



4153-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No.: HHS-OCR-2018-0002]

45 CFR Part 88

RIN 0945-ZA03

Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

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

ACTION: Proposed rule.

SUMMARY: In the regulation of health care, the United States has a long history of providing conscience-based protections for individuals and entities with objections to certain activities based on religious belief and moral convictions. Multiple such statutory protections apply to the Department of Health and Human Services (HHS, or the Department) and the programs or activities it funds or administers. The Department proposes to revise regulations previously promulgated to ensure that persons or entities are not subjected to certain practices or policies that violate conscience, coerce, or discriminate, in violation of such Federal laws. Through this rulemaking, the Department proposes to grant overall responsibility to its Office for Civil Rights (OCR) for ensuring that the Department, its components, HHS programs

and activities, and those who participate in HHS programs or activities comply with Federal laws protecting the rights of conscience and prohibiting associated discriminatory policies and practices in such programs and activities. In addition to conducting outreach and providing technical assistance, OCR will have the authority to initiate compliance reviews, conduct investigations, supervise and coordinate compliance by the Department and its components, and use enforcement tools otherwise available in civil rights law 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, the Department will require certain recipients to maintain records; cooperate with OCR's investigations, reviews, or other enforcement actions; submit written assurances and certifications of compliance to the Department; and provide notice to individuals and entities about their conscience and associated anti-discrimination rights, as applicable.

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

ADDRESSES: You may send comments, identified by RIN 0945-ZA03 or Docket HHS-OCR-2018-0002, by any of the following methods:

- *Federal eRulemaking Portal.* You may submit electronic comments at <http://www.regulations.gov> by searching for the Docket ID number HHS-OCR-2018-0002. Follow the instructions high odds prediction site for sending comments.

- *Regular, Express, or Overnight Mail:* 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, DC 20201.

- *Hand Delivery / Courier:* 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, DC 20201.

Instructions: All submissions received must include “Department of Health and Human Services, Office for Civil Rights RIN 0945-ZA03” for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Further instructions are available under PUBLIC PARTICIPATION.

Docket: For complete access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and search for Docket ID number HHS-OCR-2018-0002.

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

SUPPLEMENTARY INFORMATION:

I. Introduction

The freedoms of conscience and of religious exercise are foundational rights protected by the First Amendment to the U.S. Constitution and by Federal statutes.

These laws ensure, for example, that Americans are not compelled to speak, to salute the flag, to join a national church, or to vote for a particular candidate.¹ They also ensure that, as a general matter, the Federal government may not discriminate against its citizens for the views they hold.² Congress has passed laws protecting conscience and religious freedom with particular force in the health care context, and it is these statutes that are the subject of this proposed rule. Specifically, this proposed rule concerns Federal laws that provide:

- Conscience protections related to abortion, sterilization, and certain other health services to participants in programs—and their personnel—funded by the Department (the Church Amendments, 42 U.S.C. 300a-7);

- 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 and individuals who object to furthering or participating in abortion under programs funded by the Department's yearly appropriations acts (*e.g.*, Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Tit. V, sec. 507(d) (the Weldon Amendment) and at Div. H, Tit. II, sec. 209);

- Conscience protections under the Patient Protection and Affordable Care Act (ACA) related to assisted suicide (42 U.S.C. 18113), the ACA individual mandate

¹ U.S. Const., amend. I; *see also, e.g., West Virginia State Board of Education v. Barnette*, 319 U.S. 624 (1943); 18 U.S.C. 594.

² *See e.g., Turner Broad. Sys. Inc. v. FCC*, 512 U.S. 622 (1994); *Rust v. Sullivan*, 500 U.S. 173 (1991); *Kingsley Int'l Corp. v. Regents of the Univ. of N.Y.*, 360 U.S. 684 (1954).

(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) and (b)(4));

- 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));

- Conscience protections related to the performance of advanced directives (42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406);

- Conscience protections related to Global Health Programs to the extent administered by the Secretary (22 U.S.C. 7631(d); Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. J, Tit. VII, sec. 7018 (Helms Amendment));

- Exemptions 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 (*e.g.*, 42 U.S.C. 1320a-1, 1320c-11, 1395i-5 and 1397j-1(b)).

(These laws will be collectively referred to as “Federal health care conscience and associated anti-discrimination laws” for purposes of this Notice of Proposed Rulemaking.).

With this proposed regulation, the Department seeks to more effectively and comprehensively enforce Federal health care conscience and associated anti-discrimination laws. Specifically, the Department proposes to grant its Office for Civil Rights (OCR) overall responsibility for ensuring that the Department, its

components, HHS programs and activities, and those who participate in HHS programs or activities comply with these Federal laws. In addition to conducting outreach and providing technical assistance, OCR will have the authority to initiate compliance reviews, conduct investigations, supervise and coordinate compliance by the Department and its component(s), and use enforcement tools comparable to those available under other civil rights laws to more effectively address violations and resolve complaints. In order to ensure that recipients of Department funds comply with their legal obligations, as it does with other civil rights laws within its purview, the Department will require certain funding recipients to maintain records; cooperate with OCR's investigations, reviews, or enforcement actions; submit written assurances and certifications of compliance to the Department; and provide notice to individuals and entities about conscience and associated anti-discrimination rights (as applicable).

II. America's Tradition of Conscience Protection, Religious Freedom, and the Right to be Free from Unlawful Discrimination

Congress has a long history of protecting conscience, religious beliefs, and moral convictions in law in a variety of contexts. *See, e.g.*, 1864 Draft Act, 13 Stat. 9 (exempting religious objectors opposed to bearing arms from military service); 50 U.S.C. 3806(j) (exempting conscientious objectors from combat training or military service); 18 U.S.C. 3597(b) (exempting law enforcement employees from participating in executions "if such participation is contrary to the moral or religious convictions of the employee"); 20 U.S.C. 1681(a)(3) (exempting educational institutions from sex discrimination bans under Title IX of the Education

Amendments of 1972 where such ban “would not be consistent with the religious tenets” of the institution); 42 U.S.C. 300a-8 (prohibiting the coercion of persons to undergo abortion or sterilization procedures by threatening loss of benefits and attaching a criminal punishment of a fine of not more than \$1000, imprisonment for not more than one year, or both, to violations of that prohibition); *see also* the Religious Freedom Restoration Act, 42 U.S.C. 2000bb *et seq.* (preventing the Federal government from imposing substantial burdens on religious exercise absent a compelling government interest pursued in the manner least restrictive of that exercise).

The need and justification for these types of laws was aptly explained by the Supreme Court in 1965:

[B]oth 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.

United States v. Seeger, 380 U.S. 163, 170 (1965), quoting Harlan Fiske Stone, *The Conscientious Objector*, 21 Col. Univ. Q. 253, 269 (1919).

For decades,³ Congress has also respected the conscience of taxpayers who object to paying for abortion by legislating prohibitions on the Federal funding of

³ *See* E.O. 13535, 75 FR 15599 (Mar. 29, 2010) (establishing enforcement mechanism to “ensure that Federal funds are not used for abortion services (except in cases of rape or incest, or when the life of the woman would be endangered),

abortion. Specifically, the Hyde Amendment, which Congress has routinely attached to appropriations acts, generally prohibits Federal funding of abortion.⁴ *See, e.g.*, Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, sec. 506, 507, 131 Stat. 562 (May 5, 2017). *See also id.* at Div. E, sec. 613, 131 Stat. 372 (using Hyde language to prohibit funding of abortions through Federal employee health benefits or coverage); *id.* at Div. E, sec. 810, 131 Stat. 393 (applying Hyde language to the District of Columbia); and 20 U.S.C. 1688 (including language in Title IX to prohibit recipients of Federal education funding from requiring any person, or public or private entity, to pay for any benefit or service, including the use of facilities, related to an abortion).⁵

In a May 4, 2017, Executive Order entitled “Promoting Free Speech and Religious Liberty,” the President declared that the Executive Branch will “vigorously enforce Federal law’s robust protections for religious freedom.” E.O. 13798, 82 FR 21675 (May 8, 2017). Pursuant to that Executive Order, the Attorney General of the United States issued guidance on religious liberty clarifying that Federal law

consistent with a longstanding Federal statutory restriction that is commonly known as the Hyde Amendment”).

⁴ In *Harris v. McRae*, 448 U.S. 297, 315 (1980), the Supreme Court held that Congress has the power to limit or prohibit the funding of abortion. In *Maher v. Roe*, 432 U.S. 464, 474 (1977), the court held that the Constitution empowers Congress to make a “value judgment favoring childbirth over abortion” that it may implement “by the allocation of public funds.” *See also Rust v. Sullivan*, 500 U.S. 173, 192-193, 201 (1991).

⁵ *See* Mark L. Rienzi, *The Constitutional Right Not to Kill*, 62 Emory L.J. 121, 152 (2012) (“[L]egislators acted quickly, decisively, and at times nearly unanimously to protect conscience rights in the wake of *Roe*. . . . The speedy passage and near ubiquity of these laws demonstrate that a great majority of Americans at the time—regardless of their famously intense disputes as to the merits of the underlying abortion question—agreed that the government should not have the power to compel participation in abortions by unwilling individuals and institutions.”).

“protects not just the right to believe or the right to worship; it protects the right to *perform or abstain from performing certain physical acts in accordance with one’s beliefs.*” Memorandum from the Attorney General, Federal Law Protections for Religious Liberty at 2 (Oct. 6, 2017) (emphasis added). Pursuant to the President’s Executive Order and Executive Branch policy, and in keeping with the Attorney General’s religious liberty guidance, HHS proposes this rule to enhance the awareness and enforcement of Federal health care conscience and associated anti-discrimination laws, to further conscience and religious freedom, and to protect the rights of individuals and entities to abstain from certain activities related to health care services without discrimination or retaliation.

III. The Federal Health Care Conscience and Associated Anti-Discrimination Laws Applicable to Government, Providers, Patients, Insurers, and Other Entities That Benefit From or Administer Federally Funded Health Care Programs or Activities

As noted above, Congress has recognized that modern health care practices may give rise to conflicts with the religious beliefs and moral convictions of providers and patients alike. The existence of moral and ethical qualms on the part of health care clinicians about participating in, assisting, referring for, or otherwise being morally complicit in certain procedures is well documented by ethicists.⁶

⁶ See, e.g., Stephen J. Genuis & Chris Lipp, *Ethical Diversity and the Role of Conscience in Clinical Medicine*, 2013 Int’l. J. Family Med. 1, 9 (2013); Armand H. Matheny Antommara, *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.

Religious institutions and entities, too, have expressed qualms about the provision of, participation in, or provision of insurance coverage for, certain procedures or services. To address these problems, Congress has repeatedly legislated conscience protections for the institutions and individuals providing health care to the American public, as outlined below.

A. 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 or sterilizations 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 respecting certain health care procedures from discrimination by entities that receive Federal funding.

First, subsection (b) of the Church Amendments provides 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, sterilizations 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). Subsection (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 entity otherwise prohibits the performance of such

Clark, *Medical Ethics at Guantanamo Bay and Abu Ghraib: The Problem of Dual Loyalty*, 34 J.L. Med. & Ethics 570 (2006).

procedures on the basis of 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)(A) and (b)(2)(B). The individuals and entities protected by this provision are recipients of a grant, contract, loan, or loan guarantee under the Public Health Service Act (42 U.S.C. 201 *et seq.*) and their personnel.⁷

Second, subsection (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)(A)–(B). This subsection prohibits certain entities from discriminating in these decisions based on an individual's refusal to perform or assist in an abortion or sterilization because of 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 subsection (b), recipients of a grant, contract, loan, or loan guarantee under the Public Health Service Act must comply with subsection (c)(1).

Third, subsection (c)(2) of the Church Amendments applies to the recipients of the Department's grants or contracts for biomedical or behavioral research under

⁷ The Community Mental Health Centers Act, Pub. L. 88-164, 77 Stat. 282 (1963), and the Developmental Disabilities Services and Facilities Construction Amendments of 1970, Pub. L. 91-517, 84 Stat. 1316 (1970), were repealed by subsequent statute and accordingly are not referenced here.

any program administered by the Secretary of Health and Human Services. 42 U.S.C. 300a-7(c)(2). This subsection prohibits discrimination 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, refusal 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)(A)–(B).

Fourth, subsection (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 programs, no individual shall be required to perform or assist in the performance of 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, subsection (e) of the Church Amendments applies to health care training or study, such as internships and residencies. Subsection (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). Recipients 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 subsection (e).

Notably, the Church Amendments contain provisions protecting the rights of individuals and entities explicitly.

B. The Coats-Snowe Amendment (Section 245 of the Public Health Service Act)

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 Federal, State, or local governments receiving Federal financial assistance. 42 U.S.C. 238n. As a condition of receiving such funding, those governments may not discriminate against “health care entities,” including individual physicians; participants in programs of training in the health professions; and postgraduate physician training programs, including residency training programs, that refuse 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).

In addition, Coats-Snowe applies to accreditation of postgraduate physician training programs. Therefore, governments receiving the specified Federal funds may not deny a legal status (including a license or certificate) or financial assistance, services, or other benefits to a health care entity (which, as defined in 42 U.S.C. 238n(c)(2), includes individual physicians, postgraduate physician training

programs, and participants in programs of training in the health professions) 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. 42 U.S.C. 238n(b)(1).

C. 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., Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, sec. 507(d), 131 Stat. 135.* Weldon provides that "[n]one of the funds made available in this Act may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions."

Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, sec. 507(d)(1), 131 Stat. 135. Weldon defines "health care entity" to "include[] an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan." *Id.* at sec. 507(d)(2).

D. Conditions on Federally Appropriated Funds Requiring Compliance with Federal Health Care Conscience and Associated Anti-Discrimination Laws

In addition to Weldon, the Consolidated Appropriations Act of 2017 includes other health care conscience protections. For example, a provision, using the same language as the Weldon Amendment, prohibits the Department from denying participation in Medicare Advantage to an otherwise eligible health care entity, such as a provider-sponsored organization, on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortion. Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, sec. 209, 131 Stat. 135.

