For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[59] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[60] Under the Proposed Rule, the Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such funds are generally conditioned.[61] The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the sub-recipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.[62] When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objectives. Every year millions of low-income, including under-insured, and uninsured individuals, rely on Title X clinics to access services they otherwise might not be able to afford.[63]

Conclusion

The proposed rule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The proposed rule is discriminatory, violates multiple federal statutes, ignores

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[56] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.
[57] *See id.*
[58] *See* Rule *supra* note 1, at 180-181, 183. *See also Title X Family Planning*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (2018), https://www.hhs.gov/opa/title-x-family-planning/index.html; *Title X an Introduction to the Nation's Family Planning Program*, NAT'L FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOC. (2017) (*hereinafter* NFPRHA), https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf.
[59] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).
[60] *See* What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).
[61] *See, e.g.*, Rule *supra* note 1, at 180-185.
[62] *See* NFPRHA *supra* note 34.
[63] *See id.*

congressional intent, fosters confusion and harms patients, all of which are contrary to the Department's stated mission. For all of these reasons, Community Catalyst calls on the Department to withdraw the proposed rule in its entirety.

Respectfully submitted,

Robert Restuccia
Executive Director
Community Catalyst

EXHIBIT I

NATIONAL WOMEN'S LAW CENTER
EXPANDING THE POSSIBILITIES

March 27, 2018

Office for Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, D.C. 20201

Submitted Electronically

Attention: Comments in Response to Department of Health and Human Services, Office for Civil Rights, Conscience NPRM, RIN 0945-ZA03

Dear Secretary Azar,

The National Women's Law Center ("the Center") is writing to comment on the Department of Health and Human Services' ("the Department") and the Office for Civil Rights' ("OCR") proposed rule "Protecting Statutory Rights in Health Care" ("Proposed Rule").[1] Since 1972, the Center has worked to protect and advance the progress of women and their families in core aspects of their lives, including income security, employment, education, and reproductive rights and health, with an emphasis on the needs of low-income women and those who face multiple and intersecting forms of discrimination. To that end, the Center has long worked to end sex discrimination and to ensure all people have equal access to the full range of health care, including abortion and birth control, regardless of income, age, race, sex, sexual orientation, gender identity, ethnicity, geographic location, or type of insurance coverage.

Despite the Department's claims, the Proposed Rule is unnecessary. It is also illegal. The Proposed Rule attempts to create new rights for individuals and entities to refuse to provide patient care by expanding existing, harmful religious exemption laws in ways that exceed and conflict with both the plain language of the statutes and Congressional intent. The Proposed Rule also asserts authority over other federal laws, attempting to create new refusals to provide care. In creating these new rights and expanding its reach, the Proposed Rule conflicts with federal law thereby fostering confusion and chaos.

The Proposed Rule emboldens discrimination. By making it easier for institutions and individuals to refuse to provide comprehensive health care, the Proposed Rule endangers the health and lives of women and lesbian, gay, bisexual, transgender, and queer ("LGBTQ") people across the country. While the Center's comments focus in particular on the harm to women and access to reproductive health care, it is clear that the Proposed Rule will undermine the provision of health care and exacerbate health disparities for many patient populations, as other commentators will discuss. And yet the Department fails to take this harm into account. Contrary

[1] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (proposed Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88) [hereinafter *Rule*].

to the Department's claims, the Proposed Rule harms rather than helps the provider-patient relationship and burdens providers who want to provide comprehensive care.

For all of these reasons, explained in more detail below, the Center is strongly opposed to the Proposed Rule and calls on the Department and OCR to withdraw the Proposed Rule in its entirety.

I. Despite the Department's Claims, the Proposed Rule is Unnecessary, Emboldens Discrimination in Health Care, and Goes Far Beyond the 2008 Rule.

The Department claims that the Proposed Rule is necessary to protect individuals and health care providers from "discrimination, coercion, and intolerance."[2] But there is no need to address the so-called discrimination the Department purports to protect against. There are already ample religious exemptions in federal law, including in Title VII,[3] the Americans with Disabilities Act,[4] and the "ministerial exception" courts have read into the U.S. Constitution.[5] In addition, there are already a number of existing federal religious exemption laws that unfortunately allow individuals and entities to opt of providing critical health care services, in particular abortion and sterilization.[6] The Proposed Rule claims that more authority and enforcement of the religious exemption laws is needed, but the Notice of Proposed Rulemaking cites only forty-four complaints in ten years, which OCR is capable of handling without additional resources or authority.[7] Moreover, OCR already has authority to investigate complaints and, where appropriate, either collect funds wrongfully given while the entity was not in compliance or terminate funding altogether, and already educates providers about their rights under these laws.[8]

The reality is that the Department is seeking not to enforce existing laws but to expand them and create new rights under these laws. As explained below, this is unlawful and creates conflicts with other federal laws. Further, the Proposed Rule does not merely expand rights under existing refusal of care laws. Instead, it pulls in a host of new laws over which OCR has never before had authority, creating new rights and enforcement powers under these laws as well.

In so doing, the Proposed Rule does not address discrimination in health care, it emboldens it. The Proposed Rule intends to change existing law in order to allow any individual or entity involved in a patient's care – from a hospital's board of directors, to an insurance company, to the receptionist that schedules procedures – to use their personal beliefs to determine a patient's access to care. The Proposed Rule would further entrench discrimination against women and

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[2] *Id.* at 3903.
[3] 42 U.S.C. § 2000e-2 (1964).
[4] 42 U.S.C. § 12101 (1990).
[5] *See* Hosanna-Tabor Evangelical Lutheran Church v. Equal Emp't. Opportunity Comm'n, 132 S. Ct. 694, 704 (2012) (holding for the first time that the First Amendment requires a "ministerial exception").
[6] "Weldon Amendment", Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018); "Church Amendments" 42 U.S.C. § 300a-7 (2018); "Coats Amendment" 42 U.S.C. § 238n (2017).
[7] *Rule*, *supra* note 1, at 3886.
[8] *See* Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 45 C.F.R. pt. 88 (2011).

LGBTQ patients who already face high rates of discrimination in health care, including as a result of providers' religious beliefs. As explained in more detail below, this not only harms individuals and subjects them to discrimination, it is unlawful.

The Department tries to hide how far-reaching and dramatic this Proposed Rule is by claiming it is merely a reinstatement of the rule promulgated by the Bush Administration in 2008 and later rescinded by the Obama Administration in 2011.[9] Even if this was the case, the Proposed Rule would be dangerous. The 2008 rule was the subject of widespread opposition, including from 28 U.S. Senators and 131 Members of the U.S. House of Representatives, 14 state attorneys general, 27 state medical societies, the American Medical Association (AMA), American Hospital Association, National Association of Community Health Centers, American College of Emergency Physicians, and commissioners on the Equal Employment Opportunity Commission.[10] In fact, the AMA and several leading medical organizations argued the 2008 Rule would "seriously undermine patients' access to necessary health services and information, negatively impact federally-funded biomedical research activities, and create confusion and uncertainty among physicians, other health care professionals, and health care institutions."[11] But, the Proposed Rule reaches much further than the 2008 Rule. When compared to the 2008 Rule, the Proposed Rule seeks to allow more individuals and more entities to refuse care to patients and allow more services, or even information, to be refused, forces more entities to allow their employees to refuse care, imposes additional, unnecessary notice and compliance requirements, and invites states to further expand refusal laws.

II. The Proposed Rule Unlawfully Creates and Expands Rights to Refuse to Provide Care.

Under the Proposed Rule the Department intends to extend the reach of already harmful religious exemption laws so that any individual or entity, no matter how attenuated their involvement, can refuse to provide, participate in, or give information about any part of any health care service based on the assertion of a religious or moral belief. Furthermore, the Proposed Rule hamstrings the ability of an enormous range of entities to ensure that patients get the care they need. These expansions represent unlawful overreach by the Department and contradict the plain language of underlying federal law and Congressional intent.

a. The Proposed Rule Expands Existing Harmful Religious Exemption Laws

Although the Proposed Rule purports to merely interpret existing harmful federal laws that allow health care providers to refuse to treat an individual seeking an abortion and/or sterilization –

[9] *Rule, supra* note 1, at 3885. *See also* Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law 73 Fed. Reg. 78,071(Dec. 19, 2009) (2008 Rule) (rescinded in large part by 76 Fed. Reg. 9,968 (Feb. 23, 2011)(codified at 45 C.F.R. pt. 88)).
[10] Comment Letters on Proposed Rule Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law 73 Fed. Reg. 50,274 (Aug. 26, 2008) (on file with National Women's Law Center).
[11] American Medical Assoc. et al. Comment Letter on Proposed Rule 73. Fed. Reg. 50,274 (Aug. 26, 2008)(on file with National Women's Law Center).

namely the so-called Church, Coats, and Weldon Amendments – in fact it creates new rights that are not specifically and currently enumerated in those laws.

It does this in part by redefining words in harmful, expansive ways that belie common understandings of the terms in order to create new rights. For example:

- The Proposed Rule's definition of "assist in the performance" greatly expands not only the types of services that can be refused, but also the individuals who can refuse. It includes those merely making "arrangements for the procedure" no matter how tangential and could be read to include individuals such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees. In fact, the definition includes participation "in any program or activity with an *articulable connection* to a procedure…" (emphasis added).[12] While what is meant by "articulable connection" is not clear, the use of the term in case law indicates an intention for it to be interpreted broadly – a mere connection that one can articulate may suffice.[13]
- Through a broad definition of "entity" the Proposed Rule attempts to expand the individuals and types of entities covered by religious exemption laws and allow an even broader swath of individuals within those entities to refuse to do their jobs.[14] For example, under the Proposed Rule a Department grantee that provides health care transportation services for individuals with disabilities could attempt to claim a right to refuse to provide that service to a person who needs a sterilization procedure. Or an employee at a research and development laboratory could claim the right to refuse to accept the delivery of biomedical waste donated from a hospital with an obstetrics and gynecology practice that performs abortions.
- The Proposed Rule's definition of "referral" goes beyond any common understanding of the term, allowing refusals to provide any information that could help an individual to get the care they need. [15] The Proposed Rule does not even require that patients be informed of the individual's or entity's refusal to provide care, information, referrals, or other services, leaving patients unaware that their health care providers is not providing the care or information they need.
- The Proposed Rule's definition of "workforce" attempts to expand refusals of care to an even broader range of people and would allow almost all staff levels within an entity, including volunteers or trainees, to assert a new right to refuse to do their job.[16] For example, a volunteer at a hospital could claim a right to refuse to deliver medicine to a patient's room or even deliver meals to a patient who is recovering from a surgery to which the volunteer objects.

[12] *Rule, supra* note 1, at 3923.
[13] *Cf.* Jamerson v. Runnels, 713 F.3d 1218, 1229 (9th Cir. 2013) (describing the standard for evaluating whether a peremptory challenge was impermissibly based on race as "require[ing] only that the prosecutor express a believable and *articulable connection* between the race-neutral characteristic identified and the desirability of a prospective juror…"(emphasis added)).
[14] *Rule, supra* note 1, at 3924.
[15] *Id.*
[16] *Id.*

b. These New Rights are Contrary to Existing Law and Congressional Intent

The expansions and new and unwarranted definitions exceed and conflict with the existing federal laws the Proposed Rule seeks to enforce. For example, the Proposed Rule expands the definition of "health care entity" under existing law to include plan sponsors and third-party administrators.[17] Adding plan sponsors to the definition of "health care entity" under the Weldon Amendment is a blatant attempt to add words that plainly do not exist in the underlying federal law.[18] Indeed, just two years ago, OCR determined that the Weldon Amendment – according to its plain text – does not apply to plan sponsors.[19] This also holds true for the other ways in which the Proposed Rule attempts to expand the definition of "health care entity." Under the Coats and Weldon Amendments, "health care entity" is defined to encompass a limited and specific range of individuals and entities.[20] The Proposed Rule attempts to create a new definition of this term by combining statutory definitions of "health care entity" found in different statutes and applicable in different circumstances. Such an attempt to expand the meaning of a statutory term Congress already took the time to define goes directly against Congressional intent.[21]

The legislative history of the existing federal refusal of care laws reinforces that the Proposed Rule violates Congressional intent. For example, Congress adopted the Coats Amendment in response to a decision by the accrediting body for graduate medical education to rightfully require obstetrics and gynecology residency programs to provide abortion training. The legislative history of Coats states, "[p]roviders will continue to train the management of complications of induced abortion as well as train to handle [a] situation involving miscarriage and still birth or a threat to the life of the mother. The amendment requires no change in the practice of good obstetrics and gynecology."[22] The attempted expansion under the Proposed Rule to allow anyone to refuse to provide abortion regardless of the circumstances was clearly not intended. Similarly, proponents of the Weldon Amendment made "modest" claims about the Amendment, suggesting that the additional language was necessary only to clarify existing "conscience protections" not for it to be the sweeping license to refuse the Proposed Rule attempts to create.[23]

The Proposed Rule's expanded use of sections (c)(2) and (d) of the Church Amendments also violates Congressional Intent. These two sections were passed under Title II of the National Research Services Act in 1974, which specifically dealt with biomedical and behavioral research.[24] This Act was designed to ensure that research projects involving human subjects are

[17] *Id.*
[18] *See* Weldon Amendment, *supra* note 6.
[19] *See* Letter from Jocelyn Samuels, Director of Office for Civil Rights, to Catherine W. Short, Esq. et al. (June 21, 2016), *available at* http://www.adfmedia.org/files/CDMHCInvestigationClosureLetter.pdf.
[20] Weldon Amendment, *supra* note 6; Coats Amendment, *supra* note 6.
[21] The doctrine of *expressio unius est exclusion alterius* (the expression of one thing implies the exclusion of others) as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.
[22] 141CONG. REC. S17293 (June 27, 1995) (statement of Rep. Coats).
[23] 150 CONG. REC. H10090 (Nov. 20, 2004) (statement of Rep. Weldon).
[24] National Research Services Act of 1974, Pub. L. No, 93-348, 88 Stat. 348 § 214.

performed in an ethical manner.[25] Congress did not intend, as the Proposed Rule implies, to allow health care personnel to refuse to participate in any health care service. Such an expansion of the meaning of the Church Amendment was clearly not intended by Congress in the passage of the statute and would turn Congress' intent to protect patients on its head.

In other words, in greatly expanding the existing federal refusal laws relating to treating an individual seeking abortion or sterilization or refusing in the biomedical or behavioral research context, the Proposed Rule exceeds the scope of federal law and conflicts with congressional intent. It is therefore unlawful.

c. The Proposed Rule Overreaches Into Other Federal Laws, Undermining Congressional Intent

However, the Department does not limit its overreach to the aforementioned laws. Instead, under the Proposed Rule, the Department has unlawfully asserted authority over a greater number of federal statutes in an attempt to create new refusal provisions and to give the Department authority it previously did not have. For example, the Proposed Rule would prohibit a State agency that administers a Medicaid managed care program from requiring an organization "to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization objects."[26] However, the underlying Medicaid statute merely provides a rule of statutory construction which states that nothing in the statute should be construed to require a state agency that administers a Medicaid managed care program to use its funds for such purposes.[27] By misrepresenting the limited scope of this provision in order to create a new refusal provision, the Proposed Rule directly contradicts Congressional intent.

By attempting to create new refusal provisions, the Department also seeks to give OCR unlawful enforcement authority over these provisions. For many of these, Congress already established an enforcement scheme in the statute at issue. The Department should be reminded that "regardless of how serious the problem an administrative agency seeks to address … it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'"[28] Not only is it unlawful for the Department to alter the enforcement mechanisms contemplated by the statute, in many cases it would be nonsensical. For example, the Proposed Rule is attempting to re-delegate oversight of youth suicide early intervention and prevention strategies to OCR, despite the specific existing authority held by the Center for Substance Abuse Treatment.[29] Congress specifically created a "Center for Substance Abuse Treatment," the director of which is already charged with administering block grants and ensuring compliance with applicable law for development of youth suicide early intervention and prevention strategies.[30] The Department's attempt to alter this statutory scheme by attempting to give OCR

[25] *See, e.g.*, Todd W. Rice, *The Historical, Ethical, and Legal Background of Human-Subjects Research*, 53 RESPIRATORY CARE 2325 (2008), http://rc.rcjournal.com/content/respcare/53/10/1325.full.pdf.
[26] *Rule*, *supra* note 1, at 3926.
[27] *See* 42 U.S.C. § 1395w-22 (2010).
[28] *See* Food and Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 125-26 (2000).
[29] *See Rule*, *supra* note 1, at 3927.
[30] *See* Center for Substance Abuse Treatment, 42 U.S.C. § 290bb (2016); Youth Suicide Early Intervention and Prevention Strategies, 42 U.S.C. § 290bb-36 (2004).

authority to enforce certain provisions of the block grant is unlawful. Moreover, this change is nonsensical, given that the provision of statutory construction found within the statute outlining the program's requirement was never intended to be used to create a right to refuse.[31]

III. The Proposed Rule Conflicts with Federal Laws.

The Proposed Rule generates conflict and confusion, creating chaos with existing federal laws. It appropriates language from landmark civil rights laws while entirely failing to even mention important laws that protect patients from discrimination and unreasonable barriers to health care access, that already govern employment discrimination based on religious belief, and that ensure patients get the care they need, particularly in emergency situations. By unilaterally attempting to broaden existing refusal of care laws, the Department jettisons the careful balance present in existing federal law. The Department attempts to upset this existing federal balance without legitimate statutory authority or even a reasoned explanation.

a. The Proposed Rule Would Subvert Civil Rights Statutes by Attempting to Appropriate their Language

The Department has exceeded its authority by appropriating language from civil rights statutes and regulations that were intended to improve access to health care and applying that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the Proposed Rule creates a regulatory scheme that is not only unlawful, but is nonsensical and affirmatively harmful. For example, the notice and certification of compliance and assurance requirements simply do not make sense when applied to the laws the Proposed Rule seeks to enforce. They will place a significant and burdensome requirement on health care providers, taking resources away from patient care without adding any benefit.

Moreover, the Proposed Rule defines "discrimination" for the first time[32] and does so in a way that subverts the language of landmark civil rights statutes to shield those who would discriminate rather than to protect against discrimination. In this context, this broad definition is inappropriate. Further such a vague and inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements thereby fostering confusion.

b. The Proposed Rule Conflicts with Sections 1554 and 1557 of the Affordable Care Act

The Proposed Rule conflicts with two provisions of the Affordable Care Act.

Section 1554 of the Affordable Care Act prohibits the Secretary of Health and Human Services from promulgating any regulation that "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care."[33] As discussed in more detail below, religious refusals have been used to discriminate and deny patients the care they need based on the assertion of a religious or personal belief. By expanding the reach of refusals and permitting

[31] *See* 42 U.S.C. § 290bb-36 (2004).
[32] *Id.* at 3923-924.
[33] 42 U.S.C. § 18114(1) (2010).

objecting individuals and health care entities to deny patients needed health care services, the Proposed Rule erects unreasonable barriers to medical care and impedes access to health care services such as abortion and sterilization.[34]

Section 1557 of the Affordable Care Act prohibits discrimination in health care programs or activities on the basis of race, color, national origin, sex, age, or disability.[35] Prior to Section 1557, no broad federal protections against sex discrimination in health care existed. The ACA was intended to remedy this, as evidenced not only by the robust protection provided by Section 1557 itself, but also by the ACA's particular focus on addressing the obstacles women faced in obtaining health insurance and accessing health care.[36] As discussed in more detail below, by emboldening refusals for services that women and LGBTQ patients disproportionately or exclusively need, the Proposed Rule entrenches sex discrimination in health care and undermines the express purpose of Section 1557.

c. The Proposed Rule Conflicts with Title VII

The Proposed Rule makes no mention of Title VII, the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[37] With respect to religion, Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested unless the accommodation would impose an "undue hardship" on an employer.[38] For decades, Title VII has established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal

[34] The Proposed Rule therefore also violates § 706(2) of the APA, which instructs a reviewing court under arbitrary and capricious standard of review to consider and hold unlawful agency action found to be (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

[35] 42 U.S.C. § 18116 (2010).

[36] *See* 42 U.S.C. § 300gg(a) (2015) (allowing rating based only on family size, tobacco use, geographic area, and age, but not sex); 45 C.F.R. § 147.104(e) (2015) (prohibiting discrimination in marketing and benefit design, including on the basis of sex); *see also, e.g.*, 156 CONG. REC. H1632-04 (daily ed. March 18, 2010) (statement of Rep. Lee) ("While health care reform is essential for everyone, women are in particularly dire need for major changes to our health care system. Too many women are locked out of the health care system because they face discriminatory insurance practices and cannot afford the necessary care for themselves and for their children."); 156 CONG. REC. H1891-01 (daily ed. March 21, 2010) (statement of Rep. Pelosi) ("It's personal for women. After we pass this bill, being a woman will no longer be a preexisting medical condition."); 155 CONG. REC. S12026 (daily ed. Oct. 8, 2009) (statements of Sen. Mikulski) ("[H]ealth care is a women's issue, health care reform is a must-do women's issue, and health insurance reform is a must-change women's issue because . . . when it comes to health insurance, we women pay more and get less."); 155 CONG. REC. S10262-01 (daily ed. Oct. 8, 2009) (statement of Sen. Boxer) ("Women have even more at stake. Why? Because they are discriminated against by insurance companies, and that must stop, and it will stop when we pass insurance reform."); 156 CONG. REC. H1854-02 (daily ed. March 21, 2010) (statement of Rep. Maloney) ("Finally, these reforms will do more for women's health . . . than any other legislation in my career.").

[37] *See* 42 U.S.C. § 2000e-2 (1964); Title VII of the Civil Rights Act of 1964, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.

[38] *Id.*

obligations.[39] The Proposed Rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both the Proposed Rule and Title VII. Indeed, when similar regulations were proposed in 2008, EEOC commissioners and the Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[40]

Furthermore, the language in the Proposed Rule would seem to put health care entities in the position of being forced to hire people who intend to refuse to perform essential elements of a position even though Title VII would not require such an "accommodation." For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician who refuses to provide non-directive options counseling to women with positive pregnancy tests even though it is an essential job function. The employer would not be required to do so under Title VII. It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

d. The Proposed Rule Conflicts with Federal Law on Treatment of Patients Facing Emergency Situations

The Proposed Rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists and to stabilize the condition or, if medically warranted, to transfer the person to another facility.[41]

Because the Proposed Rule does not contain an explicit exception for situations in which an abortion – or other health service the Proposed Rule may empower individuals or entities to refuse – is needed to protect the health or life of a patient, the Proposed Rule is confusing to institutions regarding their obligations under the Proposed Rule as they relate to EMTALA. Every hospital is required to comply with EMTALA; even a religiously-affiliated hospital with an institutional objection to abortion must provide the care required in emergency situations.[42]

e. The Proposed Rule Violates the Establishment Clause

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[39] *Id.*

[40] Equal Emp't. Opportunity Comm'n. Legal Counsel Comment Letter on Proposed Rule 73 Fed. Reg. 50,274 (Sept. 24, 2008), *available at* https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html; Equal Emp't Opportunity Commissioners Christine Griffiin, Stuart Ishimaru Comment Letter on Proposed Rule 73 Fed. Reg. 50,274 (on file with National Women's Law Center).

[41] *See* 42 U.S.C. § 1395dd(a)-(c) (2003).

[42] In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. *See, e.g.*, Shelton v. University of Medicine and Dentistry of New Jersey, 223 F.3d 220, 228 (3rd Cir. 2000); *In re* Baby K, 16 F.3d 590, 597 (4th Cir. 1994); Nonsen v. Medical Staffing Network, Inc. 2006 WL 1529664 (W.D. Wis.); Grant v. Fairview Hosp. & Healthcare Servs., No. Civ. 02–4232JNEJGL, 2004 WL 326694, at *2 (D. Minn. 2006); Brownfield v. Daniel Freeman Marina Hosp., 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); Barris v. County of Los Angeles, 972 P.2d 966, 972 (Cal. 1999).

The Proposed Rule unlawfully establishes and adopts one subset of religious views while denying health care to those with differing views. In fact, staff within the Department have indicated that the Department intends to support evangelical beliefs over others.[43] These statements are consistent with the Department's actions.[44] The Department cannot promulgate proposed rules in reliance on unconstitutional preferences such as religious beliefs. Such actions are unlawful and out of line with the Department's historical mission.[45]

IV. The Proposed Rule Will Harm Patients, and the Department Has Failed to Take This Into Account.

The Proposed Rule is contrary to the Department's stated mission: "to enhance and protect the health and well-being of all Americans." In order to achieve that mission, one of the Department's primary goals is to "eliminate[ ] disparities in health, as well as [to increase] health care access and quality."[46] In its singular focus on what the Department claims is discrimination on the basis of religious or moral beliefs, it abdicates its mission. The Department ignores the pervasive discrimination in health programs and activities that individuals face, particularly those who seek reproductive health care, or because of their sex, gender identity, or sexual orientation. The Department unlawfully ignores how this discrimination is compounded by refusals of care based on personal beliefs and how the Proposed Rule will amplify that harm.

a. Certain Groups of Patients Routinely Face Discrimination in Health Care

Women have long been the subject of discrimination in health care.[47] Despite the historic achievements of the Affordable Care Act, women are still more likely to forego care because of cost,[48] and women – particularly Black women – are far more likely to be harassed by a

[43] Dan Diamond, *The Religious Activists on the Rise Inside Trump's Health Department*, POLITICO (Jan. 22, 2018), https://www.politico.com/story/2018/01/22/trump-religious-activists-hhs-351735.
[44] *See, e.g.*, Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding, 82 Fed. Reg. 49,300 (proposed Oct. 25, 2017); Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47, 792 (proposed Oct. 13, 2017).
[45] *OCR's Mission and Vision*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html ("The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").
[46] *See HHS Action Plan to Reduce Racial and Ethnic Health Disparities*, DEP'T OF HEALTH AND HUMAN SERVS., at 7, https://minorityhealth.hhs.gov/npa/files/Plans/HHS/HHS_Plan_complete.pdf.
[47] Prior to the Affordable Care Act (ACA), women were charged more for health care on the basis of sex and were continually denied health insurance coverage for services that only ciswomen, transgender, and gender non-conforming patients need. *See Turning to Fairness*, NAT'L WOMEN'S L. CTR. 1, 3-4 (2012), https://nwlc.org/wp-content/uploads/2015/08/nwlc_2012_turningtofairness_report.pdf (noting that while the ACA changed the health care landscape for women in significant ways, women still face additional hurdles).
[48] *See* Shartzer, et al., *Health Reform Monitoring Survey*, URBAN INST. HEALTH POLICY CTR. (Jan. 2015), http://hrms.urban.org/briefs/Health-Care-Costs-Are-a-Barrier-to-Care-for-Many-Women.html.

provider.[49] These barriers mean women are more likely not to receive routine and preventive care than men. Moreover, when women are able to see a provider, women's pain is routinely undertreated and often dismissed.[50] And due to gender biases and disparities in research, doctors offer women less aggressive treatment, or even no treatment, for conditions such as heart disease.[51]

LGBTQ individuals encounter high rates of discrimination in health care. According to one survey, eight percent of lesbian, gay, bisexual, and queer individuals had an experience within the year prior to the survey where a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation and seven percent experienced unwanted physical contact and violence from a health care provider.[52] Twenty-nine percent of transgender individuals were refused to be seen by a health care provider on the basis of their perceived or actual gender identity in the previous year.[53] Additionally, the 2015 U.S. Transgender Survey found that 23 percent of respondents did not see a provider for needed health care in the previous year because of fears of mistreatment or discrimination.[54]

And these barriers disproportionately impact those facing multiple and intersecting forms of discrimination, including women of color, LGBTQ persons of color, and individuals living with disabilities and those struggling to make ends meet. In one report, Black women disclosed that their doctors failed to inform them of the full range of reproductive health options regarding labor or delivery possibly due to stereotypes about Black women's sexuality.[55] Even though women living with disabilities report engaging in sexual activities at the same rate as women who do not live with disabilities, they often do not receive the reproductive health care they need for multiple reasons, including lack of accessible provider offices and misconceptions about their reproductive health needs.[56] These barriers also are often made worse by the complex web of

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[49] *See Discrimination in America: Experiences and Views of American Women*. NPR & HARVARD T.H. CHAN SCH. OF PUB. HEALTH (Dec. 2017), https://cdn1.sph.harvard.edu/wp-content/uploads/sites/21/2017/12/NPR-RWJF-HSPH-Discrimination-Women-Final-Report.pdf.

[50] *See, e.g.*, Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29:1 J. OF L., MED., & ETHICS 13, 13-27 (2001).

[51] *See, e.g.*, Judith H. Lichtman et al., Symptom Recognition and Healthcare Experiences of Young Women with Acute Myocardial Infarction, 10 J. OF THE AM. HEART ASS'N 1 (2015).

[52] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AMERICAN PROGRESS, (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/?link_id=2&can_id=d90c309ac9b5a0fa50d294d0b1cdf0b2&source=email-rx-for-discrimination&email_referrer=&email_subject=rx-for-discrimination.

[53] *Id*.

[54] *The Report of the 2015 U.S. Transgender Survey*, NAT'L CTR. FOR TRANSGENDER EQUALITY 5 (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf.

[55] *See The State of Black Women & Reproductive Justice*, IN OUR OWN VOICE (2017), http://blackrj.org/wp-content/uploads/2017/06/FINAL-InOurVoices_Report_final.pdf.

[56] RM Haynes et al., *Contraceptive Use at Last Intercourse Among Reproductive-Aged Women with Disabilities: An Analysis of Population-Based Data from Seven States*, CONTRACEPTION (2017), https://www.ncbi.nlm.nih.gov/pubmed/29253580; *see generally* Alex Zielinski, *Why Reproductive Health Can Be A Special Struggle for Women with Disabilities*, THINK PROGRESS, Oct. 1, 2015, https://thinkprogress.org/why-reproductive-health-can-be-a-special-struggle-for-women-with-disabilities-73ececea23c4/.

federal and state laws and policies that restrict access to care, particularly around certain health services like abortion.

b. Refusals of Care Based on Personal Beliefs Compound the Harm to Patients

This discrimination in health care against women, LGBTQ persons, and those facing multiple and intersecting forms of discrimination is exacerbated by providers invoking personal beliefs to deny access to health insurance and an increasingly broad range of health care services, including birth control, sterilization, certain infertility treatments, abortion, transition-related care, and end of life care.[57] For example, one woman experiencing pregnancy complications was rushed to the only hospital in her community, a religiously-affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care.[58] A transgender man was denied gender affirming surgery at a religiously-affiliated hospital that refused to provide him a hysterectomy.[59] A woman called an ambulance after experiencing abdominal pain, but the ambulance driver refused to take her to get the care she needed.[60]

When refusals of care happen, many patients are forced to delay or forego necessary care, which can pose a threat not only to their health, but their lives. This is particularly true for patients with limited resources and options. For many patients, such refusals do not merely represent an inconvenience but can result in necessary or even emergent care being delayed or denied outright. These refusals are particularly dangerous in situations where individuals have limited options, such as in emergencies, when needing specialized services, in rural areas, or in areas where religiously-affiliated hospitals are the primary or sole hospital serving a community. The reach of these types of refusals to provide care continues to grow with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously-affiliated entities that provide health care and related services.[61]

c. The Proposed Rule Will Further Harm Patients, Yet the Department Unlawfully Ignores that Harm

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[57] Directive 24 denies respect for advance medical directives. U.S. CONFERENCE OF CATHOLIC BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH CARE SERVICES (5th ed. 2009), http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf. Moreover, religiously-affiliated individuals have challenged key provisions of the federal law and implementing regulations that prohibit discrimination on the basis of sex, gender identity, or sexual orientation in health care. *Health Care Refusals Harm Patients: The Threat to Reproductive Health Care*, NAT'L WOMEN'S LAW CTR. (May 2014), http://www.nwlc.org/sites/default/files/pdfs/refusals_harm_patients_repro_factsheet_5-30-14.pdf.; *see also Health Care Denied*, AM. CIVIL LIBERTIES UNION (May 2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

[58] *See* Kira Shepherd, et al., *Bearing Faith: The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[59] *See id.* at 29.

[60] *Put Patient Health First*, NAT'L WOMEN'S LAW CENTER 1 (August 2017), https://nwlc.org/resources/continued-efforts-to-undermine-womens-access-to-health-care/.

[61] *See, e.g., Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.

By stretching refusals of care far beyond their current reach, the Proposed Rule leaves patients seeking reproductive or sexual health care services facing even greater threats to their health, life, and future fertility than they did before. In addition, the expansion of refusals of care under the Proposed Rule has far reaching implications for those providing or seeking services and information in a wide range of areas including HIV, drug addiction, infertility, vaccinations, psychology, sexually transmitted infections and end-of-life care, among others. This means that the Proposed Rule will compound harm to patients in multiple new ways, imposing additional hurdles patients must overcome to get the care they need. For example, young people in federal custody, including foster youth and unaccompanied immigrant children, already face enormous hurdles to accessing health care. Yet, the Proposed Rule seeks to allow foster parents, social service agencies, and shelters that provide services to young people to refuse even minor assistance to a young person in their care who needs health services, including STI testing or treatment and abortion care.

The reach of the Proposed Rule will create a vicious cycle where those already subject to multiple forms of discrimination in the health care system may be the most likely to find themselves seeking care from a health care professional who refuses to provide it. For example, in many states women of color are more likely than white women to give birth at a Catholic hospital.[62] By expanding refusals of care, the Proposed Rule will exacerbate the barriers to health care services patients need.

Yet despite the overwhelming evidence of discrimination against patients seeking health care services and the harm of refusals of care that are based on personal beliefs, the Department issued this Proposed Rule. The Department fails entirely to consider the impact of the Proposed Rule on patients, particularly individuals seeking reproductive health care, patients of color, and LGBTQ individuals. At no point does the Proposed Rule acknowledge the many ways it will harm patients. This consideration is required by law and by the U.S. Constitution, and the Department's failure to account for these requirements renders the Proposed Rule invalid and unlawful.

III. The Proposed Rule Erodes the Core Tenants of the Medical System.

The Proposed Rule undermines the trust in the provider-patient relationship and unduly burdens those health care providers who want to fulfill their obligations to provide patients with the care they need.

a. The Proposed Rule Undermines the Provider-Patient Relationship

A strong provider-patient relationship is the foundation of our medical system. Patients rely on their providers to give full information about their treatment options and to provide medical advice and treatment in line with the standards of care established by the medical community. Yet, the Proposed Rule allows providers to do the opposite, threatening informed consent,

[62] *See* Kira Shepherd, et al., *Bearing Faith: The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 12 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

undermining standards of care, and eroding patient trust in their providers and ultimately the medical system.

Informed consent is intended to help address the knowledge and power imbalance between providers and their patients, so patients can make their own competent and meaningful decisions about their treatment options.[63] The Proposed Rule acknowledges the importance of open, honest conversations in health care, stating "open communication in the doctor-patient relationship will foster better over-all care for patients."[64] Yet, it would allow providers, including hospitals and health care institutions, to ignore the patient's right to receive information and refuse to disclose relevant and medically accurate information about treatment options and alternatives. To make matters worse, the Proposed Rule includes provisions that specifically remove statutory requirements that health care entities at least notify patients they may be refused health care services or information. For example, it omits requirements enumerated in the counseling and referral provisions of the Medicaid managed care statute. These provisions require organizations that decline to cover certain treatments to notify enrollees of the policy.[65] The Department's attempts to affirmatively remove notice requirements underscore how little it cares about patients receiving full information. Allowing refusals to provide information and then barring patients from receiving any notice that they may not be given full information makes open communication impossible.