E. 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 Federal, State, or local governments; health care providers that receive Federal financial assistance under the ACA; and 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 the HHS Office for Civil Rights (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).

Finally, Internal Revenue Code sec. 5000A, as added by section 1501 of the ACA, provides a religious conscience exemption from the individual mandate to maintain minimum essential coverage (and avoid its corresponding tax penalty) for any member of an exempt religious organization or division or for a "health care sharing ministry." 26 U.S.C. 5000A(d)(2). Exempt religious organizations or individuals are those who adhere to established tenets or teachings in opposition to acceptance of the benefits of any private or public insurance. 26 U.S.C. 1402(g)(1). 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). 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 or the associated tax penalties imposed under Internal Revenue Code sec. 5000A, including when such individuals are exempt by reason of membership in

an exempt religious organization or health care sharing ministry. 42 U.S.C. 18081(a)(4), (b)(5).

F. Other Protections Related to the Performance of Advance Directives or Assisted Suicide

Even before the ACA, Congress had passed conscience protections related to assisting or causing death. 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 death, such as assisted suicide, euthanasia, or mercy killing; or (2) apply to or affect 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. 1396a(w)(3), 1396a(a)(57); 1396b(m)(1)(A); 1396r(c)(2)(E); and 1395cc(f)(4) (by cross-reference to 42 U.S.C. 14406).⁸ Those protections extend to Medicaid and Medicare

⁸ Similar protections exist under the Department's regulations applicable to hospitals, nursing facilities, and other medical facilities, 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

providers, such as hospitals, 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.

G. Protections Related to Counseling and Referrals Under Medicare Advantage Plans, Medicaid Plans, and Managed Care Organizations

Certain Federal protections extend beyond the context of advance directives. For example, Federal law prohibits organizations offering Medicare+Choice (now Medicare Advantage) plans and Medicaid managed care organizations from being compelled 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).

H. Conscience and Associated Anti-Discrimination Protections Applying to Global Health Programs

The Department administers certain programs under the President's Emergency Program for AIDS Relief (PEPFAR), to which additional conscience protections apply. Specifically, recipients of foreign assistance funds for HIV/AIDS

directives if the provider cannot do so "as a matter of conscience" and State law allows such conscientious objection).

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 agreements for the recipients’ refusal to do any such actions. 22 U.S.C. 7631(d)(2).

I. Exemptions from Compulsory Medical Screening, Examination, Diagnosis, or Treatment

In addition to these provider protections, multiple Federal health programs contain conscience protections for patients and parents of children who have objections to certain tests or treatments. Congress provided, for example, that neither Medicaid nor the Children’s Health Insurance Program (CHIP) should be interpreted to require any State “to compel any person to undergo any medical screening, examination, diagnosis, or treatment” against their religious objection. 42 U.S.C. 1396f. Similarly, 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).

As relevant here, four other statutory provisions protect parents who conscientiously 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, Health Resources and Services Administration (HRSA) grants may not be used to preempt or prohibit State laws, including laws which do not require hearing loss screening for newborn infants or young children where their parents object to such screening based on religious belief. 42 U.S.C. 280g-1(d). Third, providers of pediatric vaccines funded by Federal medical assistance programs must comply with any State laws relating to any religious or other exemptions. 42 U.S.C. 1396s(c)(2)(B)(ii). Fourth, 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)(1).

J. 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 object to providing many standard medical items and services, such as 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,⁹ and they provide care exclusively through nonmedical nursing personnel assisting with nutrition, comfort, support, moving, positioning, ambulation, and other activities of daily living.¹⁰

Congress has supported 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)(83) (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

⁹ <https://www.medicare.gov/coverage/rnhci-items-and-services.html>].

¹⁰ <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/RNHCIs.html>.

are “conscientiously opposed to acceptance of” medical treatment on the basis of “sincere religious beliefs” (42 U.S.C. 1395i-5) yet will remain eligible for the nonmedical care and services ordinarily covered under Medicare, Medicaid, and CHIP. 42 U.S.C. 1395x(e), 1395x(y), and 1396g(e). Federal courts have upheld the constitutionality of such religious accommodations. *See e.g., Children’s Healthcare v. Min De Parle*, 212 F.3d 1084 (8th Cir. 2000) and *Kong v. Min De Parle*, No. C 00–4285 CRB, 2001 WL 1464549 (N.D.Cal. Nov. 13, 2001).

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 a 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 the elder’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).

IV. The Original Version and Current Version of the Rule

The Department has engaged in rulemaking to enforce some of these Federal health care conscience and associated anti-discrimination provisions on two previous occasions: in the 2008 Federal Health Care Conscience Rule, and in the

revocation and replacement of that Rule in 2011. This Part briefly summarizes each action.

A. 2008 Federal Health Care Conscience Rule

The Department issued a notice of proposed rulemaking in 2008 to clarify and enforce the Church, Coats-Snowe, and Weldon Amendments. 73 FR 50274 (Aug. 26, 2008). That notice recognized: (1) the inconsistent awareness of Federal health care nondiscrimination protections among Federally funded recipients and protected persons and entities; and (2) the unavailability of remedies for victims of discrimination under the above-referenced Amendments.

The Department received a “large volume” of comments on the 2008 proposed rule. *See* 73 FR 78072, 78074 (2008 Rule). 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 nondiscrimination protections and provide for their enforcement.

The Department responded to those substantive comments and issued a final rule on December 19, 2008, 45 CFR Part 88, consisting 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 subsections of Part 88 as they related to each conscience law subject to the 2008 Rule.

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

Section 88.5 of the 2008 Rule required covered Federally funded entities to provide written certification of compliance with the laws on conscience protection subject to the 2008 Rule.

Section 88.6 of the 2008 Rule designated HHS OCR to receive complaints based on the provider conscience laws and directed OCR to coordinate handling

those complaints with the Departmental components with respect to which the covered entity receives funding.

B. 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 conscience protection and provider nondiscrimination laws. In response to the proposal to rescind the 2008 Rule, the Department received comments stating that health care workers should not be required to violate their religious 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 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 the present rule. 76 FR 9968 (Feb. 23, 2011) (2011 Rule). The 2011 Rule left in place section "88.1 Purpose," but removed the word "implementation," describing the 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 section 88.6 as section 88.2, and modified that section to read, in its entirety: "The Office for Civil Rights (OCR) of the Department of Health and Human Services is designated to receive complaints based on the Federal health care provider conscience protection statutes. OCR will coordinate the handling of complaints with the Departmental funding component(s) from which the entity, 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 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.*

V. History of OCR Enforcement of Federal Health Care Conscience Laws

Since the designation of OCR as the agency with authority to enforce Federal health care conscience laws in 2008, OCR has received a total of forty-four complaints, the large majority of which (thirty-four) were filed since the November 2016 election.¹¹ Of these forty-four complaints, thirty-five currently remain open. OCR closed six of the complaints after investigation and three on administrative grounds.

The first of the closed complaints, filed on March 8, 2010,¹² by a nurse at a private hospital, alleged that the hospital had forced her to assist in an abortion in 2009 in violation of the Church Amendments. OCR conducted an investigation and closed the complaint less than a year later after OCR determined that the hospital had agreed to sufficient corrective action in a resolution agreement. The hospital had agreed to: (1) comply with the Church Amendments; (2) continue to make best efforts to ensure that non-objecting health care personnel are available to perform job duties with respect to abortion procedures, including any abortion procedures that occur over the weekend; (3) revise its human resources policy concerning nondiscrimination as set forth in subsection (c)(1) of the Church Amendments; (4)

¹¹ After OCR proposed rescission of the 2008 Rule, forty-six members of Congress, including the Chairman of the House Energy and Commerce Committee with oversight over HHS, raised concerns about whether HHS was fully enforcing the Federal health care conscience laws. See Rep. Mike Pence, House Energy and Commerce Committee Chairman Joseph Pitts, et al., Letter to HHS Secretary Kathleen Sebelius (Feb. 11, 2011).

¹² OCR Complaint No. 10-109676.

continue to post notices of that policy on the hospital's intranet and on the operating room notice board; and (5) train personnel about the hospital's obligations under the Church Amendments to ensure proper recording of staff's objecting or non-objecting status. In addition, the hospital incorporated technical assistance from OCR regarding its process for identifying employees' objection status and the hospital's grievance procedures. OCR directed the hospital to ensure that no adverse action was taken against the complainant or others for participating in the investigation.

In January 2011,¹³ OCR closed two other complaints alleging that a university violated the Church Amendments by requiring applicants to a nurse residency program to sign a form agreeing to assist in abortion procedures. Specifically, the application form declared, "If you are chosen for the Nurse Residency Program in the Women's Health track, you will be expected to care for women undergoing termination of pregnancy. . . . If you feel you cannot provide care to women during this type of event, we encourage you to apply to a different track of the Nurse Residency Program to explore opportunities that may best fit your skills and career goals." The form further provided, "By signing this letter, I acknowledge that I am aware that I may be providing nursing care for women who are having the procedures listed above." OCR closed these two complaints after it determined that the university had engaged in adequate corrective action—which included a public announcement that the university would no longer require an applicant to the

¹³ OCR Complaint No. 11-122388; OCR Complaint No. 11-122387.

nursing program to sign the form if doing so would be inconsistent with the applicant's religious or moral beliefs.

Members of Congress raised concerns following OCR's closure of three additional complaints filed on September 10, October 1, and October 9, 2014,¹⁴ alleging that the State of California violated the Weldon Amendment by requiring insurance plans to cover elective abortions. Those complaints were filed by eighteen different complainants: one religious organization, seven churches, one church school, two religiously affiliated universities, and seven employees of one of those universities who participated in the university's health plan. Each complaint alleged that the California Department of Managed Health Care (CDMHC) had contacted seven insurers offering plans without abortion coverage on August 22, 2014, and stated that those insurers were required to include abortion coverage in order to maintain certification as insurance companies in California. All seven insurers changed their policies in response to the letter. OCR closed the complaints on the stated ground that the seven insurers did not object to providing abortion coverage on religious or moral grounds and that the Weldon Amendment required such objection.¹⁵

OCR at that time took the view that a protected entity must assert a religious or moral objection in order to merit protection under the Weldon Amendment, although the express language of the law does not require that a health care entity

¹⁴ OCR Complaint No. 14-193604; OCR Complaint No. 15-193782; OCR Complaint No. 15-195665.

¹⁵ Letter from OCR Director to Complainants (June 21, 2016), <http://www.adfmedia.org/files/CDMHCInvestigationClosureLetter.pdf>.

claim a religious or moral objection to merit protection. OCR's closures prompted 133 Members of Congress to express concern to the HHS Secretary that the Department failed to enforce the Weldon Amendment.¹⁶ Senior leaders of the House of Representatives also scheduled a meeting with the HHS Secretary and OCR Director to request information from OCR about these closures.¹⁷

Since that time, OCR has closed three more complaints on administrative grounds. The first, filed on May 5, 2016, alleged that a hospital center violated the Church Amendments by discriminating against a health care professional who performed and supported the performance of abortions,¹⁸ but the complainant withdrew that complaint nine months later. The second, filed October 25, 2016, alleged a covered entity discriminated against the complainant when it refused to perform a sterilization procedure. Though technically not a conscience complaint itself, the covered entity's answer, filed before OCR undertook any investigation, raised conscience-based defenses, specifically citing the Church Amendments. Following the complainant's request to withdraw the complaint, OCR administratively closed the case. The third, filed on January 17, 2017, concerned literature the complainant received from his employer's pharmacy benefit management company, and to which the employee had a religious or moral objection.¹⁹ OCR determined that the complainant had failed to raise sufficient facts

¹⁶ Letter from Reps. John Fleming, M.D., Diane Black, et al. to HHS Secretary Kathleen Sebelius (Nov. 25, 2014).

¹⁷ House Majority Whip Kevin McCarthy, et al., Letter to Secretary Sebelius (June 22, 2016).

¹⁸ OCR Complaint No. 15-238113.

¹⁹ OCR Complaint No. 17-259696.

to support a claim under the Federal health care conscience and anti-discrimination laws.

Of the ten complaints filed before November 2016, two (one filed August 15, 2014 and the other filed November 4, 2015) remain open. Although OCR received on average only approximately 1.25 complaints per year from the 2008 Rule until November 2016, OCR has received *thirty-four* complaints between November 2016 and mid-January 2018.

VI. Reasons for the Proposed 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, compliance, and enforcement of the Federal health care conscience and associated anti-discrimination laws. The 2011 Rule created confusion over what is and is not required under Federal health care conscience laws and narrowed OCR's enforcement authority. Since November 2016, there has been a significant increase in complaints filed with OCR alleging violations of these conscience and associated anti-discrimination laws. The increase underscores the need for the Department to have the proper enforcement tools available to appropriately enforce Federal health care conscience and associated anti-discrimination laws.²⁰

²⁰ Since 2011, conscience and coercion in health care have been the subjects of significant litigation on the State and local level. Recently, the Supreme Court agreed to determine whether certain disclosures required by a state law violate the Free Speech rights of pregnancy resource centers that do not refer for abortions. *See National Institute of Family and Life Advocates v. Becerra*, No. 16-1140 (*certiorari* granted November 13, 2017).

A. 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 or moral convictions.²¹ Yet in February 2009, the Department announced its intent to rescind the 2008 Rule just one month after its effective date.²² And it completed that rescission in 2011 despite significant evidence of an environment of discrimination and coercion, including thousands of public comments during the 2008 and 2011 rulemakings describing the same. Indeed, a 2009 article in the *New England Journal of Medicine* argued, “Qualms about abortion, sterilization, and birth control? Do not practice women’s health.”²³ 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.²⁴ Additionally, 32% of survey respondents reported having been pressured to refer a patient for a procedure to which they had moral,

²¹ 73 FR 78072, 78073 (Dec. 19, 2008) (2008 Rule).

²² Rob Stein, Obama Plans to Roll Back ‘Conscience’ Rule Protecting Health Care Qf 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 Web site, unleashed a flood of heated reaction”).

²³ 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).

²⁴ 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 Memorandum from Jonathan Imbody, Christian Medical Association, Vice President for Government Relations to Office of Public Health and Science, Department of Health and Human Services (Apr. 9, 2009).

ethical, or religious objections. Some 20% of medical students in that poll said that they would not pursue a career in obstetrics/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 2011 rulemaking 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.²⁵ One obstetrician/gynecologist commented that, during his entire time in health care—from medical school, through his residency, and to private practice—he had been pressured to participate in abortions and abortion counseling.²⁶ 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.²⁷ At least ninety commenters said that, if forced to choose between

²⁵ Comment Nos. HHS-OPHS-2009-0001-0739, -52648, -52677.

²⁶ Comment No. HHS-OPHS-2009-0001-0868.

²⁷ 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).

their careers or violating their conscience, they would quit their jobs.²⁸ Tens of thousands of comments to the proposed 2011 Rule expressed concern that, without robust enforcement of Federal health care conscience laws, individuals with conscientious objections simply would not enter the health care field at all 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.²⁹ Thousands also

²⁸Almost 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. Concerned physicians 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.

²⁹ 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, -

feared personnel with objections would be terminated or otherwise unable to find employment, training, or opportunities to advance in their field.³⁰ Commenters identified a culture of hostility to conscience concerns in health care.³¹ 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.³² 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.³³ Hundreds of commenters expressed concern over the exclusion and marginalization of health care entities and

52932, -39199, -12340, -52950 (form letter with 1916 copies), -31897, -52984 (form letter with 62 copies), -53081 (form letter with 22 copies), -52968 (form letter with 9532 copies), -52961 (patients concerned about access to pro-life doctors: form letter with 3272 copies), -53098 (patients concerned effort to push people out: form letter with 976 copies), -52977 (form letter with 3516 copies), -53021 (form letter with 4842 copies), -52949 (form letter with 688 copies), -53039 (form letter with 742 copies), -0476.

³⁰ 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 3196 copies), -52960 (evidence of discrimination: form letter with 1685 copies), -53028 (evidence of discrimination: form letter with 2002 copies).

³¹ Comment Nos. HHS-OPHS-2009-0001-0739, -52677, -26812, -53013 (form letter with 8472 copies).

³² Comment No. HHS-OPHS-2009-0001-10280, -2486, -46903, -19125, -36940, -12020, -41551.

³³ 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.

employees holding religious or moral convictions, and fears that the moral agency of the medical profession was eroding.³⁴

According to news reports, in 2010, Nassau University Medical Center disciplined eight nurses when they raised objections to assisting in the performance of abortions.³⁵ 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 (Winnebago County Cir. Ill. June 8, 2016); *Cenzon-DeCarlo v. Mount Sinai Hospital*, 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 hospital due to her objections to prescribing certain medications. *Hellwege v. Tampa Family Health Centers*, 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. *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.³⁶

³⁴ Comment Nos. HHS-OPHS-2009-0001-52974 (form letter with 428 copies).

³⁵ *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>.

³⁶ 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

In 2016, the American Congress of Obstetricians and Gynecologists (ACOG) reaffirmed a prior ethics opinion that recommended, “[i]n 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.”³⁷

B. Recently Enacted State and Local Government Health Care Laws and Policies Have Resulted in Numerous Lawsuits by Conscientious Objectors

The Department has witnessed an increase in lawsuits against State and local laws that complainants allege violate conscience. For example, many State and local governments have enacted legislation requiring pregnancy resource centers to post notices related to abortion that plaintiffs have objected to on First Amendment and analogous grounds. Courts preliminarily or permanently enjoined ordinances in New York City, Austin, Montgomery County, Baltimore, and Illinois. *Greater Baltimore Center for Pregnancy Concerns, Inc. v. Mayor and City Council of Baltimore*, No. 16-2325 (4th Cir. Jan. 5, 2018) (affirming freedom of speech claim to strike down Baltimore ordinance requiring pregnancy resource center to state abortion services are not available in their facilities); *Evergreen Association, Inc. v. City of New*

Directives for Catholic Health Services (Nov. 17, 2009) (identifying Catholic objections to performing abortions, tubal ligations, and hysterectomies).

³⁷ <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 combination of the ACOG opinion and ABOG certification requirements could constitute a violation of Federal health care conscience laws.

York, 740 F.3d 233 (2d Cir. 2014) (striking down under the First Amendment 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); *National Institute of Family and Life Advocates v. Rauner*, No. 3:16-cv-50310 (N.D. Ill. filed Sept. 29, 2016) (preliminary injunction entered on free speech grounds). But litigation continues in a case filed against Hawaii. See *Calvary Chapel Pearl Harbor v. Chin*, No. 1:17-cv-00326-DKW-KSC (D. Haw., filed July 12, 2017) (stayed pending Supreme Court's review of *NIFLA v. Becerra*). And several courts rejected challenges to California's law, see, e.g., *Mountain Right to Life v. Harris*, No. 5:16-cv-00119 (C.D. Calif. 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 these ordinances also require that pregnancy resource centers or medical professionals provide information about where abortion services can be obtained or whether facilities have licensed medical staff. The Supreme Court issued

a writ of certiorari in one such case challenging California's A.B. 775 on free speech grounds. *See NIFLA v. Becerra*, No. 16-1140 (Nov. 13, 2017).

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 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).³⁸ 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). The New York State Department of Financial Services required individual and small group employers, irrespective of the number of employees or any religious affiliation, to provide insurance coverage for abortions, *see* New York Department of Financial Services, Outpatient and Professional Services Model Language, Section IX[M], prompting additional lawsuits, *see, e.g., Roman Catholic Diocese of Albany v. Vullo*, No. 02070-16 (N.Y. Albany County S. Ct. May 4, 2016).

Over the past several years, an increasing number of jurisdictions in the United States have also legalized assisted suicide. *See* District of Columbia B21-0038 (Feb. 18, 2017), Colorado Prop. 106 (Dec. 16, 2016); California ABX2-15 (June 9,

³⁸ <https://www.dmhc.ca.gov/Portals/0/082214letters/abc082214.pdf>.

2016); 18 Vermont Act 39 (May 20, 2013) (“Act 39”). Act 39 states that health care professionals must inform patients “of all available options related to terminal care.” 18 Vt. Stat. Ann. § 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. *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 elder abuse because the cancer patient died after the oncologists on staff declined to participate in assisted suicide and before she could obtain a new physician.³⁹

Finally, some States have passed laws requiring health care professionals to provide referrals for implementation of advance directives. *See* Iowa Code Ann. section 144D.3(5) (2012) (requiring that provider 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”).

³⁹ Bob Egelko, *California's assisted-dying loophole: Some doctors won't help patients die*, San Francisco Chronicle (Aug. 12, 2017), <http://www.sfchronicle.com/news/article/California-s-assisted-dying-loophole-Some-11761312.php>.

The Department has not opined on or judged the legal merits or sufficiency of any of the above-cited lawsuits or challenged laws. They are discussed here only to illustrate that recent disputes alleging violations of conscience, broadly understood, by state and local governments exist to a notable degree, and to illustrate the need for greater clarity concerning the scope and operation of the Federal conscience and associated anti-discrimination laws that are the subject of this regulation. The Department anticipates that the proposed regulation will result in greater public familiarity with Federal health care conscience and associated anti-discrimination protections and may inform both potential plaintiffs and future State and local legislators.

C. Confusion Exists About Conscience Laws' Scope and Applicability

Even though Federal health care conscience and associated 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 health care conscience protections 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 associated anti-discrimination protections on this topic. *See 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 Corporation*, 178 F.Supp.3d 614 (E.D. Mich. 2016) (abortion); *Minton v. Dignity Health*, No. 17-558259 (Calif. Super. Ct. Apr. 19, 2017) (hysterectomy);

Chamorro v. Dignity Health, No. 15-549626 (Calif. Super. Ct. Dec. 28, 2015) (tubal ligation). A patient also recently 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. Public Hospital 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 for respect of conscience, and such conscience conditions supersede conflicting provisions of State law and must be harmonized and given effect with "cross-cutting" anti-discrimination laws, as in many other contexts. *See e.g.*, Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d *et seq.* The Department seeks to clarify the scope and application of Federal health care conscience and associated anti-discrimination laws in the proposed rule.

D. Courts have Found No Alternative Private Right of Action to Remedy Violations

In lawsuits filed by health care providers for alleged violations of certain Federal health care conscience and associated anti-discrimination laws, courts have held that such laws do not contain an implied private right of action to seek relief from such violations by non-governmental covered entities. Adequate governmental enforcement mechanisms are therefore 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 698-699. 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 Hospital*, 962 N.Y.S.2d 845 (S. Ct. Kings County 2010). The nurse then filed a complaint with OCR on January 1, 2011, and, as discussed above, OCR resolved the complaint when the hospital changed its written policy for health care professionals going forward.

Similar results were obtained in a Federal lawsuit brought by a nurse in 2014, alleging that a health center had violated subsection (d) of 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 did not confer a remedy to bring suit against a private entity in Federal court. *Id.* at 1310. In July of this year, 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. *National Institute of Family and Life Advocates, et al. v. Rauner*, No. 3:16-cv-50310, at 4 (N.D. Ill. July 19, 2017).

E. Addressing Confusion Caused by OCR Sub-Regulatory Guidance

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 health care conscience and associated 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.

This proposed regulation intends to clear up confusion caused by OCR sub-regulatory guidance issued through OCR's high-profile closing of three Weldon Amendment complaints against the state of California filed in 2014.⁴⁰ 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.⁴¹ 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, because none of the complainants were insurance issuers, the letter concluded that none qualified as an entity or person protected under the Weldon Amendment. Relying on 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," as opposed to some other

⁴⁰ OCR Complaint Nos. 14-193604, 15-193782, and 15-195665.

⁴¹ Letter from OCR Director to Complainants (June 21, 2016) available at <http://www.adfmedia.org/files/CDMHCInvestigationClosureLetter.pdf>.

reason for refusing to facilitate 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 the Constitution’s prohibition on the Federal government infringing State sovereignty through its Spending Clause power.⁴²

The Department does not opine upon, and has not made a judgment on, the compatibility of California’s policy with the Weldon Amendment. But clarifications are in order with respect to the general interpretations of the Weldon Amendment offered in OCR’s previous closure of complaints against California’s abortion coverage requirement. The Department has engaged in further consideration of these general matters and has also further reviewed the Federal health care conscience statutes, the legislative history, and the record of rulemaking and public comments under Part 88. Based on this review, the Department has concluded that the above-mentioned sub-regulatory guidance issued by OCR with respect to interpretation of the Weldon Amendment no longer reflects the current position of HHS, OCR, or the HHS Office of the General Counsel.

Specifically, and first, HHS does not believe that the “potential” constitutional concerns cited in the letter relieve HHS of the obligations Congress imposed on it to

⁴² In reaching this conclusion, the letter cited advice from “HHS’ Office of General Counsel, after consulting with the Department of Justice,” but HHS believes this advice may have been relayed orally as it 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.

not make certain funding available to covered entities that discriminate in violation of the Weldon Amendment. Instead, HHS must diligently enforce the Weldon Amendment according to its text and to the extent allowed by the Constitution. It is a bedrock principle that the Federal government is to presume that statutes passed by Congress are constitutional. Additionally, if conflicts with the Constitution are clearly present, saving constructions should be employed to avoid interpreting statutes as dead letters. The Weldon Amendment's funding remedies in cases of violation can and should be read and applied consistently with the Constitution.

Second, in contrast to OCR's previous position, HHS concludes that the Weldon Amendment's protection for health insurance and any other kind of plans is not a protection that may only be invoked or complained of by issuers.⁴³ Per the amendment, "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." Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Tit. V, sec. 507(d) (emphasis added). The amendment's broad and non-exhaustive definition indicates that the amendment takes an inclusive approach with respect to the health care entities it protects and should not be interpreted narrowly. Because the Weldon Amendment protects not only the health insurance issuer, but also the health plan itself, it can also be raised, at minimum, by the plan

⁴³ HHS believes health insurance issuers are health care entities by that term's plain meaning in the Weldon Amendment. But, notably, while the Weldon Amendment explicitly protects plans, it does not explicitly mention issuers. This further undermines OCR's previous conclusion that the amendment protects issuers, but not plans distinct from issuers.

sponsor on behalf of the plan, as well as by the issuer. Such an interpretation is not foreclosed by either the statute or the regulation. *Cf.* Department of Justice Title VI Legal Manual (“The financial assistance does not have to relate to a program in which the complainant participates or seeks to participate or [to a program] used for the complainant’s benefit. Rather, an agency only has to prove that the entity received Federal financial assistance when the alleged discrimination occurred.”).

Finally, the plain text of the Weldon Amendment prohibits discrimination against protected individuals and entities for being unwilling to take certain actions or to provide certain support in relation to abortion without requiring a specifically religious or moral motive for that decision or position.⁴⁴ The Weldon Amendment states that funding shall not be available to an agency, program, or government if that “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.” *See, e.g.*, Consolidated Appropriations Act, 2017, Pub. L. 115-31, sec. 507(d). While Weldon certainly protects objections based on conscience or religion, nothing in the text *limits* its protection to those contexts. The legislative history of the Weldon Amendment cannot be used to contradict or limit the plain text of the statute. In any event, the legislative history in the form of a floor statement from the Amendment’s sponsor,

⁴⁴ As seen by the compilation of the Federal health care conscience and associated anti-discrimination laws that are the subject of this proposed Rule, Congress uses the phrase “religious or moral convictions” (or an equivalent) when it wants to exempt only persons asserting those motivations, and does not include such language when it wants to exempt persons and institutions without any inquiry into their motivation. *See, e.g.*, 42 U.S.C. 238n (Coats-Snowe Amendment).