In addition to receiving non-biased information from their providers, patients also expect to receive treatment in line with medical practice guidelines and standards of care. Yet, the Proposed Rule seeks to allow providers, including hospitals and other health care institutions, to ignore the standards of care, particularly surrounding reproductive and sexual health. This completely undermines the provider-patient relationship and will create uncertainty and doubt where there should be trust and respect.

b. The Proposed Rule Burdens Providers that Want to Uphold the Hippocratic Oath and Provide Comprehensive Care

As the American Medical Association Code of Medical Ethics states, "the relationship between a patient and a physician is based on trust, which gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest."[66] Yet, the Proposed Rule flips this principle on its head – attempting to expand the ability of institutions to use personal beliefs to dictate patient care. In doing so, the Department allows institutions to block providers that want to provide patients with necessary or comprehensive care.

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[63] As the AMA Code of Ethics makes clear, "Informed Consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care." *Informed Consent*, AMERICAN MED. ASSOC., https://www.ama-assn.org/delivering-care/informed-consent (last visited Mar. 23, 2018).

[64] *Rule*, *supra* note 1, at 3917.

[65] The requirements of 42 U.S.C. § 1396u-2(b)(3)(B)(ii) excluded from the Proposed Rule's requirements surrounding Medicaid managed care organization. *See Rule*, *supra* note 1, at 3926.

[66] *Code of Medical Ethics: Patient-Physician Relationships*, AMERICAN MED. ASSOC., https://www.ama-assn.org/delivering-care/code-medical-ethics-patient-physician-relationships (last visited Mar. 23, 2018).

Most providers believe they should and must treat patients according to medical standards regardless of their personal beliefs. Moreover, many providers have deeply held moral convictions that affirmatively motivate them to provide patients with certain services, including abortion, transition-related care, and end-of-life care. Existing refusal of care laws already burden these providers. Hospital systems across the country use religious beliefs to prevent their employees from treating patients regardless of the professional, ethical, or moral convictions of these providers. The Proposed Rule would exacerbate these problems by expanding the number and types of institutions that can bind the hands of providers and limit the types of care, or even information, they can provide.

The Proposed Rule egregiously misuses research to falsely claim that a majority of obstetrician-gynecologists are unwilling to provide abortion.[67] In fact, the survey underlying the cited study found that over 80% of obstetrician-gynecologists are willing to help a patient obtain an abortion in the vast majority of cases. The survey also found that even where providers had a moral objection to providing abortion in a particular situation, a majority would still help the patient obtain an abortion.[68] Hospitals already discriminate against health care providers by preventing them from providing certain health care services, particularly abortion, even in life-threatening situations.[69] In fact, researchers have found that over a third of obstetrician-gynecologists experience conflict with their employers over religiously based patient care policies, with a majority of obstetrician-gynecologists at Catholic institutions reporting such conflicts.[70]

The Proposed Rule's expansion of entities that can constrain their employees not only ignores the barriers facing health care professionals who are committed to providing patients with comprehensive care regardless of personal beliefs, but it also ignores the Department's duty to enforce federal law that protects those who support abortion or sterilization. The Proposed Rule fails to acknowledge the Church Amendments' protection for health care professionals who support or participate in abortion or sterilization services. No health care professional should face discrimination from their employer because they treated or provided information to a patient seeking an abortion. But instead of acting to protect health care providers who put patients first, the Proposed Rule allows more institutions to interfere and prevent employees from providing care.

IV. The Proposed Rule Burdens States that Want to Protect Patient Access to Care.

As the Department recognized in the preamble of the Proposed Rule, forty-seven states have laws that allow health care providers and/or institutions to refuse health care to individuals based on personal beliefs.[71] These harmful existing state laws have already undoubtedly resulted in the

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[67] *Rule*, *supra* note 1, at 3916.
[68] Lisa Harris et al., *Obstetrician-Gynecologists' Objections to and Willingness to Help Patients Obtain an Abortion*, 118 OBSTETRICS & GYNECOLOGY 905 (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4185126/.
[69] *Discrimination Against Health Care Professionals Who Provide or Support Abortion* NAT'L WOMEN'S LAW CENTER (August 2017), https://nwlc.org/resources/discrimination-against-health-care-professionals-who-provide-or-support-abortion/.
[70] Stulberg et al., *Obstetrician-Gynecologists, Religious Institutions, and Conflicts Regarding Patient Care Policies*, 73 AM. J. OF OBSTETRICS AND GYNECOLOGY e1 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3383370/
[71] *Rule*, *supra* note 1, at 3931; *see also Refusing to Provide Health Services*, GUTTMACHER INSTITUTE (Feb. 2018), https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services.

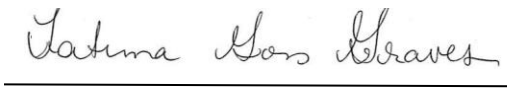
denial of health care, and in particular have endangered women's health. Now, the Proposed Rule is inviting states to enact even more sweeping laws.[72] The Proposed Rule encourages states to pass laws that go even further than the Proposed Rule does in allowing for refusals of health care. While it is clear that federal laws generally provide a minimum level of protection and allow states to enact more substantial protections, those protections are usually for the purpose of protecting individuals from discrimination and/or ensuring access to important services or benefits. As discussed above, the Proposed Rule subverts this entirely, entrenching discrimination and taking away access to health care services and benefits.

The Proposed Rule also creates a chilling effect on the enforcement of and passage of state laws that protect patient access to health care. The Department argues that the Proposed Rule is needed in order to clarify how federal religious exemption laws interact with state and local laws. To illustrate this purported need, the preamble cites several state laws intended to protect access to care. These include laws that require anti-abortion counseling centers to provide information about the full range of reproductive health care options and inform patients if the facility employs medical providers as well as state laws that ensure that individuals have comprehensive health insurance that includes abortion coverage. The discussion implies these and other laws that protect patient access to care conflict with the Proposed Rule, particularly when read in conjunction with several of the leading questions regarding state law posed in the preamble. This puts states in the untenable position of choosing between passing laws that protect their people and potentially losing millions of dollars in critical federal funding, likely resulting in a chilling effect on states attempting to pass or enforce laws intended to protect patients.

Conclusion

The Proposed Rule is illegal and harmful. It attempts to allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The Proposed Rule is discriminatory, violates multiple federal statutes and the Constitution, ignores Congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons, the Center unequivocally calls on the Department to withdraw the Proposed Rule.

Sincerely,



Fatima Goss Graves
President and CEO, National Women's Law Center

[72] *See e.g., Rule, supra* note 1, at 3888-89.

EXHIBIT J

March 27, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Public Comment in Response to the Proposed Regulation, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

To Whom it May Concern:

Empire Justice Center provides the following public comments regarding the proposed rule, "Protecting Statutory Conscience Rights in Health Care", published January 26.

Empire Justice Center is a statewide legal services organization with offices in Albany, Rochester, Westchester and Central Islip (Long Island). Empire Justice provides support and training to legal services and other community based organizations, undertakes policy research and analysis, and engages in legislative and administrative advocacy. We also represent low income individuals, as well as classes of New Yorkers, in a wide range of areas including health, immigration, public assistance, domestic violence, and SSI/SSD benefits.

Daily in the United States, LGBTQ people experience discrimination and other barriers to accessing health care. While discrimination and access barriers harm every member of the community, the barriers that transgender patients experience are especially pronounced. The proposed regulation ignores this widespread practice of discrimination and damage, and will undoubtedly lead to increased discrimination and denials of care for far too many people. This proposed rule threatens the rights to life, liberty, and self-determination that are bedrock values of our nation. Access to health care is a matter of life and death for all Americans.

1. LGBTQ individuals already face significant barriers to accessing health care services.

LGBTQ people, women, and other vulnerable groups around the country face enormous barriers to receiving necessary health care.[1] This challenge is compounded for those living in areas with

[1] *See, e.g.,* Institute of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx; Sandy E. James et al., *The Report of the U.S. Transgender Survey* 93–126 (2016), www.ustranssurvey.org/report; Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010),

already limited access to health providers. The proposed regulation will reduce access to care where it is already limited, and will eliminate it entirely in some places.

Patients living in rural areas already face many barriers to care, including lower access to health insurance coverage, lower incomes, and lower rates of paid sick leave. In upstate New York (outside of New York City), 24% of LGBTQ upstate New Yorkers reported inadequate health insurance as a barrier to care, 39% reported inadequate financial resources as a barrier to care, and 20% reported long distances to travel to providers as a barrier to care. 10% reported being denied care entirely due to being LGBTQ.[2] These numbers all jump up significantly for transgender New Yorkers, who are disproportionately affected by discrimination, harassment, and poverty. 66% of transgender New Yorkers reported that personal financial resources were a barrier to accessing transition-related health care, and 61% said that their insurance did not cover their transition-related care.[3]

This is in addition to the costs of transportation, unpaid leave, and other incidentals that accompany obtaining care in the first place. For many, the distance to a healthcare facility alone can be a significant barrier to getting care. For example, more than half of rural women live more than 30 minutes away from a hospital that provides basic obstetric care.[4] Patients seeking specialized care such as that required for fertility treatments, endocrinology, or HIV treatment or prevention are often hours away from the closest facility offering these services. For example, a 2015 survey of nearly 28,000 transgender adults nationwide found that respondents needed to travel much further to seek care for gender dysphoria as for other kinds of care.[5]

If these patients are turned away or refused treatment, it is much harder—and sometimes simply not possible—for them to find a viable alternative. In a recent study, nearly one in five LGBTQ people, including 31% of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that

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http://www.lambdalegal.org/publications/when-health-care-isnt-caring; Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

[2] Somjen Frazer and Erin Howe, *LGBT Health and Human Services Needs in New York State: A Report from the 2015 LGBT Health and Human Services Needs Assessment* (2016), http://strengthinnumbersconsulting.com/wp-content/uploads/2017/07/Needs-Assessment-WEB.pdf

[3] Somjen Frazer and Erin Howe, *Transgender Health and Economic Insecurity: A Report from the 2015 LGBT Health and Human Services Needs Assessment Survey* (2015), http://strengthinnumbersconsulting.com/wp-content/uploads/2017/06/TG-health-and-economic-insecurity-report-FINAL.pdf

[4] American College of Obstetrics and Gynecologists, *Health Disparities in Rural Women* (2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Disparities-in-Rural-Women#17.

[5] Sandy E. James et al., *The Report of the U.S. Transgender Survey* 99 (2016), www.ustranssurvey.org/report

it would be very difficult or impossible to find an alternative provider.[6] For these patients, being turned away by a medical provider is not just an inconvenience: it often means being denied care entirely with nowhere else to go.

2. The proposed regulation would broaden religious exemptions in a way that is likely to reduce access to medically necessary health care services for LGBTQ individuals.

The proposed regulation purports, among other things, to clarify current "religious refusal clauses" related to abortion and sterilization in three federal statutes. Each of these statutes refers to specific, limited circumstances in which health care providers or health care entities may not be required to participate in abortion and sterilization procedures. The proposed regulation, however, creates ambiguity about these limited circumstances and encourages an overly broad misinterpretation that goes far beyond what the statutes permit.

For example, section (d) of the Church Amendments refers to circumstances when a person may refuse to participate in any part of a health service program or research activity that "would be contrary to his religious beliefs or moral convictions." Even though longstanding legal interpretation applies this section singularly to participation in abortion and sterilization procedures, the proposed rule does not make this limitation clear. This ambiguity can encourage an overly broad interpretation of the statute that empowers a provider to refuse to provide *any* health care service or information for a religious or moral reason—potentially including not just sterilization and abortion procedures, but also Pre-Exposure Prophylaxis (PrEP), infertility care, treatments related to gender dysphoria, and even HIV treatment. Some providers may try to claim even broader refusal abilities, as a recent analysis of complaints to HHS showed that transgender patients are most often discriminated against simply for being who they are rather than for the medical care they are seeking.[7] In New York State, one in three transgender people reported having at least one negative experience with a provider related to being transgender, including verbal harassment, physical or sexual assault, or being refused treatment entirely.[8]

Due to the ambiguity created by the proposed rule, doctors may be misled into believing they may refuse on religious grounds to administer an HIV test or prescribe PrEP to a gay or bisexual man, or refuse screening for a urinary tract infection for a transgender man.[9] In fact, medical staff may interpret the regulation to indicate that they can not only refuse, but decline to tell the

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[6] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

[7] https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

[8] Sandy E. James et al., New York State Report of the U.S. Transgender Survey (2016) http://www.transequality.org/sites/default/files/USTS%20NY%20State%20Report%20%281017%29.pdf

[9] https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

patient where he would be able to obtain these lifesaving services or even inform patients of their treatment options. This puts the health of the patient, and potentially that of others, at risk. This ambiguity could lead a physician to refuse to provide fertility treatments to a same-sex couple, or a pharmacist to refuse to fill a prescription for hormone replacement therapy for a transgender customer. In addition, by unlawfully redefining the statutory term "assisting in the performance" of a procedure, the proposed rule could encourage health care workers to obstruct or delay access to a health care service even when they have only a tangential connection to delivering that service, such as scheduling a procedure or running lab tests to monitor side-effects of a medication. The extension and broadening of this clause will impair LGBTQ patients' access to care services if interpreted—as the proposed rule improperly appears to do—to permit providers to choose patients based upon sexual orientation, gender identity, or family structure.

We are particularly concerned that the proposed rule will be used to refuse medically necessary care to transgender patients. The rule's sweeping terms and HHS's troubling discussions of a case involving a transgender patient will encourage the mistaken belief that treatments that have an incidental impact on fertility, such as some procedures used to treat gender dysphoria, are sterilization procedures. Treatments for serious medical conditions may have the incidental effect of causing or contributing to infertility: for example, a hysterectomy to treat gender dysphoria, chemotherapy to treat cancer, and a wide range of medications can have the incidental effect of temporarily or permanently causing infertility. The primary purpose of such procedures, however, is not to sterilize, but to treat an unrelated medical condition. If religious or moral exemptions related to sterilization are misinterpreted or broadened to include treatments that have simply an incidental effect on fertility, as the vague and sweeping language of this rule encourages, providers will be emboldened to refuse services in situations that go even further beyond what federal law allows. The proposed regulation encourages individuals and institutions to refuse a dangerously broad range of medically needed treatments.

3. The proposed rule tramples on states' and local governments' efforts to protect patients' health and safety, including their nondiscrimination laws.

The Department claims that its unwarranted new interpretations of federal law supersede laws passed by state and local governments to ensure patients' access to health care. By claiming to allow individuals and institutions broadly to refuse care to patients based on the providers' religious or moral beliefs, the proposed rule conflicts with hundreds of state and local nondiscrimination laws around the country that apply to health care. The conflicts that will be created by the proposed rule will have to be litigated at great expense to patients, health care providers, and taxpayers.

It is, therefore, disingenuous for the Department to claim that the proposed rule "does not impose substantial direct effects on States," "does not alter or have any substantial direct effects on the relationship between the Federal government and the States," and "does not implicate" federalism concerns under Executive Order 13132.

4. The regulation lacks safeguards to protect patients from harmful refusals of care.

The proposed regulation is dangerously silent in regards to the needs of patients and the impact that expanding religious refusals can have on their health. The proposed regulation includes no limitations to its broad exemptions that would protect patients' rights under the law and ensures that they receive medically warranted treatment. Any extension of religious accommodation should always be accompanied by equally extensive protections for patients to ensure that their medical needs continue to be adequately and safely addressed, and that they are able to receive both accurate information and quality health services.

Indeed, the First Amendment's Establishment Clause, and subsequent jurisprudence, requires the government to adequately account for burdens a religious accommodation may impose on others, including patients, and prohibits granting accommodations when they would materially harm any third party. As detailed at length above, the proposed regulation would cause significant harm by interfering with patients' access to healthcare and thus, conflicts with this constitutional bar.

The expanded religious exemptions in the proposed regulations also conflict with many patient protections in federal laws like the Affordable Care Act and the Emergency Medical Treatment and Active Labor Act. While protections under these laws are subject to religious exemptions provided under federal statute, they are not subject to exemptions whose scope goes beyond federal law—including many of the exemptions expanded in this rule. Additionally, the proposed regulation's approach to religious exemptions—which appears to allow for no limitations even when those exemptions unjustifiably harm patients or employers—conflict with the well-established standard under other federal laws, like Title VII of the Civil Rights Act. Title VII ensures that employers can consider the effect that providing a religious accommodation would have on coworkers, customers, and patients, as well as factors like public safety, public health, and other legal obligations. A standard that appears to allow for none of these considerations, and instead appears to require broad, automatic exemptions, would create confusion and undermine the federal government's ability to properly enforce federal laws.

5. The Department's rushed rulemaking process failed to follow required procedures.

The Department rushed to publish this rule without first publishing any notice regarding it in its Unified Regulatory Agenda, as is normally required. The failure to follow proper procedure reflects an inadequate consideration of the rule's impact on patients' health.

The timing of the proposed rule also illustrates a lack of sufficient consideration. The proposed rule was published only two months after the close of a public comment period for a Request for Information closely related to this rule. The 12,000-plus public comments were not all posted until mid-December, a month before this proposed rule was released. Nearly all of the comments submitted at that time related to the subjects covered by the proposed rule—namely, the refusal of care by federally funded health care institutions or their employees on the basis of personal beliefs. This short period of time calls into question the comprehensiveness of the review of the

Request for Information, and whether the proposed rule was developed in an arbitrary and capricious manner.

Conclusion

The proposed rule goes far beyond established law, and appears to have been developed in a rushed and arbitrary manner. Most importantly, it will put the health and potentially even the lives of patients at risk. We urge the Department to withdraw the proposed rule.

EXHIBIT K

FAMILY EQUALITY COUNCIL

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March 27, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Public Comment in Response to the Proposed Rule, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

To Whom it May Concern:

Family Equality Council submits the following comment in response to the request for public comment regarding the proposed rule entitled "Protecting Statutory Conscience Rights in Health Care," published January 26.

Family Equality Council connects, supports, and represents the three million parents who are lesbian, gay, bisexual, transgender and queer (LGBTQ) in this country and their six million children. We are a community of parents and children, grandparents and grandchildren that reaches across this country. For over 30 years we have raised our voices toward fairness for all families.

We thank you for the opportunity to comment on HHS' Proposed Rule, RIN 0945-ZA03, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (Rule).

Every day too many LGBTQ people face discrimination and other barriers to accessing lifesaving care. These barriers are especially pronounced for transgender patients. The proposed rule ignores the prevalence of discrimination and damage it causes and will undoubtedly lead to increased discrimination and denials of care for some of the most vulnerable members of our community. We deeply value freedom of religion but sweeping exemptions that obstruct access to care are a fundamental distortion of that principle. American patients, particularly those already at heightened

risk for discrimination in health care services as documented by HHS' own Office of Civil Rights, deserve better.[1]

Family Equality Council and partner organizations have documented numerous instances of mistreatment, discrimination and denial of health care services to LGBTQ people and our children in amicus briefs to the Supreme Court and other courts. These stories illustrate not only the discrimination and degrading treatment LGBTQ individuals face when seeking medical care, but also the impact such treatment has on our families:

- Kinsey, a one-week old infant who had a life-threatening reaction to vaccine but was not immediately treated by hospital staff because the lesbian mother who had brought her could not prove she was her "real" mom.[2]

- M.C., a two-year old whose emergency treatment by a pediatric dentist was delayed because, as she was told, "a child cannot have two mothers."[3]

- A.S. and M.S., a married lesbian couple in Tennessee, who were denied service by multiple midwives and a birthing class provider during A.S.' pregnancy.[4]

- K.S., a transgender woman seeking mental health services who was subject to abusive treatment, inappropriate questioning and breaches of confidentiality, and who attempted to commit suicide twice while at the facility.[5]

- M.H., a gay man who checked into a New York City hospital with a severe infection and was treated roughly, called a 'faggot' multiple times, dragged down the hall in an office chair causing him to fall out of chair, and left on the ground where he had a seizure and convulsions.[6]

Expanding religious refusals can exacerbate the barriers to care that LGBTQ individuals and our family members already face.

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[1] See for example Sharita Gruberg & Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial, 2018* https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

[2] Brief of Amici Curiae Family Equality Council, Colage, and Kinsey Morrison in Support of Petitioners, Addressing the Merits and Supporting Reversal, *Obergefell v. Hodges*, 135 S. Ct. 2584, 2015, https://www.familyequality.org/_asset/mhfjym/VoCSCOTUS2015.pdf

[3] Brief of Amici Curiae Lambda Legal Defense and Education Fund, Inc., Family Equality Council et al., in Support of Respondents, *Masterpiece Cake Shop v. Colorado Civil Rights Commission,* (S. Ct. 2017), https://www.familyequality.org/_asset/5xtc7j/20171030-LambdaLegal-FamEq-Amicus-Brief-Masterpiece.pdf

[4] Ibid.

[5] Ibid.

[6] Ibid.

Because of the broad language of the rule that goes beyond existing statutes and regulations, we are concerned it could embolden health care providers to claim protections for the kinds of harmful mistreatment and service denials such as those outlined in the examples above.
Nearly 56% of lesbian, gay, and bisexual people have had at least one experience of mistreatment or service denials in health care and 31% of transgender people have faced such discrimination in the last year alone. [7]

In a recent study, nearly one in five LGBTQ people, including 31% of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider.[8] For these patients, being turned away by a medical provider is not just an inconvenience: it often means being denied care entirely with nowhere else to go.

The proposed rule attempts to inappropriately broaden religious exemptions in a way that can lead to dangerous denials of medically necessary treatments.

The rule purports, among other things, to clarify current "religious refusal clauses" related to abortion and sterilization in three federal statutes. Each of these statutes refers to specific, limited circumstances in which health care providers or health care entities may not be required to participate in abortion and sterilization procedures. The rule, however, creates ambiguity about these limited circumstances and encourages an overly broad misinterpretation that goes far beyond what the statutes permit.

For example, section (d) of the Church Amendments refers to circumstances when a person may refuse to participate in any part of a health service program or research activity that "would be contrary to his religious beliefs or moral convictions." Even though longstanding legal interpretation applies this section singularly to participation in abortion and sterilization procedures, the proposed rule does not make this limitation clear. This ambiguity can encourage an overly broad interpretation of the statute that empowers a provider to refuse to provide *any* health care service or information for a religious or moral reason. Some providers may try to claim even broader refusal abilities, as a recent analysis of complaints to HHS showed that transgender patients are most often discriminated against simply for being who they are rather than for the medical care they are seeking.[9]

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[7] Movement Advancement Project, *LGBT Policy Spotlight: Public Accommodations Nondiscrimination Laws,* 2018, http://www.lgbtmap.org/file/Spotlight-Public-Accommodations-FINAL.pdf
[8] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* , 2016, https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.
[9] Sharita Gruberg & Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial, 2018* https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

Medical staff may interpret the rule to indicate that they can not only refuse but decline to tell the patient where he would be able to obtain these lifesaving services or even inform patients of their treatment options. This puts the health of the patient, and potentially that of others, at risk. In addition, by unlawfully redefining the statutory term "assisting in the performance" of a procedure, the rule could encourage health care workers to obstruct or delay access to a health care service even when they have only a tangential connection to delivering that service, such as scheduling a procedure or running lab tests to monitor side-effects of a medication. The extension and broadening of this clause will impair LGBTQ patients' access to care services if interpreted—as the proposed rule improperly appears to do—to permit providers to choose patients based upon sexual orientation, gender identity, or family structure.

We are particularly concerned that the proposed rule will be used to refuse medically necessary care to transgender patients. We are concerned that the rule's sweeping terms and HHS's troubling discussions of a case involving a transgender patient will encourage the mistaken belief that treatments that have an incidental impact on fertility, such as some procedures used to treat gender dysphoria, are sterilization procedures. Treatments for serious medical conditions may have the incidental effect of causing or contributing to infertility: for example, a hysterectomy to treat gender dysphoria, chemotherapy to treat cancer, and a wide range of medications can have the incidental effect of temporarily or permanently causing infertility. The primary purpose of such procedures, however, is not to sterilize, but to treat an unrelated medical condition. If religious or moral exemptions related to sterilization are misinterpreted to include treatments that have simply an incidental effect on fertility—as the vague and sweeping language of this rule encourages—it can lead to refusals that go even further beyond what federal law allows and unlawfully encourages individuals and institutions to refuse a dangerously broad range of medically needed treatments.

Expanding exemptions undermines the Department's mandate to protect the health and well-being of all Americans.

Reducing discrimination and other barriers to accessing health care services, as well as reducing the accompanying health disparities, is core to the Department's mission and its obligations under laws authorizing its programs. Weakening protections and limiting program access by expanding religion-based exemptions fundamentally runs contrary to this mission.

The Department's core mission is to "enhance and protect the health and well-being of all Americans…by providing for effective health and human services."[10] Ensuring that beneficiaries of Department programs and other patients have fair and equal access to services and reducing barriers to those services is an inseparable and necessary component of this responsibility. The Department's ability to ensure equal, nondiscriminatory access to services would be significantly weakened by the proposed rule. In order to meet its legal obligations and its statutory mission, HHS must prioritize the needs and rights of patients over those of organizations seeking federal funds and individual health

[10] Dep't. of Health & Human Servs., *About HHS*, 2017, https://www.hhs.gov/about/index.html.

care workers. Creating new or expanded exemptions for recipients of federal funds at the cost of patients' access to health services prevents the Department from meeting its responsibilities to HHS program beneficiaries and patients around the country.

The proposed rule undermines states' and local governments' efforts to protect patients' health and safety, including their nondiscrimination laws.

The Department claims that its unwarranted new interpretations of federal law supersede laws passed by state and local governments to ensure patients' access to health care. By claiming to allow individuals and institutions to refuse care to patients based on the providers' religious or moral beliefs in such a sweeping way, the proposed rule creates conflicts with hundreds of state and local nondiscrimination laws around the country that apply to health care. It therefore is inaccurate for the Department to claim that the proposed rule "does not impose substantial direct effects on States," "does not alter or have any substantial direct effects on the relationship between the Federal government and the States," and "does not implicate" federalism concerns under Executive Order 13132.

Foster children face unique harms due to health care service refusals.
Allowing Such Refusals Undermines States' and Local Governments' Statutorily Required Efforts to Promote Safety, Permanency, and Well-Being of Foster Youth, Including Child-Welfare Specific Nondiscrimination Laws

Foster children, including LGBTQ foster youth, are particularly vulnerable to health care service refusals, and the rule could lead to unlawful service refusals and worsened outcomes for youth in care. The rule could undermine the core statutory objectives of those providing services in the child welfare context, who must act in the best interests of the child, with the objectives of child safety, permanency and well-being. Instead, a health care provider could prioritize personal religious beliefs over the best interests of the child. A broadening of the interpretation of the Church Amendment could lead to a medical professional funded by federal health programs who is providing health care services to foster children, including those in a restricted setting, to feel emboldened to refuse the child a range of services that are in his or her best interests such as reproductive health care for a girl in care, transition related care for a transgender foster youth, or counseling for an LGBTQ-identified foster youth that affirms her or his identity.

Foster children are uniquely dependent on those providing their care, including health care. For example, a child placed in a group home may not have access to the internet, phone service, email, or other means to communicate with health providers other than those entrusted with their care. This means if these children are refused needed health services, it may simply not be possible for them to find a viable alternative.

LGBTQ and female foster youth are particularly vulnerable. HHS-funded research has shown that LGBTQ youth, who comprised 19% of foster youth over 12 in the study of Los Angeles foster care, suffer unacceptably high rates of mistreatment, hospitalizations, placements in group homes (instead of with loving families), serial placements, and homelessness.[11] A study conducted in New York City's child welfare system further found that more than half (56%) of the LGBTQ-identified youth who had been interviewed said that they had chosen living in the streets at one point as they felt safer there than living in group or foster homes.[12] Affirming care that supports LGBTQ foster youths' identities is essential for achieving the child welfare goals of safety, permanency, and well-being. This care includes affirming health care, including reproductive care, transition-related health care for transgender youth, and mental health care that helps LGBTQ foster youth address issues of trauma related to family rejection, violence, harassment, and discrimination due to their sexual orientation or gender identity or expression. Service refusals by medical professionals could greatly exacerbate the trauma these youth have already experienced, particularly as they face few options for accessing alternative providers.

It is impermissible to allow those who care for foster children to deny them access to reproductive health care.

The government is legally obligated to provide medical care and family planning services to the youth in its care, without exception.[13] Yet, the proposed Rule could allow foster parents and social service agencies that provide services to children and young people to refuse even minor assistance to a young person in foster care who needs reproductive health services, including birth control, testing or treatment for sexually transmitted infection, and abortion care. This means that a social service agency or even just one person at that agency could block a young person in foster care from making an appointment or getting to a doctor's office for reproductive health care. A bus driver who is supposed to take a foster child to a doctor's appointment, for example, could refuse to drive the young person to a family planning clinic, claiming that doing so would "assist in the performance" of providing birth control.

Comprehensive, non-judgmental, and trauma informed reproductive health care is critical for youth in foster care. Girls in foster care are twice as likely as girls not in foster care to have sex and less likely to use birth control when they do have sex.[14] As a result, girls in foster care are more likely to

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[11] Wilson, B.D.M., Cooper, K., Kastanis, A., & Nezhad, S. (2014). *Sexual and Gender Minority Youth in Foster care: Assessing Disproportionality and Disparities in Los Angeles.* Los Angeles: The Williams Institute, UCLA School of Law.

[12] G.P. Mallon, *We don't exactly get the welcome wagon: The experience of gay and lesbian adolescents in North America's child welfare system*, in Child Welfare League of America Best Practice Guidelines (Child Welfare League of America, 2006).

[13] *Flores v. Reno*, No. CV 85-4544- RJK(Px) (C.D. Cal. Jan. 17, 1997).

[14] Alison Stewart Ng & Kelleen Kaye, The National Campaign to Prevent Teen and Unplanned Pregnancy, *Teen Childbearing and Child Welfare*, 2013, 1, *available at* https://thenationalcampaign.org/sites/default/files/resource-primary-download/childbearing-childwelfare.pdf.

become parents: A national study found that twice as many girls in foster care give birth compared to girls not in foster care.[15]

It is critical, therefore, that young people in foster care be able to access comprehensive reproductive health care and counselling. Girls in foster care also experience higher rates of sexual violence.[16] They are twice as likely as boys to be removed from their homes and placed in foster care because of sexual abuse (6 percent of girls versus 2.9 percent of boys),[17] making it that much more crucial that they are provided timely, unimpeded access to a full range of reproductive health care services in a manner that is both respectful and non-stigmatizing.

Allowing young people to be placed in a setting with caregivers who are unwilling to allow a young person to access reproductive health care services would lead to discriminatory and substandard care. No young person in foster care should be denied access to needed health care services because the people or organizations who are supposed to care for the young person object to the care.

The proposed rule undermines states' and local governments' efforts to protect foster children's health and safety, including their nondiscrimination laws.

The Department claims that its new interpretations of federal law supersede laws passed by state and local governments to ensure patients' access to health care. Yet, by allowing health care providers to refuse care to patients based on the providers' religious or moral beliefs in such a sweeping way, the proposed rule conflicts with state and local nondiscrimination laws, regulations, and policies that provide protections to foster youth.

Thirty-seven states provide protections against discrimination based on sexual orientation for youth receiving foster care and adoption services by law, regulation, or policy, and twenty-four states provide such protections based on gender identity and expression.[18] Further, "all States, the District of Columbia, American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands have statutes requiring that the child's best interests be considered whenever specified types of decisions are made regarding a child's custody, placement, or other critical life issues." (from HHS Children's Bureau website, with links to all statutes.)[19]

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[15] Lois Thiessen Love et al., The National Campaign to Prevent Teen Pregnancy, *Fostering Hope: Preventing Teen Pregnancy Among Youth in Foster Care*, 2005, 7, *available at* https://thenationalcampaign.org/sites/default/files/resource-primary-download/FosteringHope_FINAL.pdf.

[16] Karen Banes-Dunning & Karen Worthington, "Responding to the Needs of Girls in Foster Care," *Georgetown Journal on Law & Poverty* 20 no. 2, 2013, 321-49, *available at* http://www.karenworthington.com/uploads/2/8/3/9/2839680/adolescent_girls_in_foster_care.pdf.

[17] National Women's Law Center calculations of unpublished data by National Data Archive on Child Abuse and Neglect.

[18] See https://www.lambdalegal.org/map/child-welfare for a map of sex, sexual orientation, and gender identity anti-discrimination statutes, regulations, and policies in place for foster youth by state.

[19] Available at https://www.childwelfare.gov/pubPDFs/best_interest.pdf

Two examples of state nondiscrimination laws and policies that protect LGBTQ foster youth from discrimination include (emphasis added):

California

Statute: Cal. Welf. & Inst. Code 16001.9
Rights of minors and non-minors in foster care.
"It is the policy of the state that all minors and nonminors in foster care shall have the following rights:
. . .
(23) To have fair and equal access to all available services, placement, **care, treatment, and benefits,** and to not be subjected to discrimination or harassment on the basis of actual or perceived race, ethnic group identification, ancestry, national origin, color, religion, **sex**, **sexual orientation**, **gender identity**, mental or physical disability, or HIV status.

(25) To have caregivers and child welfare personnel who have received instruction on cultural competency and sensitivity training relating to, and best practices for, providing adequate care to **lesbian**, **gay**, **bisexual**, and **transgender** youth in out-of-home care."

Idaho

Policy: Idaho Youth in Care Bill of Rights (Oct. 2015)
"Youth have the right to learn about their **sexuality** in a safe and supportive environment.
. . .
Youth have the most basic right to receive care and services that are free of discrimination based on race, color, national origin, ancestry, **gender**, **gender identity** and **gender expression**, religion, **sexual orientation**, physical and mental disability, and the fact that they are in foster care."

Because of explicit nondiscrimination protections in the provision of care and services to foster youth, including health care services, it is inaccurate for the Department to claim that the proposed rule "does not impose substantial direct effects on States," "does not alter or have any substantial direct effects on the relationship between the Federal government and the States," and "does not implicate" federalism concerns under Executive Order 13132. In fact, the rule could prove financially burdensome to states attempting to ameliorate the high costs of disproportionately negative outcomes for LGBTQ foster youth. An HHS-funded study found that LGBTQ foster youth had been hospitalized for emotional reasons at three times the rate of non-LGBTQ foster youth, and the report therefor recommended "address[ing] the needs of LGBTQ youth in care so their experience begins to approximate those of their non-LGBTQ counterparts. This will result in much needed cost avoidance for already over-burdened child welfare systems."[20]

[20] Wilson, B.D.M., Cooper, K., Kastanis, A., & Nezhad, S., 2014. *Sexual and Gender Minority Youth in Foster care: Assessing Disproportionality and Disparities in Los Angeles.* Los Angeles: The Williams Institute, UCLA School of Law.

Conclusion

The proposed rule goes far beyond established law, improperly undermines state nondiscrimination laws, and most importantly will put the health and potentially even the lives of some of the most underserved and vulnerable patients at risk. We urge you to withdraw the proposed rule.