Representative Dave Weldon, reinforces the plain meaning of the amendment.

Representative Weldon stated that his amendment “simply states you cannot force the unwilling” to participate in abortion, and that it protects those “who choose not to provide abortion services,” including health professionals who say they are pro-choice and supportive of *Roe v. Wade*, but would rather not perform abortions themselves.⁴⁵

The Department is concerned that segments of the public have been dissuaded from complaining about religious discrimination in the health care setting to OCR, at least in part, as the result of these previous unduly narrow interpretations of the Weldon Amendment. For example, Foothill Church 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 health care conscience laws. *See Foothill Church v. Rouillard*, No. 2:15-cv-02165-KJM-EFB, 2016 WL 3688422 (E.D. Calif. July 11, 2016).

With the proposed 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 and moral convictions to enter, or remain in, the health care industry; and, by clarifying the Department’s general views regarding the operation and applicability of the Weldon Amendment, to prevent

⁴⁵ 150 Cong. Rec. H10090 (Statement of Rep. Weldon) (Nov. 20, 2004); 151 Cong. Rec. H177 (Statement of Rep. Weldon) (Jan. 25, 2005).

others from being similarly dissuaded from filing complaints due to OCR sub-regulatory guidance that is no longer reflective of the views of the Department.

F. Additional Federal Health Care Conscience and Associated Anti-Discrimination Laws

Finally, in addition to all of the concerns discussed above that support the proposed rulemaking, the Department proposes to use this rulemaking to address various other Federal health care conscience and associated anti-discrimination laws not discussed in the 2008 and 2011 Rules. These provisions include the Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, sec. 209; *Id.*, Div. E, sec. 726 and 808; 22 U.S.C. 7631(d); 29 U.S.C. 669(a)(5); 42 U.S.C. 1396f, 5106i(a)(1) and (2), 280g-1(d), 290bb-36(f), 1396s(c)(2)(B)(ii), 1395w-22(j)(3)(B), 1396u-2(b)(3)(B), 1395cc(f), 1396a(w)(3), 1320a-1, 1320c-11, 1395i-5, 1395x(e), 1395x(y)(1), 1396a(a), 1397j-1(b), and 14406. Some of these provisions were enacted after 2008. All provide additional protections for health care providers, patients, beneficiaries of human services, or providers of human services from coercion and discrimination because of moral convictions or religious beliefs.

VII. Summary of the Proposed Rule

This proposed rule would generally reinstate the structure of the 2008 Rule, supplemented with further definition of Federal health care conscience and associated anti-discrimination laws and robust notice and enforcement provisions. Specifically, the proposed rule would require certain recipients of Federal financial assistance from the Department or of Federal funds from the Department to both notify individuals and entities who are protected under the Federal health care

conscience and associated anti-discrimination laws (such as employees, applicants, or students) of their rights and also to assure and certify to the Department their compliance with the requirements of these laws. It would also set forth in more detail the investigative and enforcement responsibility of OCR, along with the tools at OCR's disposal in carrying out its responsibility with respect to those Federal health care conscience and associated anti-discrimination laws.

By virtue of Congress's enactment of all the Federal health care conscience and associated anti-discrimination laws cited herein, the Department is required to ensure its own compliance with those statutes, 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 Departmental components that provide Federal financial assistance. Congress later designated OCR as having enforcement authority 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. With the publication of this proposed rule in the Federal Register, the Secretary thus provides notice of the delegation to OCR of full enforcement authority over a significantly larger universe of Federal statutes compared to the 2008 and 2011 Rules.

The compliance and enforcement sections specify in much greater detail than either the 2008 or 2011 Rule how OCR will enforce the Federal health care and associated anti-discrimination laws beyond the receipt and handling of complaints and the coordination with other Department components. Implementation of the requirements set forth in this proposed rule would 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 would be based on complaints, referrals, news reports, and OCR-initiated compliance reviews and communications activities. If OCR were to become aware of a potential violation of Federal health care conscience and associated anti-discrimination laws, OCR would assist or require such government or entity to come into compliance. If, despite the Department's assistance, compliance were not achieved, the Department would consider all legal options available to overcome the effects of such discrimination or violations. Enforcement mechanisms would include termination of relevant funding in whole or in part, claw backs, referral to the Department of Justice, or other measures. This proposed rule clarifies that recipients are liable for their own compliance with Federal health care conscience and associated anti-discrimination laws and implementing regulations, as well as for ensuring their sub-recipients comply with these laws. The rule also clarifies that parties subject to OCR investigation have a duty to cooperate and preserve documents and to report that they if they are subject to an OCR enforcement action or investigation to their funding agency.. Finally, the rule grants OCR authority to remedy claims of intimidation and retaliation against those who file a complaint or assist in an OCR investigation.

VIII. Section-by-Section Descriptions of the Proposed Rule

Proposed Section 88.1 Purpose.

The “Purpose” section of the regulation sets forth the objective that the proposed regulation would, when finalized, provide for the implementation and enforcement of Federal health care conscience and associated anti-discrimination laws. It also states that the statutory provisions and regulations contained in this part are to be interpreted and implemented broadly to effectuate their protective purposes.

Proposed Section 88.2 Definitions.

Administered by the Secretary: The Department proposes 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.” This term was used but not defined in the 2008 Rule, and is defined here in order to add clarity.

Assist in the Performance: The Department proposes that “assist in the performance” means “to participate in any activity with an articulable connection to a procedure, health service or health service program, or research activity, so long as the individual involved is a part of the workforce of a Department-funded entity. This includes counseling, referral, training, and other arrangements for the procedure, health service, or research activity.” This definition mirrors the definition used for this term in the 2008 Rule.

In interpreting the term “assist in the performance,” the Department seeks to provide broad protection for individuals, consistent with the plain meaning of the statutes. The Department believes that a more narrow definition of the statutory term “assist in the performance,” such as a definition restricted to those activities

that constitute direct involvement with a procedure, health service, or research activity, would fall short of implementing the protections Congress provided. But the Department acknowledges that the rights in the statutes are not unlimited, and it proposes to limit the definition of “assist in the performance” to activities with an articulable connection to the procedure, health service, health service program, or research activity in question.

Department: The Department proposes to define “the Department” to mean the U.S. Department of Health and Human Services and any component thereof.

Discriminate or Discrimination: The Department proposes to define “discriminate” or “discrimination” to mean, as applicable and as permitted by the applicable statute, (1) to withhold, reduce, exclude, terminate, restrict, or otherwise 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, terminate, restrict, or otherwise make unavailable or deny any benefit or privilege; (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 tends to subject individuals or entities protected under this part to any adverse effect described in this definition, or to have the effect of defeating or substantially impairing accomplishment of a health program or activity with respect to individuals, entities, or conduct protected under this part; or (4) to otherwise engage in any activity reasonably regarded as discrimination, including intimidating or retaliatory action. The 2008 Rule did not

define this term—it is defined here in order to provide clearer notice to the public about what sort of conduct certain provisions of this proposed rule would prohibit.

A functional concept of “discrimination” in this context must account for the various forms that violations of the right of conscience can take. One way Federal law prohibits such violations is by requiring that religious individuals or institutions be allowed a level playing field, and that their beliefs not be held to disqualify them from participation in a program or benefit. For example, a medical school that receives a grant under the Public Health Service Act may not deny admission to an applicant based on that applicant’s conscientious objection to participating in an abortion. 42 U.S.C. 300a-7(e). This form of discrimination, broadly conceived—denial of participation in a program, service, or benefit—parallels the type of discrimination typically prohibited with respect to other protected characteristics such as race, color, or national origin. See 45 CFR 80.3 (HHS regulations implementing Title VI nondiscrimination requirements and prohibiting, *inter alia*, “Deny[ing] an individual any service...”, “Subject[ing] an individual to segregation or separate treatment...”, “Treat[ing] an individual differently from others in determining whether he satisfies any admission...requirement...”, etc., on the basis of race, color, or national origin). HHS believes it appropriate to apply the general principles of nondiscrimination enshrined in Title VI with full force to discrimination on the basis of religious belief or moral conviction.

Freedom from discrimination on the basis of religious belief or moral conviction, however, does not just mean the right not to be treated differently or adversely; it also means being free not to act contrary to one’s beliefs. To that end,

Federal law carves out exemptions based on religious and/or conscientious objection to otherwise generally applicable requirements that compel certain conduct. For instance, as discussed *infra*, although the ACA's individual mandate compels, via force of a tax penalty, the purchase of minimum essential health coverage, that mandate exempts certain religious organizations and individuals who conscientiously oppose acceptance of the benefits of any private or public insurance. 26 U.S.C. 1402(g)(1). OCR solicits comments regarding the impact on the proposed regulation of the planned elimination of the penalty for failure to carry ACA-mandated health insurance as set forth in the major tax reform legislation passed at the end of 2017.

The intersection of religion and health care may also create the more unusual and insidious circumstance in which governmental authorities unlawfully seek to target religious organizations or individuals for additional legal or regulatory burdens, precisely because of their exercise of a particular religious belief or moral conviction. *See Church of the Lukumi Babalu Aye, Inc. v. Hialeah*, 508 U.S. 520 (1993) (striking down facially neutral ordinance gerrymandered to apply only to religiously motivated conduct). The Supreme Court has made clear that governmental burdens on speech targeting particular viewpoints are presumptively unconstitutional. *Matal v. Tam*, 137 S.Ct. 1744, 1766 (2017) (“A law found to discriminate based on viewpoint is an egregious form of content discrimination, which is presumptively unconstitutional.” (internal citations and quotations omitted)). Thus, within OCR's regulatory ambit, and to the extent permitted by law, OCR will regard as presumptively discriminatory any law, regulation, policy, or other such exercise of

authority that has as its purpose, or explicit or otherwise clear application, the targeting of religious or conscience-motivated conduct. In determining the purpose or justification of such an exercise of authority, OCR will consider all relevant factors and proposes to include in that analysis, when supported by the applicable statute, whether or not the exercise of authority has a disparate impact on religious believers or those who share a particular religious belief or moral conviction. The Department solicits comment on whether disparate impact analysis is appropriate, as a policy or legal matter, to apply to any of the statutes implemented by this rule; whether it is appropriately included in the definition of discrimination, and, if so, how disparate impact analysis would be best performed in the context of applicable Federal health care conscience and associated anti-discrimination laws (e.g., how groups suffering the disparate impact can be described under the various statutes).

Entity: The Department proposes to define the term “entity” consistent with the definition of “person” in 1 U.S.C. 1 and also to include any State, political subdivision of any State, instrumentality of any State or political subdivision thereof, and any public agency, public institution, public organization, or other public entity in any State or political subdivision of any State. The 2008 Rule provided identical definitions for both “entity” and “health care entity.” Here, the Department proposes this definition of “entity,” distinct from the definition of “health care entity” set out *infra*, to better fit the use of these terms in the statutes at issue in this proposed rule.

Federal Financial Assistance: The Department proposes to define the term “Federal financial assistance” to include “(1) the grant or loan of Federal funds; (2) the grant or donation 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 Federal agreement, arrangement, or other contract which has as one of its purposes the provision of assistance.” Note that Federal financial assistance includes forms of non-cash assistance. The 2008 Rule did not use the term “Federal financial assistance.” It is employed here to provide greater clarity about what sort of Federal assistance triggers obligations under this part. The Department notes that this term will likely be familiar to much of the health care industry, and is intended in the proposed rule to carry its traditional meaning, such as that provided in the Department’s regulations implementing Title VI of the Civil Rights Act of 1964. *See* 45 CFR 80.13.

Not all of the statutes that the proposed rule would enforce use the term “Federal financial assistance.” This is reflected in the text of the various provisions in § 88.3 of the proposed rule, which set out the proposed rule’s terms regarding the applicability of the statutes being enforced. However, the proposed rule would establish separate requirements regarding assurance and certification of compliance with applicable Federal health care conscience and associated antidiscrimination laws, and regarding the posting of notices regarding those laws. The proposed rule employs the term “Federal financial assistance” in order to help

define who must comply with those separate requirements regarding assurance and certification of compliance and notices.

Health Care Entity: The Department proposes to define the term “health care entity” to include an individual physician or other health care professional, health care personnel, a participant in a program of training in the health professions, an applicant or participant for training or study in the health professions, a postgraduate 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. It may also include components of State or local governments.

The Department’s proposed definition is an illustrative, not exhaustive, list. Like the statutory definitions in the Weldon Amendment and Public Health Service Act, the Department uses the words “include” and “any other kind” to indicate that the list is illustrative. Thus, the Department’s proposed inclusion of the terms “health care professional” and “health care personnel” is intended, for example, to cover pharmacists, nurses, occupational therapists, public-health workers, and technicians, as well as psychiatrists, psychologists, counselors, and other mental health providers, but the definition does not enumerate these health care job categories because they are reasonably included in such terms. To attempt to employ an exhaustive list would run the risk of inadvertently omitting certain types of health care professionals or health care personnel.

With regard to the term “health insurance plan,” the Department proposes that it include the sponsors, issuers, and third-party administrators of health care plans or insurance. The Weldon Amendment specifically includes in its definition of the term “health care entity” “a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of . . . plan” and protects such health care entities from being subject to discrimination on the basis that they do not provide, pay for, cover, or refer for abortions. Thus, to ensure that Congress’s explicit protection for health insurance plans and health care organizations is fully enforced, the Department considers it appropriate to include plan sponsors not primarily engaged in the business of health care as “health care entities” for purposes of the proposed regulation.

We ask for comment on this proposed approach. We also ask for comment on whether the terms “entity” and “health care entity,” as we propose to employ them in relation to the various statutes that this rule implements, clearly and accurately reflect the intent and scope of each of those statutes.

Health Program or Activity: The Department proposes to define “health program or activity” to include 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. In developing an appropriate definition for “health program or activity,” HHS looked at Section 1128B(f)(1) of the Social Security Act, 42 U.S.C. 1320a-7b(f)(1), which defines a similar term, “Federal health care

program,” as “any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government.” This term was not used in the 2008 Rule, and is added here in order that this proposed rule may correspond more precisely to the intended application of the statutes at issue, where the term “health service program” may not suffice.

Health Service Program: For the purposes of this part, the Department proposes to define “health service program” to include 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. This definition mirrors the definition used for this term in the 2008 Rule.

Because subsection (d) of the Church Amendments covers health service programs or research activities administered by the Secretary, these programs include those where the Department provides care or health services directly (*e.g.*, Indian Health Service, NIH Clinical Center); programs administered by the Secretary that provide health services through grants, cooperative agreements, or otherwise (*e.g.*, Administration for Children and Families programs such as the Unaccompanied Alien Children program, and HRSA programs such as community health centers); programs where the Department reimburses another entity that provides care (*e.g.*, Medicare); and health insurance programs where Federal funds are used to provide access to health coverage (*e.g.*, CHIP, Medicaid, and Medicare Advantage). It may also include components of State or local governments. The

Department believes this definition would appropriately effectuate Congress's intent to protect health service programs and research activities funded in whole or in part by, and/or administered by the Secretary.

We have proposed definitions for both "health program or activity" and "health service program" because the phrases are used in different statutes that are the subject of this proposed rule. We ask for comment on whether the terms mean the same thing and should or could be defined interchangeably for purposes of this regulation.

Individual: For purposes of this part, the Department proposes to define "individual" as a member of the workforce of an entity or health care entity. The Department adopts the concept of "workforce" from the Health Insurance Portability and Accountability Act Rules, where it includes volunteers, trainees, or other members or agents of a covered entity, broadly defined, when the conduct of the person is under the control of such entity. This definition mirrors the definition used for this term in the 2008 Rule.

Instrument: The Department proposes to define "instrument" to be the means by which Federal funds are conveyed to a recipient, and to include grants, cooperative agreements, contracts, grants under a contract, memoranda of understanding, loans, loan guarantees, stipends, and any other funding or employment instrument or contract. There are a variety of means by which the Department conveys Federal financial assistance or other Federal funds from the Department to organizations, including: grants, cooperative agreements, contracts, grants under a contract, and memoranda of understanding. The definition of

“instrument” is intended to include all means by which the Department conveys funding and resources. Save for the addition of the phrase “loans, loan guarantees, stipends,” this definition mirrors the definition used for this term in the 2008 Rule.

OCR: The Department proposes to define OCR to signify the Office for Civil Rights of the Department of Health and Human Services.

Recipient: The Department proposes to define “recipient” to mean “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 would include State and local governments, public and private institutions of higher education, public and private hospitals, commercial organizations, and other quasi-public and private nonprofit organizations such as, but not limited to, community action agencies, research institutes, educational associations, and health centers. The term may include foreign or international organizations (such as agencies of the United Nations). This definition differs from the definition used for this term in the 2008 Rule in part because this proposed rule employs the term “Federal financial assistance,” whereas the 2008 Rule did not. Other changes made in this definition are intended to provide clarity about the types of entities that may qualify as recipients.

As discussed elsewhere in this notice of proposed rulemaking, recipients would be subject to this part's requirements regarding assurances and certifications of compliance. The Department seeks to minimize the financial and administrative burdens of the proposed rule by accomplishing the assurances and certifications required of recipients through the forms that recipients are already filing to assure or certify compliance with other applicable nondiscrimination laws. The Department anticipates that the vast majority, if not all, of recipients will be able to fulfill their assurance and certification requirements by using the modified versions of the forms already in use. Accordingly, if an entity is currently required to file an HHS-690 Form, HHS-5161-1 Form, or another similar form assuring or certifying compliance with nondiscrimination requirements in connection with Federal financial assistance from or through the Department, that entity can reliably assume that it is a "recipient" for the purposes of this part.

Referral or Refer for: The Department proposes to define "referral"⁴⁶ or "refer for" as including the provision of any information (including but not limited to

⁴⁶ Various ethicists have discussed how referral constitutes moral cooperation with a conscientiously objected activity. See, e.g., William W. Bassett, *Private Religious Hospitals: Limitations Upon Autonomous Moral Choices in Reproductive Medicine*, 17 J. Contemp. Health L. & Pol'y 455, 529 (2001) ("The moral principle involved in the cooperation and referral situations is called the principle of moral cooperation"); Armand H. Matheny Antommara, *Adjudicating Rights or Analyzing Interests: Ethicists' Role in the Debate Over Conscience in Clinical Practice*, 29 Theor. Med. Bioeth. 201, 206 (2008) ("not contravening one's conscience through illicit cooperation is a significant interest that may obligate one to forego other important interests, such as one's job or even career"); Stephen J. Genuis & Chris Lipp, *Ethical Diversity and the Role of Conscience in Clinical Medicine*, 2013 Int'l. J. Family Med. 1, 9 (2013) ("Facilitating a clinical course of action that the *health provider sincerely deems* to be ill-advised, unethical, or against the patient's best interests may

name, address, phone number, email, or website) by any method (including but not limited to notices, books, disclaimers, or pamphlets online or in print) pertaining to a service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or direction 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. This term was not used in the 2008 Rule. It is added here to address confusion the Department perceives among the public about what sorts of actions may be properly regarded as referrals for the purposes of protecting rights of conscience under the statutes at issue in this proposed rule.

The Weldon Amendment prohibits discrimination on the basis that a health care entity does not “refer for abortions.” The Coats-Snowe Amendment prohibits discrimination on the basis that an entity refuses to “provide referrals for [induced abortions],” “refuses to make arrangements for” such referrals, or attends a health profession training program that does not “refer for training in the performance of induced abortions.” Section 1303 of the ACA prohibits qualified health plans offered through an exchange from discriminating against any individual health care provider or health care facility because of its unwillingness to refer for abortions. 42 U.S.C. 18023(b)(4). Medicare Advantage contains a protection for entities that

compromise the integrity of the professional role and may violate fundamental tenets of such ethical codes”).

inform HHS that they will not provide referrals for abortions. Consolidated Appropriations Act of 2017, Pub. L. 115-31, 131 Stat. 502, Div. H, sec. 209 (2017). Certain recipients of funds administered by Secretary under the Foreign Assistance Act cannot be required to make a referral to a program or activity to which the recipient has a religious or moral objection. 22 U.S.C. 7631(d). Medicare Advantage plans and Medicaid managed care organizations are protected from being required to provide certain referral services. 42 U.S.C. 1395w-22(j)(3); 42 U.S.C. 1396u-2.

The Department believes that Congress provided, in these Federal health care statutes, protections for entities from discrimination in a broad way related to referring for abortions or abortion training, or, as specified in applicable statutes, for other kinds of services. In the Coats-Snowe Amendment, for example, Congress protected not only the refusal to provide referrals for abortion, but also the refusal to make arrangements to provide referrals for abortion. This protects entities that object not just to making referrals, but to rendering aid to anyone else who is reasonably likely to make an abortion referral. Likewise, in the Weldon Amendment and Section 1303 of the ACA, Congress specified that it 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.

Under the proposed definition, to provide an abortion referral, refer for abortion, or make arrangements for an abortion referral, would include such activities as providing to a patient seeking abortion contact information of a physician or clinic that may provide an abortion, or telling a patient that funding is

available for abortion and providing a phone number where she can be referred to abortion services or funding. It would include such activities by any method, such as orally, in writing, digitally, or through the posting of notices. The Department believes defining referral or refer in a more narrow way, for example to only mean an endorsement, recommendation, facilitated referral to a physician, or transfer of records to a specific provider, would fail to implement Congress's broad protection for entities unwilling to be complicit in the provision of items or services they cannot in good conscience themselves provide.

State: The Department proposes to define "State" to include, in addition to the several States, the District of Columbia. For those provisions in this part related to or relying upon the Public Health Service Act, the term "State" is proposed to include the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands. For those provisions in this part related to or relying upon the Social Security Act, the term "State" is proposed to incorporate the definition of "State" found at 42 U.S.C. 1301. This term was not defined in the 2008 Rule but is added here to reflect that the term carries different meanings in certain statutes at issue in this proposed rule. The Department seeks comment on whether this definition fully and accurately implements the scope of the statutes that are the subject of this proposed rule, especially with regard to statutes that cover State and local government or other public authorities.

Sub-recipient: The Department proposes to define "sub-recipient" to mean "any political subdivision of any State, any 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 another 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 includes State and local governments, public and private institutions of higher education, public and private hospitals, commercial organizations, and other quasi-public and private nonprofit organizations such as, but not limited to, community action agencies, research institutes, educational associations, and health centers. The term may include foreign or international organizations (such as agencies of the United Nations). As with the definition of “recipient,” this definition differs from the 2008 Rule’s definition of this term in part because of the use of the term “Federal financial assistance,” and also in order to provide greater clarity about the types of potentially covered entities.

Workforce: The Department proposes to define “workforce” to consist of 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. This definition substantially mirrors the definition used for this term in the 2008 Rule.

Proposed Section 88.3 Applicable Requirements and Prohibitions.

The proposed “Applicability” section outlines the specific requirements of the Federal health care conscience and associated anti-discrimination laws that apply to various persons and entities. These provisions are 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” section explains the obligations that the Federal health care conscience and associated anti-discrimination statutes impose on the Department and on entities that receive applicable Federal financial assistance and other Federal funding from the Department. These provisions are taken from the relevant statutory language.

We intend for the proposed requirements and prohibitions to be interpreted using the definitions proposed in section 88.2.

Proposed Section 88.4 Assurance and Certification of Compliance Requirements.

In the “Assurance and Certification of Compliance” section, the Department would require certain recipients to submit written assurances and certifications of compliance with the Federal health care conscience and associated anti-discrimination laws, as applicable, as a condition of the terms of acceptance of the Federal financial assistance or other Federal funding from the Department. While the 2008 Rule required only the submission of a certification of compliance, the Department believes that both an assurance and certification provide important protections to persons and entities under these laws and would be consistent with requirements under other civil rights laws. We are concerned that there is a lack of

knowledge on the part of States, local governments, and the health care industry of the rights of protected persons and entities, and the corresponding obligations on covered entities provided by the Federal health care conscience and associated anti-discrimination laws. Certifications provide a demonstrable way of ensuring that applicants for such funding know of, and attest that they will comply with, applicable Federal health care conscience and associated anti-discrimination laws.

Applicants for Department grants, loans, contracts, Federal financial assistance, or other Federal funds from the Department are currently required to sign assurances and certifications of compliance with several specific civil rights laws, such as Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975. *See* HHS-690 Form, OMB No. 0945-0006 (Medicare Part A); HHS-5161-1 Form, OMB No. 0930-0367 (HHS Grant Applications). The assurances and certifications of compliance required by this part would be accomplished via submission of modified versions of the applicable civil rights clearance forms, such as the HHS-5161-1 Form, HHS-690 Form, or similar forms that may be developed and implemented in the future.

The HHS-690 Form (Assurance of Compliance) briefly identifies the prohibited discriminatory conduct covered by each civil rights law. Although many Federal health care conscience and associated anti-discrimination laws were enacted at approximately the same time as those other civil rights laws, such conscience laws are not specifically mentioned in Form HHS-690 Form or HHS-5161-1 Form. Adding the above-referenced laws to these forms would increase

awareness of the Federal health care conscience and associated anti-discrimination laws and demonstrate the Department's commitment to consistently enforcing all civil rights protections on an equal basis. The certification form serves to provide a formal statement by the recipient, generally subsequent to the submission of the assurance that the recipient actually is currently in compliance with the referenced requirements.

Given this backdrop, section 88.4 proposes 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 health care conscience and associated anti-discrimination provisions and this part. Consistent with current practice, we propose covered applicants file the HHS-690 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, proposed § 88.4(b)(6) permits an applicant to incorporate the assurance by reference in subsequent applications to the Department. The proposed rule explains that both the assurance and certification shall 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) clarifies that a violation of the requirements of the certification may result in enforcement by the Department, as provided in section 88.7 of this part.

The Department believes that requiring assurances and certifications of compliance by applicants for and recipients of Federal financial assistance and other

Federal funds from the Department would provide an important vehicle for increasing awareness of Federal health care conscience and associated anti-discrimination laws and thereby increasing compliance. While many people in the health care field may have general knowledge that Federal health care conscience and associated anti-discrimination protections exist for persons and health care providers, the scope of these protections is not always widely understood. Because Congress has enacted several different protections, a person or entity may be aware that, for instance, a physician may not be compelled to perform abortions, but may not be aware of other aspects of the statutes providing Federal health care conscience and associated anti-discrimination protections. Others may become aware of these laws, at least in detail, only when a dispute arises and a person, provider, or entity attempts to assert their Federal health care conscience rights, and there may be subsequent disagreement over the nature of the rights asserted.

The Department recognizes that it needs to undertake significant outreach efforts in order for the rule to be maximally effective. Thus, the Department will consider all avenues available for increasing public awareness of Federal health care conscience laws. The Department welcomes public comment on the various options available for public education and outreach.

Paragraph (b) identifies specific requirements for the proposed assurance and compliance requirements: (b)(1) addresses the timing to submit the assurance for current applicants or recipients as of the effective date of this part; (b)(2) addresses the form and manner of such submittals; and (b)(3) addresses the duration of obligations for both the assurance and certification. In regard to the

form and manner of the submission, the Department is committed to leveraging existing grant, contract, and other Departmental forms where possible rather than creating additional, separate forms for recipients to sign. To this end, § 88.5(4)(2) explains that applicants shall 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. Such certifications should be clearly written so that applicants and recipients know, by means of the certification, which provisions they must comply with based on the nature of the recipient or the funding mechanism through which it receives funds.