Should you have any questions about these comments, I would be happy to visit your offices in Washington, DC to discuss them, or you can reach me via telephone or email at 646.829.9314 or ssloan@familyequality.org.

Sincerely,

Rev. Stan J. Sloan
Chief Executive Officer

EXHIBIT L

March 27, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

By electronic submission

RE: Public Comment in Response to the Proposed Regulation, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

To Whom it May Concern:

I am writing on behalf of National Latina Institute for Reproductive Health (NLIRH) in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. As a reproductive justice organization, NLIRH believes a health care provider's personal beliefs should never determine the care a patient receives. NLIRH strongly opposes the Department of Health and Human Services' (the "Department") proposed rule ("Proposed Rule"), which seeks to permit discrimination in all aspects of health care.[1]

NLIRH is the only national reproductive justice organization dedicated to building Latina power to advance health, dignity, and justice for 28 million Latinas, their families, and communities in the United States through leadership development, community mobilization, policy advocacy, and strategic communications. NLIRH works to ensure that all Latinas of all racial identities[2] are informed about all their options for safe, effective, and acceptable forms of contraception and family planning. NLIRH supports affordable, accessible, and quality health care for all persons regardless of their age, gender identity, or sexual orientation.

The Latinx[3] community faces several challenges to care and therefore, any ability for providers to discriminate against patients will only exacerbate these barriers. For example, twenty-four percent of Latinas do not have health insurance. Latinas have the highest uninsured rates when

[1] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (proposed Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88) [hereinafter Rule].
[2] Racial and ethnic identity is multifaceted and in a recent study, 24 percent of U.S. Latinos identified themselves as afro-Latinos, while only 18 percent answered Black as their race. Pew Research Center. "Afro-Latino: A deeply rooted identity among U.S. Hispanics." March 1, 2016. http://www.pewresearch.org/fact-tank/2016/03/01/afro-latino-a-deeply-rooted-identity-among-u-s-hispanics.
[3] NLIRH, conscious of the importance of gender equity in the production of educational materials utilizes gender-neutral terms throughout this document. "Latinx" is a term that challenges the gender binary in the Spanish language and embraces the diversity of genders that often are actively erased from spaces. Due to the limitations of data collection, we use "Latina(s)" or "women" where research only shows findings for cisgender women, including Latinas.

compared to other groups in the U.S., making the act of accessing affordable health care services and finding a provider difficult for many. These challenges can be compounded by cultural and linguistic differences. A person's immigration status can negatively impact one's ability to access care; therefore, for many immigrant women getting in the door of a provider is hard enough, and further discrimination based on a medical professional's religious or moral beliefs can prevent someone from accessing lifesaving care.

Lesbian, gay, bisexual, transgender, and queer (LGBTQ) Latinxs are subject to a number of intersecting barriers to quality health care and increased health disparities. Due to systematic barriers and discrimination, LGBTQ individuals face higher rates of depression, an increased risk of some cancers, HIV/AIDS, and are twice as likely as their heterosexual peers to have a substance use disorders.[4] Additionally, for transgender patients these inequities and challenges to care are especially pronounced. By giving a provider the ability to deny care on the basis of moral or religious beliefs, only prevents individuals from accessing critical health care services they need when they need it.

The Proposed Rule seeks to unlawfully expand refusals to provide care by attempting to allow individuals and health care entities who receive federal funding to refuse to provide any part of a health service or program. The Proposed Rule unlawfully attempts to create new refusals that further undermine access to care. Such expansions exceed the Department's authority, violate the Constitution, undermine the ability of states to protect their citizens, undermine critical HHS programs like Title X, interfere with the provider-patient relationship, and threaten the health and well-being of people across the country and around the world.

By issuing the Proposed Rule and creating a new division within the Office of Civil Rights (OCR) – the new Conscience and Religious Freedom Division – the Department seeks to inappropriately use OCR's limited resources in order to affirmatively allow institutions, insurance companies, and almost anyone involved in patient care to use their personal beliefs to deny people the care they need. For these reasons NLIRH calls on the Department and OCR to withdraw the Proposed Rule in its entirety.

I. The Proposed Rule Carries Severe Consequences for the Latinx community and will Exacerbate Already Existing Inequities for Individuals Seeking Care

The Proposed Rule attempts to expand the reach of existing harmful refusal of care laws and create new refusals of care where none were intended. This Rule will exacerbate health inequities by expanding the ability to refuse critical services, including abortion and gender affirming care. Specifically, the Department and OCR are attempting to require a broad swath of entities to allow individuals to refuse "any lawful health service or activity based on religious beliefs or moral convictions (emphasis added)."[5] Read in conjunction with the rest of the Proposed Rule, it is clear this is intended to allow any entity involved in a patient's care—from a hospital board of directors to the receptionist that schedules procedures—to use their personal beliefs to determine a patient's access to care.

[4] Kellan Baker, "Open Doors for All" (Washington: Center for American Progress, 2015), available at https://www.americanprogress.org/issues/lgbt/reports/2015/04/30/112169/open-doors-for-all/.
[5] See Rule *supra* note 1, at 12.

Women, communities of color, individuals living with disabilities, LGBTQ individuals, and people living in rural communities face severe health and health care disparities, and these disparities are compounded for individuals who hold these multiple identities. For example, among adult women, 15.2 percent of those who identified as lesbian or gay reported being unable to obtain medical care in the last year due to cost, as compared to 9.6 percent of straight individuals.[6] Women of color experience health care disparities such as high rates of cervical cancer and are disproportionately impacted by HIV.[7] Meanwhile, people of color in rural parts of the United States are more likely to live in an area with a shortage of health professionals, with 83 percent of majority-Black counties and 81 percent of majority-Latinx counties designated by the federal Health Resources and Services Administration (HRSA) as Health Professional Shortage Areas (HPSAs).

Additionally, due to limited provider networks in some areas and to the important role that case managers and personal care attendants play in coordinating care, it may be more difficult for people with disabilities and older adults to find alternate providers who can help them. Furthermore, the religious and moral objections to the rule is not limited to providers, but also health care entities and institutions that want to bind the hands of providers and attempt to limit the types of care they can provide and this will only exacerbate these problems facing communities of color. By allowing providers, including hospitals and health care institutions, to refuse to provide patients with information, the Proposed Rule makes it impossible for individuals to have full information regarding their own health care decisions. While the Department claims the Proposed Rule improves communication between individuals and providers, in truth it will deter open and honest conversations that are vital to ensuring that a patient can control their medical circumstances.[8]

The expansion of refusals as proposed under this Rule will exacerbate already devastating health inequities and undermine the ability of these individuals to access comprehensive and unbiased health care, including sexual and reproductive health information and services. Any efforts by providers or other health care personnel to limit the information and access that patients are entitled to receive, even when the organization may not provide those services itself, is incompatible with individual decision making.

a. Refusals of Care are Especially Dangerous for Latinxs Already Facing Barriers to Care

Refusals of care based on personal beliefs already make it difficult for many individuals to access health care and have real consequences for those denied the care they need because of a health care provider's or hospital's religious beliefs. This is especially true for immigrant patients who often lack access to transportation and may have to travel great distances to get the

[6] Brian P. Ward et al., Sexual Orientation and Health Among U.S. Adults: National Health Interview Survey, NAT'L CTR FOR HEALTH STATISTICS, 2013 9 (2014), https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf.
[7] In 2014, Latinas had the highest rates of contracting cervical cancer and Black women had the highest death rates. Cervical Cancer Rates By Rates and Ethnicity, CTRS. FOR DISEASE CONTROL & PREVENTION, (Jun. 19, 2017), https://www.cdc.gov/cancer/cervical/statistics/race.htm.;At the end of 2014, of the total number of women diagnosed with HIV, 60 percent were Black. HIV Among Women, CTRS. FOR DISEASE CONTROL & PREVENTION, Nov. 17, 2017, https://www.cdc.gov/hiv/group/gender/women/index.html.
[8] See Rule *supra* note 1, at 150-151.

care they need.[9] In rural areas there may be no other sources of health care[10] and when these individuals encounter refusals of care, they may have nowhere else to go.

Broadly-defined and widely-implemented refusal clauses undermine access to basic health services for all, but can particularly harm women with low-incomes. These burdens can be insurmountable when women and families are uninsured,[11] locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services nor travel to another location. This is particularly relevant for immigrant women. In comparison to their U.S. born peers, immigrant women are more likely to be uninsured.[12] Notably, immigrant, Latina women have far higher uninsured rates than Latina women born in the United States (48 percent versus 21 percent, respectively).[13]

According to a recent report, doctors often fail to inform Black women of the full range of reproductive health options regarding labor or delivery largely due to stereotypes about Black women's sexuality and reproduction.[14] Young Black women noted that they were shamed by providers when seeking sexual health information and contraceptive care in part, due to their age, and in some instances, sexual orientation.[15]

New research also shows that women of color in many states disproportionately receive their care at Catholic hospitals, subjecting them to treatment that does not comply with the standards of care.[16] These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provides guidance on wide range of hospital matters, including reproductive health care. In practice, the ERDs prohibit the provision of emergency contraception, sterilization, abortion, fertility services, and some treatments for ectopic pregnancies. Providers in one 2008 study disclosed that they could not provide the standard of

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[9] Athena Tapales et al., The Sexual and Reproductive Health of Foreign-Born Women in the United States, CONTRACEPTION 8, 16 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf; Nat'l Latina Inst. For Reproductive Health & Ctr. For Reproductive Rights, *Nuestra Voz, Nuestra Salud, Nuestro Texas: the Fight for Women's Reproductive Health in the Rio Grande Valley* 1, 7 (2013), http://www.nuestrotexas.org/pdf/NT-spread.pdf.

[10] Since 2010, eighty-three rural hospitals have closed. See Rural Hospital Closures: January 2010 – Present, THE CECIL G. SHEPS CTR FOR HEALTH SERVS. RES. (2018), http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

[11] In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. KAISER FAMILY FOUND., Women's Health Insurance Coverage 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage.

[12] Athena Tapales et al., The Sexual and Reproductive Health of Foreign-Born Women in the United States, CONTRACEPTION 8 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf.

[13] *Id*. at 8, 16.

[14] Ctr. for Reprod. Rights, Nat'l Latina Inst. for Reprod. Health & Sistersong Women of Color Reprod. Justice Collective, *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care* 20-22 (2014), available at https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD_Shadow_US_6.30.14_Web.pdf [*hereinafter* Reproductive Injustice]; IN OUR OWN VOICE: NAT'L BLACK WOMEN'S REPROD. JUSTICE AGENDA, *The State of Black Women & Reproductive Justice* 32-33 (2017), available at http://blackrj.org/wp-content/uploads/2017/06/FINAL-InOurVoices_Report_final.pdf.

[15] Reproductive Injustice, *supra* note 14, at 16-17.

[16] Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT (2018), available at https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

care for managing miscarriages at Catholic hospitals and as a result, women were delayed care or transferred to other facilities, risking their health.[17]

In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals.[18] One example of this is New Jersey where women of color make up 50 percent of women of reproductive age in the state, yet have twice the number of births at Catholic hospitals compared to their white counterparts.[19] Specifically, despite the fact that white women had over 15,000 more births than Latinas overall, Latinas had over twice the number of births at Catholic hospitals than white women.[20] Another example are Catholic hospitals in Maryland where three-quarters (75 percent) of births are to women of color, as compared with non-Catholic hospitals, where less than half (48 percent) of births are to women of color, additionally, 31 percent of Latinas who give birth in Maryland did so in facilities operating under the ERDs.[21]

The proposed rule will give health care providers a license, such as Catholic hospitals, to opt out of evidence-based care that the medical community endorses. If this rule were to be implemented, more women, particularly women of color, will be put in situations where they will have to decide between receiving compromised care or seeking another provider to receive quality, comprehensive reproductive health services. For many, this choice does not exist.

b. The Proposed Rule Will Negatively Impact Latinxs Living in Rural Communities

Immigrant and Latina women often face cultural and linguistic barriers to care, especially in rural areas.[22] These women often lack access to transportation and may have to travel great distances to get the care they need.[23] In rural areas there may simply be no other sources of health and life preserving medical care. When these women encounter health care refusals, they have nowhere else to go.

The ability to refuse care to patients will leave many individuals in rural communities with no health care options. Medically underserved areas already exist in every state,[24] with over 75 percent of chief executive officers of rural hospitals reporting physician shortages.[25] Many rural communities experience a wide array of mental health, dental health, and primary care health

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[17] Lori R. Freedman et al., *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.
[18] *Id*. at 12.
[19] *Id*. at 9.
[20] *Id*. at 14.
[21] *Id*. at 15.
[22] Michelle M. Casey et al., *Providing Health Care to Latino Immigrants: Community-Based Efforts in the Rural Midwest*, AM. J. PUB. HEALTH (2011), available at http://ajph.aphapublications.org/doi/full/10.2105/AJPH.94.10.1709.
[23] Nat'l Latina Inst. for Reprod. Health & Ctr. for Reprod. Rights, *Nuestra Voz, Nuestra Salud, Nuestro Texas: The Fight For Women's Reproductive Health In The Rio Grande Valley*, 7 (2013), available at http://www.nuestrotexas.org/pdf/NT-spread.pdf.
[24] Health Res. & Serv. Admin, *Quick Maps – Medically Underserved Areas/Populations*, U.S. DEP'T OF HEALTH & HUM. SERV., https://datawarehouse.hrsa.gov/Tools/MapToolQuick.aspx?mapName=MUA, (last visited Mar. 21, 2018).
[25] M. MacDowell et al., *A National View of Rural Health Workforce Issues in the USA*, 10 RURAL REMOTE HEALTH (2010), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760483/.

professional shortages, leaving individuals in rural communities with less access to care that is close, affordable, and high quality, than their urban counterparts.[26] Among the many geographic and spatial barriers that exist, individuals in rural areas often must have a driver's license and own a private car to access care, as they must travel further distances for regular checkups, often on poorer quality roads, and have less access to reliable public transportation.[27] For undocumented individuals seeking care, the cost of driving to a doctor appointment can mean interactions with law enforcement or deportation. Those putting everything on the line to get in the door of a health care provider, once they enter the door, they should not be discriminated against based on the provider's religious or moral beliefs.

Moreover, the Proposed Rule could also hinder transgender individuals living in rural areas from seeking health care. A transgender advocate in Texas noted, "I know of people who don't even try for fear of being rejected. Now that there are laws out there that say, yeah, it's okay to discriminate, a lot of people just say, yeah, I don't go shopping in Williamson County. And that's true of any of the rural counties in Texas."[28] The Proposed Rule could allow religiously affiliated hospitals to not only refuse gender affirming care, but also deny surgeons, who otherwise have admitting privileges, to provide gender affirming surgery in the hospital. Gender affirming care is not only medically necessary, but for many transgender people it is lifesaving. In addition to gender affirming services, basic health care need for the transgender community in rural areas can be difficult to meet when providers have the option to deny care based on religious or moral beliefs.

Accessing quality, culturally competent care and overcoming outright discrimination is an even greater challenge for those living in areas with already limited access to health providers.

c. *The Proposed Rule Will Negatively Impact Latinxs Living With Low-Incomes Who Rely On Title X Clinics For Access To Care*

The Proposed Rule would seemingly allow health care entities to receive grants and contracts under HHS-funded programs, while refusing to provide key services required by those programs, once example of this being Title X.[29] Title X Family Planning Centers provide access to contraception and related information and services to anyone who needs them, but priority is given to persons who are living with low-incomes.[30] Title X patients are disproportionately

[26] Carol Jones et al., *Health Status and Health Care Access of Farm and Rural Populations*, ECON. RESEARCH SERV. (2009), available at https://www.ers.usda.gov/publications/pub-details/?pubid=44427.
[27] Thomas A. Arcury et al., *The Effects of Geography and Spatial Behavior on Health Care Utilization Among the Residents of a Rural Region*, 40 HEALTH SERV. RESEARCH (2005) available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1361130/.
[28] Human Rights Watch, *All We Want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States*, (Feb. 2018), https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people.
[29] See Rule *supra* note 1, at 180-181, 183. See also Title X Family Planning, U.S. DEP'T OF HEALTH & HUMAN SERVS. (2018), https://www.hhs.gov/opa/title-x-family-planning/index.html; Title X an Introduction to the Nation's Family Planning Program, NAT'L FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOC. (2017) (hereinafter NFPRHA), https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf.
[30] National Family Planning and Reproductive Health Association. *Title X: An Introduction to the Nation's Family Planning Program*. February 2017. https://www.nationalfamilyplanning.org/file/Title-X-101-February-2017-final.pdf.

Black or Latinx, with thirty-two percent of Title X patients identifying as Latinx and attacks on Title X negatively impact the ability of many Latinxs to receive necessary care. As such the Proposed rule will have a disproportionate impact on communities of color and individuals living with low-incomes.

Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[31] and current regulations require that pregnant people receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[32] Under the Proposed Rule, the Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such funds are generally conditioned.[33] The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the sub-recipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs which are meant to provide access to basic health services and information for populations with low-incomes.[34]

When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objectives. Every year millions with low-incomes, including under-insured, and uninsured individuals, rely on Title X clinics to access services they otherwise might not be able to afford.[35]

II. Religious Refusals Make It Difficult for Latinxs to Access the Reproductive Health Care They Need

The Proposed Rule seeks to allow providers and institutions to ignore the standards of care, particularly surrounding reproductive and sexual health. Individuals seeking reproductive health care, regardless of their reasons for needing these services, should be treated with dignity and respect. Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care to communities harms them and impairs their ability to make the health care decision that is right for them.

a. Contraception Access

Contraception helps Latinxs plan their families and their futures, improving their health and well-being. Unfortunately, lack of access to affordable and available contraception further exacerbates the severe health inequities that Latinxs experience. These inequities include: unintended pregnancies,[36] lack of comprehensive sexuality education, and high rates of maternal

[31] See, e.g., Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).
[32] See What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).
[33] See, e.g., Rule *supra* note 1, at 180-185.
[34] See NFPRHA *supra* note 34.
[35] See *id.*
[36] In 2014, Latina youth experienced pregnancies at about twice the rate of their white counterparts. Centers for Disease Control and Prevention. *Reproductive Health: Teen Pregnancy. Social Determinants and Eliminating Disparities in Teen Pregnancy*. https://www.cdc.gov/teenpregnancy/ about/social-determinants-disparities-teen-pregnancy.htm (last visited on September 7, 2016).

mortality.[37] Furthermore, there is some evidence showing that lesbian, gay, and bisexual youth may experience unintended pregnancies at even higher rates than their heterosexual peers, suggesting that LGBTQ Latinx youth also need access to contraception.[38]

Individuals who are struggling to make ends meet are disproportionately impacted by unintended pregnancy. In 2011, 45 percent of pregnancies in the U.S. were unintended – meaning that they were either unwanted or mistimed.[39] Women with low-incomes have higher rates of unintended pregnancy as they are least likely to have the resources to obtain reliable methods of family planning, and yet, they are most likely to be impacted negatively by unintended pregnancy.[40] Furthermore, Latinas experience unintended pregnancy at twice the rate of their white peers.

Immigrant women face numerous roadblocks in accessing affordable contraception. These include: lack of transportation, geographically inaccessible providers, pharmacy refusals and point of sales barriers, and affordability. However, a pressing barrier in accessing contraception is a person's inability to gain insurance coverage due to their immigration status.

In light of the pervasive and severe health inequities that Latinxs face, resources and tools, such as contraception, which help decide when and whether to become pregnant are necessary to achieve positive health outcomes. According to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care[41] and Latinas are 1.7 times more likely than white adults to have been diagnosed with diabetes.[42] Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant.[43] The ability of Latinxs to access contraception and to ensure health equity for the Latinx community is threatened by providers having the ability to deny care based on religious or moral beliefs.

Denying Latinxs access to contraceptive information and services violates medical standards that recommend pregnancy prevention for these medical conditions. The importance of the ability of

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[37] According to the Centers for Disease Control and Prevention, during 2011 to 2012, the pregnancy-related mortality ratios were 11.8 deaths per 100,000 live births for white women, 41.1 deaths per 100,000 live births for Black women, and 15.7 deaths per 100,000 live births for women of other races. Given these statistics, the Afro-Latinx community may disproportionately face maternal mortality and the underlying factors of maternal mortality. Centers for Disease Control and Prevention. Reproductive Health. Pregnancy Mortality Surveillance System. http://www.cdc. gov/reproductivehealth/maternalinfanthealth/pmss.html (last visited October 7, 2016).

[38] Lisa L. Lindley & Katrina M. Walsemann, *Sexual Orientation and Risk of Pregnancy Among New York City High-School Students*, 105 AMERICAN JOURNAL OF PUBLIC HEALTH 1379 (2015).

[39] Unintended Pregnancy in the United States, Guttmacher Inst. (Sept. 2016), available at https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states.

[40] Lawrence B. Finer & Stanley K. Henshaw, *Disparities in rates of unintended pregnancy in the United States*, 1994 and 2001, 38 PERSPECTIVES ON SEXUAL & REPROD. HEALTH 90-6 (2006).

[41] Am. Diabetes Ass'n, *Standards Of Medical Care In Diabetes-2017*, 40 DIABETES CARE S115, S117 (2017), available at http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf.

[42] Office of Minority Health. *Diabetes and Hispanic Americans*. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=63.

[43] *Id*.

individuals to make decisions for themselves to prevent or postpone pregnancy is well-established within the medical guidelines across a range of practice areas. Ninety-nine percent of all sexually active women have used contraception at some point in their lives — including 98 percent of Latinas and 99 percent of Catholics. Additionally, numerous studies have demonstrated that access to birth control strengthens families, increases women's earning power, and narrows the gender pay gap. A person knows what is best for them and their family and a medical professional should not be able to prevent a person from accessing critical contraception based on a religious or moral objection. Communities of color, women, and LGBTQ individuals must have the tools they need, including contraception, to make the best decisions for themselves and their families, and access to doctors that will not discriminate based on religious or moral objections.

b. Emergency Contraception

The proposed rule will magnify the harm in circumstances where individuals are already denied the standard of care. For Latinxs in particular, expanded access to emergency contraception is essential. Latinxs face a number of barriers to care, including poverty, language, immigration status, and lack of insurance, that prevent them from accessing contraception. Data shows young Latinas are the most likely group to skip taking prescription birth control because they cannot afford it. Current restrictions on accessing emergency contraception over-the-counter keep this birth control method out of reach for younger Latinxs and any woman who does not have a photo ID, so for those who are relying on a provider to access emergency contraception, it is critical that the only doctor they may have access to, does not deny them care.

Additionally, Catholic hospitals have a record of providing substandard care or refusing care altogether for a range of medical conditions and crises that implicate reproductive health. For example, in a 2005 study of Catholic hospital emergency rooms by Ibis Reproductive Health for Catholics for Choice, it was found that 55 percent would not dispense emergency contraception under any circumstances.[44] Twenty three percent of the hospitals limited emergency contraception to victims of sexual assault.[45] These hospitals violated the standards of care established by medical providers regarding treatment of sexual assault. Medical guidelines state that survivors of sexual assault should be provided emergency contraception subject to informed consent and that it should be immediately available where survivors are treated.[46] At the bare minimum, survivors should be given comprehensive information regarding emergency contraception.[47]

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[44] Teresa Harrison, *Availability of Emergency Contraception: A Survey of Hospital Emergency Department Staff*, 46 ANNALS EMERGENCY MED. 105-10 (Aug. 2005), http://www.annemergmed.com/article/S0196-0644(05)00083-1/pdf.

[45] *Id*. at 105.

[46] Committee Opinion 592: Sexual Assault, Am. Coll. Obstetricians & Gynecologists (Apr. 2014), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co592.pdf?dmc=1&ts=20170213T2116487879; Management of the Patient with the Complaint of Sexual Assault, Am. Coll. Emergency Med. (Apr. 2014), https://www.acep.org/Clinical---Practice-Management/Management-of-the-Patient-with-the-Complaint-of-Sexual-Assault/#sm.00000bexmo6ofmepmultb97nfbh3r.

[47] Access to Emergency Contraception H-75.985, AMA (2014), https://policysearch.ama-assn.org/policyfinder/detail/emergency%20contraception%20sexual%20assault?uri=%2FAMADoc%2FHOD.xml-0-5214.xml.

c. Abortion Care

This Proposed Rule will only create more barriers for those seeking abortion care. Obstacles including cultural and linguistic differences, as well as restrictions based on age, economic status, immigration status, and geographic location already prohibit many, especially Latinxs, from obtaining safe abortion services.

For the Latinx communities, making multiple trips to doctors delays access to care or prevents an individual from seeking services altogether. Religious refusals will only exacerbate a distrust of the medical community and keep people from the care they desperately need. In the Latinx community, many forgo medical care because they fear that ICE, rather than a doctor, will be waiting for them at a health care provider or hospital. To couple this culture of fear with the fear that a doctor will turn someone away based on their religious or moral beliefs is unconscionable.

In addition, the Proposed Rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to individual's health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility.[48] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[49] Because the Proposed Rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

The Proposed Rule ignores the many providers with deeply held moral convictions that affirmatively motivate them to provide abortion services. Moreover, the Proposed Rule fails to acknowledge the Church Amendments' protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[50] No health care professional should face discrimination from their employer because they treated or provided information to a patient seeking an abortion.

[48] 42 U.S.C. § 1295dd(a)-(c) (2003).

[49] In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. See, e.g., Shelton v. University of Medicine and Dentistry of New Jersey, 223 F.3d 220, 228 (3rd Cir. 2000); In In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); Nonsen v. Medical Staffing Network, Inc. 2006 WL 1529664 (W.D. Wis.); Grant v. Fairview Hosp., 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); Brownfield v. Daniel Freeman Marina Hosp., 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); Barris v. County of Los Angeles, 972 P.2d 966, 972 (Cal. 1999).

[50] See The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).

III. Expanding Religious Refusals Can Exacerbate The Barriers To Care That LGBTQ Latinxs Already Face

Given the broadly-written and unclear language of the Proposed Rule, if implemented, some providers may misuse this Rule to deny LGBTQ individuals services on the basis of perceived or actual gender identity or sexual orientation. Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care impairs the ability of a person to make a health decision that expresses their self-determination. LGBTQ people around the country already face enormous barriers to getting the care they need.[51] In fact, many physicians are not trained to provide culturally competent care for LGBTQ patients and self-report a lack of knowledge regarding the concerns of the community.[52] The Proposed Rule will compound the barriers to care that LGBTQ individuals face, particularly the effects of ongoing and pervasive discrimination, by potentially allowing health care professionals to refuse to provide services and information that is critical to LGBTQ health.

LGBTQ people face discrimination in many areas of their lives, including health care, on the basis of their gender identity and sexual orientation. The Department's Healthy People 2020 initiative recognizes, "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."[53] LGTBQ people face discrimination in a wide variety of services, affecting access to health care, including reproductive services, adoption and foster care services, child care, as well as physical and mental healthcare services.[54] In a recent study published in *Health Affairs*, researchers examined the intersection of gender identity, sexual orientation, race, and economic factors in healthcare access.[55] They concluded that discrimination as well as insensitivity or disrespect on the part of health care providers were key barriers to health care access and that increasing efforts to provide culturally sensitive services would help close the gaps in health care access.[56]

The Proposed Rule allowing providers to deny needed care would reverse recent gains in combatting discrimination and health care disparities for LGBTQ individuals. Refusals also

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[51] See, e.g., Institute of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx; Sandy E. James et al., *The Report of the U.S. Transgender Survey* 93–126 (2016), www.ustranssurvey.org/report; Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010), http://www.lambdalegal.org/publications/when-health-care-isnt-caring; Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

[52] IOM (Institute of Medicine). 2011: 65. *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding*. Washington, DC: The National Academies Press.

[53] Healthy People 2020, Lesbian, Gay, Bisexual, and Transgender Health, U.S. DEPT. HEALTH & HUMAN SERV., https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health, (last accessed on Mar. 24, 2018).

[54] HUMAN RIGHTS WATCH, *All We want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States*, (Feb. 2018), https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people.

[55] Ning Hsieh and Matt Ruther, HEALTH AFFAIRS, *Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities In Access To Care* (Oct. 2017) 1786–1794.

[56] *Id.*

implicate standards of care that are vital to LGBTQ health. Under the Affordable Care Act, medical professionals are expected to provide everyone, regardless of gender identity or sexual orientation, with the same quality of care. The American Medical Association recommends that providers use culturally appropriate language and have basic familiarity and competency with LGBTQ issues as they pertain to any health services provided.[57]

LGBTQ individuals already experience significant health inequities. For example, LGBTQ adults are still more likely than non-LGBTQ adults to lack insurance. Denying medically necessary care on the basis of sexual orientation or gender identity exacerbates barriers to obtaining health care services. Expanding religious refusals will further put needed care, including reproductive health care, out of reach for many.

a. The Proposed Rule Can Further Discrimination Against the Latinx Transgender Community

The transgender community already experience high rates of discrimination, harassment, and violence when seeking health care services. Transgender individuals are less likely to have health insurance than heterosexual or lesbian, gay, or bisexual (LGB) individuals. A study conducted by the National Center for Transgender Equality and the TransLatin@ Coalition found that 17 percent of transgender Latinxs did not have health insurance, compared to 12 percent of their white counterparts.[58]

Transgender individuals already face many barriers when seeking health care services simply because of their gender identity. The Proposed Rule could embolden some providers to continue to act in a discriminatory manner against transgender individuals. According to a 2011 national survey of transgender people conducted by the National Gay and Lesbian Task Force and National Center for Transgender Equality, one in three Latinx respondents reported unequal treatment by a doctor or hospital.[59] Undocumented transgender respondents were found to be particularly vulnerable to physical attack in doctors' offices, hospitals, and emergency rooms.[60] Additionally, transgender persons have been denied care even for medically necessary treatment, and this discrimination has sometimes resulted in death.[61] For example, transgender and gender

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[57] *Community Standards of Practice for the Provision of Quality Health Care Services to Lesbian, Gay, Bisexual, and Transgender Clients*, GAY LESBIAN BISEXUAL & TRANSGENDER HEALTH ACCESS PROJECT, http://www.glbthealth.org/CommunityStandardsofPractice.htm (last visited Jan. 26, 2018, 12:59 PM); *Creating an LGBTQ-friendly Practice*, A.M.A., https://www.ama-assn.org/delivering-care/creating-lgbtq-friendly-practice#Meet a Standard of Practice (last visited Jan. 26, 2018).

[58] James, S. E. & Salcedo, B. (2017). *2015 U.S. Transgender Survey: Report on the Experiences of Latino/a Respondents*. Washington, DC and Los Angeles, CA: National Center for Transgender Equality and TransLatin@ Coalition.

[59] Grant JM et al. National Gay and Lesbian Taskforce; National Center for Transgender Equality. *Injustice at every turn: A report of the National Transgender Discrimination Survey*, 73-74, 2011, available at http://www.thetaskforce.org/downloads/reports/reports/ntds_full.pdf.

[60] *Id*.

[61] Ravishankar M. *The story about Robert Eads*. THE JOURNAL OF GLOBAL HEALTH. January 18, 2013. http://www.ghjournal.org/jgh-online/the-story-about-robert-eads/.

non-conforming Latinxs with cervixes may disproportionately experience cervical cancer given that Latinas overall experience high rates of cervical cancer incidence.[62]

One fourth of transgender individuals experienced a problem in the past year with their insurance related to being transgender, such as being denied coverage for gender affirming care or being denied other types of health care because they were transgender.[63] Thirty-two percent, about one-third, of transgender individuals who saw a health care provider in the past year reported having at least one negative experience related to being transgender.[64] The reported negative experiences included being refused treatment, being verbally harassed, being physically or sexually assaulted, or having to teach the provider about transgender people in order to get appropriate care.[65] The 2015 U.S. Transgender Survey showed that over a fourth of transgender individuals did not see a doctor when they needed to because of fear of being mistreated as a transgender person, and 37 percent, more than a third, did not see a doctor when needed because they could not afford it.[66]

The World Professional Association for Transgender Health guidelines provide that gender-affirming interventions, when sought by transgender individuals, are medically necessary and part of the standard of care.[67] The American College of Obstetricians and Gynecologists warns that failure to provide gender-affirming treatment can lead to serious health consequences for transgender individuals.[68] Twenty-nine percent of transgender individuals were refused to be seen by a health care provider on the basis of their perceived or actual gender identity and 29 percent experienced unwanted physical contact from a health care provider.[69]

The 2015 U.S. Transgender Survey found that 23 percent of transgender respondents avoided seeking medical care when they needed it because of fear of being mistreated.[70] Additionally,

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[62] National Latina Institute for Reproductive Health. *Cervical Cancer & Latinxs: The Fight for Prevention and Health Equity.* January 2018, available at http://www.latinainstitute.org/sites/default/files/NLIRH_CervicalCancer_FactSheet18_Eng_R1.pdf.

[63] James, S. E. & Salcedo, B. (2017). *2015 U.S. Transgender Survey: Report on the Experiences of Latino/a Respondents*. Washington, DC and Los Angeles, CA: National Center for Transgender Equality and TransLatin@ Coalition.

[64] *Id*.

[65] *Id*.

[66] *Id*.

[67] Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, World Prof. Ass'n for Transgender Health (2011), https://s3.amazonaws.com/amo_hub_content/Association140/files/Standards%20of%20Care%20V7%20-%202011%20WPATH%20(2)(1).pdf.

[68] Committee Opinion 512: Health Care for Transgender Individuals, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (Dec. 2011), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Transgender-Individuals.

[69] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, Ctr. for American Progress, (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/?link_id=2&can_id=d90c309ac9b5a0fa50d294d0b1cdf0b2&source=email-rx-for-discrimination&email_referrer=&email_subject=rx-for-discrimination.

[70] James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. *The Report of the 2015 U.S. Transgender Survey*, 2016, Washington, DC: National Center for Transgender Equality, available at https://www.transequality.org/sites/default/files/docs/usts/USTS%20Full%20Report%20-%20FINAL%201.6.17.pdf.

the survey found that, just in the past year, 33 percent of those who saw a health care provider face some form of mistreatment or discrimination because of being transgender, such as being refused care, harassed, or physically or sexually assaulted, and more than one in five respondents reported that a health care provider used abusive or harsh language when treating them.[71]
The Proposed Rule, while cloaked in the language of non-discrimination, is designed to deny care and exclude vulnerable populations. The adverse consequences of health care refusals and other forms of discrimination are well documented. As the Department stated in its proposed rulemaking for Section 1557 of the Affordable Care Act (ACA),

> "[e]qual access for all individuals without discrimination is essential to achieving the ACA's aim to expand access to health care and health coverage for all, as discrimination in the health care context can often…exacerbate existing health disparities in underserved communities."[72]

Data obtained by Center for American Progress (CAP) under a FOIA request indicates the Department's enforcement was effective in resolving issues of anti-LGBTQ discrimination. CAP received information on closed complaints of discrimination based on sexual orientation, sexual orientation-related sex stereotyping, and gender identity that were filed with the Department under Section 1557 of the ACA from 2012 through 2016. CAP found that "[i]n approximately 30% of these claims, patients alleged denial of care or insurance coverage simply because of their gender identity – not related to gender transition."[73] Additionally, "[a]pproximately 20% of the claims were for misgendering or other derogatory language."[74] Individuals who were "denied care due to their gender identity or transgender status included a transgender woman denied a mammogram and a transgender man refused a screening for a urinary tract infection."[75]

b. The Proposed Rule Will Worsen Discrimination Based on Sexual Orientation

Many lesbian, gay, bisexual, and queer (LGBQ) people lack insurance.[76] Moreover, providers are not competent in health care issues and obstacles that the LGBQ community experiences.[77] For example, lesbian and bisexual individuals are less likely to get routine health care and

[71] *Id.*
[72] Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,194 (Sept. 8, 2015) (codified at 45 C.F.R. pt. 2).
[73] Sharita Gruberg & Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, Center for American Progress, (March 7, 2018), available at https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/.
[74] *Id.*
[75] *Id.*
[76] Medical schools often do not provide instruction about LGBTQ health concerns that are not related to HIV/AIDS. Jen Kates et al., *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender Individuals in the U.S*, KAISER FAMILY FOUND.12 (2017), http://files.kff.org/attachment/Issue-Brief-Health-and-Access-to-Care-and-Coverage-for-LGBT-Individuals-in-the-US.
[77] *Id.*

cervical cancer screenings than their heterosexual counterparts.[78] Additionally, adolescent and young lesbians and bisexuals are less likely to receive the preventative HPV vaccine.[79] Barriers and inequities already exist among LGBQ individuals, and this Proposed Rule would further exacerbate such inequities.

Fear of discrimination causes many LGB people to avoid seeking health care, and, when they do seek care, lesbian, gay, and bisexual (LGB) people are frequently not treated with the respect that all individuals deserve. According to one survey, 8 percent of lesbian, gay, bisexual, and queer individuals had an experience within the year prior to the survey where a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation and 7 percent experienced unwanted physical contact and violence from a health care provider.[80] The study "When Health Care Isn't Caring" found that 56 percent of LGB people reported experiencing discrimination from health care providers – including refusals of care, harsh language, or even physical abuse – because of their sexual orientation.[81] Almost ten percent of LGB respondents reported that they had been denied necessary health care expressly because of their sexual orientation.[82] Delay and avoidance of care due to fear of discrimination compound the significant health disparities that affect the lesbian, gay, and bisexual population.

For example, queer Latinxs are more likely to disproportionately experience cervical cancer because of racial, ethnic, sexual orientation, and gender identity health disparities.[83] Health inequities already exist, and this Proposed Rule threatens to make access to healthcare information and services even harder and, for some people, nearly impossible.

III. The Department is Abdicating its Responsibility to Individuals Seeking Health Care

The Proposed Rule exceeds OCR's authority by abandoning OCR's mission to address health disparities and discrimination that harms patients.[84] Instead, the Proposed Rule appropriates

[78] National Latina Institute for Reproductive Health, *Cervical Cancer & Latinxs: The Fight for Prevention and Health Equity* January 2018, available at http://www.latinainstitute.org/sites/default/files/NLIRH_CervicalCancer_FactSheet18_Eng_R1.pdf.
[79] National Latina Institute for Reproductive Health, *Cervical Cancer & Latinxs: The Fight for Prevention and Health Equity* January 2018, available at http://www.latinainstitute.org/sites/default/files/NLIRH_CervicalCancer_FactSheet18_Eng_R1.pdf.
[80] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, Ctr. for American Progress, (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/?link_id=2&can_id=d90c309ac9b5a0fa50d294d0b1cdf0b2&source=email-rx-for-discrimination&email_referrer=&email_subject=rx-for-discrimination.
[81] Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV* 5 (2010), *available at* http://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf.
[82] *Id.*
[83] National Latina Institute for Reproductive Health, *Cervical Cancer & Latinxs: The Fight for Prevention and Health Equity* January 2018, available at http://www.latinainstitute.org/sites/default/files/NLIRH_CervicalCancer_FactSheet18_Eng_R1.pdf
[84] OCR's Mission and Vision, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html ("The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to

language from civil rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the Proposed Rule creates a regulatory scheme that is not only nonsensical but is affirmatively harmful. For example, the notice and certification of compliance and assurance requirements simply do not make sense when applied to the laws the Proposed Rule seeks to enforce.[85] They will place a significant and burdensome requirement on health care providers and impose unique challenges for those working in other countries by taking resources away from patient care without adding any benefit.

The Department, including OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health inequities. If finalized, however, the Proposed Rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care, and eliminate health disparities.[86] Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.[87]

Nevertheless, there is still work to be done, and the Proposed Rule seeks to divert limited resources away from ending discrimination. Health disparities based on race and ethnicity do not occur in isolation. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. Black women, for example, are three to four times more likely than white women to die during or after childbirth.[88] While Black women are dying at much higher rates than their Latinx and white counterparts, some studies indicate that in certain

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participate in and receive services from HHS programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

[85] See Rule *supra* note 1, at 203-214.

[86] As one of its first official acts in 1967, the Office of Equal Health Opportunity undertook the massive effort of inspecting 3,000 hospitals to ensure they were complying with Title VI's prohibition against discrimination on the basis of race, color, or national origin. 42. U.S.C. § 2000d (1964). After this auspicious start, the Office of Equal Health Opportunity which would eventually become OCR would go on to ensure that health programs and activities it regulated complied with key anti-discrimination laws including Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (1973), Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 (1972), the Age Discrimination Act of 1976, 42 U.S.C. § 6101 (1976), and Section 1557 of the Affordable Care Act, 42 U.S.C. §18116 (2010), among others. Through robust enforcement of these laws, OCR has worked to reduce discrimination in health care.

[87] See, e.g., *Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead*, Dep't Of Health And Human Servs. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html; Protecting the Civil Rights and Health Information Privacy Rights of People Living with HIV/AIDS, Dep't Of Health And Human Servs. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html; National Origin Discrimination, Dep't Of Health And Human Servs. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/index.html; Health Disparities, Dep't Of Health And Human Servs. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

[88] See Nina Martin, *Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why*, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why.

parts of the country (the Rio Grande and areas of California) maternal death rates are higher for Latinas. According to a recent study, Hispanic women in Texas make up 31 percent of maternal deaths and account for nearly half of all births in Texas (Black women account for 30 percent). Another recent study showed that Mexican-born women in California are more likely to die from birthing related complications than their white counterparts. Further, the disparity in maternal mortality is growing rather than decreasing,[89] which in part may be due to the reality that women have long been the subject of discrimination in health care and the resulting health disparities. For example, women's pain is routinely undertreated and often dismissed.[90]

OCR must work to address these disparities, yet the Proposed Rule seeks to prioritize the expansion of existing religious refusal laws beyond their statutory requirements and create new religious exemptions where none had previously existed rather than using already limited resources to protect patient access to health care. The Proposed Rule will harm patient care and is antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality.[91]

IV. In Proposing this Rule, the Agency has Abandoned its Legal Obligations to Adequately Account for Harm

It is evident that the harm caused by this Proposed Rule will fall hardest on those most in need of care by allowing individuals and health care entities to use their personal beliefs to dictate patient care. The Department should remember, under Executive Order 13563, an agency may only propose regulations where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on society."[92] The Proposed Rule plainly fails on both counts. Although the Proposed Rule attempts to quantify the costs of compliance, it completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs.[93]

Moreover, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant religious exemptions and, in fact, bars granting an exemption when it would detrimentally affect any third party.[94] Because the Proposed Rule would cause substantial harm, including to patients, it would violate the Establishment Clause.[95]

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[89] See *id*.
[90] See, e.g., Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29:1 J. OF L., MED., & ETHICS 13, 13-27 (2001).
[91] See *supra* note 83.
[92] Improving Regulation and Regulatory Review, Executive Order 13563 (Jan. 18, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review.
[93] See Rule *supra* note 1, at 94-177
[94] U.S. Const. amend. I; Cutter v. Wilkinson. 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment Clause, courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing Estate of Thornton v. Caldor, 472 U.S. 703, 710 (1985)); see also Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, 2781 n.37 (2014); Holt v. Hobbs, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).
[95] Respecting religious exercise may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." See Burwell v. Hobby Lobby, 134 S. Ct. at 2787. When considering

Conclusion

The inability of providers to give comprehensive, medically accurate information and options that will help Latinxs make the best health decisions violates respect for autonomy, and justice. This rule, which allows misinformation and personal feelings to get in the way of science and lifesaving treatment, will not help achieve the goals of the administration; it will instead prevent critical care.

The expansion of religious refusals as envisioned in the Proposed Rule may compel medical professionals to provide care and information that harms the health, well-being, and goals of communities of color.

The Proposed Rule goes far beyond established law and will allow religious beliefs to dictate health care by unlawfully expanding already harmful refusals. The Proposed Rule is discriminatory, violates multiple federal statutes and the Constitution, ignores congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. Most importantly, this Proposed Rule puts the lives of our community at risk. For all of these reasons National Latina Institute for Reproductive Health calls on the Department to withdraw the Proposed Rule in its entirety.

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whether the birth control coverage requirement was the least restrictive means in Hobby Lobby, the Court considered that the accommodation offered by the government ensured that affected employees "have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing coverage." See id. at 2759. In other words, the effect of the accommodation on women would be "precisely zero." Id. at 2760.

EXHIBIT M

Lambda Legal
making the case for equality

March 27, 2018

VIA ELECTRONIC SUBMISSION

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Public Comment in Response to the Proposed Rule, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

To Whom It May Concern:

Lambda Legal Defense and Education Fund, Inc. ("Lambda Legal") appreciates the opportunity provided by the Department of Health and Human Services ("HHS" or the "Department") to offer comments in response to the Proposed Rule, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03 ("Proposed Rule" or "Rule"), published in the Federal Register on January 26, 2018.[1] As described herein, the Proposed Rule both exceeds its statutory authority and contravenes this Department's mission, the legal rights of patients, the ethical obligations of health professionals, and the legal rights and responsibilities of institutional health care providers. It should be withdrawn.

Lambda Legal is the oldest and largest national legal organization dedicated to achieving full recognition of the civil rights of lesbian, gay, bisexual, and transgender ("LGBT") people and everyone living with HIV through impact litigation, policy advocacy, and public education. For decades, Lambda Legal has been a leader in the fight to ensure access to quality health care for our vulnerable communities. In recent years, Lambda Legal has submitted a series of comments to HHS regarding the importance of reducing discrimination against LGBT people in health care services, the fact that current law already protects health worker conscience rights appropriately, and the ways that conscience-based exemptions to health standards endanger LGBT people and others.[2] Recently, Lambda Legal also has opposed an HHS proposal to expand

[1] 83 Fed. Reg. 3880 *et seq*. (proposed Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88).

[2] *Lambda Legal Comments on Proposed Rule 1557 Re: Nondiscrimination in Health Programs and Activities, 1557 NPRM (RIN 0945-AA02)* (submitted Nov. 9, 2015) ("Lambda Legal 1557 Comments"), https://www.lambdalegal.org/in-court/legal-docs/hhs_dc_20151117_letter-re-1557; *Lambda Legal Comments on Request for Information Regarding Nondiscrimination in Certain Health Programs or Activities (RIN 0945-AA02 & 0945-ZA01)* (submitted Sept. 30, 2013) ("Lambda Legal Nondiscrimination Comments"), https://www.lambdalegal.org/in-court/legal-docs/ltr_hhs_20130930_discrimination-in-health-services. *See also* Brief of Amici Curiae Lambda Legal et al., *Zubik v. Burwell*, 136 S. Ct. 1557

the ability of religiously-affiliated health care institutions and individuals to impose their religious beliefs on workers and on patients, cautioning in detail about the likely harmful consequences of any such expansions for LGBT people and people living with HIV.[3]

As to the Proposed Rule now under consideration, Lambda Legal emphatically recommends its withdrawal because:

(1) It improperly expands statutory religious exemptions in multiple ways, including by:

(a) permitting workers to refuse job duties that cannot reasonably be understood as "assisting" with an objected-to procedure, [4] and instead have merely an "articulable" connection to the procedure[5];

(b) expanding who may assert religious objections from employees performing or assisting in specified procedures to any member of the workforce[6];

(c) using an improperly expanded definition of "referral"[7] that includes providing any information or directions that could assist a patient in pursuing care; and

(d) defining "discrimination" to focus on protecting the interests of health care providers in continuing to receive favorable financial, licensing or other treatment, rather than on patients' interest in receiving medically appropriate care[8]; and

(e) defining health care entity to include health insurance plans, plan sponsors, and third-party administrators.[9]

(2016) (Nos. 14-1418, 14-1453, 14-1505, 15-35, 15-105, 15-119, 15-191), http://www.lambdalegal.org/in-court/legal-docs/zubik_us_20160217_amicus.

[3] *See, e.g., Lambda Legal Comments on Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (RIN 0938-AT46)* (submitted Dec. 5, 2017), https://www.lambdalegal.org/in-court/legal-docs/dc_20171205_aca-moral-exemptions-and-accommodations; *Lambda Legal Comments on Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (RIN 0938-AT20)* (submitted Dec. 5, 2017), https://www.lambdalegal.org/in-court/legal-docs/dc_20171205_aca-religious-exemptions-and-accommodations.

[4] 42 U.S.C.A. § 300a-7(b) and (d).

[5] Section 88.2, 83 Fed. Reg. at 3923.

[6] Section 88.2, 83 Fed. Reg. at 3924.

[7] *Id*.

[8] *Id*.

[9] *Id*.

(2) It encourages workers and institutions to refuse care and does not acknowledge the rights of patients, such as the right against sex discrimination provided by Section 1557 of the Affordable Care Act.[10]

(3) It encourages workers and institutions to refuse care and does not acknowledge the legal rights and duties of health care providers, such as those under Title VII of the Civil Rights Act of 1964,[11] or health professionals' ethical obligations to patients.

(4) Using broad, vague language, it addresses a purported "problem" of health workers being pressed to violate their conscience, suggesting that workers should have broad religious rights to decline care and refuse other work of any sort in any context, going far beyond the narrow contexts specified in the authorizing statutes.

(5) Its proposed enforcement mechanisms are draconian, threatening the loss of federal funding and even the potential of funding "claw backs," with limited if any due process protections, all of which would skew health systems improperly in favor of religious refusals and against patient care.

(6) The heavy-handed enforcement mechanisms inevitably would invite discrimination and aggravate existing health disparities and barriers to health care faced by LGBT people and others, contrary to the mission of HHS and, in particular, its Office for Civil Rights.

(7) It is the result of a rushed, truncated process inconsistent with procedural requirements including the Administrative Procedure Act.[12]

In sum, the role of the HHS Office for Civil Rights ("OCR") described in the Proposed Rule is not to promote access to health care and to safeguard patients against discrimination, but instead to impose vague, overbroad *restraints* on health care provision, as a practical matter elevating "conscience" objections of workers over the needs of patients. In so doing, the Proposed Rule turns the mission of HHS/OCR on its head. Freedom of religion is a core American value, which is why it is already protected by the First Amendment of the Constitution. But, that freedom does not and must not allow anyone to impose their beliefs on others or to discriminate. This basic principle is nowhere more important than in medical contexts where religion-based refusals can cost patients their health and even worse.

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[10] 42 U.S.C.A. § 18116.

[11] Civil Rights Act of 1964 § 7, 42 U.S.C.A. § 2000e *et seq.* (1964).

[12] 5 U.S.C.A. § 500 *et seq*.

I. The Proposed Rule Improperly Expands Statutory Religious Exemptions.

The Proposed Rule improperly expands statutory religious exemptions beyond their narrow, specific parameters in numerous ways. It includes definitions that would broaden the exemptions in the Church Amendments, which currently allow health workers to decline to assist in an abortion or sterilization procedure if doing so "would be contrary to [their] religious beliefs or moral convictions."[13] The Proposed Rule reinterprets what it means to "assist in the performance" of a procedure from participating in "any activity with a *reasonable* connection" to a procedure [14] to "any … activity with an *articulable* connection" to an objected-to procedure.[15] In other words, any connection that can be described, no matter how tenuous, potentially could suffice. Confirming the potentially indefinite expansion of *what* can be deemed "assistance" is a broad definition of *who* may object. From the prior common language understanding of who might be involved in a medical procedure, the new definition appears to authorize any member of the workforce to object to performing their job duties.[16]

The Proposed Rule also includes an aggressive expansion of the concept of "referral" from the common understanding of actively connecting a patient with an alternate source of a particular service to the provision of any information or directions that could possibly assist a patient who might be pursuing a form of care to which the employee objects.[17] This goes far beyond a reasonable understanding of what the underlying statute justifies.

Similarly, where the statute authorizes "health care entities" to assert religious objections, the Proposed Rule grossly expands the entities covered by that term to include health insurance plans, plan sponsors, and third-party administrators.[18] It also adds a definition of "discrimination" that focuses not on patients' interest in receiving equal, medically appropriate services, but rather on protecting health care providers' interests in continuing to receive favorable financial, licensing or other treatment while refusing on religious or moral objections to provide care despite medical standards, nondiscrimination rules, or other requirements.[19]

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[13] 42 U.S.C.A. § 300a-7.

[14] 45 C.F.R. § 88.2 (2008) (emphasis added).

[15] Proposed Rule, 83 Fed. Reg. at 3923 (emphasis added).

[16] Section 88.2, 83 Fed. Reg. at 3924.

[17] Section 88.2, 83 Fed. Reg. at 3924.

[18] Section 88.2, 83 Fed. Reg. at 3924.

[19] Section 88.2, 83 Fed. Reg. at 3924.

In numerous places, the Proposed Rule seems to indicate that HHS is adopting interpretations that would extend the Amendments' reach beyond current understanding that the exemptions only concern abortion and sterilization and follow the common medical understanding of those terms.[20] As one example, it seems likely that the "sterilization" references within the Proposed Rule could be applied to deny health care to transgender patients because the Rule itself, at footnote 36, cites *Minton v. Dignity Health* approvingly.[21] *Minton* addresses whether a Catholic hospital was legally justified when it blocked a surgeon from performing a hysterectomy for a transgender man as part of the prescribed treatment for gender dysphoria. The hospital defended on religious freedom grounds, arguing that it was bound "to follow well-known rules laid down by the United States Conference of Catholic Bishops," including rules prohibiting "direct sterilization."[22]

But, to equate hysterectomy to treat gender dysphoria with direct sterilization is medically inaccurate. Sterilization procedures undertaken for the *purpose* of sterilization are fundamentally different from procedures undertaken for other medical purposes that incidentally affect reproductive functions. Regardless of whether the United States Conference of Catholic Bishops considers gender transition-related care to be sterilization as a religious matter, were the federal government to approve a religious rationale as grounds for stretching a federal statute and permitting denial of medically necessary care would be problematic for both statutory interpretation and Establishment Clause reasons.

The Proposed Rule's apparent embrace of the Bishops' view poses an overtly discriminatory and unacceptable threat to transgender patients. This concern is not speculative. The Proposed Rule's footnote referencing *Minton* supports the following statement: "Many religious health care personnel and faith-based medical entities have further alleged that health care personnel are being targeted for their religious beliefs."[23] For the Proposed Rule to equate a transgender patient expecting to receive medically necessary care from health care personnel with those personnel "being targeted for their religious beliefs" is a chilling indicator of the direction the Proposed Rule would take health care in this country. Not only would health providers be invited to turn away transgender patients, but those that abide by their obligation to

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[20] *Compare* cases describing statute's applicability to provision or refusal provide abortions or sterilization, *e.g.*, *Cenzon-DeCarlo v. Mount Sinai Hosp.*, 626 F.3d 695 (2d Cir. 2010), *and Chrisman v. Sisters of St. Joseph of Peace*, 506 F.2d 308 (9th Cir. 1974), *with Geneva Coll. v. Sebelius*, 929 F. Supp. 2d 402 (W.D. Pa. 2013), *on reconsideration in part* (May 8, 2013) (statute does not apply to provision of emergency contraception, which is not abortion or sterilization).

[21] No. 17-558259 (Calif. Super. Ct. Apr. 19, 2017).

[22] Defendant Dignity Health's Reply Brief in Support of Demurrer to Verified Complaint, *Minton v. Dignity Health*, No. 17-558259, at 2 (Calif. Super. Ct. Apr. 19, 2017) (filed Aug. 8, 2017), https://www.aclusocal.org/sites/default/files/brf.sup_.080817_defendant_dignity_healths_reply_in_support_of_demurrer_to_verified_complaint.pdf.

[23] Proposed Rule, 83 Fed. Reg. at 3888 n. 36.

provide nondiscriminatory care and require their employees to act accordingly could be stripped of federal funding if equal treatment of those patients offended any workers' personal beliefs.

The overbroad definitions and suggestive language all contribute to the alarming overall theme of the Proposed Rule—that it addresses a purported problem of health workers ostensibly being pressed wrongfully to act against their rights of conscience. The Proposed Rule's suggested cure appears to be that workers should have broad religious rights to decline care of any sort in any context. This theme starts with the broad language stating the Proposed Rule's purpose and runs throughout the rule.[24] It creates at least a serious concern that, for example, language long understood to be bounded by its statutory context only to concern abortion and sterilization could be misconstrued as authorizing health care providers to refuse to participate in *any* part of *any* health service program or research activity "contrary to [their] religious beliefs or moral convictions."[25] While such an interpretation obviously could be challenged legally, many patients have neither the knowledge nor the means to resist such improper care refusals and would simply suffer the delay or complete denial of medically needed treatments.

II. The Proposed Rule Invites Workers And Institutions To Refuse Care And Does Not Acknowledge The Rights Of Patients.

By issuing the Proposed Rule, HHS invites health workers and institutions to refuse to provide medical care for religious reasons, without acknowledging that patients often have countervailing rights. Yet, all federal agencies, including HHS, must comply with the federal statutes that protect LGBT people and others from discrimination, such as Section 1557 of the Affordable Care Act, which bars discrimination based on sex in federally funded health services and programs.[26] Properly understood, Section 1557 protects transgender patients from discriminatory denials of care based on their gender identity or transgender status.[27] It also protects lesbian, gay, and bisexual patients.[28] Even if it were not contrary to the mission of OCR

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[24] *See, e.g.*, Section 88.1 (Purpose); Appendix A (required notice to employees) to 45 C.F.R., 83 Fed. Reg. at 3931 (declaring broad right to accommodation for any religious or moral belief); 83 Fed. Reg. at 3881, 3887-89, 3903 (addressing "problem" of workers being required to meet patient needs despite their personal beliefs).

[25] 42 U.S.C.A. § 300a-7(d). See cases cited *supra* note 20.

[26] 42 U.S.C.A. § 18116.

[27] *Rumble v. Fairview Health Services*, 2015 WL 1197415 (D. Minn. March 16, 2015) (Affordable Care Act, Section 1557). *See also Whitaker v. Kenosha Unified School District No. 1 Board of Education, 858 F.3d 1034 (7th Cir. 2017*) (analogous protection against sex discrimination in Title IX protects transgender students); *EEOC v. R.G. v. G.R. Harris Funeral Homes, Inc.*, __ F.3d __, 2018 WL 1177669 (6th Cir. March 7, 2018) (analogous protection against sex discrimination in Title VII protects transgender workers).

[28] *Cf. Zarda v. Altitude Express, Inc.*, 883 F.3d 100 (2d Cir. 2018) (sexual orientation discrimination is sex discrimination under Title VII); *Hively v. Ivy Tech Comm'ty College*, 853 F.3d 339 (7th Cir. 2017) (same).

to undermine patient protections against discrimination, the agency lacks the authority to reduce the protections provided to patients by separate statutes.

The ACA also includes patient protections to ensure access to essential health services, including reproductive health services. Yet, the Proposed Rule's aggressive approach to advancing conscience rights offers nothing to explain how those refusal rights are to coexist with patients' rights under the ACA. As to these conflicts, Lambda Legal joins the comments submitted by the National Health Law Program.

Moreover, the Proposed Rule also is inconsistent with several core constitutional guarantees: (1) each of us is entitled to equal protection under law; (2) the Establishment Clause forbids our government from elevating the religious wishes of some above the needs of others to be protected from harm, including the harms of discrimination; and (3) congressional spending powers have limits. On the latter point, the Proposed Rule references the spending powers of Congress as grounds for the new enforcement powers created for HHS to condition federal funding upon health care providers' acquiescence in religious refusal demands of their workers.[29] However, as well-established by *South Dakota v. Dole*[30] and its progeny, Congress's spending powers are limited. Any exertion of power must be in pursuit of the general welfare; must not infringe upon states' abilities "to exercise their choice knowingly, cognizant of the consequences of their participation"; must be related "'to the federal interest in particular national projects or programs;'" and must be otherwise constitutionally permissible.[31]

Multiple Equal Protection and Establishment Clause concerns implicate the final prong of the *South Dakota v. Dole* test for unconstitutional conditions on federal funds. But the first prong deserves immediate focus because it obviously does not serve the general welfare to use severe de-funding threats to intimidate medical facilities into deviating from medical practice standards in favor of religious interests in secular settings, to the detriment of individual and public health.

In addition, with its explicit intention to enforce federal "conscience" rights despite contrary state and local protections for patients, the Proposed Rule further implicates federalism concerns. It states: "Congress has exercised the broad authority afforded to it under the Spending Clause to attach conditions on Federal funds for respect of conscience, and such conscience conditions supersede conflicting provisions of State law[.]"[32] It then asserts that it "does not impose substantial direct effects on States," "does not alter or have any substantial direct effects on the relationship between the Federal government and the States," and "does not implicate" federalism concerns under Executive Order 13132.[33] Yet, by inviting health professionals and

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[29] Proposed Rule, 83 Fed. Reg. at 3889.

[30] 483 U.S. 203 (1987).

[31] *Id*. at 207-08.

[32] Proposed Rule, 83 Fed. Reg. at 3889.

[33] *Id.* at 3918-19.

other workers to turn away patients and refuse job duties in such a sweeping way, the Proposed Rule directly conflicts with state and local nondiscrimination laws and other patient protections. Its assertions to the contrary are patently inaccurate.

III. The Proposed Rule Invites Workers To Refuse Care And Does Not Acknowledge The Legal Rights And Duties, And Ethical Obligations, Of Health Care Providers.

The Proposed Rule aims improperly to empower workers to object to job duties without addressing the impacts on employers and coworkers left somehow to try to ensure that patient needs are met by others, with whatever increased costs, workload, and other burdens it may entail. The proposed approach fails to acknowledge that the federal employment nondiscrimination law, Title VII of the Civil Rights Act of 1964, limits the extent to which employers are to be burdened by employee demands for religious accommodation.[34] Undue burdens on employers could include objections by coworkers to unfair additional job duties or to coworker proselytizing. Likewise, it certainly would impose unjustifiable burdens to require employers to hire duplicate staff simply to ensure patient needs are met by employees willing to perform basic job functions. Indeed, courts have confirmed that when denial of a requested accommodation is "reasonably necessary to the normal operation of the particular business or enterprise,"[35] employers, including health care employers,[36] need only show that they "offered a reasonable accommodation *or* that a reasonable accommodation would be an undue burden."[37]

Such limitations on employee religious rights are essential to ensure that health care employers can hire those who will perform the essential functions of their jobs, and will comply with all statutory obligations including prohibitions against discrimination. If instead, employees who claim "conscience" objections to providing the health care services to LGBT people or people living with HIV are empowered by the Proposed Rule to threaten their employees with loss of federal funding if they do not allow such discrimination, employers will face logistical

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[34] 42 U.S.C.A. § 2000e *et seq. See, e.g., See, e.g., Bruff v. North Miss. Health Servs., Inc.*, 244 F.3d 495, 497-98 (5th Cir. 2001) (Title VII duty to accommodate employees' religious concerns did not require employer to accommodate employee's requests to be excused from counseling patients about non-marital relationships, which meant "she would not perform some aspects of the position itself"); *Berry v. Dep't of Social Servs.*, 447 F.3d 642 (9th Cir. 2006) (employer entitled to prohibit employee from discussing religion with clients).

[35] 42 U.S.C.A. § 2000e-2(e).

[36] *See, e.g., Grant v. Fairview Hosp. & Healthcare Servs.*, No. Civ. 02-4232JNEJGL, 2004 WL 326694 (D. Minn. Feb. 18, 2004) (hospital wasn't required to accommodate employee's request to be able to proselytize or provide pastoral counseling to patients to try to persuade them not to have abortions); *Robinson v. Children's Hosp. Boston*, Civil Action No. 14-10263-DJC, 2016 WL 1337255 (D. Mass. Apr. 5, 2016) (granting hospital employee's request to forgo flu shot would have been an undue hardship for hospital).

[37] *See, e.g., Sánchez-Rodríguez v. AT & T Mobility P. R., Inc.*, 673 F.3d 1, 8 (1st Cir. 2012).

nightmares and the employees without such beliefs will be unfairly subjected to increased workloads.

This seems like an inevitable repercussion particularly in light of the Proposed Rule's explanation in its definition of prohibited "discrimination" that "religious individuals or institutions [must] be allowed a level playing field, and that their beliefs not be held to disqualify them from participation in a program or benefit."[38] This definition lacks any qualifying language confirming that employers may condition employment on willingness to perform essential parts of a job. The likely effects would include increased burnout among those staff who have additional work delegated to them when religious exemptions are claimed. The Proposed Rule also would drain institutional resources as employers must respond (with management time and legal fees) to complaints filed by overburdened workers and by those who file implausible "conscience" objections upon receiving negative work evaluations. The waste of essential health care resources in service of improper denials of medical care cannot be justified.

Moreover, the Proposed Rule similarly ignores that health professionals are bound by ethical standards to do no harm and to put patient needs first. Concerning the application of this point to ensuring patients' reproductive health needs are not improperly subordinated to others' religious concerns, Lambda Legal endorses the comments submitted by the National Health Law Program. Concerning patients' needs to be treated equally regardless of gender identity, sexual orientation, and other irrelevant personal characteristics, the Joint Commission's accreditation standards and the ethical rules of the American Medical Association and other leading medical associations all impose a duty of nondiscrimination. For example, AMA Ethical Rule E-9.12 prohibits discrimination against patients and Ethical Rule E-10.05 provides that health professionals' rights of conscience must not be exercised in a discriminatory manner.[39] But that is precisely what results when, for example, a medically necessarily hysterectomy is denied to a patient because it is needed as treatment for gender dysphoria, and is provided to other patients as treatment for fibroids, endometriosis, or cancer.[40]

The Tennessee Counseling Association has expressed the bottom line cogently. Like many medical associations across the country, the TCA has codified the "do no harm" mandate and issued a formal statement opposing legislation proposing to allow denials of medical care through religious exemptions in that state: "When we choose health care as a profession, we

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[38] Proposed Rule, 83 Fed. Reg. at 3892.

[39] AMA ethical rule E-9.12, "Patient-Physician Relationship: Respect for Law and Human Rights," E-10.05, "Potential Patients."

[40] See discussion of Proposed Rule reference to *Minton v. Dignity Health*, No. 17-558259 (Calif. Super. Ct. Apr. 19, 2017), at page 5, footnote 22. *See also Conforti v. St. Joseph's Healthcare Sys.* (D. N.J. filed Jan. 5, 2017), case documents at https://www.lambdalegal.org/in-court/cases/nj-conforti-v-st-josephs; Amy Littlefield, *Catholic Hospital Denies Transgender Man a Hysterectomy on Religious Grounds*, Rewire.News, Aug. 31, 2016, https://rewire.news/article/2016/08/31/catholic-hospital-denies-transgender-man-hysterectomy-on-religious-grounds/.

choose to treat all people who need help, not just the ones who have goals and values that mirror our own."[41]

IV. The Proposed Rule's Enforcement Mechanisms Are Draconian And Would Skew Health Systems In Favor Of Religious Refusals And Against Patient Care.

The Proposed Rule's enforcement mechanisms include aggressive investigation, require medical facilities to subject themselves to an extensive scheme of regulatory surveillance by HHS, and allocate authority to OCR "to handle complaints, perform compliance reviews, investigate, and seek appropriate action."[42] The Proposed Rule even "make[s] explicit the Department's authority to investigate and handle violations and conduct compliance reviews *whether or not a formal complaint has been filed*."[43] In addition to conditioning federal funding on prospective pledges to comply with broad, vague requirements, penalties can include not just the loss of future federal funding but even the potential of funding "claw backs,"[44] all with limited if any due process protections.

For many major medical providers, the threat of loss of federal funding is a threat to the facilities' very existence. It is nearly unfathomable that the government intends to force medical facilities either to forego their ethical obligations not to harm their patients or to close their doors. But, that easily could be the effect of the Proposed Rule in many instances. More often, the likely result would be simply to skew health systems dangerously in favor of religious refusals and against patient care. Doing so would both invite discrimination and aggravate existing health disparities and barriers to health care faced by LGBT people and others, contrary to the mission of HHS and, in particular, its Office for Civil Rights.

V. The Proposed Rule Inevitably Would Invite Discrimination And Worsen Health Disparities Affecting LGBT People And Others.

Discrimination and related health disparities already are widespread problems for LGBT people and people living with HIV.[45] In 2010, Lambda Legal conducted the first-ever national

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[41] *See* Emma Green, *When Doctors Refuse to Treat LGBT Patients*, The Atlantic, April 19, 2016, https://www.theatlantic.com/health/archive/2016/04/medical-religious-exemptions-doctors-therapists-mississippi-tennessee/478797/, citing Tenn. Counseling Assoc., *TCA Opposes HB 1840* (2016), http://www.tncounselors.org/wp-content/uploads/2016/03/TCA-Opposes-HB-1840-3.9.16.pdf.

[42] Proposed Rule, 83 Fed. Reg. at 3898.

[43] *Id*. (emphasis added).

[44] *Id*.

[45] *See, e.g.*, Inst. of Med., *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011) ("IOM Report") (undertaken at the request of the National Institutes of Health, and providing an overview of the public health research concerning health disparities for LGBT people and the adverse health consequences of anti-LGBT attitudes),

survey to examine the refusals of care and other barriers to health care confronting LGBT people and people living with HIV, *When Health Care Isn't Caring: Survey on Discrimination Against LGBT People and People Living with HIV*.[46] Of the nearly 5,000 respondents, more than half reported that they had experienced at least one of the following types of discrimination in care:

- Health care providers refusing to touch them or using excessive precautions;
- Health care providers using harsh or abusive language;
- Health care providers being physically rough or abusive;
- Health care providers blaming them for their health status.[47]

Almost 56 percent of lesbian, gay, or bisexual (LGB) respondents had at least one of these experiences; 70 percent of transgender and gender-nonconforming respondents had one or more of these experiences; and almost 63 percent of respondents living with HIV experienced one or more of these types of discrimination in health care.[48] Almost 8 percent of LGB respondents reported having been denied needed care because of their sexual orientation,[49] and 19 percent of respondents living with HIV reported being denied care because of their HIV status.[50] The picture was even more disturbing for transgender and gender-nonconforming respondents, who reported the highest rates of being refused care (nearly 27 percent), being subjected to harsh language (nearly 21 percent), and even being abused physically (nearly 8 percent).[51]

Respondents of color and low-income respondents reported much higher rates of hostile treatment and denials of care. Nearly half of low-income respondents living with HIV reported that medical personnel refused to touch them, while the overall rate among those with HIV was

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https://www.ncbi.nlm.nih.gov/books/NBK64806; Sandy E. James et al., Nat'l Ctr. For Transgender Equality, *The Report of the 2015 U.S. Transgender Survey* 93-129 (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf; Lambda Legal, Health Care; Shabab Ahmed Mirza & Caitlin Rooney, Ctr. For Am. Progress, *Discrimination Prevents LGBTQ People from Accessing Health Care* (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

[46] Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010) ("Lambda Legal, Health Care"), http://www.lambdalegal.org/publications/when-health-care-isnt-caring.