Department components will 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 intends 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 fails or refuses to furnish a required assurance or certification, OCR, in coordination with the relevant Department component, may effect compliance by any of the remedies provided in § 88.7.

While both recipients and sub-recipients, as defined herein, must comply with the substantive requirements of Federal health care conscience and associated anti-discrimination laws, as applicable, sub-recipients are not subject to the requirements of section 88.4 regarding assurance and certifications of compliance. This approach departs from the 2008 Rule, which required certifications of

compliance to be submitted by both recipients and sub-recipients. By exempting sub-recipients from this requirement, the Department seeks to cut down on administrative burdens. The Department invites 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.

Section 88.4(c) also contains 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 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.

Requiring the large number of entities in these four categories to submit assurance and certification requirements would pose significant implementation hurdles for Departmental components, programs, and services. Furthermore, the Department believes that, due primarily to their generally smaller size, several of the excepted categories of recipients of Federal financial assistance or other Federal funds from the Department are less likely to encounter the types of issues sought to

be addressed in this regulation. For example, State Medicaid programs are already responsible for ensuring the compliance of their sub-recipients as part of ensuring that the State Medicaid program is operated consistently with applicable nondiscrimination provisions. Similarly, certain programs currently administered by the Administration for Children and Families and the Administration on Community Living involve the provision of grants to States and other governments, or cash assistance or vouchers rather than direct services, and they are not likely to involve medical research, the participation of health care providers, or referral to health care providers.

Excepted providers, however, may become subject to the assurance and certification requirement if they receive Federal financial assistance or Federal funds from the Department through a mechanism or in a manner not excepted by this section. For example, a physician office participating in Medicare Part B may become subject to the written certification requirement by receiving Department funds to conduct clinical research. And it is important to emphasize that no exemption from the requirements of this regulation regarding notice, assurances, or certifications relieves the Department, recipients, or sub-recipients, and State and local governments, of their obligations to comply with these longstanding Federal health care conscience laws.

The Department seeks 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.

Proposed Section 88.5 Notice Requirement.

The proposed rule adds a “Notice” section that was not contained in the 2008 Rule. This section requires the Department and recipients to notify the public, patients, and employees, which may include students or applicants for employment or training, of their protections under the Federal health care conscience and associated anti-discrimination statutes and this regulation.

For consistency with other notice requirements in civil rights regulations, paragraph (a) of § 88.5 proposes to require the Department and recipients to post the notice in Appendix A within 90 days of the effective date of this part. This notice advises persons and entities about their rights and the Department’s and recipients’ obligations under Federal health care conscience and associated anti-discrimination laws. The notice provides information about how to file a complaint with OCR. We seek comment on whether there are categories of recipients that should be exempted from this requirement to post such notices.

The proposed rule requires all Department components and recipients to use the notice text in Appendix A. This approach maximizes efficiency and economies of scale by enabling recipients to leverage the text of an HHS-authored notice. We invite 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) sets forth two categories of locations where the notice must 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) imposes readability requirements without identifying prescriptive font-size or other display requirements. The proposed readability specifications advance the goal for the notice content to appear sufficiently conspicuous and visible that persons observing it could reasonably be expected to see and be able to read the information.

Proposed paragraph (c) incentivizes recipients to display the notice in locations other than their websites and physical establishments. In the event that the OCR Director, pursuant to the proposed enforcement authority in section 88.7 of this part, investigates or initiates a compliance review of a recipient, the OCR Director will consider as one of many factors in compliance whether the recipient posted the notice in the documents described in paragraphs (c)(1)-(3), as applicable. Because this part regulates a diverse range of recipients, we identified three categories of documents most common across all recipients. We seek comment on the proposed approach of paragraph (c) and on the categories of documents identified in paragraphs (c)(1)-(3).

Finally, we recognize that recipients may be subject to other notice requirements under Federal and State law. Paragraph (d) of § 88.5 proposes to permit recipients to combine the text of the notice required in paragraph (a) with other notices under the condition that the recipient retains all of the language provided in Appendix A of this part in an unaltered state. Instead of regulating the manner of compliance, we considered permitting recipients to integrate and revise the text of the notice required in paragraph (a) with other notices. Although this

approach permits greater flexibility, it invites potential unintentional misrepresentation of Federal health care conscience and associated anti-discrimination rights. We request comment on whether paragraph (d) strikes the best balance based on recipients' experiences.

Proposed Section 88.6 Compliance Requirements.

This section identifies specific requirements for compliance with the Federal health care conscience and associated anti-discrimination laws. Recipients and other agency components must maintain records evidencing compliance with these laws and the proposed regulation and are required to cooperate with OCR in the enforcement process. If a recipient or sub-recipient is subject to an OCR compliance review, investigation, or complaint filed with OCR regarding the recipient's or sub-recipient's compliance with Federal health care conscience and associated anti-discrimination laws, the recipient or sub-recipient must inform any Departmental funding component of such review, investigation, or complaint. The recipient or sub-recipient must also, in any application for new or renewed Federal financial assistance or Departmental funding, disclose the existence of such compliance review or investigation, and must also report on such applications the existence of any complaints filed with OCR if a complaint had been filed in the previous five years before the recipient's or sub-recipient's application. This section also addresses 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.

Proposed Section 88.7 Enforcement Authority.

This section reaffirms the delegation to OCR of the Department's authority to enforce the Federal health care conscience laws, in collaboration with the relevant Department components. OCR has been expressly delegated the authority to enforce the Church, Coats-Snowe, and Weldon Amendments since the 2008 Rule. Enforcement of section 1553 is expressly delegated to OCR in the ACA. Each of the Federal health care conscience laws, by virtue of Congressional enactment, requires compliance by the Department and covered entities. This NPRM provides notice that the Secretary has delegated to OCR the authority to enforce all Federal health care conscience and associated anti-discrimination laws that are the subject of the proposed rule. This section also includes retaliation claims in the event a covered entity takes any such retaliatory actions against those who participate in or assist an OCR enforcement action.

This section also specifies that OCR's enforcement authority includes 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 health care conscience and associated anti-discrimination laws and the proposed regulation, as allowed by law. The current text of § 88.7 of this part grants 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 Director may, in coordination with a relevant Department component, restrict funds for noncompliant entities in whole or in part, including by limiting funds to certain

programs and particular covered entities, or by restricting a broader range of funds or broader categories of covered entities, as allowed by law to effectuate the Federal health care conscience laws. In addition to withdrawal of funding, possible corrective actions include settlements or voluntary resolution agreements where allowed. OCR can also refer cases to the Department of Justice for additional enforcement, and in coordination with the relevant Department component.

The proposed rule would also make explicit the Department's authority to investigate and handle violations and conduct compliance reviews whether or not a formal complaint has been filed. That language is consistent with OCR's enforcement practices under other civil rights laws, and with the Department's obligation to enforce Federal health care conscience and associated anti-discrimination laws. Under the proposed rule, OCR would also be explicitly authorized to investigate "whistleblower" complaints, or complaints made on behalf of others, whether or not the particular complainant is a person or entity protected by conscience and associated antidiscrimination laws.

This section adopts the enforcement procedures for other civil rights laws, such as Title VI and Section 504 of the Rehabilitation Act. *See, e.g.*, 45 CFR 80.8 through 80.10 and 84.7. If the Department becomes aware that a State or local government or an entity may have undertaken activities in violation of statutory conscience and associated antidiscrimination laws, the Department will work with such government or entity to provide assistance and guidance to recipients to help them comply voluntarily with the law and this part. For compliance, recommended best practices (as identified in the Department's other civil rights regulations)

include such procedures as: (1) the designation of at least one employee responsible for compliance, (2) the adoption of internal grievance procedures to provide for prompt and equitable resolution of complaints, and (3) the preparation of internal compliance reports by recipients, sub-recipients, participants, and beneficiaries.

If, despite the Department's assistance, compliance is not achieved, the Department will consider all legal options, up to and including termination of funding and return of funds, as applicable. Remedial measures include the temporary withholding of cash payments in whole or part, pending correction of the deficiency, the denial of funds and any applicable matching credit in whole or in part, the suspension or termination of the Federal award in whole or in part, the withholding of new Federal financial assistance or other Federal funds from the Department, referral of the matter to the Attorney General for enforcement proceedings, and any other remedies that may be legally available.

The Department solicits 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 health care conscience and associated antidiscrimination 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(j)(3) of the proposed rule. For example, comment is 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. We also request comment on whether and in what circumstances it is appropriate to require remedies against a recipient for the violations of a sub-recipient, or against entities whose subsidiaries are found to be in violation of any Federal health care conscience and associated antidiscrimination law or the proposed regulation.

Proposed Section 88.8 Relationship to Other Laws.

This section clarifies the relationship between this part and other Federal, State, and local laws that protect religious freedom and moral convictions. Many State laws provide additional conscience protections for providers who have objections to abortion, fertility treatments, sterilization, capital punishment, assisted suicide, and euthanasia.⁴⁷ The Department proposes to uphold the

⁴⁷ See, e.g., Ala. Code 15-18-82.1(i) (2017); Alaska Stat. 18.16.010(b), 13.52.060(e) (2017); Ariz. Rev. Stat. Ann. 20-826(Z), 20-1057.08(B), 20-1402(M), 20-1404(V), 20-2329(B), 20-2329(C), 36-3205(C)(1), 36-2154 (2017); Ark. Code Ann. 20-13-1403(b), 20-16-304(4)-(5), 20-16-601, 23-79-1103(b), 23-79-1104(b)(3) (2017); Cal. Prob. Code 4734 (West 2017); Cal. Penal Code 3605(c) (West 2017); Cal. Bus. & Prof. Code 733(b)(3) (West 2017); Cal. Health & Safety Code 443.14(b), (e), 443.15, 1367.25(c), 1374.55(e)-(f), 123420 (West 2017); Cal. Ins. Code 10119.6(d)-(e), 10123.196(e) (West 2017); Colo. Rev. Stat. 25-6-102(9), 25-6-207, 25-3-110(3) (2017); Conn. Gen. Stat. 38a-503e(b), (e), 38a-536(c), 38a-509(c), 38a-530e(b), (e), (2017); Del. Code Ann. tit. 24, 1791, tit. 18, § 3559(d) (2017); Fla. Stat. 381.0051(5), 390.0111(8), 409.973(1)(h), 765.1105, 922.105(9) (2017); Ga. Code Ann. 16-12-142, 17-10-38(d), 31-20-6, 49-7-6 (2017); Haw. Rev. Stat. 431:10A-116.7, 453-16(e), 327E-7(e) (2017); Idaho Code Ann. 18-611, 18-612, 39-3915 (2017); 745 Ill. Comp. Stat. 70/1-70/14 (2017); 215 Ill. Comp. Stat. § 5/356m(b)(2) (2017); 720 Ill. Comp. Stat. § 510/13 (2017); 745 Ill. Comp. Stat. § 30/1 (2017); Ind. Code 16-34-1-3 to -7 (2017); Iowa Code 146.1-.2 (2017); Kan. Stat. Ann. 65-443, -444, 65-446, -447, 65-1637(n), 65-6737 (2017); Ky. Rev. Stat. Ann. § 311.800(3)-(5) (West 2017); La. Rev. Stat. Ann. 15:569(C), 15:570(C), 40:1061.2-.3, 40:1061.4(C), 40:1061.20 (2017); Me. Rev. Stat. tit. 18-A, 5-807(e), tit. 32, 13795(2-3), tit. 22, 1591-1592, 1903(4), tit. 24, 2332-J(2), tit. 24-A, 2756(2), 2847-G(2), 4247(2), tit. 34-B, § 7016

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 will not construe Federal law to preempt or impair the application of that law, unless expressly provided.

This section is new to this proposed rule with no analog in the 2008 Rule.

The proposed rule does 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

(2017); Md. Code Ann., Health-Gen. 20-214 (West 2017); Md. Code Ann., Ins. 15-810(i), 15-826(c) (West 2017); Mass. Gen. Laws ch. 112, 12I, ch. 272, 21B, ch. 175, 47W(f), ch. 176A, 8W(f), ch. 176B, 4W(f), ch. 176G, 40(c) (2017); Mich. Comp. Laws Serv. 333.20181 to 333.20184 (2017); Minn. Stat. 145.414, 145.42, 145.925(6) (2017); Miss. Code Ann. 41-41-215(5), 41-107-5 to -9 (2017); Mo. Rev. Stat. 188.105-.110, 191.724, 197.032, 338.255 (2017); Mont. Code Ann. § 50-20-111, 50-5-502 to -505 (2017); Neb. Rev. Stat. 28-337 to -341 (2017); Nev. Rev. Stat. 449.191, 632.475, 689A.0415(5), 689A.0417(5), 689B.0376(5), 689B.0377(5), 695B.1916(5), 695B.1918(5), 695C.1694(5), 695C.1695(5) (2017); N.J. Stat. Ann. 2A:65A-1, to -3, 17B:27-46.1x(b), 17:48A-7w(b), 17:48-6x(b), 17:48E-35.22(b), 26:2J-4.23(b), 17:48-6ee, 17:48A-7bb, 17:48E-35.29, 17B:27-46.1ee, 17B:26-2.1y, 26:2J-4.30, 17B:27A-19.15, 17:48F-13.2, 17B:27A-7.12 (West 2017); N.M. Stat. Ann. 24-8-6(A)(2), 24-7A-7(E), 30-5-2, 59A-22-42(D), 59A-46-44(C) (2017); N.Y. Civ. Rights Law § 79-i (McKinney 2017); N.Y. Ins. Law 3221(l)(16)(A), 4303(cc)(1) (McKinney 2017); N.C. Gen. Stat. § 14-45.1(e)-(f), 58-3-178(e) (2017); N.D. Cent. Code § 23-16-14 (2017); Ohio Rev. Code Ann. § 4731.91 (West 2017); Okla. Stat. tit. 63, 1-568, 1-728c to -728f, 1-741 (2017); Or. Rev. Stat. 127.625, 127.885, 435.225, 435.475, 435.485 (2017); 43 Pa. Cons. Stat. 955.2 (2017); 18 Pa. Cons. Stat. 3213(d) (2017); R.I. Gen. Laws 23-17-11, 27-18-57, 27-19-48, 27-20-43, 27-41-59 (2017); S.C. Code Ann. 44-41-40, 44-41-50 (2017); S.D. Codified Laws 34-23A-11 to -14, 36-11-70 (2017); Tenn. Code Ann. 39-15-204 to -205, 68-34-104(5) (2017); Tex. Ins. Code Ann. 1271.007, 1366.006, 1369.108 (West 2017); Tex. Occ. Code Ann. 103.001-.004 (West 2017); Utah Code Ann. sec. 76-7-306 (West 2017); Vt. Stat. Ann. tit. 18, 5285-5286 (2017); Va. Code Ann. sec. 32.1-134, 18.2-75, 54.1-2957.21 (2017); Wash. Rev. Code Ann. 9.02.150, 48.43.065(2), 70.47.160(2), 70.245.190 (2017); W. Va. Code 16-2B-4, 16-11-1, 16-30-12 (2017); Wis. Stat. 253.07(3)(b), 253.09, 441.06(6), 448.03(5)(A) (2017); Wyo. Stat. Ann. 42-5-101(d) -102, 35-6-105 to-106 (2017).