[47] *Id*. at 5, 9-10.

[48] *Id*.

[49] *Id*. at 5, 10.

[50] *Id*.

[51] *Id*. at 10-11.

nearly 36 percent.[52] And while transgender respondents as a whole reported a care-refusal rate of almost 27 percent, low-income transgender respondents reported a rate of nearly 33 percent.[53] People of color living with HIV and LGB people of color were at least twice as likely as whites to report experiencing physically rough or abusive treatment by medical professionals.[54]

Also detailed in the report are particular types of discrimination in health care based on gender identity, sex discrimination against LGB people, and discrimination against people living with HIV. Such discrimination can take many forms, from verbal abuse and humiliation to refusals of care;[55] to refusal to recognize same-sex family relationships in health care settings to the point of keeping LGBT people from going to the bedsides of their dying partners;[56] to lack of understanding and respect for LGBT people.[57] The resulting harms are manifold, from transgender patients denied care postponing, delaying, or being afraid to seek medical treatment, sometimes with severe health consequences, or resorting out of desperation to harmful self-treatment;[58] to the mental and physical harms of stigma;[59] to other immediate physical harms from being denied medical care.

As described, the discriminatory treatment of LGBT people too often occurs in the name of religion. When it does, that religious reinforcement of anti-LGBT bias often increases the mental health impacts of discrimination.[60]

Since the 2010 Lambda Legal survey, other studies have similarly documented the disparities faced by LGBT people seeking health care. For example, *The Report of the 2015 U.S. Transgender Survey*, a survey of nearly 28,000 transgender adults nationwide, found that 33 percent "of respondents who had seen a health care provider in the past year reported having at least one negative experience related to being transgender, such as verbal harassment, refusal of treatment, or having to teach the health care provider about transgender people to receive

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[52] *Id*. at 11.

[53] *Id*.

[54] *Id*. at 12.

[55] *Id*. at 5-6.

[56] *Id*. at 15-16.

[57] *Id*. at 12-13.

[58] *Id.* at 6, 8, 12-13.

[59] *Id*. at 2.

[60] Ilan H. Meyer et al., *The Role of Help-Seeking in Preventing Suicide Attempts among Lesbians, Gay Men, and Bisexuals*, Suicide & Life Threatening Behavior, 8 (2014), http://www.columbia.edu/~im15/papers/meyer-2014-suicide-and-life.pdf ("[A]lthough religion and spirituality can be helpful to LGB people, negative attitudes toward homosexuality in religious settings can lead to adverse health effects") (internal citations omitted).

appropriate care" and that "23% of respondents did not see a doctor when they needed to because of fear of being mistreated as a transgender person[.]"[61]

The Center for American Progress in 2017 conducted another nationally representative survey with similar results about LGBT health disparities, including findings that:

> Among lesbian, gay, bisexual, and queer (LGBQ) respondents who had visited a doctor or health care provider in the year before the survey:
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> > 8 percent said that a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation.
> >
> > 6 percent said that a doctor or other health care provider refused to give them health care related to their actual or perceived sexual orientation.
> >
> > 7 percent said that a doctor or other health care provider refused to recognize their family, including a child or a same-sex spouse or partner.
> >
> > 9 percent said that a doctor or other health care provider used harsh or abusive language when treating them.
> >
> > 7 percent said that they experienced unwanted physical contact from a doctor or other health care provider (such as fondling, sexual assault, or rape).[62]
>
> Among transgender people who had visited a doctor or health care providers' office in the past year:
>
> > 29 percent said a doctor or other health care provider refused to see them because of their actual or perceived gender identity.
> >
> > 12 percent said a doctor or other health care provider refused to give them health care related to gender transition.
> >
> > 23 percent said a doctor or other health care provider intentionally misgendered them or used the wrong name.

[61] James et al., *supra* n. 45, at 93.

[62] Mirza & Rooney, *supra* n. 45.

> 21 percent said a doctor or other health care provider used harsh or abusive language when treating them.
>
> 29 percent said that they experienced unwanted physical contact from a doctor or other health care provider (such as fondling, sexual assault, or rape).[63]

Independently of our own and others' research studies, Lambda Legal has become distressingly aware of the nature and scope of the discrimination problem from our legal work and requests for assistance received by our Legal Help Desks. We have repeatedly submitted information about the pattern of religion-based refusals of medical care to LGBT people in response to HHS requests. For example, in our 2013 response to the Request For Information for Section 1557 of the ACA, we documented numerous cases in which health professionals had denied medical care or otherwise discriminated against LGBT people and/or people living with HIV, based on the professionals' personal religious views, including:

> • Guadalupe "Lupita" Benitez was referred for infertility care to North Coast Women's Care Medical Group, a for-profit clinic that had an exclusive contract with Benitez's insurance plan. After eleven months of preparatory treatments, including medication and unwarranted surgery, Lupita's doctors finally admitted they would not perform donor insemination for her because she is a lesbian. The doctors claimed a right not to comply with California's public accommodations law due to their fundamentalist Christian views against treating lesbian patients as they treat others. In a unanimous decision, the California Supreme Court held that religious liberty protections do not authorize doctors to violate the civil rights of lesbian patients. *North Coast Women's Care Med. Grp., Inc. v. San Diego Cnty. Superior Court (Benitez)*, 189 P.3d 959 (Cal. 2008)
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> • Counseling student's objections to providing relationship counseling to same-sex couples. *Keeton v. Anderson-Wiley*, 664 F.3d 865 (11th Cir. 2011) (finding student unlikely to prevail on free speech and religious liberty claims challenging her expulsion from counseling program due to her religiously based refusal to counsel same-sex couples, contrary to professional standards requiring nonjudgmental, nondiscriminatory treatment of all patients).
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> • Physician's objection to working with an LGB person. *Hyman v. City of Louisville*, 132 F. Supp. 2d 528, 539-540 (W.D. Ky. 2001) (physician's religious beliefs did not exempt him from law prohibiting employment discrimination based on sexual orientation or gender identity), *vacated on other grounds by* 53 Fed. Appx. 740 (6th Cir. 2002).

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[63] *Id.*

> • Proselytizing to patients concerning religious condemnation of homosexuality. *Knight v. Connecticut Dep't of Pub. Health*, 275 F.3d 156 (2d Cir. 2001) (rejecting free exercise wrongful termination claim of visiting nurse fired for antigay proselytizing to home-bound AIDS patient).
>
> • Refusal to process lab specimens from persons with HIV. *Stepp v. Review Bd. of Indiana Emp. Sec. Div.*, 521 N.E.2d 350, 352 (Ind. 1988) (rejecting religious discrimination claim of lab technician fired for refusing to do tests on specimens labeled with HIV warning because he believed "AIDS is God's plague on man and performing the tests would go against God's will").[64]

In addition, testimonies received in Lambda Legal's health survey describe similar encounters with health professionals who felt free to express their religiously grounded bias toward LGBT patients:

> • Kara in Philadelphia, PA: "Since coming out, I have avoided seeing my primary physician because when she asked me my sexual history, I responded that I slept with women and that I was a lesbian. Her response was, 'Do you know that's against the Bible, against God?'"[65]
>
> • Joe in Minneapolis, MN: "I was 36 years old at the time of this story, an out gay man, and was depressed after the breakup of an eight-year relationship. The doctor I went to see told me that it was not medicine I needed but to leave my 'dirty lifestyle.' He recalled having put other patients in touch with ministers who could help gay men repent and heal from sin, and he even suggested that I simply needed to 'date the right woman' to get over my depression. The doctor even went so far as to suggest that his daughter might be a good fit for me."[66]

Lambda Legal documented additional recent examples of health care denials or discriminatory treatment in its amicus brief to the Supreme Court in *Masterpiece Cakeshop v. Colorado Civil Rights Commission*,[67] including the following two Lambda Legal cases:

- Lambda Legal client Naya Taylor, a transgender woman in Mattoon, Illinois, who sought hormone replacement therapy (HRT), a treatment for gender dysphoria, from the health clinic where she had received care for more than a decade. When her primary care physician refused her this standard treatment, clinic staff told her that, because of

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[64] Lambda Legal Nondiscrimination Comments (citations partially omitted).

[65] *Id.*

[66] *Id.*

[67] *See* Brief of Amici Curiae Lambda Legal et al., *Masterpiece Cakeshop Ltd. v. Colorado Civil Rights Comm'n*, No. 16-111, at 11-14, 17-18, 26, 30 (filed Oct. 30, 2017), https://www.lambdalegal.org/in-court/cases/masterpiece-cakes-v-co-civil-rights-commission.

the religious beliefs of the clinic's doctors, they do not have to treat "people like you."[68]

- Lambda Legal client Jionni Conforti, who was refused a medically necessary hysterectomy despite his treating physician's desire to perform the surgery. The hospital where the surgeon had admitting privileges was religiously affiliated and withholds permission for all gender transition-related care.[69]

These examples are just a tip of the iceberg, a few of many incidents across the country in which religion has been used to justify denial of health care or other discrimination against LGBT people and people living with HIV. Although courts consistently have rejected such reliance on religion to excuse discrimination, examples of religion-based discrimination in health care continue to occur with regularity.[70] This mistreatment contributes to persistent health disparities, including elevated rates of stress-related conditions.[71]

Given this landscape, Lambda Legal is deeply concerned that this Proposed Rule, designed to protect and even encourage religious refusals of health care, inevitably will facilitate further discrimination by health professionals in contexts involving sexual orientation, gender identity, or HIV status. As a result, the health of patients across the country, as well as others, would be at risk, and "conscience" claims could too easily become a way for providers to turn away LGBT patients. The past examples of religiously-based discrimination indicate there is significant likelihood that too-many individual and institutional care providers will demand exemptions from rules and standards designed to ensure that patients receive proper treatment regarding the following needs:

- Treatment of patients who need counseling, hormone replacement therapy, gender confirmation surgeries, or other treatments for gender dysphoria.
- For patients with a same-sex spouse or who are in a same-sex relationship, bereavement counseling after the loss of a same-sex partner or other mental health care that requires

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[68] In April 2014, Lambda Legal filed a claim of sex discrimination on Ms. Taylor's behalf under Section 1557 of the ACA; however, Ms. Taylor subsequently passed away and her case was voluntarily dismissed. *See* Complaint, *Taylor v. Lystila*, 2:14-cv-02072-CSB-DGB (C.D. Ill., Apr. 15, 2014), *available at* https://www.lambdalegal.org/in-court/legal-docs/taylor_il_20140416_complaint.

[69] *See Conforti v. St. Joseph's Healthcare Sys.* (D. N.J. filed Jan. 5, 2017) case documents at https://www.lambdalegal.org/in-court/cases/nj-conforti-v-st-josephs. *See also* Amy Littlefield, *Catholic Hospital Denies Transgender Man a Hysterectomy on Religious Grounds*, Rewire.News, Aug. 31, 2016, https://rewire.news/article/2016/08/31/catholic-hospital-denies-transgender-man-hysterectomy-on-religious-grounds/.

[70] *See* Lambda Legal 1557 Comments; Brief of Amici Curiae Lambda Legal et al., *Zubik v. Burwell*, 136 S. Ct. 1557 (2016).

[71] *See* Mark Hatzenbuehler, *Structural Stigma: Research Evidence and Implications for Psychological Science*, 71 AM. PSYCHOLOGIST, 742, 742–51 (2016), http://dx.doi.org/10.1037/amp0000068; IOM Report, *supra* n. 45.

respectful acknowledgment of a person's sexual orientation or gender identity.

- Care for patients living with HIV, including the option of pre-exposure prophylaxis (PrEP), a highly effective medication that dramatically reduces the risk of HIV infection among those who are otherwise at high risk, including people who are in a sexual relationship with a partner who is living with HIV.
- Treatment of patients who are unmarried or in a same-sex relationship and require infertility treatment or other medical services related to pregnancy, childbirth or pediatric needs.

In addition, the Proposed Rule threatens to undermine the community's trust in health care providers. Although there may be health care facilities that remain safer places for patients who face increased risk of discrimination in health care facilities, those facilities that are more welcoming of LGBT patients and patients seeking HIV care and willing to provide them with full health care access will become overburdened and increasingly unable to meet the needs of all who come through their doors.

If the number of health care facilities that LGBT people can feel comfortable going to, knowing they won't be turned away is reduced as the inevitable result of this Proposed Rule, access to health care will become harder, and nearly impossible for some, who, for example, are low income[72] or who live in remote areas and cannot travel long distances for medical care. Patients seeking more specialized care such as infertility treatments or HIV treatment or prevention are already often hours away from the closest facility. The Proposed Rule threatens to build even greater barriers between those who are most vulnerable and the health care they need.

For the Proposed Rule to transform the role of HHS from an agency focused on ensuring nondiscriminatory provision of health care to one that facilitates refusals of care is a disturbing about-face contrary to the Department's mission and authorizing statutes. Its failure to explain how the enhanced powers of health care providers to refuse patient care in the name of "conscience" should be reconciled with the protections for patients under the ACA and other statutes, and for employers under Title VII, make clear that this proposal is legally untenable as well as unjustifiably dangerous as a matter of federal health policy.

VI. The Proposed Rule Is The Result Of A Rushed, Truncated Process Contrary To The Department's Mission And Inconsistent With Procedural Requirements.

Considering the well-recognized health disparities and difficulty obtaining nondiscriminatory care that already confront the LGBT community, the Proposed Rule's apparent goal of inviting more discrimination and care denials to LGBT people and is peculiar

[72] Contrary to some misperceptions, LGBT people and people living with HIV are disproportionately economically disadvantaged. *See, e.g.*, M.V. Lee Badgett et al., *New Patterns of Poverty in the Lesbian, Gay, and Bisexual Community*, WILLIAMS INST. (June 2013), https://williamsinstitute.law.ucla.edu/research/census-lgbt-demographics-studies/lgbt-poverty-update-june-2013.

and alarming. Indeed, the lack of concern for the Proposed Rule's inevitable impacts is especially shocking because this Department itself has conducted studies revealing disparities in LGBT health outcomes. As reported in the 2014 National Health Statistics Reports:

> [R]ecent studies have examined the health and health care of lesbian, gay, and bisexual (LGB) populations and have found clear disparities among sexual minority groups (i.e., gay or lesbian and bisexual) and between sexual minorities and straight populations. These disparities appear to be broad-ranging, with differences identified for various health conditions (e.g., asthma, diabetes, cardiovascular disease, or disability) … health behaviors such as smoking and heavy drinking … and health care access and service utilization …. Across most of these outcomes, sexual minorities tend to fare worse than their nonminority counterparts.[73]

Thus, in addition to the legal and ethical conflicts it would generate, the Proposed Rule also would undermine HHS's national and local efforts to reduce LGBT health disparities. For example, this Department's "Healthy People 2020 initiative" and the Institute of Medicine have called for steps to be taken to address LGBT health disparities"[74]; medical associations including the American Medical Association, the Association of American Medical Colleges, the American College of Physicians, the American Psychiatric Association, and others are committed to improving medical care for LGBT people through education and cultural competency training; and legislation is increasingly being considered and passed to improve LGBT health access and reduce health disparities.[75] The Proposed Rule endangers the important progress made on this front.

With this Department's past focus on addressing LGBT health disparities, it would be a bizarre and disturbing reversal of course for HHS now to become an active participant in the very denials of health care and discriminatory treatment that cause these disparities. Years of careful study and deliberation went into framing the protections against discrimination implemented pursuant to Section 1557 of the ACA, including the explicit protections against gender identity discrimination and other forms of sex discrimination and the accompanying

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[73] Brian W. Ward et al., *Sexual Orientation and Health Among U.S. Adults: National Health Interview Survey, 2013*, Nat'l Health Statistics Report No. 77, 1, (July 15, 2014), https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf.

[74] Dep't of Health & Human Servs., *Healthy People 2020: LGBT Health Topic Area* (2015), http://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health; IOM Report.

[75] *See* Timothy Wang et al., The Fenway Inst., *The Current Wave of Anti-LGBT Legislation: Historic Context and Implications for LGBT Health* at 6, 8-9 (June 2016), http://fenwayhealth.org/wp-content/uploads/The-Fenway-Institute-Religious-Exemption-Brief-June-2016.pdf.

value statement that "HHS supports prohibiting sexual orientation discrimination as a matter of policy[.]"[76]

In addition, the Proposed Rule has been issued without adequate time spent considering the thousands of comments submitted on related proposals. It lacks acknowledgment of countervailing interests of patients and many health provider institutions, let alone any explanation of how those interests are to be reconciled with the proposed aggressive enforcement of inconsistent religious interests. All in all, the Department's process has been arbitrary, capricious, and dangerous.[77] Consequently, along with its numerous other legal infirmities, it also violates the Administrative Procedure Act.[78]

VII. Conclusion

The Proposed Rule would have a chilling effect on the full and unbiased provision of health care, including to members of the LGBT community and everyone living with HIV, in a manner that conflicts with ethical, legal, and constitutional standards. While freedom of religion is a fundamental right protected by our Constitution and federal laws, it does not give anyone the right to use religious or moral beliefs as grounds for violating the rights of others. Instead, the Constitution commands that any religious or moral accommodation must be "measured so that it does not override other significant interests" or "impose unjustified burdens on other[s]."[79] Indeed, when the Supreme Court addressed the related question in *Burwell v. Hobby Lobby Stores, Inc.*, it explained that a religious accommodation should be provided in that case because the impact on third parties would be "precisely zero."[80]

Here, the Proposed Rule conflicts with statutory rights of health care providers to operate with reasonable efficiency and cost, and within their ethical obligations to care for patients according to professional standards. Most importantly, it also conflicts with legal and ethical protections for patients, potentially putting their health and even lives at risk. It is ill conceived and has no place in federal health policy.

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[76] Press Release, U.S. Dep't of Health & Human Servs., HHS Finalizes Rule to Improve Health Equity Under the Affordable Care Act (May 13, 2016), https://wayback.archive-it.org/3926/20170127191750/https://www.hhs.gov/about/news/2016/05/13/hhs-finalizes-rule-to-improve-health-equity-under-affordable-care-act.html.

[77] 5 U.S.C.A. § 706(2)(a).

[78] 5 U.S.C.A. § 500 *et seq*.

[79] *Cutter v. Wilkinson*, 544 U.S. 709, 722, 726 (2005).

[80] 134 S. Ct. 2751, 2760 (2014). Indeed, every member of the Court, whether in the majority or in dissent, reaffirmed that the burdens on third parties must be considered. *See id* at 2781 n. 37; *id.* at 2786–87 (Kennedy, J., concurring); *id.* at 2790, 2790 n. 8 (Ginsburg, J., joined by Breyer, Kagan, and Sotomayor, JJ., dissenting).

For the foregoing reasons, we emphatically recommend that the Department set aside this Proposed Rule.

Most respectfully,

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EXHIBIT N

The Williams Institute
UCLA SCHOOL OF LAW

March 27, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, D.C. 20201
Submitted through the Federal eRulemaking portal

RE: DEPARTMENT OF HEALTH AND HUMAN SERVICES; Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (83 Fed. Reg. 3800–3931) (**Docket: HHS-OCR-2018-00002**)

To Whom It May Concern:

Thank you for the opportunity to comment on the Notice of Proposed Rulemaking of the Office for Civil Rights ("OCR") of the U.S. Department of Health and Human Services ("HHS"), titled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" ("Proposed Rule"). The undersigned are scholars at the Williams Institute, an academic research center at UCLA School of Law dedicated to conducting rigorous and independent research on sexual orientation and gender identity, including on health disparities and discrimination facing lesbian, gay, bisexual, and transgender (LGBT) people.

The mission of HHS and OCR is to protect and enhance the health and well-being of all Americans and eliminate discrimination in health care and health coverage. Indeed, the civil rights laws that OCR is charged with enforcing – including Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, and Section 1557 of the Affordable Care Act – require that health care entities avoid discriminating based on race, national origin, disability, age, and sex as a condition of their receipt of federal funds.

But that mission is undermined, and those civil rights laws potentially violated, if OCR authorizes refusals of care that go beyond the narrow terms permitted in the provider-conscience statutes. The Proposed Rule risks these consequences in numerous respects, as we explain below with respect to the Church, Coats-Snowe, and Weldon Amendments. We recognize that Congress drafted the provider-conscience laws to protect religious liberty, which is a core principle of our democracy, but drafted these laws narrowly in light of the importance of health care. As a result, any Final Rule and OCR's enforcement of it must strictly comply with the narrow refusals of care that Congress has authorized, and should minimize unauthorized denials of care or other barriers to care any Final Rule encourages.

In addition, because at least some, if not all, anti-LGBT prejudice in society (including discrimination in the provision of health care) is associated with some religious or faith-based beliefs, OCR must consider – including as part of a Regulatory Impact Analysis – how the Proposed Rule and any Final Rule will increase barriers for LGBT and other people to fully access vital programs, services, and activities, and will adversely impact the health and well-being of the LGBT population and other vulnerable populations in the United States.

I. To Pass Legal Muster, Any Final Rule Must Conform to the Underlying Statutes and be Consistent with the Mission of HHS and the Various Civil Rights Laws that OCR Enforces.

In the Church, Coats-Snowe, and Weldon Amendments, Congress insulated certain medical providers from being required – or being discriminated against for refusing – to perform abortions and certain specific other services that may violate their religious or moral beliefs. Each of these statutes was carefully and narrowly drafted, and each is different; as a result, each must be read separately and applied in careful compliance with Congressional intent. For the purposes of this comment, we accept the provider-conscience laws as written.

For example, the Weldon Amendment prohibits certain federal funding to federal, state, and local agencies and programs that "subject[] any institutional or individual health care entity to discrimination [for refusing to] provide, pay for, provide coverage for, or refer for abortions."[1] The Coats-Snowe Amendment prohibits the federal government, as well as state and local governments receiving federal funding, from discriminating against a "health care entity" that "refuses to undergo training in the performance of induced abortion, to require or provide such training, to perform such abortion, or to provide referrals for such training or such abortions,"[2] and certain other similar activities.[3] Neither the Weldon Amendment nor the Coats-Snowe Amendment mention on its face religious beliefs. However, OCR has determined that Congress intended the Weldon Amendment to apply only to health care entities that have objections to abortion based on religious or moral grounds; this limitation is necessary to comport the statute with clear Congressional intent.[4] Legislative history on the Coats-Snowe Amendment indicates it, too, should have such a limitation.[5]

In addition, the Church Amendments are largely focused on religious or moral objections to abortion and sterilization. The Church Amendments protect individual and entity recipients of "any grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act" from being required by "any court or any public official or other public

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[1] *See, e.g.*, *Consolidated Appropriations Act, 2018*, H.R. 1625, 115th Cong. § 507(d) (2018).

[2] 42 U.S.C. § 238n(a)(1).

[3] *Id.* §§ 238n(a)(2), (a)(3), (b).

[4] *See* U.S. Dep't of Health and Human Services, Opinion Letter from Office of Civil Rights Director re: OCR Transaction Numbers: 14-193604, 15-193782, & 15-195665, at 3-4 (June 21, 2016) (on file with agency); *see also* 83 Fed. Reg. 3886 (citing Letter from OCR Director to Complainants (June 21, 2016)).

[5] *See, e.g.*, 142 Cong. Rec. S2268-2276 (daily ed. Mar. 19, 1996) (statements of Senators Snowe, Coats, Boxer, Kennedy, Feinstein).

authority" to "perform or assist in the performance of any sterilization procedure or abortion if his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions,"[6] among certain other similar protections related to abortion and sterilization.[7]

Thus, the primary purpose of the provider-conscience laws was to insulate certain providers from certain obligations related to abortion and, in the case of the Church Amendments, sterilization. Only the Church Amendments in any way go further. Subsection (d) of the Church Amendments 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 Secretary of Health and Human Services if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions."[8] By its terms, this protection applies only to individuals, not entities such as hospitals. And unlike the Weldon and Coats-Snowe Amendments, only the Church Amendments explicitly allow providers to deny medical care based on "moral convictions."[9]

The limitations in the language and application of the statutes reflect Congress's intent to carefully circumscribe the occasions on which providers are authorized to refuse medical care. This is because it is clear that denials of care, even when based on religious or moral beliefs, impose harms on patients, undermine the mission of HHS to protect the health and well-being of all Americans, and can violate the terms of fundamental civil rights protection. Any Final Rule must strictly conform to these statutes and must make clear the limited circumstances in which each statute applies.

Any Final Rule must also make clear that the Weldon, Coats-Snowe, and Church Amendments are not absolute and are to be applied consistent with the obligations placed on health care entities by other laws. For example, nothing in the provider-conscience laws exempts hospitals from the requirement to comply with the Emergency Medical Treatment and Active Labor Act (EMTALA), which requires all Medicaid- and Medicare-funded hospitals with an emergency department to screen, stabilize, and at times transfer patients with emergency medical concerns.[10] Not only does EMTALA not contain an exemption for religious or moral beliefs,[11]

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[6] 42 U.S.C. § 300a-7(b)(1).

[7] *Id.* § 300a-7(b)(2)-(c)

[8] *Id.* § 300a-7(d).

[9] *Id.* § 300a-7.

[10] 42 U.S.C. § 1395dd.

[11] *See id.*; *see also* U.S. Dep't of Health and Human Services, Centers for Medicare and Medicaid, *Medicare Program; Clarifying Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions*, https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/Downloads/CMS-1063-F.pdf; *California v. United States*, No. C 05-00328 JSW, 2008 WL 744840, at *4 (N.D. Cal. Mar. 18, 2008) ("[I]t is far from clear whether the Weldon Amendment would prohibit California from enforcing its own version of the EMTALA in medical emergencies [which does exempt health care workers with religious objections to abortion from assisting in emergency or spontaneous abortions]."); *see generally In the matter of Baby "K"*, 16 F.3d 590, 598 (4th Cir. 1994) ("Congress rejected a case-by-case approach to determining what emergency medical treatment hospitals and physicians must provide and to whom they must provide it; instead, it required hospitals and physicians to provide stabilizing care to any individual

EMTALA was directed at stopping patient dumping by limiting hospitals' ability to refuse patients.[12]

Any Final Rule must not only conform to the underlying statutes and be construed consistently with other statutory obligations on health care providers, but must also adhere to HHS's mission "to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services."[13] Likewise, one of the primary purposes of the Patient Protection and Affordable Care Act ("ACA") was to expand access to health care and health coverage.[14] And the ACA has, in fact, expanded health insurance coverage in the United States, including among LGBT people.[15] Any Final Rule should be consistent with this purpose of the ACA, as well.

Moreover, in some circumstances, religiously-motivated denials of care risk violating the core civil rights laws that OCR is charged with enforcing. In fact, in support of HHS's mission, OCR was established in response to a need to remove discriminatory barriers to HHS-funded programs.[16] Since its creation, OCR has been instrumental in enhancing access to health care and health coverage by enforcing civil rights laws that bar discrimination on the basis of race, color, national origin, disability, age, or sex in health care activities and programs that HHS conducts or funds.[17] Indeed, OCR's most recent civil rights statute, Section 1557, was passed as part of the ACA because Congress recognized that discriminatory barriers to health care and

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presenting an emergency medical condition."); *Bryan v. Rectors and Visitors of the Univ. of Va.*, 95 F.3d 349, 352 (4th Cir. 1996) (holding, once stabilizing treatment has been provided for a patient who arrives with an emergency condition, "the patient's care becomes the legal responsibility of the hospital and the treating physicians" and is no longer governed by EMTALA).

[12] *See, e.g.*, G. Smith, II, The Elderly and Patient Dumping, Fla. B.J. 85 (Oct. 1999) ("Before COBRA and EMTALA limited a hospital's right to refuse medical treatment to patients, the common law's no-duty rule was restricted only by four exceptions: 1) once a hospital provides medical care, it must do so nonnegligently; 2) once a person gains "patient" status, the caregiver must aid and protect that patient; 3) where a person relies upon a caregiver's custom of providing emergency care, a duty to provide that care exists; and 4) true "emergency" cases obviate the no-duty rule.").

[13] U.S. Dep't of Health and Human Services, *Introduction: About HHS*, https://www.hhs.gov/about/strategic-plan/introduction/index.html.

[14] The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010); *see also* U.S. Dep't of Health and Human Services, Office for Civil Rights, *Nondiscrimination in Health Programs and Activities; Final Rule*, 81 Fed. Reg. 31376, 31444 ("One of the central aims of the ACA is to expand access to health care and health coverage for all individuals.").

[15] *See, e.g.*, M. Karpman et al., *QuickTake: Uninsurance Rate Nearly Halved for Lesbian, Gay, and Bisexual Adults since Mid-2013*, Health Reform Monitoring Survey (April 2015), http://hrms.urban.org/quicktakes/Uninsurance-Rate-Nearly-Halved-for-Lesbian-Gay-and-Bisexual-Adults-since-Mid-2013.html; G. Gonzales et al., *The Affordable Care Act and Health Insurance Coverage for Lesbian, Gay, and Bisexual Adults: Analysis of the Behavioral Risk Factor Surveillance System*, LGBT HEALTH 62-67 (2017).

[16] *See, e.g.*, U.S. Commission on Civil Rights, *Funding Federal Civil Rights Enforcement: 2000 and Beyond*, http://www.usccr.gov/pubs/crfund01/ch5.htm.

[17] *See* U.S. Dep't of Health and Human Services, *Office for Civil Rights (OCR)*, https://www.hhs.gov/ocr/index.html; U.S. Office of Health and Human Services, *Summaries of select case activities*, https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/examples/index.html.

coverage remained and wanted to provide additional tools to limit discrimination against vulnerable communities.[18]

Thus, any Final Rule must protect OCR's ability to fully enforce the civil rights laws within its jurisdiction. For example, there is nothing in the provider-conscience laws that we believe would authorize providers to offer abortion services to Caucasian women but deny them to women of color, even were the providers to claim that doing so was consistent with religious belief. The Final Rule cannot impinge on basic civil rights protections.

For all of these reasons, the Final Rule must, at a minimum:

- **Make clear that the authorizations under subsection (d) of the Church Amendments apply only to individuals and not to health care entities**, as required by the plain language of the statute.

- **Make clear that the authorizations under subsections (b) and (c) of the Church Amendments apply only to abortion and sterilization in the limited circumstances provided for in the statute, and that these protections only apply where there are religious or moral objections**, as required by the plain language of the statute.

- **Make clear that the protections of the Coats-Snowe and Weldon Amendments apply only to particular abortion services in the limited circumstances provided for in the statutes,** as required by the plain language of the statutes, **and that these protections only apply where there are religious or moral objections** in order to be consistent with Congressional intent.

- **Identify when "moral" objections, as distinct from religious objections, will permit a provider to deny care, and define the limits of those objections.**

- **Make clear that these provider-conscience laws apply only to specific services and procedures, but nothing in the laws authorizes a denial of care based on the provider's rejection of persons because of their demographic characteristics or identity or status.** For example, any Final Rule should make clear that providers cannot deny cardiac care or setting of a broken leg to an individual based on the provider's disapproval or rejection of that individual's LGBT identity or status, if they provide these services to persons who are not LGBT, whatever the provider's religious or moral views are about that individual's LGBT status.

- **Ensure that definitions do not go beyond the meanings authorized under the relevant statute.** The Proposed Rule appears to broaden the definitions of several keys words in the provider-conscience laws, and any Final Rule should adhere to the narrower definitions found in the statutes.

[18] *See* U.S. Dep't of Health and Human Services, *Section 1557 of the Patient Protection and Affordable Care Act*, https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html.

- **Make clear that nothing in the rule authorizes hospitals or other providers to refuse care when EMTALA or other applicable law or duty of care requires them to provide it.**

- **Make clear that in its enforcement, OCR will balance the harm to patients from denials of medical care with the religious liberty interests of the provider denying the care.** As noted above, provisions of provider-conscience laws are not absolute. Balancing is necessary not only because health care is so critical, but also to avoid constructions of the laws that would violate the Establishment Clause.[19] Balancing would also be consistent with federal laws that weigh statutory religious liberty protections against other state interests.[20] Such balancing should take into account all relevant factors in a particular case, which may include the medical necessity of the service or procedure, the availability of alternative providers within the reasonable distance, and whether delay in care risks significant harm to the patient.

As a result of these points, it is clear that any Final Rule can permissibly have only limited, if any, impact on health care for LGBT individuals. There is nothing in the underlying statutes that would permit, *for example*, a cardiologist to deny cardiac care based on a patient's sexual orientation or gender identity. Similarly, whatever protections may attach to an individual health professional, there is nothing in the underlying statutes that would authorize a hospital or other institution to, *for example*, deny fertility treatment to same-sex couples, HIV treatment or prevention treatment to gay or bisexual men, or hormones for gender transition to a transgender patient.

Failure to clarify these points in any Final Rule risks impermissibly encouraging providers to deny care beyond the limited circumstances authorized by Congress, violating HHS and OCR's mission of enhancing health and well-being, and impermissibly elevating provider-conscience laws above the civil rights laws OCR enforces. Indeed, as currently drafted, the rule may improperly signal to providers that religious beliefs should be prioritized over medical standards or the health and care of patients, and could lead people to avoid seeking care as to which there can be no right to deny service just for fear of being turned away – all of which risk exacerbating barriers to care that vulnerable populations experience, as we discuss below.

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[19] U.S. CONST. amend. I; *Cutter v. Wilkinson*. 554 U.S. 709, 714, 720 (2005) ("At some point, accommodation may devolve into an unlawful fostering of religion. . . . [Therefore, courts] must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries." (internal quotation marks and citations omitted)); *see also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).

[20] *See, e.g., Shelton v. University of Med. and Dentistry of N.J.*, 223 F.3d 220 (3d Cir. 2000) (holding, under Title II of the Civil Rights Act, hospital offered reasonable accommodation to transfer a nurse to a different unit when she refused on religious grounds to treat emergencies that she believed would result in abortions); Religious Freedom Restoration Act, 42 U.S.C. § 2000bb (1993) (establishing the federal government is permitted to substantially burden a person's exercise of religion in furtherance of a compelling government interest that is advanced in the least restrictive manner).

II. Any Final Rule Must Conform to the Underlying Statutes to Avoid Significant Harm to the Health and Well-Being of Vulnerable Populations; OCR Must Consider the Costs Related to Potential Harm to LGBT and Other Patients of the Proposed Rule, Including as Part of a Regulatory Impact Analysis

Under Executive Orders 12866 and 13563, OCR must conduct a Regulatory Impact Analysis ("RIA") that "analyzes the benefits, costs, and other impacts of" the Proposed Rule and any Final Rule.[21] A RIA is required here because the Proposed Rule and any Final Rule is likely to "impose costs, benefits, or transfers of $100 million or more in any given year"[22] and because the rule is significant for other reasons, as well.[23] As part of its RIA, OCR must consider the costs in terms of harm to patients that denials of health care and other barriers to care the Proposed Rule and any Final Rule are likely to cause.[24] Even if a RIA is not required, OCR should still consider these harms and make every effort to minimize them consistent with HHS's mission and the civil rights laws OCR enforces.

Denials of health care can result in several categories of harm, including:

- to the patient's physical and mental health when necessary medical services to treat particular medical conditions are denied;

- to the patient's health and well-being because refusals of service, independent of the underlying medical condition, result in dignitary harm to the individual; and

- to the community of which the patient is a member and the ability and willingness of others in that community to seek medical care.

Below we discuss these harms with respect to the LGBT population, which has been subject to persistent and pervasive stigma and discrimination and which, as a result, faces numerous health disparities. Because at least some anti-LGBT stigma and discrimination in society stems from or is otherwise related to certain religious or faith-based beliefs – regardless of moral intent – the Proposed Rule risks encouraging or excusing denials of care and other forms of discrimination against LGBT people in the health care context. Any Final Rule that does not strictly comply with the narrow circumstances permitted for denials of care in the underlying provider-conscience laws and does not minimize the potential for unauthorized denials of care risks

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[21] U.S. Dep't of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Guidelines for Regulatory Impact Analysis* 1 (2016), https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf, [hereinafter *HHS Guidelines for Regulatory Impact Analysis*].

[22] Exec. Order No. 12866, §§ 1(a), 3(f)(1); *HHS Guidelines for Regulatory Impact Analysis* at 2-3.

[23] *HHS Guidelines for Regulatory Impact Analysis*,at 3.

[24] Exec. Order No. 12866 § 1(a), 58 Fed. Reg. 51735 (Oct. 4, 1993); Exec. Order No. 13563 §§ 1(b), 1(c), 76 Fed. Reg. 3821 (Jan. 21, 2011) ("In applying these [regulatory impact and review] principles, each agency is directed to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. Where appropriate and permitted by law, each agency must consider (and discuss qualitatively) values that are difficult or impossible to quantify, *including equity, human dignity, fairness, and distributive impacts*." (emphasis added)).

impermissibly perpetuating these harms in violation of HHS's and OCR's mission, the purpose of the ACA, and laws that prohibit race, sex, and other forms of discrimination in health care.

Despite recent advances in the legal and social acceptance of LGBT people, research finds that LGBT people continue to experience persistent and pervasive discrimination as well as widespread stigma, prejudice, and violence.[25] The existence of this discrimination and stigma in health care, as well as other barriers to care and well-being for LGBT people, is well-documented.[26] According to the Institute of Medicine, "LGBT individuals face discrimination in the health care system that can lead to an outright denial of care or to the delivery of inadequate care. There are many examples of manifestations of enacted stigma against LGBT individuals by health care providers. LGBT individuals have reported experiencing refusal of treatment by health care staff, verbal abuse, and disrespectful behavior, as well as many other forms of failure to provide adequate care."[27]

Denials of, or other forms of discrimination in, health care have repercussions for an LGBT people's dignity, health, and well-being. As is explained in detail in the attached amici brief that scholars, including the undersigned, recently filed with the U.S. Supreme Court in *Masterpiece Cakeshop v. Colorado Human Rights Commission*,[28] refusals of service based on

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[25] *See e.g.*, INSTITUTE OF MEDICINE, THE HEALTH OF LESBIAN, GAY, BISEXUAL, AND TRANSGENDER PEOPLE: BUILDING A FOUNDATION FOR BETTER UNDERSTANDING, 5, 13 (2011); Ilan H. Meyer, The Elusive Promise of LGBT Equality, 106:8 AM. J. PUB. HEALTH 1356 (2016).

[26] *See, e.g.*, INSTITUTE OF MEDICINE, *supra*, at 212-14 (discussing evidence of stigma, discrimination, and violence against LGBT people because of their sexual orientation or gender identities), Ilan H. Meyer et al., Demographic Characteristics and Health Status of Transgender Adults in Select US Regions: Behavioral Risk Factor Surveillance System, 2014, 107 AM. J. PUB. HEALTH 582 (2017). LGBT people can face discrimination and stigma in a wide variety of settings and from many sources in addition to health care, such as employment, housing, and family life. *See, e.g.*, Jennifer Pizer et al., Evidence of Persistent and Pervasive Workplace Discrimination Against LGBT People: The Need for Federal Legislation Prohibiting Discrimination and Providing Equal Employment Benefits, 45 LOY. L.A. L. REV. 715, 720-42 (2012). In turn, such discrimination can have negative consequences for the health and well-being of LGBT individuals. *See, e.g.*, INSTITUTE OF MEDICINE, *supra*, at 734-42 (discussing research documenting that workplace discrimination negatively affects the income and health of LGBT people). Moreover, contrary to popular stereotypes about the affluence of the LGBT community, research demonstrates the economic diversity of LGBT people, including higher rates of poverty and food insecurity for LGBT people nationally compared to non-LGBT people. *See, e.g.*, M.V. Lee Badgett et al., Williams Institute, *New Patterns of Poverty in the Lesbian, Gay, and Bisexual Community* (2013), http://williamsinstitute.law.ucla.edu/wp-content/uploads/LGB-Poverty-Update-Jun-2013.pdf; Taylor N.T. Brown et al., Williams Institute, *Food Insecurity and SNAP Participation in the LGBT Community* (2016), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Food-Insecurity-and-SNAP-Participation-in-the-LGBT-Community.pdf; Gary J. Gates & Frank Newport, Gallup, *Special Report: 3.4% of U.S. Adults Identify as LGBT* (2013), http://www.gallup.com/poll/158066/special-report-adults-identify-lgbt.aspx; Sandy E. James et al., *The Report of the U.S. Transgender Survey* (2016), www.ustranssurvey.org/report. Given poverty, homelessness, and other evidence of economic and social vulnerability among LGBT people—including in child welfare contexts—it is crucial that HHS ensure not only that health programs and activities but also the various human services it funds and regulates are available to all in a non-discriminatory manner.

[27] INSTITUTE OF MEDICINE, *supra*, at 62.

[28] Amici Brief of Ilan H. Meyer, PhD, and Other Social Scientists and Legal Scholars Who Study the LGB Population in Support of Respondents, *Masterpiece Cakeshop Ltd. v. Colorado Human Rights Commission*, No. 16-111 (filed Oct. 30, 2017), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Williams-Masterpiece-Cakeshop-Amici-Brief.pdf.

sexual orientation or gender identity are "minority stressors" that can profoundly harm the health and well-being of LGBT people who are directly subject to these refusals of service.

When a health care provider denies care or provides lesser care to a LGBT person because of their sexual orientation or gender identity – regardless of the intent behind the discrimination – it is a prejudice event, a type of minority stress, which has both tangible and symbolic impacts on the LGBT patient. If a provider denies care to an individual patient, that denial creates harmful repercussions for the patient: An individual who is denied care must, at a minimum, experience the inconvenience of seeking alternative providers for the service. This can be especially critical for individuals who live in communities where no such alternatives are available or where reaching an alternative care provider can only be done with great cost and effort. Where delay in obtaining care has consequences for physical or mental health, those damaging repercussions are further exacerbated and could, in emergency cases, result in disability or death.

Prejudice events, such as health care denials, also carry a strong symbolic message of disapprobation. This symbolic message makes a prejudice event more damaging to the victim's psychological health than a similar event not motivated by prejudice. Research also indicates that "[f]ear of stigmatization or previous negative experiences with the health care system may lead LGBT individuals to delay seeking care."[29] Such expectations of discrimination generate a state of extra vigilance in LGBT people that is also stressful and could lead to people not finding care when it is needed.

Stress related to being part of a group that is systematically stigmatized and discriminated against, due to religious or cultural belief systems, affects overall health, which HHS has recognized with respect to LGBT people. For example, in stating that the LGBT population requires special public-health attention, HHS explained that "[p]ersonal, family and social acceptance of sexual orientation and gender identity affects the mental health and personal safety of LGBT individuals."[30] Indeed, according to HHS, "[s]ocial determinants affecting the health of LGBT individuals largely relate to oppression and discrimination."[31] Similarly, the Centers for Disease Control and Prevention ("CDC") reports that homophobia, stigma, and discrimination can negatively affect the physical and mental health of gay and bisexual men, as well as the quality of the healthcare they receive.[32] HHS's Office of Women's Health has recognized that discrimination and stigma may lead lesbians and bisexual women to have higher rates of depression and anxiety than other women, as well as to be less likely than other women to get routine mammograms and clinical breast exams.[33] The CDC also reports that

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[29] *Id.* (discussing "felt stigma"); *see also id.* at 63-64 (discussing "internalized stigma" and other personal barriers to care).

[30] *Id.*

[31] *Id.*

[32] U.S. Dep't of Health and Human Services, Centers for Disease Control and Prevention, Gay and Bisexual Men's Health, Stigma and Discrimination, http://www.cdc.gov/msmhealth/stigma-and-discrimination.htm.

[33] U.S. Department of Health and Human Services, Office of Women's Health, Lesbian and Bisexual Health, https://www.womenshealth.gov/a-z-topics/lesbian-and-bisexual-health (last visited Nov. 20, 2017) (an archive of this webpage is available at https://web.archive.org/web/20170919061935/https://www.womenshealth.gov/a-z-topics/lesbian-and-bisexual-health).

discrimination and social stigma may help explain the high risk for HIV infection among transgender women,[34] among other health concerns facing transgender people. With respect to LGBT youth, the Institute of Medicine (now called the National Academies of Sciences, Engineering, and Medicine), which operates under a congressional charter and provides independent, objective analysis of scientific research, has observed that "the disparities in both mental and physical health that are seen between LGBT and heterosexual and non-gender-variant youth are influenced largely by their experiences of stigma and discrimination during the development of their sexual orientation and gender identity and throughout the life course."[35]

The disparities between health outcomes for LGBT and non-LGBT people have been well-documented. For example, in Healthy People 2010 and Healthy People 2020, which set health priorities for the country,[36] HHS found that LGBT people face these health disparities:

- LGBT youth are 2 to 3 times more likely to attempt suicide;
- LGBT youth are more likely to be homeless;
- Lesbians are less likely to get preventive services for cancer;
- Gay men are at higher risk of HIV and other STDs, especially among communities of color;
- Lesbians and bisexual females are more likely to be overweight or obese;
- Transgender individuals have a high prevalence of HIV/STDs, victimization, mental health issues, and suicide and are less likely to have health insurance than heterosexual or LGB individuals;
- Elderly LGBT individuals face additional barriers to health because of isolation and a lack of social services and culturally competent providers;
- LGBT populations have the highest rates of tobacco, alcohol, and other drug use.[37]

The discrimination and related health disparities facing the LGBT population stand to worsen if health care providers are authorized to refuse to serve LGBT people. In light of the importance of health care to the public's health, the provider-conscience laws must carefully and narrowly delineate those circumstances where denials of care are authorized, and any Final Rule must adhere to those limitations. Any Final Rule must also make the explicit point that hospitals and other entities are not permitted to turn away a LGBT or any other person because of rejection of the class of people they belong to or appear to belong to. Any Final Rule must make these points clear so as to avoid unauthorized denials and improperly chilling patients in accessing care.

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[34] U.S. Dep't of Health and Human Services, Centers for Disease Control and Prevention, HIV Among Transgender People, http://www.cdc.gov/hiv/group/gender/transgender/index.html.

[35] INSTITUTE OF MEDICINE, THE HEALTH OF LESBIAN, GAY, BISEXUAL, AND TRANSGENDER PEOPLE: BUILDING A FOUNDATION FOR BETTER UNDERSTANDING 142 (2011), https://www.ncbi.nlm.nih.gov/books/NBK64806/pdf/Bookshelf_NBK64806.pdf.

[36] U.S. Dep't of Health & Human Services, Office of Disease Prevention and Health Promotion, Healthy People, Lesbian, Gay, Bisexual, and Transgender Health, https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health?topicid=25.

[37] *Id.*

III. OCR Must Continue To Devote Sufficient Resources To Its HIPAA and Civil Rights Functions.

We are concerned that any Final Rule – along with OCR's concomitant decision to create a separate Conscience and Religious Freedom Division – will result in the allocation of an enhanced portion of OCR's resources to defending refusals of medical care. That reallocation of resources will come at the expense of OCR's other critical enforcement responsibilities and will undermine the protections of both fundamental civil rights laws and the Health Insurance Portability and Accountability Act (HIPAA).

"In FY 2017, OCR received approximately 30,166 complaints, a 23 percent increase over the 24,523 complaints received in FY 2016" and its "[c]ase receipts are expected to further rise in FY 2019."[38] The lion's share of complaints received by OCR are for alleged HIPAA violations, but OCR also receives thousands of civil rights complaints each year.

By comparison, "[s]ince the designation of OCR as the agency with authority to enforce Federal health care conscience laws in 2008…. OCR has received on average, only about 1.25 [conscience] complaints per year from the [timeframe of] 2008 until November 2016."[39] OCR has reportedly received 300 provider-conscience complaints recently, but the number of such complaints OCR has ever received still represents a very small fraction of OCR's overall workload.[40] In light of these statistics and HHS's mission, it is crucial that OCR continue to devote sufficient resources to its HIPAA and civil rights functions.

Nor is there any reason to believe that OCR was not already devoting sufficient resources to enforcing provider-conscience laws. In the last ten years, OCR has resolved three sets of complaints filed under provider-conscience laws with written agreements or letters of finding.[41] In one of these instances, a private hospital adopted new policies in response to a complaint alleging that a nurse was forced to participate in an abortion despite her conscience objections;[42] similarly, Vanderbilt University took corrective action when it was alleged that it had coerced applicants for its nurse residency program to agree to assist in abortion procedures.[43] In each of these instances, OCR appropriately investigated and reached resolutions to ensure that the entities took corrective action.[44] Although there has been one instance in which HHS was

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[38] U.S. Dep't of Health and Human Services, *Budget In Brief*, 124 (Feb. 19, 2018), https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf.

[39] *See* 83 Fed. Reg. 3886 (stating that since 2008 OCR has received a total of forty-four complaints, and that prior to the 2016 presidential election, OCR had only received 10 such complaints); *but,* Jesse Hellman, *New HHS office that enforces health workers' religious rights received 300 complaints in a month*, The Hill (Feb. 20, 2018), http://thehill.com/policy/healthcare/374725-hhs-new-office-that-enforces-religious-moral-rights-of-health-workers.

[40] *Id.*

[41] *See* 83 Fed. Reg. 3886 (*citing* OCR Complaint No. 10–109676; OCR Complaint No. 11–122388; OCR Complaint No. 11–122387).

[42] OCR Complaint No. 10–109676.

[43] OCR Complaint No. 11–122388; OCR Complaint No. 11–122387.

[44] *See* 83 Fed. Reg. 3886.

accused of improperly handling conscience protection claims,[45] there is no evidence that those claims, if in fact they were improperly processed, could not be handled under the current regulations governing the provider-conscience laws and without creation of a new division.

We are additionally concerned about the allocation of resources at OCR in light of a future decrease in OCR's budget. In FY 2016, OCR's budget was approximately $38 million. That same year, only 35 percent of "civil rights complaints requiring formal investigation [were] resolved within 365 days."[46] We appreciate that OCR, in response, requested a budget of nearly $43 million dollars for FY 2017, because it expected "complex cases that involve novel issues of law and complicated facts [to] dramatically increase" and that an increased budget would be needed to increase its capacity to handle such.[47] However, under the Consolidated Appropriations Act, 2018, OCR's FY 2018 budget is approximately $39 million.[48] And for FY 2019, HHS is requesting only $31 million for OCR.[49]

As a result, it appears OCR will have to divert substantial resources away from its HIPAA and/or civil rights functions to meet any enhanced budget for enforcing the provider-conscience laws. Moreover, given OCR's ability to appropriately resolve conscience complaints in the past and the agency's budget realities, the economic expenditures associated with this new rule and the creation of OCR's new division appear unjustified. OCR must continue to devote sufficient resources to its core civil rights and HIPAA functions.

IV. Conclusion

For the foregoing reasons, should OCR choose to issue a Final Rule, we urge OCR to limit it as discussed above, conduct a RIA or otherwise accounts for the impact of the Proposed Rule and any Final Rule has on patients, and to continue to devote sufficient resources to its HIPAA and civil rights functions.

Respectfully Submitted,

[Signatures on next page.]

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[45] *See id.*

[46] *See* U.S. Dep't of Health and Human Services, *Fiscal Year 2017 Office of Civil Rights Justification of Estimates for Appropriations Committee* 9, https://www.hhs.gov/sites/default/files/fy2017-budget-justification-ocr_1.pdf.

[47] *Id.* at 7.

[48] *Consolidated Appropriations Act, 2018*, H.R. 1625, 115th Cong., 919 (2018), https://www.congress.gov/115/bills/hr1625/BILLS-115hr1625eah.pdf.

[49] U.S. Dep't of Health and Human Services, *Budget in Brief*, 124 (Feb. 19, 2018) ("The fiscal year (FY) 2019 Budget request for the Office for Civil Rights (OCR) is $31 million, $8 million below the 2018 Continuing Resolution level"), https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf

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No. 16-111

In The Supreme Court of the United States

MASTERPIECE CAKESHOP, LTD.; AND
JACK C. PHILLIPS,

Petitioners,

v.

COLORADO CIVIL RIGHTS COMMISSION; CHARLIE CRAIG; AND DAVID MULLINS.

Respondents.

ON WRIT OF CERTIORARI TO THE COLORADO COURT OF APPEALS

BRIEF OF *AMICI CURIAE* ILAN H. MEYER, PHD, AND OTHER SOCIAL SCIENTISTS AND LEGAL SCHOLARS WHO STUDY THE LGB POPULATION IN SUPPORT OF RESPONDENTS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

I. INTEREST OF AMICI CURIAE[1]

Amici include scholars in public health and social sciences who are recognized experts on the health and well-being of sexual minorities, including lesbians, gay men, and bisexuals ("LGB"). Many of the *amici* have conducted extensive research and authored publications in peer-reviewed academic journals on the effects of discrimination on LGB people. *Amici* also include legal scholars who are recognized experts on law and policy affecting LGB people's health and well-being. The Appendix identifies the individual *amici*.

This Court and other courts have expressly relied on the research of many of the *amici*, and several of the *amici* have served as expert witnesses. *See, e.g.*, *Obergefell v. Hodges*, 135 S. Ct. 2584, 2600 (2015) (citing Brief of Gary J. Gates as *Amicus Curiae*); *Baskin v. Bogan*, 766 F.3d 648, 663, 668 (7th Cir. 2014); *Nungesser v. Columbia Univ.*, 169 F. Supp. 3d 353, 365 n.8 (S.D.N.Y. 2016); *Roberts v. United Parcel Serv. Inc.*, 115 F. Supp. 3d 344, *passim* (E.D.N.Y. 2015); *Stawser v. Strange*, 307 F.R.D. 604, 609 (S.D. Ala. 2015); *Campaign for S. Equality v. Bryant*, 64 F. Supp. 3d 906, 943 n.42 (S.D. Miss.

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[1] As required by Rule 37 of the Rules of this Court, *amici curiae* obtained consent of counsel of record for all parties to file this brief. Blanket permission from petitioners and the Colorado Civil Rights Commission have been filed with the Court. Respondents, Charlie Craig and David Mullins, emailed their permission to *amici*. A copy of which was included with the filing of this brief. *Amici curiae* also represent that no counsel for a party authored this brief in whole or in part, and that no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief.

2014); *DeBoer v. Snyder*, 973 F. Supp. 2d 757, 763-64 (E.D. Mich.), *rev'd*, 772 F.3d 388 (6th Cir. 2014), *rev'd sub nom.*, *Obergefell v. Hodges*, 135 S. Ct. 2584 (2015); *Bassett v. Snyder*, 951 F. Supp. 2d 939, 967 (E.D. Mich. 2013); *Dragovich v. U.S. Dep't of Treasury*, 872 F. Supp. 2d 944, *passim* (N.D. Cal. 2012); *Log Cabin Republicans v. United States*, 716 F. Supp. 2d 884, 917 (C.D. Cal. 2010); *Perry v. Schwarzenegger*, 704 F. Supp. 2d 921, *passim* (N.D. Cal. 2010).

As scholars who specialize in issues related to LGB people, *amici* have a substantial interest in this matter. In this brief, *amici* present public health and social science research relevant to the legal questions before this Court. In particular, *amici* describe the harmful effects on LGB people of stigma- and prejudice-related stress (referred to as "minority stress") when a business or other place of public accommodation discriminates against them on the basis of sexual orientation.[2] Eliminating discrimination against LGB people, and the harms of minority stress to LGB people's health and well-being, are compelling government interests, especially in light of the long history of invidious discrimination that this population has suffered.

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[2] Stigma and prejudice against transgender people leads to minority stress that adversely impacts this population's health and well-being, as well. *See, e.g.*, Bockting *et al.*, *Adult Development and Quality of Life of Transgender and Gender Nonconformity People*, 23 Current Op. Endocrinology, Diabetes & Obesity 188 (Apr. 2016). Because this case concerns sexual orientation discrimination, we do not address the transgender population.

II. SUMMARY OF ARGUMENT

When a place of public accommodation refuses to serve, or provides lesser services to, LGB people because of their sexual orientation, that experience can have powerful tangible and symbolic effects on them—just as the denial of equal service can adversely impact other minorities. A discriminatory experience can be humiliating and result in harm to health, well-being, and dignity.

After Petitioners rejected the request of Charlie Craig and David Mullins to purchase a wedding cake, Charlie left the bakery shaking, crying, embarrassed, and feeling like a failure before his mother, who witnessed the incident.[3] The symbolic power of such incidents affects not only the LGB person treated unequally but also the larger LGB community, as it becomes aware of the discrimination and fears future such experiences. This Court has recognized that public accommodation antidiscrimination laws protect against these types of harms and, in doing so, "plainly serve[] compelling state interests of the highest order." *Roberts v. United States Jaycees*, 468 U.S. 609, 624 (1984).

The denial of equal service by a bakery or other business to a LGB person because of his or her sexual orientation is an example of what research identifies as a "minority stressor." While everyone has the potential to experience "general stressors"—such as losing a job—LGB people also face minority stressors that stem from anti-LGB stigma and prejudice. A

[3] Munn, *How It Feels When Someone Refuses to Make Your Son a Wedding Cake*, Time (2017), http://time.com/4991839/masterpiece-cakeshop-supreme-court-gay-discrimination/.

large body of research has shown that LGB people, as a group, experience more stress than heterosexuals, and that this excess exposure to stress is caused by anti-LGB stigma and prejudice.[4]

Another minority stressor facing LGB people relates to *expectations* of rejection and discrimination. Because LGB people learn that they may be rejected and discriminated against in society, they come to expect or fear such occurrences in day-to-day social interactions. The expectation of discrimination causes LGB people to be vigilant as they go through life. For example, a same-sex couple walking down the street may reasonably fear that they will be shouted at with homophobic slurs or even assaulted; as a result, the couple may attempt to conceal their LGB identity (such as by not holding hands). This state of vigilance is stressful and can be damaging to LGB people.[5]

Furthermore, if businesses are allowed to discriminate against people because of their sexual orientation, LGB people may reasonably expect discrimination by other businesses and modify their behavior accordingly. This expectation of discrimination can inhibit LGB people's ability to fully participate in the public marketplace. *See, e.g.*, *Washington v. Arlene's Flower's, Inc.*, 389 P.3d 543, 548-49 (Wash. 2017) (same-sex couple abandoned

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[4] *See, e.g.*, Meyer *et al.*, *Social Patterning of Stress and Coping: Does Disadvantaged Social Statuses Confer More Stress and Fewer Coping Resources?*, 3 Soc. Sci. Med. 67 (2008).

[5] *See, e.g.*, Sawyer *et al.*, *Discrimination and the Stress Response: Psychological and Physiological Consequences of Anticipating Prejudice in Interethnic Interactions*, 102 Am. J. Pub. Health 1020 (2012).

plans for a large wedding after being discriminated against by a florist, citing the "emotional toll" of the discrimination and fear of additional discrimination by other vendors, and instead married at home before a small group of people). Antidiscrimination laws exist in part to prevent such market distortions.

Stigma-related minority stress experienced by LGB people has been linked to a disproportionately high prevalence of psychological distress, depression, anxiety, substance-use disorders, and suicidal ideation and attempts—many of which are two to three times greater among sexual minorities than the heterosexual majority.[6] Minority stress may also adversely impact same-sex couples' relationship quality and stability, thereby undercutting one of the advantages of marriage this Court recognized in *Obergefell*, 135 S. Ct. at 2600-01.

Research also has shown that LGB people fare better in regions where social and legal conditions are more hospitable to them.[7] These studies suggest that antidiscrimination laws that prohibit public accommodations from discriminating against LGB people help reduce minority stress and resultant health disparities.

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[6] *See, e.g.*, Institute of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (Nat'l Acads. Press 2011).

[7] Hatzenbuehler *et al.*, *State Level Policies and Psychiatric Morbidity in Lesbian, Gay, and Bisexual Populations*, 99 Am. J. Pub. Health 2275 (2009); Hatzenbuehler *et al.*, *The Impact of Institutional Discrimination on Psychiatric Disorders in Lesbian, Gay, and Bisexual Populations: A Prospective Study*, 100 Am. J. Pub. Health 452 (2010).

Ultimately, *Amici* conclude that the minority stress literature supports a finding that Colorado has a compelling interest in barring public accommodations from discriminating against LGB people. Indeed, this case is not just about a wedding cake. Something much larger is at stake for LGB people: their health, well-being, and dignity. Allowing businesses to avoid their obligations to serve LGB people equally would undercut the "equal dignity" of same-sex couples that this Court has protected. *Obergefell*, 135 S. Ct. at 2608; *see also United States v. Windsor*, 133 S. Ct. 2675, 2692, 2694 (2013); *Lawrence v. Texas*, 539 U.S. 558, 567, 574-75 (2003). Should the Court agree with Petitioners here, LGB people would likely face increased discrimination in a variety of settings, which antidiscrimination laws would not be able to prevent or remedy.

One of Petitioners' *amici* has alleged that the minority stress literature does not apply here, and that the particular incident in question was not stressful. *See* Brief of Amici Curiae Mark Regnerus et al. in Support of Petitioners, *Masterpiece Cakeshop, LTD v. Colorado Civil Rights Commission*, No. 16-111 (filed Sept. 7, 2017) (hereinafter "the Regnerus Brief"). None of the Regnerus Brief's arguments undermines our conclusions in this brief, as we explain below.

III. ARGUMENT

As Respondents demonstrate, this case involves a discriminatory denial of service; it does not involve any targeting of speech, compelled speech, or regulation of expressive conduct. Respondent Colorado Civil Rights Commission Br. 20-27, 32-44;

Respondents Craig and Mullins Br. 15-28; *R.A.V. v. City of St. Paul,* 505 U.S. 377, 390 (1992) ("acts are not shielded from regulation merely because they express a discriminatory idea or philosophy"); *Rumsfeld v. Forum for Acad. & Institutional Rights, Inc.*, 547 U.S. 47, 62 (2006) (regulation forbidding discrimination against military recruiters did not compel speech endorsing military policy). Even if the Colorado law were deemed to regulate protected expressive conduct, Petitioners' free-speech challenge must fail if the law furthers "an important or substantial governmental interest" that "is unrelated to the suppression of free expression," and "if the incidental restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest." *United States v. O'Brien*, 391 U.S. 367, 377 (1968). Nor can Petitioners object to a neutral law of general applicability on free-exercise grounds if the law is rationally related to a legitimate government interest. *Church of Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 531 (1993).

Regardless of whether the governmental interest need be legitimate, substantial, or compelling, that requirement is clearly met by the Colorado law. Protecting the dignity of, and eradicating discrimination against, LGB people is a compelling state interest, for "eliminating discrimination and assuring its citizens equal access to publicly available goods and services . . . , which is unrelated to the suppression of expression, plainly serves compelling state interests of the highest order." *Roberts*, 468 U.S. at 624; *see also Bd. of Dirs. of Rotary Int'l v. Rotary Club*, 481 U.S. 537, 549 (1987). In a similar

vein, this Court, in upholding the public accommodations provision of the 1964 Civil Rights Act, recognized Congress's power to "vindicate the deprivation of personal dignity that surely accompanies denials of equal access to public establishments." *Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. 241, 250 (1964) (internal quotation marks omitted); *see also id.* at 291-92 (Goldberg, J., concurring); *Bob Jones Univ. v. United States*, 461 U.S. 574, 604 (1983) (government's compelling interest in eradicating race discrimination in education overrode burden on religious exercise).

Consistent with this line of cases, this Court has repeatedly made clear that our Constitution protects and ensures the "equal dignity" of individuals in same-sex couples and LGB people more broadly. *Obergefell*, 135 S. Ct. at 2608; *see also Windsor*, 133 S. Ct. at 2692, 2694; *Lawrence*, 539 U.S. at 567, 574-75; *Romer v. Evans*, 517 U.S. 620, 634-35 (1996).

Just as this Court's jurisprudence protects same-sex couples and LGB people from discriminatory state action, Colorado prohibits its places of public accommodation from discriminating based on sexual orientation, among other personal characteristics. Colorado Rev. Stat. § 24-34-601(2)(a) (2017). The purpose of Colorado's antidiscrimination law is to "eradicate the underlying causes of discrimination and halt discriminatory practices" that stigmatize and make second-class citizens of many Coloradans. *Red Seal Potato Chip Co. v. Colo. Civil Rights Comm'n*, 618 P.2d 697, 700 (Colo. Ct. App. 1980). *See generally* Sepper, *The Role of Religion in State Public Accommodation Laws*, 60 St. Louis Univ. L.J. 631, 663-67 (2016) (public accommodation anti-

discrimination laws "vindicate individual and societal interests in material, dignitary, and expressive terms").

Although this Court has already stated that prevention of exclusion and stigmatization is a compelling interest in the public accommodations context, *amici* write to provide the Court with relevant research that finds that LGB people are subject to "minority stress" due to anti-LGB stigma and prejudice. *Amici* describe how being refused service by a business due to stigma and prejudice against LGB people is a minority stressor. Thus, public-accommodation discrimination leads to dignitary harm and can cause adverse outcomes for health and well-being for LGB people. In addition, should this Court accept Petitioners' claims, widespread discrimination could ensue, leading LGB people to reasonably expect discrimination, which, in turn, increases the risk that they will not fully participate in the marketplace. Minority stress may also negatively impact same-sex couples' relationship quality and stability. In contrast, research shows that where social and legal conditions are more hospitable to LGB people, the health of sexual minorities improves, and health disparities between LGB people and heterosexuals are reduced.

A. LGB People Face Discrimination and Other Minority Stressors Stemming From Anti-LGB Stigma

1. LGB people have long endured discrimination.

LGB people have faced a long, painful history of public and private discrimination in the United States. In *Obergefell*, this Court observed that gays and lesbians have been "prohibited from most government employment, barred from military services, excluded under immigration laws, targeted by police, and burdened in their rights to associate." 135 S. Ct. at 2596; *see also Windsor*, 133 S. Ct. at 2693 ("The avowed purpose and practical effect of the law here in question are to impose a disadvantage, a separate status, and so a stigma upon all who enter into same-sex marriages made lawful by the unquestioned authority of the States."); *Lawrence*, 539 U.S. at 575 (discussing stigmatization from criminal sodomy statutes); *Romer*, 517 U.S. at 632 (discussing animus in anti-LGB legislation). Speaking to both public and private discrimination, the Seventh Circuit has explained that "homosexuals are among the most stigmatized, misunderstood, and discriminated-against minorities in the history of the world, the disparagement of their sexual orientation, implicit in the denial of marriage rights to same-sex couples, is a source of continuing pain to the homosexual community." *Baskin v. Bogan*, 766 F.3d 648, 658, 663 (7th Cir. 2014); *accord Windsor v. United States*, 699 F.3d 169, 182 (2d Cir. 2012) ("It is easy to conclude that homosexuals have suffered a

history of discrimination."), *aff'd*, 133 S. Ct. 2675 (2013).

Despite advances that LGB people have made to protect their autonomy and equality under the Constitution and some state and local laws, research finds evidence of persistent and pervasive discrimination against LGB people in employment,[8] education,[9] housing,[10] and public accommodations,[11] as well as widespread stigma, prejudice, and

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[8] *See, e.g.*, Pizer *et al.*, *Evidence of Persistent and Pervasive Workplace Discrimination Against LGBT People*, 45 Loy. L.A. L. Rev. 715, 721-728 (2012); Tilcsik, *Pride and Prejudice: Employment Discrimination Against Openly Gay Men in the United States*, 117 Am. J. Sociology 586, 586-626 (2011).

[9] *See, e.g.*, Kosciw *et al.*, GLSEN, *The 2015 National School Climate Survey: The Experiences of Lesbian, Gay, Bisexual, Transgender, and Queer Youth in Our Nation's Schools* (2016); Wolff *et al.*, *Sexual Minority Students in Non-Affirming Religious Higher Education: Mental Health, Outness, and Identity*, 3 Psychol. Sexual Orientation & Gender Diversity 201 (2016).

[10] *See, e.g.*, Levy *et al.*, Urban Institute, *A Paired-Tested Pilot Study of Housing Discrimination Against Same-Sex Couples and Transgender Individuals* (2017).

[11] *See, e.g.*, Badgett *et al.*, Williams Institute, *Bias in the Workplace: Consistent Evidence of Sexual Orientation and Gender Identity Discrimination* 19-20 (2007); Mallory *et al.*, Williams Institute, *The Impact of Stigma and Discrimination against LGBT People in Florida* 30-32 (2017); Mallory *et al.*, Williams Institute, *The Impact of Stigma and Discrimination Against LGBT People in Georgia* 27-28 (2017); Mallory *et al.*, Williams Institute, *The Impact of Stigma and Discrimination Against LGBT People in Texas* 29-31(2017); Mallory & Sears, Williams Institute, *Evidence of Discrimination in Public Accommodations Based on Sexual Orientation and Gender Identity: An Analysis of Complaints Filed with State Enforcement Agencies, 2008-2014* (2016).

violence.[12] With respect to public accommodations specifically, 31% of gay men, 29% of lesbians, and 15% of bisexual men and women respondents to a national survey conducted by the Pew Research Center in 2013 reported that they had "received poor service at a restaurant, hotel, or other place of business."[13]

2. LGB People Face Minority Stressors Stemming from Anti-LGB Stigma and Prejudice

Experiences of discrimination are among other significant minority stressors that adversely impact LGB people's health and well-being. Stress is "any condition having the potential to arouse the adaptive machinery of the individual."[14] Using engineering analysis, stress can be described as the load relative to supportive surface.[15] Like a surface that may break when load weight exceeds its capacity to withstand the load, so too has stress been described as reaching a breaking point beyond which an organism may reach "exhaustion" and even death.[16] Stress is

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[12] *See, e.g.*, *infra* nn. 65-68 and accompanying text.

[13] Pew Research Center, *A Survey of LGBT Americans: Attitudes, Experiences and Values in Changing Times* 41 (2013).

[14] Pearlin *et al.*, *Stress and Mental Health: A Conceptual Overview, in A Handbook for the Study of Mental Health: Social Contexts, Theories, and Systems* 161, 175 (Cambridge Univ. Press 1999).