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. OCR will enforce all civil rights laws consistent with the Constitution and the statutory language.

Proposed Section 88.9 Rule of Construction.

This section ensures that the protections for religious freedom and moral conviction provided by this part shall be construed broadly and to the maximum extent permitted by law and the Constitution.

Proposed Section 88.10 Severability.

This section is a “severability clause” for the proposed regulation that provides that, if any provision or part of a provision of the proposed regulation is held to be invalid or unenforceable, either facially or as applied, the provision in question will be construed in a manner that allows it to remain in force to the maximum extent permitted by law. Furthermore, if a provision of the proposed regulation is held to be invalid or unenforceable, that provision is severable from the rest of the proposed regulation, which remains in full force and effect to the maximum extent permitted by law. A severed provision shall not affect the remainder of the proposed regulation, and where possible the severed provision remains in effect as applied to other persons or situations not similarly situated, or to other dissimilar circumstances.

IX. Request for Comment

In addition to the requests for comments mentioned elsewhere in this notice of proposed rulemaking, the Department, in order to draft its final rule to best

reflect the experiences and concerns of those most impacted, seeks comment on this Proposed Rule. In particular, the Department seeks the following:

- Comment on all issues raised by the proposed regulation.
- Information, including any facts, surveys, audits, or reports, about the occurrence or nature of coercion, discriminatory conduct, or other violations of the Federal health care conscience and associated anti-discrimination laws.
- Information, including any facts, surveys, audits, or reports, with regard to the general knowledge, or lack thereof, of the protections established by the Federal health care conscience and associated anti-discrimination provisions among the general public, as well as within the health care field, health care insurance industry, and employment law field.
- Information, including any facts, surveys, audits, or reports, on whether public authorities continue to claim that the receipt of Federal funds is a sufficient basis for entities to be required to participate in abortions or sterilizations. If so, comment on how the Department should address this problem.
- Information, including any facts, surveys, audits, or reports, about whether parents or legal guardians are discriminated against based on objections to testing or treatment of their minor children.
- Information, including any facts, surveys, audits, or reports, about whether individuals or entities have been coerced or discriminated against based on their religious or moral objection to counseling or referral.

- Information, including any facts, surveys, audits, or reports, about whether health care insurers, health plan sponsors, and health plan participants have religious or moral objections to certain health insurance coverage.

- Information, including any facts, surveys, audits, or reports, about whether applicants for Federal financial assistance from the Department, who would otherwise been eligible for such assistance, have been discriminated against based on their religious or moral objections.

- Information, including any facts, surveys, audits, or reports, about whether individuals did not enter a health care field or a certain specialty because of concerns that their conscientious objections would not be accommodated.

- Information, including any facts, surveys, audits, or reports, about whether certain populations in the health care field, such as students or nurses, face or are vulnerable to discrimination in violation of the Federal health care conscience and associated anti-discrimination laws, and how outreach and enforcement might be tailored to respond to those needs.

- Information, including any facts, surveys, audits, or reports, about the occurrence of coercion or discrimination against health care practitioners or professionals related to the implementation of advance directives.

- Information, including any facts, surveys, audits, or reports, about coercion or discrimination against religious nonmedical health care institutions and their patients.

- Information, including any facts, surveys, audits, or reports, 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.

- Comment on whether particular circumstances might exist that present a higher risk of undetected unlawful discrimination, such as the medical residency application process, and how the rule might address such problems.

- Comment on whether the voicing of health care conscience and associated anti-discrimination objections protected by Federal law is chilled by State laws, State agency action, lack of perceived remedies, threat of litigation, or threat of losing legal status, such as a medical license.

- Comment on whether the definition of “individual” in relation to “workforce” artificially circumscribes the scope of protections afforded by the Church Amendments that protect individuals and individual rights.

- Comment on whether the definition of “recipient” appropriately defines the scope of entities that should be subject to the rule’s requirements regarding notice and assurances or certifications, including whether those requirements should be extended to sub-recipients.

- Comment on whether the definition of “referral or refer for” appropriately defines the scope of activities that should be encompassed by the rule’s protections.

- Comment on whether the definition of “assist in the performance” appropriately defines the scope of activities that should be encompassed by the rule’s protections.

- Comment on whether written certifications of compliance with nondiscrimination laws should contain additional language.
- Comment on the appropriateness of exceptions to the certification requirements.
- Comment on what constitutes the most effective method of educating recipients of Department funds and their employees about the protections of the Federal health care conscience and associated anti-discrimination laws.
- Comment on what constitutes the most effective method for recipients of Department funds to provide notice about the requirements and prohibitions in the Federal health care conscience and associated anti-discrimination laws to employees, students, applicants, and sub-recipients.
- Comment on whether State or local government laws, policies, or enforcement activities conflict with or make it difficult to ensure compliance with Federal health care conscience and associated anti-discrimination laws.
- Comment on whether policies and practices at covered entities appear to conflict with the health care conscience and associated anti-discrimination laws or make it difficult to ensure compliance with those laws.
- Comment on whether the rule provides adequate clarity regarding the respective obligations of recipients and sub-recipients, and regarding the potential consequences of noncompliance with those obligations.
- Comment on whether the exemptions in section 88.4(c) for certain grant programs currently administered by the Administration for Children and Families and the Administration for Community Living are meaningful given the requirement

that the grant program involve no significant likelihood of referral for the provision of health care.

- Comment on whether, and how, the proposed rule should address the scheduled elimination of the penalty under the Patient Protection and Affordable Care Act for an individual's failure to carry minimum essential health coverage.

- Comment on whether alternate remedies, such as lawsuits, have been sufficient to protect individuals and entities from discrimination, coercion, or other treatment prohibited by the health care conscience and associated anti-discrimination laws.

- Comment on whether any provisions in the proposed rule would result in an unjustified limitation on access to health care or treatments.

- Comment on which enforcement tools OCR, as a policy matter, ought to employ, such as compliance reviews, investigations, and alternate disbursement of funds.

- Comment on whether the proposed rule 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), and whether the rule clearly and appropriately addresses its application to Federal funds that are contracted or compacted out to tribal nations.

- Comment on whether Urban Indian organizations, as defined by 25 U.S.C. 1603(29), operating a Title V Urban Indian Health Program that currently has a grant or contract with the IHS under Title V of the Indian Health Care Improvement

Act, (Pub. L. 93-437), should be exempted from the proposed rule's requirements regarding assurances and certifications of compliance.

- Comment on whether the proposed rule should apply to Tribes, which are recipients of Federal financial assistance through compact agreements or are awarded Federal contracts. Furthermore, the Department requests comment on exemptions for any Indian Tribes under the notice and certification requirements. Additionally, the Department solicits comment on the rule's impact on Tribal sovereignty.

- Comment on whether the notice text provided in Appendix A to this rule strikes the appropriate balance between, on the one hand, affirming rights of conscience in a simple and reader-friendly manner, in general terms suitable for use by all recipients; and on the other, reflecting the complexities and variations in the application of Federal health care conscience and associated anti-discrimination laws to different covered entities and protected parties in different contexts.

- Consistent with the Paperwork Reduction Act, comments regarding the burden of the requirement for covered entities to report if they are the subject of an OCR investigation the Department in any requests for new or renewed Federal financial assistance or Federal funds in the five years subsequent to the filing of the relevant OCR complaint.

- Consistent with the Paperwork Reduction Act, comments regarding the burden and cost estimates, or regarding any other aspect of the collection of information proposed in this rule as discussed below.

X. Public Participation

Because of the large number of public comments we normally receive on *Federal Register* documents, we are not able to acknowledge or respond to them individually. We will consider all comments that are received by the date and time specified in the DATES section of the Preamble.

Written comments mailed or hand delivered must include one original and two copies. Mailed comments may be subject to security delays due to security procedures. Please allow sufficient time for mailed comments to be timely received in the event of delivery delays. Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the lobby of the building. Electronic comments with attachments should be in Microsoft Word or Excel; however, we prefer Microsoft Word. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.

XI. Delegations of Authority

Notice is hereby given that I have delegated to the Director of the Office for Civil Rights (OCR), with authority to redelegate, the authority to enforce the following Federal health care conscience and associated anti-discrimination laws:

- Conscience protections related to abortion, sterilization, and other lawful health services among recipients of funds and participants in programs, and their personnel, where funded by the Department (the Church Amendments, 42 U.S.C. 300a-7);

- Conscience protections for health care entities related to abortion, training, or accreditation (the Coats-Snowe Amendment, section 245 of the Public Health Service Act, 42 U.S.C. 238n);
- Provisions protecting health care entities and individuals that do not act to further abortion or other practices from discrimination by recipients of funding under the Department's annual appropriations acts (*e.g.*, Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, sec. 507(d) (the Weldon Amendment); Div. H, sec. 209);
- Patient Protection and Affordable Care Act protections related to assisted suicide (42 U.S.C. 18113), the requirement to issue certifications of exemption from the individual mandate with respect to membership in exempt religious sects or divisions or health care sharing ministries (26 U.S.C. 5000A(d)(2)), and the conscience provisions with respect to abortion (42 U.S.C. 18023(c)(2)(A), (b)(1)(A), and (b)(4));
- 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));
- Protections related to the performance of advanced directives in Medicare and Medicaid (42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406);
- Protections related to Global Health Programs to the extent administered by the Secretary (22 U.S.C. 7631(d); Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. J, sec. 7018 (Helms Amendment));

- Exemptions 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 care in the Medicare, Medicaid, and CHIP programs (42 U.S.C. 1320a-1; 1320c-11; 1395i-5; 1395x(e); 1395x(y)(1); 1396a(a); 1396b(i)(4); 1397j-1(b); and 5106i(a)(2)).

Pursuant to these delegations, the OCR Director shall have the authority:

To receive and handle complaints of discrimination or any other potential violation of the Federal health care conscience and associated anti-discrimination laws and/or these regulations at 45 CFR Part 88 by recipients, sub-recipients, or Department components;

To initiate and conduct compliance reviews and investigate incidents of discrimination or any other potential violation of the Federal health care conscience and associated anti-discrimination laws and/or these regulations by recipients, sub-recipients, or Department components;

To supervise and coordinate OCR's investigations or compliance reviews with the relevant Department components;

To delegate responsibilities to other officials of the Department in connection with the effectuation of Federal health care conscience and associated anti-discrimination laws and these regulations, including the achievement of effective coordination and maximum uniformity within the Department; and

To take remedial action as the Director of OCR deems necessary and as allowed by law to overcome the effects of violations of Federal health care conscience and associated anti-discrimination laws and this part, in coordination with the relevant component or components of the Department.

If there appears to be a failure or threatened failure to comply with Federal health care conscience and associated 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 funding component:

Temporarily withholding cash payments, in whole or in part, pending correction of the deficiency;

Denying use of Federal financial assistance or other Federal funds from the Department, including any applicable matching credit, in whole or in part;

Wholly or partly suspending award activities;

Terminating Federal financial assistance or other Federal funds from the Department, in whole or in part;

Withholding new Federal financial assistance or other Federal funds from the Department, in whole or in part, 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;

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, created by Federal law; and

Taking any other remedies that may be legally available.

This delegation is effective upon signature. I hereby affirm and ratify any actions taken by the OCR Director or the Director's subordinates which involved the exercise of the authorities delegated herein from April 1, 2017, to the effective date of this delegation.

XII. Regulatory Impact Analysis

A. Introduction and Summary

The Department has examined the impacts of the proposed 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, section 654, 5 U.S.C. 601 (note)), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

This rule proposes to revise the regulation that allows OCR to accept and coordinate the handling of complaints alleging violations of the Weldon, Church, and Coats-Snowe Amendments 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, the proposed rule:

1) Aligns the regulation’s scope to comport with the full panoply of Federal health care conscience and associated anti-discrimination laws that exist across the Department and that the Secretary has delegated to OCR to enforce,

2) Expands the scope of enforcement mechanisms available to OCR to be consistent with mechanisms used by OCR to enforce similar civil rights laws, as appropriate,

3) Requires certain persons and entities covered by this proposed rule to adhere to certain procedural and administrative requirements that aim to elevate awareness of Federal health care conscience and associated anti-discrimination rights and certain obligations of persons and entities.