[15] Wheaton *et al.*, *The Nature of Stressors, in A Handbook for the Study of Mental Health: Social Contexts, Theories, and Systems* 176-97 (Cambridge Univ. Press 1999)

[16] Selye, *History and Present Status of the Stress Concept, in Handbook of Stress: Theoretical and Clinical Aspect* 7-17 (Goldbeger & Breznitz eds., Free Press 2nd ed. 1993).

detrimental because it requires an adaptation effort by the individual exposed to stress.[17] Research over more than 40 years has shown that stress causes mental and physical disorders.[18]

LGB people are exposed to stressors that researchers refer to as "minority stressors" that stem from anti-LGB stigma and prejudice.[19] In addition, all people (including LGB people) are exposed to "general stressors," which do not stem from stigma and prejudice.[20]

Exposure to minority stress is chronic, in that it is attached to persistent social processes characterized by anti-LGB stigma and prejudice. Similarly, because it relates to stigma and prejudice against LGB people, minority stress refers to *excess* exposure of LGB people to stress as compared with heterosexuals.[21] Thus, minority stress requires

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[17] *Id.*; Pearlin *et al.* (1999), *supra.*

[18] Thoits, *Stress and Health: Major Findings and Policy Implications*, 51(S) J. Health & Soc. Behav. S41 (2010).

[19] Stigma is "a function of having an attribute that conveys a devalued social identity in a particular context." Crocker *et al.*, *Social Stigma, in* 4 *The Handbook of Social Psychology* 506 (Gilbert *et al.*, eds., McGraw-Hill 1998).

[20] Meyer, *Minority Stress and Mental Health in Gay Men*, 36:1 J. Health & Behav. 38 (1995); Meyer, *Prejudice, Social Stress and Mental Health in Lesbian, Gay, and Bisexual Populations: Conceptual Issues and Research Evidence*, 129:5 Psychol. Bull. 674-697 (2003); Meyer *et al.* (2008), *supra.*

[21] Meyer *et al.* (2008), *supra*; Herek, *Sexual Stigma and Sexual Prejudice in the United States: A Conceptual Framework, in Contemporary Perspectives on Lesbian, Gay, and Bisexual Identities* 65-111 (D. A. Hope ed., 2009); Springer & Herek, *Hate Crimes and Stigma-Related Experiences Among Sexual Minority Adults in the United States: Prevalence Estimates from a*

special adaptation by LGB individuals but not by non-LGB individuals.[22] Because stress can cause mental and physical disorders, the excess exposure to minority stress among LGB people, as compared with heterosexuals, confers an excess risk for diseases that are caused by stress.[23]

Minority stress is defined by specific stress processes, including "prejudice events" and "expectations of rejection and discrimination," among others.[24] "Prejudice events" refers to events that stem from societal anti-LGB stigma and prejudice. Thus, being fired from a job is a general stressor that could affect any person, but it is classified as a prejudice event—a minority stressor—when it is motivated by discrimination against LGB people.

Structural exclusion from resources and advantages available to heterosexuals—such as (1) the historical exclusion of LGB people from the institution of marriage prior to *Obergefell*, (2) the historical exclusion of gay men and lesbians from federal civilian and military employment, and (3) and the current omission of express protections against sexual orientation discrimination in Titles II and VII of 1964 Civil Rights Act, among other federal antidiscrimination laws—leads to prejudice events. Prejudice events also include interpersonal events, perpetrated by individuals acting either in violation

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National Probability Sample, 24:1 J. Interpersonal Violence 54-74 (2009); Meyer (2003), *supra.*

[22] Frost & Meyer, *Internalized Homophobia and Relationship Quality Among Lesbians, Gay Men, and Bisexuals*, 59 J. Counseling Psychol. 97-109 (2009).

[23] Meyer *et al.* (2008), *supra.*

[24] Meyer (2003), *supra.*

of the law (e.g., hate crimes) or within the law (e.g., lawful but discriminatory employment practices).

A prejudice event may be perpetrated by one person, but it carries a symbolic message of social disapprobation. The added symbolic value makes a prejudice event more damaging to the victim's psychological health than a similar event not motivated by prejudice.[25] This exemplifies an important quality of minority stress: Prejudice events have a powerful impact because they convey deep cultural meaning.[26] Even "a seemingly minor event, such as a slur directed at a gay man, may evoke deep feelings of rejection and fears of violence [seemingly] disproportionate to the event that precipitated them."[27] Therefore, assessment of stressors related to stigma and prejudice must consider not only the tangible impact of stress—typically defined as the amount of adaptation required by the event—but also the symbolic meaning within the social context.

In sum, stressors are ubiquitous in our society and experienced by LGB and heterosexual people alike. But the quality of stressors the two populations experience differ in that LGB people are uniquely exposed to minority stressors that stem from stigma and prejudice toward them. This added source of stress experiences exposes LGB people to excess stress compared with heterosexuals and leads to

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[25] Frost *et al., Minority Stress and Physical Health Among Sexual Minority Individuals*, 38 J. Behav. Med. 1 (2015); Herek *et al., Psychological Sequelae of Hate-Crime Victimization Among Lesbian, Gay, and Bisexual Adults*, 57:6 J. Consult. & Clin. Psychol. 945 (1999).

[26] Meyer (1995), *supra.*

[27] *Id.*

excess adverse health outcomes in LGB as compared with heterosexual populations. *See infra* Part III.C.

B. Exclusion From a Public Accommodation is a Prejudice Event and Increases Expectations of Rejection and Discrimination

Based on the large body of research on minority stress, *amici* conclude that when a baker refuses to sell a wedding cake to a LGB person, it is a prejudice event, a type of minority stress, which has both tangible and symbolic impacts on the LGB customer. From a practical perspective, the rejected customer is faced with an additional adaptational task—a concrete problem to resolve: finding a replacement for the needed service or good (here, a wedding cake). This demonstrates the basic premise of minority stress as an *excess* stress: the extra burden of finding an alternative provider adds to the stress of planning a wedding compared with heterosexual couples not affected by such discrimination. This added burden is unique to the class of customers who are shunned by the baker because of their same-sex fiancés.

While the couple here was able to procure another cake, the rejected customer may not always have the ability or time to find a replacement because an alternative business may not be available or because of the immediacy of the need. *See, e.g.*, First Amended Complaint, *Zawadski v. Brewer Funeral Services, Inc.*, No. 55CI1:17-cv-00019-CM (Miss. Cir. Ct., filed Mar. 7, 2017) (widow alleging funeral home refused to transport and cremate deceased same-sex spouse because of their sexual orientation, leaving the decedent's body without proper storage for hours and

the family scrambling to find alternative funeral services).

In addition to such tangible challenges, being rejected by a business for one's sexual orientation underscores the stigmatization that LGB people face. Here, the baker's rejection of a same-sex couple amplifies social rejection and reiterates decades-old stigma and prejudice. In the context of marriage, this is an especially powerful rejection because it relates to the couple's relationship, which inherently embodies their sexual orientation. *See also Obergefell*, 135 S. Ct. at 2600 ("'[W]hen sexuality finds overt expression in intimate conduct with another person, the conduct can be but one element in a personal bond that is more enduring.'" (quoting *Lawrence*, 539 U.S. at 567)). Being rejected by a business is a stark reminder to same-sex couples that even after this Court concluded that their relationships and dignity are protected by the U.S. Constitution, *Obergefell*, 135 S. Ct. at 2608; *Windsor*, 133 S. Ct. at 2692, 2694; *Lawrence*, 539 U.S. at 567, 574-75, they may continue to experience rejection and discrimination in the public marketplace.

Being rejected—and even the threat of rejection—in public accommodations will also increase expectations of future rejection and discrimination among LGB people. This is another form of minority stress.[28] An expectation of rejection and discrimination is a stressor because it requires vigilance by members of minority groups to defend themselves against potential rejection,

[28] Meyer (2003), *supra.*

discrimination, or violence.[29] Unlike prejudice events, which entail concrete events, expectations of rejection and discrimination are stressful even in the absence of a specific prejudice event because the expectation is based on what has been learned from repeated exposure to a stigmatizing social environment.[30] For example, gay couples must remain vigilant when walking in a public space, especially if they demonstrate affection, such as by holding hands, for fear of harassment or violence. The vigilance required in such a state is similar to the classic example of stress experienced by a person in a flight-or-fight stress response, which brings about biophysiological changes that can be harmful to one's health.[31]

Furthermore, it is reasonable to conclude that rejection by a baker or other business will reproduce expectations of rejection and may lead LGB people not to fully participate in the marketplace. For example, in *Washington v. Arlene's Flowers*, the Washington Supreme Court observed that after a florist turned the same-sex couple away, the couple abandoned plans for a large, 100-guest wedding. 389 P.3d at 548. The "emotional toll" of the incident and fear being of denied service by other vendors prompted the couple to forego their plans and marry at home in front of 11 guests. *Id.* at 549.

Should this Court conclude that the First Amendment protects Petitioners' actions here, an

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[29] *Id.*

[30] Crocker, *Social Stigma and Self-Esteem: Situational Construction of Self-Worth*, 35:1 J. Experimental Soc. Psychol. 89-107 (1999).

[31] Selye, *The General Adaptation Syndrome and the Diseases of Adaptation*, 6:2 J. Clin. Endocrinology 117 (1946).

untold number of businesses may turn away LGB people. As a result, in order to ensure they will not be refused service when they need it, LGB customers would experience an additional burden of having to come out as LGB in advance of seeking services or goods, or face the risk of being turned away too late. If a same-sex couple getting married doesn't come out to, for example, an event space where they are planning their wedding party, they may find out at the last minute that the event space will not host them. Or, if planning a honeymoon at an inn, LGB customers would have to inquire in advance whether the inn-keeper would accommodate them, lest they arrive only to find out too late that they are not welcome. If the business rejects the LGB customer when he or she comes out, the LGB person must undertake the additional burden of trying to find an alternative provider, if such an alternative provider even exists or is available in the locale.

These experiences inflict dignitary harms on LGB people and are stressful, as they require LGB people to expend greater effort and expense to arrive at the same services or goods provided to non-LGB people with less effort and expense.[32] Moreover, the possibility of public rejection from services and goods creates a stigmatizing social environment. As we discuss next, a stigmatizing social environment and

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[32] Comparisons of LGB and heterosexual people throughout our analysis assume everything else being equal in terms of other sources of potential discrimination, such as minority racial/ethnic identity. Of course, other forms of discrimination would similarly apply to LGB people and heterosexuals. Thus racist discrimination would apply equally to Black heterosexual and LGB people, but only the LGB people would experience the additional anti-LGB discrimination.

minority stress adversely impact LGB people's health and well-being.

C. Minority Stress Adversely Affects the Health and Well-Being of LGB People and May Impact Relationship Quality and Stability

1. Minority Stress Negatively Impacts the Health and Well-Being of the LGB People

Stigma is a "fundamental social cause" of disease, in that it influences multiple disease outcomes through multiple risk factors across a widespread population.[33] This makes stigma "a central driver of morbidity and mortality at a population level."[34] Stigma leads to poor health outcomes by blocking resources "of money, knowledge, power, prestige, and beneficial social connections," increasing social isolation and limiting social support, and increasing stress.[35]

To date, hundreds of peer-reviewed research articles have reported on studies using the minority stress framework. By and large, this body of work shows that exposure to minority stress has a negative impact on the health and well-being of LGB people. This has led the Institute of Medicine (now called The National Academies of Sciences, Engineering, and Medicine), which operates under a congressional

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[33] Hatzenbuehler *et al.*, *Stigma As a Fundamental Cause of Population Health Inequalities*, 103:5 Am. J. Pub. Health 813, 813 (2013).

[34] *Id.* at 813.

[35] *Id.* at 814.

charter and provides independent, objective analysis of scientific research, to determine that minority stress is a core perspective for understanding LGB health and disparities in health between LGB and heterosexual people.[36]

Other leading public-health authorities have also recognized health disparities of LGB as compared with heterosexual populations. In Healthy People 2010 and Healthy People 2020, which set health priorities for the United States, the Department of Health and Human Services (HHS) identified the LGB population as having disparities in health outcomes, faring worse than heterosexuals.[37] In explaining why the LGB population required special public-health attention, HHS provided a minority stress explanation, noting that "[p]ersonal, family, and social acceptance of sexual orientation and gender identity affects the mental health and personal safety of LGBT individuals."[38]

This burden has most clearly been articulated in the minority stress literature.[39] Studies have concluded that minority stress processes are related to an array of mental health problems, including depressive symptoms, substance use, and suicide

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[36] Institute of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (Nat'l Acads. Press 2011).

[37] *See* United States Dep't of Health & Human Services, Office of Disease Prevention and Health Promotion, Healthy People, *Lesbian, Gay, Bisexual, and Transgender Health*, https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health

[38] *Id.* (citing Healthy People 2010).

[39] Institute of Medicine (2011), *supra*.

ideation and attempts.[40] LGB individuals also have lower levels of social well-being, which reflects a person's acceptance by his or her social environment,[41] than heterosexual people because of exposure to minority stress.[42]

Minority stress is also associated with a higher incidence of reported suicide attempts among LGB individuals than heterosexuals (especially in youth, when sexual identity is first disclosed to friends and family).[43] The higher prevalence of suicide attempts

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[40] Mays & Cochran, *Mental Health Correlates of Perceived Discrimination Among Lesbian, Gay, and Bisexual Adults in the United States*, 91:11 Am. J. Pub. Health 1869-76 (2001); Herek *et al.*, *Sexual Orientation and Mental Health*, Ann. Rev. Clin. Psychol. 3 (2007); King *et al.*, *A Systematic Review of Mental Disorder, Suicide, and Deliberate Self Harm in Lesbian, Gay and Bisexual People*, 70 BMC Psychiatry 8 (2008); Meyer (2003), *supra*; Cochran & Mays, *Sexual Orientation and Mental Health, in Handbook of Psychology and Sexual Orientation*, 204-22 (Oxford Univ. Press 2013).

[41] Kertzner *et al.*, *Social and Psychological Well-Being in Lesbians, Gay Men, and Bisexuals: The Effects of Race, Gender, Age, and Sexual Identity*, 79:4 Am. J. Orthopsychiatry 500 (2009).

[42] Kertzner *et al.*, *Psychological Well-Being in Midlife and Older Gay Men, Gay and Lesbian Aging: Research and Future Directions* 97-115 (2004); Riggle *et al.*, *LGB Identity and Eudaimonic Well Being in Midlife*, 56:6 J. Homosexuality 786 (2009).

[43] *E.g.*, Cochran & Mays, *Lifetime Prevalence of Suicide Symptoms and Affective Disorders Among Men Reporting Same-Sex Sexual Partners: Results From NHANES III*, 90:4 Am. J. Pub. Health 573 (2000); Gilman *et al.*, *Risk of Psychiatric Disorders Among Individuals Reporting Same-Sex Sexual Partners in the National Comorbidity Survey*, 91:6 Am. J. Pub. Health 933 (2001); Herrell *et al.*, *Sexual Orientation and Suicidality: A Co-Twin Control Study in Adult Men*, 56:10 Arch. Gen. Psychiatry 867 (1999); Friedman *et al.*, *A Meta-Analysis of*

among LGB youth is influenced by minority stress encountered by youths, for example, experiencing rejection by their family.[44]

Minority stressors stemming from social structural discrimination have serious negative consequences on mental health. For example, LGB people who live in states without laws that extend protections to sexual minorities (e.g., job discrimination or hate crimes) demonstrate higher levels of mental health problems compared to those living in states with laws that provide such protections.[45] Furthermore, the denial of marriage rights for same-sex couples had a demonstrated negative effect on the mental health of lesbians and gay men, regardless of their relationship status.[46]

Several studies have also demonstrated links between minority stress factors and some physical

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Disparities in Childhood Sexual Abuse, Parental Physical Abuse, and Peer Victimization Among Sexual Minority and Sexual Nonminority Individuals, 8 Am. J. Pub. Health 101 (2011); Meyer *et al.*, *Lifetime Prevalence of Mental Disorders and Suicide Attempts in Diverse Lesbian, Gay, and Bisexual Populations,* 6 Am. J. Pub. Health 98 (2008); Safren & Heimberg, *Depression, Hopelessness, Suicidality, and Related Factors in Sexual Minority and Heterosexual Adolescents*, 67:6 J. Consult. Clin. Psychol. 859 (1999).

[44] Ryan *et al.*, *Family Rejection As a Predictor of Negative Health Outcomes, in White and Latino Lesbian, Gay, and Bisexual Young Adults*, 1 Pediatrics 123 (2009).

[45] Hatzenbuehler *et al.* (2009), *supra.*

[46] Riggle *et al.*, *Psychological Distress, Well-Being, and Legal Recognition in Same-Sex Couple Relationships*, 1 J. Fam. Psychol. 24 (2010); Rostosky *et al.*, *Marriage Amendments and Psychological Distress in Lesbian, Gay, and Bisexual (LGB) Adults*, 1 J. Counseling Psychol. 56 (2009); Hatzenbuehler *et al.* (2010), *supra.*

health problems. For example, one study found that LGB people who had experienced a prejudice-related stressful life event were about three times more likely than those who did not experience a prejudice-related life event to have suffered a serious physical health problem over a one-year period.[47] This effect remained statistically significant, even after controlling for the experience of other non-prejudicial stress events and other factors known to affect physical health. Thus, prejudice-related stressful life events were more damaging to the physical health of LGB people than general stressful life events that did not involve prejudice. In another study, exposure to discrimination at work was related to an increased number of sick days and physician visits among LGB people.[48]

2. Minority Stress May Adversely Impact Same-Sex Couples' Relationship Quality and Stability

LGB people have the same aspirations for achieving intimate relationships as heterosexuals, but they face greater social barriers to maintaining long-term relationships.[49] This Court's decisions in *Lawrence*, *Windsor*, and *Obergefell* have helped remove some major barriers. Indeed, emerging evidence suggests "that legal relationship recognition

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[47] Frost *et al.* (2015), *supra.*

[48] Huebner & Davis, *Perceived Antigay Discrimination and Physical Health Outcomes*, 5 Health Psychol. 26 (2007);

[49] Frost, *Similarities and Differences in the Pursuit of Intimacy Among Sexual Minority and Heterosexual Individuals: A Personal Projects Analysis*, 67:2 J. Soc. Issues 282 (2011).

and parenting may act as stabilizing factors for [both same-sex and different-sex] couples."[50]

But minority stress remains a burden for same-sex partners.[51] Some studies indicate that minority stress in LGB people's lives may negatively affect couples' relationship quality and stability.[52] Consistently, some findings suggest that social approval and support appears to be important to couple stability.[53]

While different-sex and same-sex couples all experience general stressors—such as stresses related to finances or household chores—same-sex couples experience additional minority stressors that stem from the stigmatization of same-sex

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[50] Rostosky & Riggle, *What Makes Same-Sex Relationships Endure? in LGBTQ Divorce and Relationship Dissolution: Psychological and Legal Perspectives and Implications for Practice* (Goldberg & Romero, eds., Oxford Univ. Press forthcoming 2018) (on file with counsel).

[51] Clark *et al.*, *Windsor and Perry: Reactions of Siblings in Same-Sex and Heterosexual Couples*, 62:8 J. Homosexuality 993 (2015).

[52] Doyle & Molix, *Social Stigma and Sexual Minorities' Romantic Relationship Functioning: A Meta-Analytic Review*, 41:10 Pers. Soc. Psychol. Bull. 1363 (2015); Rostosky & Riggle, *Same-Sex Relationships and Minority Stress*, 13 Current Opinion Psychol. 29 (2017); Frost & LeBlanc, *Stress in the Lives of Same-Sex Couples: Implications for Relationship Dissolution and Divorce*, *in LGBTQ Divorce and Relationship Dissolution: Psychological and Legal Perspectives and Implications for Practice* (Goldberg & Romero, eds., Oxford Univ. Press, forthcoming 2018) (on file with counsel).

[53] Lehmiller & Agnew, *Perceived Marginalization and the Prediction of Romantic Relationship Stability*, 69:4 J. Marriage & Family 1036 (2007).

relationships.[54] Societal stigma surrounding same-sex relationships can also be uniquely internalized, contributing to feelings of internalized homophobia among people in same-sex relationships,[55] which has been shown to be detrimental to relationship quality among sexual minority individuals.[56] Moreover, societal stigma of same-sex relationships can lead to adverse mental health effects among LGB individuals, which create the potential for mental health problems in the couple (e.g., depression) that jeopardize the relationship.[57]

D. Better Social and Legal Conditions are Associated with Fewer Adverse Effects of Minority Stress

Research has shown that in U.S. regions where LGB people have better social and legal conditions, they also have better health and lesser health disparities compared with heterosexuals.[58] Because minority stress stems from societal stigma, its root

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[54] Frost, *Stigma and Intimacy in Same-Sex Relationships: A Narrative Approach*, 25:1 J. Fam. Psychol. 1 (2011); Frost & LeBlanc (forthcoming 2018), *supra*; LeBlanc *et al.*, *Similar Others in Same-Sex Couples' Social Networks*, 62:11 J. Homosexuality 1599 (2015); Meyer (2003), *supra*.

[55] Frost & Meyer (2009), *supra*.

[56] Balsam & Szymanski, *Relationship Quality and Domestic Violence in Women's Same-Sex Relationships: The Role of Minority Stress,* 29:3 Psychol. Women Q. 258 (2005); Edwards *et al.*, *The Perpetration of Intimate Partner Violence Among LGBTQ College Youth: The Role of Minority Stress*, 42:11 J. of Youth & Adolescence 1721 (2013).

[57] Rostosky & Riggle (forthcoming 2018), *supra*; Frost & LeBlanc (forthcoming 2018), *supra.*

[58] Hatzenbuehler *et al.* (2009), *supra*; Hatzenbuehler *et al.* (2010), *supra.*

can only be eliminated through social and structural intervention.[59] Antidiscrimination laws that prohibit public accommodations from discriminating against LGB people would propel improved social and legal conditions. Indeed, as this Court has recognized, public accommodations laws "protect[] the State's citizenry from a number of serious social and personal harms" by ensuring that members of historically disadvantaged groups can participate as full members of civic society. *Roberts*, 468 U.S. at 625.

But just as laws can help eradicate and dismantle stigma and enhance a nation's health, laws can "be a part of the problem by enforcing stigma."[60] Indeed, the role of law in shaping stigma is so clear to public health professionals that they explicitly debate the ethics of using law to promote stigma, for example, related to smoking, even when such laws have undeniable benefits to the public's health by preventing morbidity and mortality.[61]

If this Court accepts Petitioners' arguments here, then future denial of service to LGB customers would be enshrined in the authority of the U.S. Constitution—leading to greater stigmatization of LGB people and same-sex relationships. At the same time, LGB people would feel less protected by the

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[59] Meyer & Frost, *Minority Stress and the Health of Sexual Minorities, in Handbook of Psychology and Sexual Orientation* 252-66 (Oxford Univ. Press 2013).

[60] Burris, *Stigma and the Law*, 367 Lancet 529 (2006); Link & Hatzenbuehler, *Stigma as an Unrecognized Determinant of Population Health: Research and Policy Implications*, 41 J. Health Politics, Policy, & Law 653 (2016).

[61] Bayer, *Stigma and the Ethics of Public Health: Not Can We But Should We*, 67:3 Soc. Sci. & Med. 463 (2008).

state than their heterosexual counterparts, and would need to be increasingly vigilant to secure their families' well-being.

E. Regnerus *Amici* Brief Does Not Undermine the Significance of the Minority Stress Literature to this Case

One of Petitioners' *amici* briefs (the "Regnerus Brief," *supra*) asserts a variety of arguments that purport to undermine the significance of minority stress to the issues before the Court. Contrary to the claims made by the Regnerus Brief, none of the arguments therein undermines our arguments and conclusions here.

The Regnerus Brief asserts some methodological objections to studies on minority stress. But these methodological challenges are not unique to the minority stress literature and are routinely handled by scientists, who are trained to discern the implications of these challenges.

In generating knowledge, scientists generally rely on theory, hypotheses posed based on theory, and empirical evidence that enables them to assess these hypotheses using quantitative and qualitative methods. To collect and assess evidence, scientists use conventions and rules about causal inference developed over decades of methodological writings. These are the same processes that were used by scientists studying the incidence and impact of minority stress, and their conclusions are no less worthy of respect than scientific conclusions drawn in other contexts.

Moreover, in all fields of inquiry, no one research article is determinative, and all studies have methodological limitations. Indeed, a good scientific article provides the reader with a thorough review of the study's limitations, as well as suggestions for further study that may address limitations. The mere existence of methodological limitations in any one study, or even in a group of studies, does not by itself discredit the study or area of investigation. Relying on conventions of scientific research methodology and causal inference, a scientist uses his or her expertise and judgment about the significance and potential impact of the limitations in any particular study or group of studies to form conclusions about the questions under study.

First, the Regnerus Brief raises a host of alleged methodological limitations that the authors erroneously claim invalidate minority stress research and conclusions. But none of these alone or together invalidate minority stress research and conclusions, or disqualify the weight of scientific findings we discuss. For example, contrary to the Regnerus Brief, the fact that research evidence on minority stress stems from hundreds of independent research studies, done with varying methodologies, and using a variety of measures is a *strength* of this body of work. Indeed, an established method to assess the validity of scientific findings relies on the assessment of *convergences* of results across *divergent* methods. To the extent that convergences are shown from different studies leading to the same conclusions, this provides evidence that the findings are not

singularly, and spuriously, confounded by a particular method or measure.[62]

Second, the Regnerus Brief alleges that the literature conflates causation and association, but discusses only one study to demonstrate this, and, even then, does not actually describe the purported error of this study's causal inference. Instead, the Regnerus Brief addresses some limitations that do not go to causality. In fact, the one study mentioned is perfectly suited for testing causal relationships in that it is longitudinal and carefully measured and tracked instances of the minority stressor as a cause and its health effect.[63]

In any event, this Court has never required in public accommodations cases that the government must prove that a specific exclusion *caused* the various harms that antidiscrimination laws aim to ameliorate, contrary to the Regnerus Brief's assertion. Regnerus Br. at 1 & 15 (citing *Brown* v. *Entertainment Merchants Ass'n*, 564 U.S. 786 (2011)). Rather, in *Roberts*, for example, it was nothing less than obvious to the Court that discrimination by public accommodations causes dignitary, economic, and other harms. 468 U.S. at 625. Furthermore, this is not a case like *Brown*, cited by the Regnerus Brief, in which the government was attempting to ban protected speech because of harms caused by the speech.

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[62] Campbell & Fiske, *Convergent and Discriminant Validation by the Multitrait-Multimethod Matrix*, 56 Psychol. Bull. 81 (1959).

[63] Frost *et al*. (2015), *supra*.

Third, the Regnerus Brief critiques some studies assessing minority stress that use non-probability, or non-random, samples. But the Regnerus Brief's blanket statement that "[t]hat is not how research on populations ought to be conducted," Regnerus Br. 23, is wrong and contrary to scientific method. Clearly, studies that use non-probability samples differ from studies that use probability (representative) samples, but both types of studies are appropriately utilized by scientists.[64] Probability samples are required to make unbiased population estimates about statistics, such as prevalence of a disorder in a population. But non-probability samples provide insight into studied phenomena and often are preferred for assessing causal relationships. Indeed, one of the definitive textbooks on scientific causal inference describes numerous considerations for causal inference that do not rely on probability samples.[65]

Fourth, the Regnerus Brief argues that some of the data on minority stress are too old to be relevant today because of "recent changes in societal norms and increasing acceptance of LGB persons." Regnerus Br. 4. But evidence from recent studies suggests that improvements in societal norms have not been far-reaching enough to weaken our arguments here. For example, recent data on youth in U.S. high schools—perhaps the population most likely to have adopted more-accepting norms—shows that LGB youth continue to be disproportionally targeted for harassment. The survey of high school students

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[64] Meyer & Wilson, *Sampling Lesbian, Gay, and Bisexual Populations*, 56:1 J. Counseling Psychol. 23, 23-31 (2009).

[65] Shadis *et al.*, *Experimental and Quasi-Experimental Designs for Generalized Causal Inference.* (Houghton Mifflin Co. 2002).

conducted in 2015 by the Centers for Disease Control and Prevention (CDC) uses a national probability sample of youth in high schools and therefore is representative of all U.S. youth in high schools. As reported by the CDC, results of the survey showed, among other findings, that 10% of LGB students, compared with 5% of heterosexual students, reported being threatened or injured with a weapon on school property, and 34% of LGB students, compared with 19% of heterosexual students, reported being bullied on school property.[66] And consistent with minority stress explanations, the LGB students were more likely to report being sad or hopeless (60% of LGB versus 26% of heterosexual students), seriously considered attempting suicide (43% of LGB versus 15% of heterosexual students), and actually attempted suicide (29% of LGB versus 6% of heterosexual students).[67] Similarly, the number of anti-LGB bias crimes reported to the FBI in the country has been steady for the past decade. For example, in 2005, 1,213 victims of crimes stemming from sexual-orientation bias were reported to the FBI; in 2015, 1,263 victims of these crimes were reported to the FBI.[68]

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[66] Kann *et al.*, *Sexual Identity, Sex of Sexual Contacts, and Health-Related Behaviors Among Students in Grades 9-12—United States and Selected Sites, 2015*, 65 Morbidity & Mortality Weekly Report 1 (Aug. 12, 2016).

[67] *Id.*

[68] United States Dep't of Justice, Federal Bureau of Investigation, *Hate Crime Statistics 2005*, *Victims*, https://www2.fbi.gov/ucr/hc2005/victims.htm; United States Dep't of Justice, Federal Bureau of Investigation, Criminal Justice Information Services Division, *2015 Hate Crime Statistics*, *Victims*, https://ucr.fbi.gov/hate-crime/2015/topic-

Thus, contrary to the Regnerus Brief, despite the increase in social acceptance of LGB people in today's society, stigma, prejudice, and discrimination persist.[69] *See supra* Part III.A.1.

Fifth, the Regnerus Brief notes that minority stress research describes some LGB people as resilient in the face of adversity. Regnerus Br. 9. While research has found that some LGB people are resilient in the face of adversity, others succumb to adverse health effects of minority stress. And, that some people may be able to rebound from adversity does not justify placing adversity in their path. In fact, one of the purposes of antidiscrimination law is to clear discriminatory obstacles in people's paths.

The Regnerus Brief suggests that the issue at stake here is a minor experience that could be "waved off by the plaintiffs as 'Oh well, we realize some people aren't on board with same-sex marriage.'" (Br. 10). The Regnerus Brief misconstrues minority stress writings to claim that this experience does not represent minority stress because the actions of Petitioners were not chronic or acute. In fact, minority stress is chronic not because each stressful event is chronic, but because LGB people repeatedly encounter such events. As we have explained here, the issue at stake is greater than the one-time interaction of the parties to this case. If this Court

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pages/victims_final; *see also* Park & Mykhyalyshyn, *L.G.B.T. People Are More Likely Targets of Hate Crimes Than Any Other Minority Group*, N.Y. Times, June 16, 2016, https://www.nytimes.com/interactive /2016/06/16/us/hate-crimes-against-lgbt.html?_r=0.

[69] Meyer, *The Elusive Promise of LGBT Equality*, 106:8 Am. J. Pub. Health 1356 (2016).

accepts Petitioners' arguments and allows for exemptions to antidiscrimination laws, it would change the social environment of LGB people for the worse, leading to repeated and acute experiences of being rejected from businesses and to expectations of such rejection and discrimination in LGB people's daily interactions within the public marketplace.

Finally, we are compelled to address the Regnerus Brief's false claim that "politics have crowded out sound scientific methodology" in research on minority stress. (Br. 21.). The studies we rely on herein—and many others in this body of research that we do not have room to cite—meet established standards for scientific rigor, as evidenced by their publication in demanding peer-reviewed journals. Furthermore, the Regnerus Brief's assertion about politics is incredible given that a federal court has already found that Mark Regnerus himself conducted results-oriented research in order to "oblige" a politically-driven funder. *DeBoer v. Snyder,* 973 F. Supp. 2d 757, 766 (E.D. Mich.), *rev'd*, 772 F.3d 388 (6th Cir. 2014), *rev'd sub nom.*, *Obergefell v. Hodges*, 135 S. Ct. 2584 (2015).[70]

In the end, the Regnerus Brief does not successfully dispute that a stigmatizing social

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[70] Indeed, the court concluded that Regnerus's testimony was "entirely unbelievable and not worthy of serious consideration." *DeBoer*, 973 F. Supp. 2d at 766. The court also concluded that Regnerus had "fringe viewpoints," *id.* at 768, which is underscored by the fact that Regnerus's own academic colleagues at his university took the extraordinary step of publicly distancing themselves from his findings. *Id.* at 766; UT Austin College of Liberal Arts, *Statement Regarding Sociology Professor Mark Regnerus* (2014), https://liberalarts.utexas.edu/public-affairs/news/7531.

environment damages the health of LGB people by bringing about life events and other conditions that are stressful. It is an environment that demands vigilance of its LGB citizens as they watch to protect themselves from potential discrimination and violence. It is an environment where, in an attempt to protect themselves from the stress of anti-LGB stigma, LGB people are moved to conceal their sexual identity. And it is an environment where stigma and stereotypes are internalized by both heterosexual and LGB people. Each of these stressors causes serious injury in the form of psychological distress, physical and mental health problems, suicide, and lowered sense of well-being. These stressors also negatively impact same-sex couples' relationship quality and stability.

IV. CONCLUSION

The minority stress literature converges on one conclusion: that when a place of public accommodation refuses to serve, or provides lesser services to, LGB people because of their sexual orientation, that experience can have powerful tangible and symbolic effects on LGB people, which adversely impact their health and well-being. Because of the power of law, if this Court countenances such discrimination, our Constitution will be a source of stigma rather than dignity for LGB people. For the foregoing reasons, the Court should affirm.

Respectfully submitted,

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APPENDIX

APPENDIX: LIST OF *AMICI* SCHOLARS

1. **Ilan H. Meyer**, Ph.D., is Distinguished Senior Scholar for Public Policy at the Williams Institute, UCLA School of Law, and Professor Emeritus of Sociomedical Sciences at Columbia University. Dr. Meyer studies public health issues related to minority health, including stress and illness in minority populations, in particular, the relationship of minority status, minority identity, prejudice and discrimination and health outcomes in sexual minorities and the intersection of minority stressors related to sexual orientation, race/ethnicity, and gender. In several highly cited papers, Dr. Meyer has developed a model of minority stress that describes the relationship of social stressors and adverse health outcomes and helps to explain LGBT health disparities. The model has guided his and other investigators' population research on lesbian, gay, bisexual, and transgender health disparities by identifying the mechanisms by which social stressors impact health and by describing the harm to LGBT people from prejudice and stigma. For this work, Dr. Meyer received the Outstanding Achievement Award from the Committee on Lesbian, Gay, Bisexual, and Transgender Concerns of the American Psychological Association (APA) and Distinguished Scientific Contribution award from the APA's Division 44. Dr. Meyer has served as an expert in several court cases and hearings, including *Perry v. Schwarzenegger*, 704 F. Supp. 2d 921 (N.D. Cal. 2010); United States Commission on Civil Rights briefing on peer-to-peer violence and bullying in K-12 public schools (2011); *Garden State Equality v. Doe* (N.J. Sup. Ct. 2013);

Bayev v. Russia (European Court of Human Rights 2014); and *Sexual Minorities Uganda v. Scott Lively* (D. Mass. 2016). Dr. Meyer has been a principal investigator for over 20 research projects and is currently the principal investigator of two important National Institutes of Health funded studies, the *Generations Study*, a study of stress, identity, health, and health care utilization across three cohorts of lesbians, gay men, and bisexuals; and the TransPoP study, the first national probability sample of transgender individuals, both in the United States.

2. **M. V. Lee Badgett**, Ph.D., is a Professor of Economics at the University of Massachusetts Amherst and a Williams Distinguished Scholar at the Williams Institute, UCLA School of Law. Her current research focuses on poverty in the LGBT community, employment discrimination against LGBT people in the U.S., and the cost of homophobia and transphobia in global economies. Dr. Badgett's latest book is *The Public Professor: How to Use Your Research to Change the World*. Her book, *When Gay People Get Married: What Happens When Societies Legalize Same-Sex Marriage*, analyzes the positive U.S. and European experiences with marriage equality for gay couples. Her first book, *Money, Myths, and Change: The Economic Lives of Lesbians and Gay Men*, presented her groundbreaking work debunking the myth of gay affluence. Dr. Badgett's work includes testifying as an expert witness in legislative matters and litigation (including as an expert witness in California's Prop 8 case), consulting with development agencies (World Bank and UNDP), analyzing public policies, consulting with regulatory

bodies, briefing policymakers, writing op-ed pieces, speaking with journalists, and advising businesses.

3. **Juan Battle**, Ph.D., is a Professor of Sociology, Public Health, & Urban Education and the Coordinator of the Africana Studies Certificate Program at the Graduate Center of the City University of New York (CUNY). His research focuses on race, sexuality, and social justice. Dr. Battle has over 75 grants and publications, including books, book chapters, academic articles, and encyclopedia entries. In addition to having delivered lectures at a multitude of academic institutions, community-based organizations, and funding agencies throughout the world, Dr. Battle's scholarship has included work throughout North America, South America, Africa, Asia, and Europe. Among his current projects, he is heading the Social Justice Sexuality initiative—a project exploring the lived experiences of Black, Latina/o, and Asian lesbian, gay, bisexual, and transgender (LGBT) people in the United States and Puerto Rico. He is also heading a project examining LGBT poverty in New York City. Dr. Battle is a Fulbright Senior Specialist and was the Fulbright Distinguished Chair of Gender Studies at the University of Klagenfurt, Austria and was an Affiliate Faculty of the Institute for Gender and Development Studies (IGDS), The University of the West Indies, St. Augustine, Trinidad and Tobago.

4. **Stuart Biegel**, J.D., has been a longtime member of the faculty at both the UCLA School of Law and the UCLA Graduate School of Education and Information Studies. He has served as Director of Teacher Education at UCLA, Special Counsel for the California Department of Education, and the Consent

Decree Monitor for the federal court in the San Francisco school desegregation case. Professor Biegel is the original author of the West casebook *Education and the Law* (4th ed. 2016), which focuses on both K-12 and higher education communities, and also includes major coverage of technology issues, privacy law issues, and disability rights. Among many other publications, his scholarship includes *The Right to Be Out: Sexual Orientation and Gender Identity in America's Public Schools* (University of Minnesota Press, 2d ed. forthcoming 2018) and *Unfinished Business: The Employment Non-Discrimination Act (ENDA) and the K-12 Education Community,* 14 *NYU Journal of Legislation & Public Policy* 357 (2011). He has also consulted with the National Education Association and the U.S. Commission on Civil Rights on issues relating to marginalized and disenfranchised youth.

5. **Susan D. Cochran**, Ph.D, M.S., is a Professor of Epidemiology at the UCLA Fielding School of Public Health and a Professor of Statistics, UCLA. Her research focuses on the mechanisms by which social adversity affects health. She has received numerous awards for her research and professional activities including the prestigious 2001 Award for Distinguished Contributions to Research in Public Policy from the American Psychological Association. In 2010, she was a member of the APA Presidential Task Force on "Reducing and preventing discrimination against and enhancing benefits of inclusion of people whose social identities are marginalized in society." Using funding from the National Institute on Drug Abuse, she conducted three large-scale population-based studies of mental

health and substance use concerns among lesbian, gay, and bisexual individuals in California. She is also a member of the World Health Organization ICD-11 Working Group on the Classification of Sexual Disorders and Sexual Health. She has served as *Amicus curiae* (*Baehr v. Lewin*, Circuit Court, State of Hawaii, October, 1996; *Baehr v. Lewin*, Appeals Court, State of Hawaii, July, 1997) and provided expert testimony (*Howard v. Arkansas Department of Human Services*, 2004; *Doe v. Doe, Miami-Dade County*, 2008; and *Cole v. Arkansas*, 2010) for LGB-related matters.

6. **Kerith Conron**, Sc.D., M.P.H., is the Blachford-Cooper Distinguished Scholar and Research Director at the Williams Institute, UCLA School of Law. Dr. Conron earned her doctorate from the Harvard School of Public Health and MPH from the Boston University School of Public Health. She is a social and psychiatric epidemiologist whose work focuses on documenting and reducing health inequities that impact sexual and gender minority populations. Dr. Conron is committed to altering the landscape of adversity and opportunity for the most marginalized lesbian, gay, bisexual, and transgender (LGBT) communities through collaborative activities that impact the social determinants of health. She has been supported by the National Institutes of Health to conduct community-based participatory research with LGBT youth of color and to train scholars in LGBT population health research. Dr. Conron has been active in LGBT health for over 15 years, serving on the first Steering Committee of the National Coalition for LGBT Health and as the first coordinator of the Office of LGBT Health for the City

of Boston. Her current research focuses on socioeconomic status and strategies to reduce poverty and to promote health. Her publications appear in the American Journal of Public Health, Archives of Pediatrics and Adolescent Medicine, and Psychological Medicine. Her expertise and commentary have been featured by major media outlets including the New York Times, the Associated Press, and National Public Radio.

7. **Brian de Vries**, Ph.D., is a (retired) professor of Gerontology at San Francisco State University, with adjunct appointments at both Simon Fraser University (in Vancouver) and the University of Alberta (in Edmonton). Dr. de Vries has been instrumental in guiding his professional associations through his role as fellow of the Gerontological Society of America (GSA), past Board member of the American Society on Aging (ASA), and former co-Chair of the LGBT Aging Issues Network constituent group. Similarly, Dr. de Vries was appointed to the Institute of Medicine's Board on the Health of Select Populations Committee which authored the influential book: *The Health of Lesbian, Gay, Bisexual and Transgender People: Building a Foundation for Better Understanding*. Dr. de Vries has co-edited several professional journals and acclaimed academic books as well as authored or co-authored approximately 100 journal articles and book chapters, and has given over 150 presentations to local, national, and international professional audiences on the social and psychological well-being of midlife and older LGBT persons, among other topics.

8. **Brian Dodge**, Ph.D., is an Associate Professor in the Department of Applied Health Science and Associate Director of the Center for Sexual Health Promotion at the Indiana University School of Public Health-Bloomington. A nationally recognized expert on bisexual health, he is a co-director of the Bisexual Research Collaborative on Health (BiRCH), a partnership of Indiana University, University of Illinois at Chicago, and The Fenway Institute. His research focuses on understanding social and behavioral aspects of sexual health and other aspects of well-being among a variety of understudied and underserved sexual minority communities, with a specific emphasis on the impact of stigma and minority stress on health among bisexual individuals. His work includes some of the first National Institutes of Health-funded studies on health among bisexual men and women, relative to their exclusively heterosexual and homosexual counterparts. He also collaborates on assessments of health among probability samples of sexual minority individuals in the U.S., including as a co-investigator of the ongoing nationally representative National Survey of Sexual Health & Behavior. Dr. Dodge has provided expert legal consultation on bisexuality-related cases for the Maricopa County, Phoenix, Arizona Public Defenders' Office and the U.S. Military.

9. **Jessica N. Fish**, Ph.D., is a Postdoctoral Research Fellow at the University of Texas at Austin Population Research Center and Visiting Assistant Professor in the Department of Family Science at the University of Maryland School of Public Health. Dr. Fish studies the sociocultural factors that shape the

development and health of sexual minorities. Her area of research, in particular, focuses on how prejudice and discrimination influence the prevalence and developmental patterns of substance use and mental health among sexual minority youth and adults. Among other findings, her research demonstrates the deleterious effects of discrimination on sexual minority health across the life course.

10. **Andrew R. Flores**, Ph.D., is Assistant Professor of Political Science in the Public Policy & Political Science Department at the Lorry I. Lokey Graduate School of Business and Public Policy at Mills College and a Visiting Scholar at the Williams Institute, UCLA School of Law. Dr. Flores studies attitude formation and change about marginalized groups, particularly lesbian, gay, bisexual, and transgender people (LGBT); the political behavior of LGBT people with a central focus on the role of linked fate in LGBTQ politics, and research on the demography of LGBT people; and the experiences of LGBT people while incarcerated. Dr. Flores has also analyzed the effects of social attitudes about LGBT populations on the physical and mental health of LGBT populations. Dr. Flores's research has appeared in or are forthcoming in the *American Journal of Public Health*, *Political Psychology, Public Opinion Quarterly*; the *Journal of Social Issues*, *Political Research Quarterly*; *Politics, Groups, and Identities*; the *Journal of Youth and Adolescence*; *Aggression and Violent Behavior*; the *International Journal of Public Opinion Research*; *Research and Politics*, *Transgender Studies Quarterly;* and the *Indiana Journal of Law and Social Equality*.

11. **David M. Frost**, Ph.D., is a Senior Lecturer (Associate Professor) in Social Psychology in the Department of Social Science at University College London. His research focuses on close relationships, stress, stigma, and health. His primary line of research examines on how stigma, prejudice, and discrimination constitute minority stress and, as a result, affect the health and well-being of marginalized individuals. He also studies how couples psychologically experience intimacy within long-term romantic relationships and how their experience of intimacy affects their health. These two lines of research combine within recent projects examining same-sex couples' experiences of stigmatization and its resulting impact on their relational, sexual, and mental health. His research has been published in several top tier social science, public health, and policy journals and has been recognized by grants and awards from the U.S. National Institutes of Health, the Society for the Psychological Study of Social Issues, and the New York Academy of Sciences.

12. **Nanette Gartrell**, M.D., is a Visiting Distinguished Scholar at the Williams Institute, UCLA School of Law. She has a Guest Appointment at the University of Amsterdam, and she was formerly on the faculties of Harvard Medical School and UCSF. Dr. Gartrell is a psychiatrist, researcher, and writer whose 48 years of scientific investigations have focused primarily on sexual minority parent families. Dr. Gartrell is the principal investigator of the U.S. National Longitudinal Lesbian Family Study, now in its 31st year. Her research has been cited internationally in litigation and legislation

concerning equality in marriage, foster care, and adoption, and it contributed to the American Academy of Pediatrics' 2013 endorsement of marriage equality. "The U.S. National Longitudinal Lesbian Family Study: Psychological Adjustment of the 17-year-old Adolescents," published in *Pediatrics,* was cited by *Discover Magazine* as one of the top 100 science stories of 2010.

13. **Jeremy Goldbach**, Ph.D., is an Assistant Professor at the University of Southern California Suzanne Dworak-Peck School of Social Work. Dr. Goldbach joined the faculty in 2012 after completing both his master's and doctoral degrees in social work at the University of Texas at Austin. His research is broadly focused on the relationship between social stigma, minority stress, and health among lesbian, gay, bisexual and transgender (LGBT) youth and adults. He has conducted studies in psychometric measurement development and is currently leading one of the first studies to examine how discrimination during adolescence may impact healthy development.

14. **Abbie E. Goldberg**, Ph.D., is an Associate Professor in the Department of Psychology at Clark University in Worcester, Massachusetts. She received her Ph.D. in clinical psychology from the University of Massachusetts Amherst. Her research examines diverse families, including lesbian- and gay-parent families and adoptive-parent families. A particular focus of her research is key life transitions (e.g., the transition to parenthood, the transition to kindergarten, and the transition to divorce) for same-sex couples. She has also studied the experiences of transgender college students, families formed through reproductive technologies, and bisexual

mothers partnered with men. She is the author of over 90 peer-reviewed articles and two books: Gay Dads (NYU Press) and Lesbian- and Gay-Parent Families (APA). She is the co-editor of LGBT-Parent Families: Innovations in Research and Implications for Practice (Springer) and the editor of the Encyclopedia of LGBTQ Studies (Sage). She has received research funding from the American Psychological Association, the Alfred P. Sloan Foundation, the Williams Institute, the Gay and Lesbian Medical Association, the Society for the Psychological Study of Social Issues, the National Institutes of Health, and the Spencer Foundation.

15. **Suzanne B. Goldberg**, J.D., is the Herbert and Doris Wechsler Clinical Professor of Law and founding director of the Sexuality and Gender Law Clinic at Columbia Law School. She also co-directs the Law School's Center for Gender & Sexuality Law. Professor Goldberg has written extensively about discrimination against lesbians, gay men, bisexuals and transgender people and has worked for nearly three decades on efforts to redress this discrimination.

16. **Gary J. Gates**, Ph.D., is a recognized expert on the geography and demography of the lesbian, gay, bisexual, and transgender (LGBT) population. Justice Anthony Kennedy cited his friend-of-the-court brief in his majority opinion in *Obergefell v. Hodges* (2015), holding that same-sex couples have a constitutional right to marriage. Dr. Gates holds a PhD in Public Policy and Management from the Heinz College, Carnegie Mellon University, a Master of Divinity degree from St. Vincent Seminary, and a Bachelor of Science degree in

Computer Science from the University of Pittsburgh at Johnstown. He is co-author of *The Gay and Lesbian Atlas* and publishes extensively on the demographic and economic characteristics of the LGBT population. National and international media outlets regularly feature his work. Dr. Gates is retired as a Distinguished Scholar and Research Director at the Williams Institute, UCLA School of Law. He has also held positions as a Senior Researcher at Gallup, a Research Associate at the Urban Institute in Washington, DC and Director of the AIDS Intervention Project in Altoona, PA.

17. **John C. Gonsiorek**, Ph.D., holds a Diplomate in Clinical Psychology from the American Board of Professional Psychology. He is past president of American Psychological Association Division 44, and has published widely on sexual orientation and identity. He is a fellow of APA Divisions 9, 12, 29, 36, and 44. Until August 2012, he was Professor in the PsyD Program at Argosy University/Twin Cities; and has taught at a number of other institutions. For over 25 years, he had an independent practice of clinical and forensic psychology in Minneapolis, and provided expert witness evaluation and testimony on a number of areas, including sexual orientation. Expert witness testimony regarding sexual orientation has included helping prepare *amicus curiae* briefs for the American Psychological Association; testimony in major cases includes: *Evans et al, v. Romer et al*., *Equality Foundation et al. v. Cincinnat*i, and *Nabozny v. Podlezny et al*. He has been a consulting editor for *Professional Psychology: Research & Practice,* and currently serves as Founding Editor for

Psychology of Sexual Orientation and Gender Diversity. His major publications include: Homosexuality: Research implications for public policy, and Homosexuality and psychotherapy: A practitioner's handbook of affirmative models.

18. **Perry N. Halkitis**, Ph.D., M.S., M.P.H., is dean of the Rutgers School of Public Health at Rutgers University–New Brunswick. Previously, he was professor of global public health, applied psychology, and medicine at NYU, where he has focused a significant amount of his research on HIV/AIDS, drug abuse, and mental health disease and how they are impacted by psychiatric and psychosocial factors. Dr. Halkitis also served as senior associate dean of the New York University (NYU) College of Global Public Health; director of NYU's Center for Health, Identity, and Behavior and Prevention Studies; and interim chair of the Department of Biostatistics at the College of Global Public Health. As senior associate dean for academic and faculty affairs at the NYU College of Global Public Health, Dr. Halkitis managed the academic portfolio of the college and administers the curriculum; directed faculty appointments and hiring; and participated in the college's and university's fund-raising efforts. He was NYU's inaugural associate dean for research and doctoral studies from 2005 to 2013 and earlier chaired the NYU Department of Applied Psychology.

19. **Gary W. Harper**, Ph.D., M.P.H., is a Professor of Health Behavior and Health Education, Professor of Global Public Health, and Director of the Office of Undergraduate Education at the School of Public Health at the University of Michigan. Dr.

Harper has conducted extensive research for more than 20 years with sexual minority youth/young adults, and has authored more than 130 publications in peer-reviewed academic journals. His research and community work have focused on the health and well-being of sexual minority youth and young adults, especially gay/bisexual male youth of color. This work includes the development of evidence-based interventions aimed at improving the health and well-being of sexual minority youth and young adults who experience discrimination, prejudice, and stigma. Dr. Harper's health promotion interventions for sexual minority youth are being utilized by community organizations and health centers in various states across the U.S., as well as in Kenya. Dr. Harper has testified as an expert witness in the City and County of San Francisco, California, and was appointed by the 2008 U.S. Secretary of Health and Human Services (under the George W. Bush administration) to serve on the Department of Health and Human Service's Office on AIDS Research Advisory Council.

20. **Amira Hasenbush**, J.D., M.P.H., is the Jim Kepner Law and Policy Fellow at the Williams Institute, UCLA School of Law. She researches discrimination based on sexual orientation and gender identity, family law issues for LGBT parents and children, and the legal needs of people living with HIV. She has completed empirical research on the existence and impact of public accommodations laws at the state and local level.

21. **Mark L. Hatzenbuehler**, Ph.D., is Associate Professor of Sociomedical Sciences and Sociology at Columbia University's Mailman School

of Public Health. Dr. Hatzenbuehler's research examines how structural forms of stigma—including social policies and community-level norms—increase risk for adverse health outcomes among members of stigmatized populations, with a particular focus on lesbian, gay, and bisexual individuals. He also developed a widely cited theoretical model that identifies psychosocial mechanisms linking stigma-related stressors to the development of psychopathology. Dr. Hatzenbuehler has published over 100 peer-reviewed articles and book chapters, and his work has been published in several leading journals, including *American Psychologist, Psychological Bulletin, American Journal of Public Health,* and *JAMA Pediatrics*. In recognition of this work on stigma and health inequalities, Dr. Hatzenbuehler received the 2015 Louise Kidder Early Career Award from the Society for the Psychological Study of Social Issues, the 2016 Early Career Award for Distinguished Contributions to Psychology in the Public Interest from the American Psychological Association, and the 2016 Janet Taylor Spence Award for Transformational Early Career Contributions from the Association for Psychological Science.

22. **Jody L. Herman**, Ph.D., is Scholar of Public Policy at the Williams Institute, UCLA School of Law. Dr. Herman has worked on issues of poverty, women's rights, and anti-discrimination policy development with non-profit research, advocacy, and direct-service organizations in the United States and Mexico. Before joining the Williams Institute, she worked as a research consultant on issues of voting rights in low-income minority communities and gender identity discrimination. She served as a co-

author on the groundbreaking report Injustice at Every Turn, based on the National Transgender Discrimination Survey conducted by the National Gay and Lesbian Task Force and the National Center for Transgender Equality. At the Williams Institute, her work has included research on the fiscal and economic impact of marriage for same-sex couples, the fiscal impact of employment discrimination against people who are transgender, and the development of trans-inclusive questions for population-based surveys. Her main research interests are the impact of gender identity-based discrimination and issues related to gender regulation in public space and the built environment.

23. **Ning Hsieh**, Ph.D., is an assistant professor of sociology at Michigan State University. Dr. Hsieh studies disparities in health outcomes and health care access by sexual orientation. Her research focuses on how sexual minorities' experiences of marginalization, prejudice, and discrimination contribute to their lower access to social, economic, and other coping resources, which eventually leads to poorer mental and physical health. Her recent publications reveal the heterogeneity in health risks among sexual minorities, suggesting that sexual minorities of color and bisexual individuals are particularly disadvantaged in health and healthcare experience.

24. **Laura T. Kessler**, J.D., J.S.D., is a Professor of Law at the University of Utah, S.J. Quinney School of Law. Dr. Kessler studies discrimination and families. Her expertise includes the harms of discrimination with regard to marriage, parentage, child custody, and family leave for LGB

individuals. Professor Kessler has developed a theory of equal citizenship for LGB individuals rooted in their intimate relationships. Her papers document the long and continuing history of disapproval of LGB relationships; how this denial serves to disrespect and subordinate gays and lesbians; and the consequent emotional, political, and expressive significance for LGB individuals of legal recognition of their intimate relationships. Her research is widely cited and recognized as providing rigorous, comprehensive, interdisciplinary analyses of the stubborn problem of discrimination against minority families, including LGB families. She was co-author of Brief of Amici Curiae Family Law Professors in Support of Plaintiffs-Appellees and Affirmance, filed in *Kitchen v. Herbert*, 755 F.3d 1193 (10th Cir. 2014), addressing, among other issues, the harm of the state of Utah's marriage ban to the well-being of different-sex couples and their children.

25. **Suzanne A. Kim**, J.D., is Professor of Law at Rutgers Law School at Rutgers University in Newark. Her research interests include the socio-legal regulation of intimacy; discrimination; intersections of family law with gender, sexuality, culture, and race; critical legal theory; law and social science; and vulnerability and resilience, including as concerning minority stress. Professor Kim has served as Associate Dean for Faculty Development at Rutgers Law. A recipient of the Dream Professor Award from the Association of Black Law Students at Rutgers Law, Professor Kim has been a visiting scholar at Emory University's interdisciplinary Vulnerability and the Human Condition Initiative and Columbia Law School's Center for Gender and

Sexuality Law and has also taught at Fordham Law School. Professor Kim also serves on the Executive Committee of the Institute for Research on Women at Rutgers University.

26. **Nancy J. Knauer**, J.D., is a Professor of Law and Director of the Law & Public Policy Program at Temple University, Beasley School of Law. For the past twenty-five years, Professor Knauer has explored the impact of federal policies on the lives of LGBT people. She is the author of Gay and Lesbian Elders: History, Law and Identity Politics in the US and more than forty academic articles, books, and book chapters. Her most recent scholarship focuses on the challenges faced by LGBT older adults, including health disparities and issues related to minority stress. Professor Knauer has received a Dukeminier Award and the Stu Walter Prize from the Williams Institute for her scholarship on LGBT aging issues. She is the co-founder of the Aging, Law & Society Collaborative Research Network of the Law & Society Association and served on the Executive Committee of the Family Law Institute of the National LGBT Bar Association. Professor Knauer was selected as one of 26 law professors from across the nation to be featured in the book What the Best Law Teachers Do, published by Harvard University Press in 2013.

27. **David J. Lick**, Ph.D., is User Experience Researcher at Facebook. Dr. Lick received his doctorate in Psychology from the University of California, Los Angeles. His research examines a number of issues related to sexual orientation, ranging from the psychological factors that contribute to prejudice against LGBT people to the downstream

health consequences of such prejudice. He recently collaborated on a scientific review that synthesized the growing body of research linking sexual minorities' experiences with prejudice to physical health disparities. He and his colleagues outlined the psychological, physiological, and behavioral pathways through which prejudice could hinder overall health for LGBT people. Dr. Lick has received numerous honors and awards for his work, including funding from the National Science Foundation, American Psychological Association, American Psychological Foundation, and Society for the Psychological Study of Social Issues.

28. **Marguerita Lightfoot**, Ph.D., is Professor of Medicine at the University of California, San Francisco School of Medicine. She is Chief for the Division of Prevention Science, Director of the Center for AIDS Prevention Studies (CAPS), Director of the UCSF Prevention Research Center and she holds the Walter Gray Endowed Chair. As a counseling psychologist, her research focus has been on improving the health and well-being of adolescents and young adults as well as the development of efficacious interventions to reduce health disparities among those populations disproportionately burdened by HIV and poorer mental and physical health outcomes. Her domestic and international research has included developing culturally appropriate interventions for runaway/homeless youth, juvenile justice involved adolescents, youth in medical clinics and settings, youth with a parent living with HIV, youth living with HIV, and LGBT youth, among others. She also studies the factors and approaches that strengthen resilience and mitigate the societal

impacts of stressors among these vulnerable populations of youth.

29. **Christy Mallory**, J.D., is the Director of State & Local Policy at the Williams Institute, UCLA School of Law. She studies the prevalence and impact of discrimination against LGBT people and same-sex couples in areas such as employment, housing, public accommodations, and education. Her work has been published in various journals and books, including *When Mandates Work* (UC Press, 2013), the *Loyola of Los Angeles Law Review*, the *LGBTQ Policy Journal at the Harvard Kennedy School*, and the *Albany Government Law Review*.

30. **Michael P. Marshal**, Ph.D., is an Associate Professor of Psychiatry at the University of Pittsburgh, and a Licensed Clinical Psychologist. Dr. Marshal is also a Standing Member of the "Health Disparities and Equity Promotion" Study Section within the Center for Scientific Review, at the National Institutes of Health (NIH). His expertise includes the investigation of mental health disparities among lesbian, gay, and bisexual (LGB) adolescents, particularly adolescents under the age of 18 years old. Dr. Marshal's program of research has been supported by multiple NIH-funded grants. His peer-reviewed publications have provided strong scientific evidence for the following: (1) On average, compared with heterosexual adolescents, LGB adolescents report higher rates of substance use, depressive symptoms, suicidality, and violent victimization experiences; (2) Mental health disparities among LGBT adolescents persist as they transition into young adulthood; and (3) Consistent with Dr. Ilan Meyer's Minority Stress Model, gay-

related victimization experiences are strongly associated with these disparities.

31. **Miguel Muñoz-Laboy**, Dr.P.H., is an Associate Professor of Social Work at Temple University's College of Public Health. Dr. Muñoz-Laboy conducts studies on: 1) social and cultural factors that impact access to HIV/sexually transmitted infections, mental health, and/or substance abuse treatments in Latino communities in the United States; 2) the roles of acculturative stress and minority stress in the health and well-being for bisexual populations; and 3) linkage and retention in HIV among Latinos(as) with severe opioids use disorder. Drawing on Dr. Ilan Meyer's minority stress model, Muñoz-Laboy published research has documented how sexual minority stress increased the severity of anxiety and depressive symptoms among Latino bisexual men. To support his research program, he has received nine grants by the U.S. National Institutes of Health and private foundations as the Principal Investigator (PI) or co-Principal Investigator (co-PI) and has served as co-Investigator in 11 additional grants. Dr. Muñoz-Laboy has published over 70 articles in peer-reviewed journals, authored 10 chapters in edited books, and co-edited two books.

32. **John Pachankis**, Ph.D., is an Associate Professor of Public Health at Yale University. Dr. Pachankis studies the mental health of sexual and gender minority individuals. He developed a highly-cited model of stigma concealment, which has been used to understand the reasons that people conceal stigmatized identities and the psychological costs of doing so. He also studies the psychological impact of

stigma and discrimination on sexual and gender minority mental health over the lifespan. Drawing on his background as a clinical psychologist, he has translated this research into some of the first evidence-based mental health treatments for LGBT individuals. He has tested the delivery of these treatments via novel technologies (e.g., smartphones), in diverse settings (e.g., Eastern Europe), and with diverse segments of the LGBT community (e.g., rural youth). He is the recipient of the 2017 Distinguished Contributions to Knowledge award of the American Psychological Association's Division 44.

33. **Charlotte J. Patterson**, Ph.D., is a professor of Psychology at the University of Virginia. She is best known for her research on the role of sexual orientation in human development and family lives—specifically for her work on child development in lesbian- and gay-parented families. Patterson's research has been published in the field's top journals and she has co-edited four books on the psychology of sexual orientation. Patterson is a Fellow of the American Psychological Association (APA) and of the Association for Psychological Science (APS) and a past president of the Society for Psychological Study of Lesbian, Gay, and Bisexual Issues. She has won a number of awards, including APA's Distinguished Contributions to Research in Public Policy Award. She also served as a member of the United States Institute of Medicine Committee on Lesbian, Gay, Bisexual, and Transgender (LGBT) Health Issues, whose 2011 report on LGBT health disparities was instrumental in leading the National Institutes of Health to reorganize research and increase funding for studies in this area.

34. **John L. Peterson**, Ph.D., is emeritus professor of psychology at Georgia State University. Prior to his faculty position at Georgia State, he was on the faculty at the University of California, San Francisco, in the Department of Medicine. Dr. Peterson studies the effects of sexual prejudice and violence toward sexual minorities and psychological issues related to the HIV/AIDS prevention among nonwhite gay and bisexual men. His work has been well cited regarding the interactive effects of sexual prejudice, masculine ideology, and violence toward sexual minorities and the sociocultural and psychological factors associated with HIV risk behavior and the social determinants of racial disparity in HIV infection. Dr. Peterson served on the Institute of Medicine (IOM) Committee on Lesbian, Gay, Bisexual & Transgender Health Issues and Research Gaps at the National Academies.

35. **Nancy Polikoff**, J.D., is Professor of Law at American University Washington College of Law where she teaches Family Law and a seminar on Children of LGBT Parents. She was previously the Visiting McDonald/Wright Chair of Law at UCLA School of Law and Faculty Chair of the Williams Institute. For more than 40 years, she has been writing about, teaching about, and working on litigation and legislation about LGBT families. Among her many publications is the book *Beyond (Straight and Gay) Marriage: Valuing All Families under the Law* (2008). Professor Polikoff was instrumental in the development of the legal theories that support second-parent adoption and custody and visitation rights for legally unrecognized parents. She was successful counsel in *In re M.M.D.*, which

established joint adoption for lesbian, gay, and unmarried couples in DC, and *Boswell v. Boswell*, a Maryland case that overturned restrictions on a gay noncustodial father's visitation rights. From 2007-2009, she played a primary role in the drafting and passage of groundbreaking parentage legislation in DC. She is a former chair of the Association of American Law Schools Section on Sexual Orientation and Gender Identity Issues. In 2011, Professor Polikoff received the Dan Bradley award from the National LGBT Bar Association, the organization's highest honor.

36. **Ellen D.B. Riggle**, Ph.D., is Professor of Political Science and Gender and Women's Studies at the University of Kentucky. Dr. Riggle studies the impact of stigma and identity strengths on the health and well-being of LGBT people and same-sex couples. Her areas of research include the effects of minority stress on LGBT individuals and same-sex couples, how laws and policies affect LGBT individuals' reports of distress and well-being, and the role of positive LGBT identity factors in well-being and resilience. Dr. Riggle is the co-author of A Positive View of LGBTQ: Embracing Identity and Cultivating Well-Being, winner of the 2012 American Psychological Association Division 44 Distinguished Book Award, and Happy Together: Thriving as a Same-Sex Couple in Your Family, Workplace, and Community (published by the American Psychological Association LifeTools series).

37. **Sharon Scales Rostosky**, Ph.D., is Professor and Director of Training in the Counseling Psychology program at the University of Kentucky. She is also a licensed psychologist. Dr. Rostosky uses

qualitative and quantitative methodologies to document the negative psychosocial impacts of prejudice and discrimination against LGB individuals and same-sex relationships that is sourced at all levels of the ecological system (intrapersonal, interpersonal, and socio-cultural). Her research on same-sex couple relationships was first funded by the American Psychological Foundation in 2000 and most recently by NIH in 2017. In addition to over 70 peer-reviewed articles, Dr. Rostosky has co-authored two books based on her research findings: *A Positive View of LGBTQ: Embracing Identity and Cultivating Well-Being* (Riggle & Rostosky, 2012, Rowman & Littlefield; American Psychological Association Division 44 Distinguished Book Award for 2012.), and *Happy Together: Thriving as a Same-Sex Couple in Your Family, Workplace, and Community* (Rostosky & Riggle, 2015, American Psychological Association).

38. **Esther D. Rothblum**, Ph.D., is Professor of Women's Studies at San Diego State University and Visiting Distinguished Scholar at the Williams Institute at UCLA School of Law. She is editor of the Journal of Lesbian Studies, a former president of Division 44 (Society for the Psychological Study of LGBT Issues) of the American Psychological Association, and a Fellow of seven divisions of APA. Her research and writing have focused on LGBT relationships and mental health, focusing on using heterosexual and cisgender siblings as a comparison group. Since 2001 Dr. Rothblum has compared same-sex couples in legal relationships with their heterosexual married siblings. She has edited 27 books and has over 130 publications in academic journals and books.

39. **Jocelyn Samuels**, J.D., is the Executive Director of the Williams Institute with close to three decades of experience in interpretation and enforcement of federal civil rights laws. She has served in numerous roles in the federal government, including as Acting Assistant Attorney General for the Civil Rights Division at the U.S. Department of Justice, and Director of the Office of Civil Rights at the U.S. Department of Health and Human Services. She has deep expertise in issues related to LGBT law and policy, including with respect to barriers that continue to limit access for the LGBT community to services and benefits and the application of existing laws to discrimination based on sexual orientation and gender identity.

40. **R. Bradley Sears**, J.D., is the David Sanders Distinguished Scholar of Law and Policy at the Williams Institute and Associate Dean of Public Interest Law at UCLA School of Law. Over the past two decades, Sears has published a number of research studies and articles, primarily on discrimination against LGBT people in the workplace in the private and public sectors, HIV discrimination by health care providers, the economic and fiscal impact of discrimination against same-sex couples, and the economic and fiscal impact of LGBT health disparities at the state-level.

41. **Ari Ezra Waldman**, J.D., Ph.D., is an Associate Professor of Law at New York Law School. He is the Director of the Innovation Center for Law and Technology and the Founder and Director of the Institute for CyberSafety, a full service academic and direct outreach program that includes, among other things, the first and, to-date, only law school clinic

representing LGBTQ victims of online harassment. Professor Waldman's research focuses, in relevant part, on the frequency and effects of bullying and cyberbullying on marginalized populations; the impact face-to-face and online harassment have on queer youth and adolescent success and health; and how federal, state, and local laws and policies can reduce cybervictimization and improve the lives of members of the LGBTQ community. His work has been published in leading law reviews and his forthcoming work explores nonconsensual image sharing among gay men and the effect of mobile apps on queer social life. He is an internationally sought-after speaker and commentator on privacy and cyberharassment.

42. **Bianca D.M. Wilson**, Ph.D., is a Senior Scholar of Public Policy at the Williams Institute, UCLA School of Law, and affiliated faculty with the UCLA California Center for Population Research. She earned a Ph.D. in Psychology from the Community and Prevention Research program at the University of Illinois at Chicago (UIC) with a minor in Statistics, Methods, and Measurement, and received postdoctoral training at the UCSF Institute for Health Policy Studies and the UCSF Lesbian Health and Research Center through an Agency for Health Research and Quality (AHRQ) postdoctoral fellowship. Her research focuses on the relationships between culture, oppression, and health, with an emphasis on racial and sexual and gender minorities. Her most current work focuses on LGBT economic instabilities and population research among foster youth, homeless youth, and youth in juvenile custody,

with a focus on sampling, data collection, and assessing disproportionality in these systems.

43. **Richard G. Wight**, Ph.D., M.P.H., is a retired Researcher from the Department of Community Health Sciences at the UCLA School of Public Health. For more than two decades, he conducted interdisciplinary research on stress and health experiences of individuals vis-à-vis the people and places around them, and his work has been widely published in the U.S. and internationally. His early publications were among the first to address public health and health policy issues relating to informal AIDS caregiving in the United States and he is an expert on the neighborhood context of health. Wight has developed life course studies that examine aging, minority stress, and health processes among the growing population of midlife and older lesbians and gay men, with a particular focus on the health effects of same-sex legal marriage. His recent work examines minority stress and health experiences of the parents of sexual minorities.

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