Table 1. Accounting Table of Benefits and Costs of All Proposed Changes

	Present Value		Annualized	
	over 5 Years by		Value over 5 Years by	
	Discount Rate		Discount Rate	
	(Millions of		(Millions of 2016	
	2016 Dollars)		Dollars)	
BENEFITS	3	7	3	7
	Percent	Percent	Percent	Percent
Quantified				
Benefits	--	--	--	--
Non-quantified Benefits				
Balance of personal freedom and moral commitment; more diverse and				

inclusive workforces; improved provider patient relationships; equity, fairness, nondiscrimination				
COSTS	3	7	3	7
	Percent	Percent	Percent	Percent
Quantified Costs	692	562	165	168
	.1	.7	.1	.1
Non-quantified Costs Any ancillary costs resulting from a protection of conscience rights				

The Department estimates that the benefits of this rule, although not quantifiable or monetized, justify the burdens of the regulatory action. The Department estimates that implementation of this rule will, on average, cost \$312.3 million in year one and \$125.5 million annually in years two through five. Considering the number of entities affected and excluding the costs to OCR, this rule is estimated to cost each affected person, entity, and health care entity, on average, \$665 in year one, which drops by 60% to about \$266 annually in years two through five.

Analysis of Economic Impacts: Executive Orders 12866 and 13563

HHS has examined the economic implications of this proposed 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).

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.

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.

As discussed throughout this impact analysis, the Department considered these objectives in its analyses of this proposed rule. In doing so, the Department used the best reasonably obtainable technical and economic information to determine that this proposed 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 Proposed Rule

(i) Problems that the Proposed 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 proposed rule seeks to address two categories of problems: (1) inadequate enforcement tools to address discrimination and coercion associated with conscience objections by persons, entities, or health care entities, and (2) intolerance for certain Federal health care conscience and associated anti-discrimination rights, in part due to confusion about the law, leading to possible violations of law and increased complaints. The array of issues described *supra* in Parts IV (The Original Version and Current Version of the Rule) and Part VI (Reasons for the Proposed Rule) fall into one or both of these two overarching categories.

Protection of religious beliefs and moral convictions not only serves individual rights, it serves society as a whole. Protections for conscience help ensure a society free from discrimination and more respectful of personal freedom. Although the boundaries of protection for conscience may be tested when that

protection appears to impede other public goods, it is in those cases where fidelity to the law becomes paramount.⁴⁸

Despite the longstanding nature of the Federal health care conscience and associated anti-discrimination laws that this rule proposes to enforce, discrimination and coercion continue to occur. Relevant situations where persons, entities, and health care entities with religious beliefs or moral convictions may be coerced or suffer discrimination include:

- being asked to perform, participate in, pay for, counsel or refer for abortion, sterilization, euthanasia, or other health services;
- engaging in health professions training that pressures students, residents, fellows, etc., to perform, assist in the performance of, or counsel for abortion;
- considering a career in obstetrics, family medicine, or elder care, when one has a religious or moral objection to abortion, sterilization, or euthanasia;
- raising religious or moral objections to participating in certain services within the scope of one's employment; and,
- being required to administer or receive certain vaccinations derived from aborted fetal tissues as a condition of work or receipt of educational services.

Discrimination, coercion, and intolerance for religious beliefs or moral convictions continue to occur due to (1) the poor functioning of Federal government frameworks to enforce Federal health care conscience and associated anti-discrimination laws and (2) inadequate information and understanding about the

⁴⁸ See Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals*, 49 Ariz. St. L.J. 549, 550-51 (2017).

obligations of persons and entities and the rights of persons, entities, and health care entities under these laws. These deficiencies in Federal governing frameworks include:

An inadequate, minimalistic regulatory scheme at part 88 of 45 CFR due to the Department's 2011 Rule that rescinded the comprehensive 2008 Rule, *see supra* Part IV.A-B (describing content of the existing and prior versions of the rule) and Part VI.C (identifying confusion about conscience laws' scope and applicability);

An unduly narrow Departmental interpretation of the Weldon Amendment adopted by OCR in connection with the 2011 Rule that limited the scope of discrimination contrary to the language that Congress passed, *see supra* Part VI.E (addressing confusion caused by OCR sub-regulatory guidance); and

A lack of strategic coordination across the Department to address the enforcement of Federal health care conscience and associated anti-discrimination laws set forth in authorizing statutes of programs that the Department's components conduct, *see supra* Part III.F (identifying additional Federal health care conscience and associated anti-discrimination laws).

The absence of adequate Federal governing frameworks to remedy discrimination may have undermined incentives for covered persons and entities proactively to institute measures to protect conscience, prohibit coercion, and promote nondiscrimination.

OCR is aware 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 experience real harm that is

significant psychologically, emotionally, and financially. Such persons claim that their harm amounts to an actionable violation of the Federal health care conscience and associated anti-discrimination laws that OCR can remedy through administrative enforcement.⁴⁹ Indeed, since November of 2016, OCR has received thirty-four complaints concerning Federal health care conscience and associated anti-discrimination laws. *See supra* Part V (identifying when OCR complaints were received).

(ii) How the Proposed Rule Seeks to Address those Problems

This proposed regulatory action corrects those problems. First, the Department proposes to revise 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 impose procedural requirements (*e.g.*, assurances of compliance, notices to the public) to further compliance with those substantive rights and obligations. In addition, such schemes outline the enforcement procedures to provide regulated entities notice of the enforcement tools available to OCR and the type of remedies OCR may seek. Part 88, by contrast, is currently only three sentences long and therefore provides considerably less notice and clarity about the

⁴⁹ As discussed earlier, several courts have declined to recognize a private right of action for persons protected under certain Federal health care conscience and associated anti-discrimination laws. In such cases, persons must rely on OCR for enforcement.

conduct prohibited under Federal law and the enforcement mechanisms available to OCR.

Department components, recipients, and sub-recipients must comply with the Federal laws that are the subject of this proposed rulemaking. In addition to conducting outreach and providing technical assistance, OCR would have the authority to initiate compliance reviews, conduct investigations, and supervise and coordinate appropriate action with the relevant Department component to assure compliance.

To assist OCR in ensuring compliance with and enforcement of the Federal health care conscience and associated anti-discrimination laws, the proposed rule would require certain persons and entities: to maintain records; cooperate with OCR investigations, reviews, interviews, or other parts of OCR's enforcement process; submit written assurances and certifications of compliance to the Department; and provide notice to persons, entities, and health care entities about Federal health care conscience and associated anti-discrimination protections, as applicable. These procedural and administrative requirements are similar to those in other civil rights regulations and have a proven record of improving compliance with, and enforcement of, other Federal civil rights laws. Together, these requirements would support the Department's renewed effort for strategic coordination with respect to the compliance and enforcement of the Federal health care conscience and associated anti-discrimination laws that exist across the Department.

Second, this proposed rule seeks to promote voluntary compliance with laws governing the ability of persons, entities, and health care entities to act in accord with their religious beliefs or moral convictions by ensuring that persons and entities are aware of and understand Federal health care conscience and associated anti-discrimination laws. Persons and entities would be more likely to accommodate conscience and associated anti-discrimination rights if persons and entities understand that they are legally obligated to do so. Persons and entities would also be in a better position to accommodate these rights if they understand these rights to be akin to other civil rights to be free from discrimination on the basis of race, national origin, disability, etc. – rights that recipients and sub-recipients are already familiar with respecting.

The Department anticipates, as anticipated with the 2008 Rule, that this proposed rule would promote accommodation of protected persons, entities, and health care entities. *See e.g.*, 73 FR 78074, 78081 (2008 Rule). Greater transparency of practices through open communication of recipient and sub-recipient policies “should strengthen relationships between patients and providers, as well as those between entities and their . . . [workforce members].” *Id.* at 78074. The Department intends that OCR’s outreach and guidance, investigations, compliance reviews, and enforcement actions, would provide institutions with an incentive to review their compliance with Federal health care conscience and associated anti-discrimination laws, as applicable, resulting in increased voluntary compliance.

2. Affected Persons and Entities

The proposed rule affects: (1) persons and entities obligated to comply with 45 CFR part 88 because they are subject to the Weldon Amendment, Coats-Snowe Amendment, or Church Amendments (or a combination thereof); and (2) persons and entities obligated to comply with at least one of the nearly two dozen Federal laws that this revision of part 88 proposes to enforce.

(i) Scope of Persons and Entities that 45 CFR Part 88 Covers

This proposed rule affects persons and entities obligated to comply with the Weldon, Church, and Coats-Snowe Amendments of which 45 CFR part 88 provides for the enforcement.

Current part 88 extends:

- To almost every program and activity administered by the Secretary;
- To all State and local governments that receive Federal financial assistance as recipients or sub-recipients; and
- To recipients that operate a health service program or research activity or biomedical or behavioral research administered by the Secretary, or for the implementation of programs or activities authorized in the Public Health Service Act (“PHS Act”) or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (“DD Act”) through specified instruments. As described in the following paragraphs, the current part 88 thus covers a synthesis of actors subject to the Church, Coats-Snowe, and Weldon Amendments.

(A) The Department

Part 88 applies to the Department because the Weldon and Coats-Snowe Amendments, as well as specific paragraphs of the Church Amendments, apply to the Department.

The Weldon Amendment states that “[n]one of the funds made available in this Act 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”⁵⁰ The Department is a Federal agency that receives substantial funds made available in the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act (“Labor/HHS/Education Appropriation”), which are the funds addressed in Weldon.⁵¹ To continue to receive those funds, the Department cannot discriminate on a basis prohibited by Weldon.

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 all of the Department’s 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

⁵⁰ *E.g.*, Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Tit. V, sec. 507(d), 131 Stat. 135, 562 (May 5, 2017).

⁵¹ *See id.*

research under any program administered by the Secretary.”⁵² The Department administers many such programs, either directly or through its components.

Examples include:

- The Health Resources and Services Administration (HRSA) administers grant programs, such as the operation of a grant program for community health centers,
- The National Institute of Health operates grant programs to fund research,
- The Centers for Medicare & Medicaid Services (CMS) administers Medicare and Federally-facilitated Health Insurance Marketplaces,⁵³ and CMS jointly administers Medicaid with States,⁵⁴ and

The Indian Health Service (IHS) operates a system of direct health care for certain Tribes and Tribal organizations and also administers contracts and self-governance compacts under the Indian Self-Determination and Education Assistance Act (ISDEAA),⁵⁵ as amended, which allows Tribes and Tribal Organizations to assume control and management of health care that IHS would otherwise provide.⁵⁶

(B) State and Local Governments

⁵² 42 U.S.C. 300a-7(c)(2) and (d).

⁵³ <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/ffe.html>.

⁵⁴ <https://www.medicare.gov/>.

⁵⁵ Pub. L. 93-638, 88 Stat. 2203 (Jan. 4, 1975).

⁵⁶ IHS FY 2018 Congressional Justification of Estimates to the Appropriations Committees 199, 203 (2017), https://www.ihs.gov/budgetformulation/includes/themes/responsive2017/display_objects/documents/FY2018CongressionalJustification.pdf

Part 88 applies 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 Labor/HHS/Education Appropriation.⁵⁷ Second, the Coats-Snowe Amendment applies to State and local governments that receive HHS Federal financial assistance (regardless of funding source), “includ[ing] governmental payments provided as reimbursement for carrying out health-related activities.”⁵⁸

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 to the extent that such State or local government receives partial or full funding for a health service program or research activity under a program administered by the Secretary.⁵⁹

⁵⁷ Pub. L. 115-31, Div. H, Tit. V, sec. 507(d), 131 Stat. at 562 (“None of the funds made available in this Act may be made available to a . . . State or local government[] if such . . . government . . .”).

⁵⁸ 42 U.S.C. 238n(a), (c)(1).

⁵⁹ *Id.* at § 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 . . .”).

State and local governments (such as counties or cities) and instrumentalities of governments (such as State health and human services agencies) subject to current part 88 receive Federal financial assistance or Federal funds from the Department from a variety of financing streams as recipients or sub-recipients. Examples of these financing streams, which include reimbursement for health-related activities, include:

- Medicaid and the Children’s Health Insurance Program,
- 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 justice abuse.

(C) Persons and Entities

Part 88 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;”⁶⁰ receive a grant, contract, loan, or loan guarantee under the PHS Act or the DD Act; or receive an interest subsidy under the DD Act. Several statutory provisions support this application. First, paragraphs (c)(1)-(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

⁶⁰ 42 U.S.C. 300a-7(d).

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.⁶¹ 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.”⁶²

The broad array of recipients and sub-recipients in this category is a function of two statutory features. First, paragraph (d) of the Church Amendment does not tie the funding source to a particular appropriation, instrument, or authorizing statute. Second, the PHS Act contains thirty titles and authorizes dozens of programs. Examples of entities that receive funds under programs authorized by the PHS Act include:

⁶¹ 42 U.S.C. 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; thus, there are no entities receiving funds under programs authorized by these statutes to consider in this RIA. *See* Omnibus Reconciliation Act of 1981, Pub. L. 97-35, Title IX, sec. 902(e)(2)(B), 95 Stat. 560 (1981); Developmental Disabilities Assistance and Bill of Rights Act of 2000, Pub. L. 106-402, Title IV, sec. 401(a), 114 Stat. 1737 (2000).

⁶² *Id.* at 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 . . .”).

- 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;
- 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,⁶³ and
- State Councils on Developmental Disabilities⁶⁴ and States' Protection and Advocacy Systems that receive funds to implement the DD Act.⁶⁵

(ii) Persons and Entities Obligated to Comply With Additional Federal Laws that this NPRM Proposes to Enforce

This proposed rule would affect persons and entities obligated to comply with at least one of the approximately two dozen Federal laws that this revision of part 88 proposes to enforce. There is substantial overlap between persons and entities obligated to comply with the current part 88 and persons and entities

⁶³ E.g., <https://www.acl.gov/node/466>.

⁶⁴ E.g., <https://www.acl.gov/node/110>.

<https://www.acl.gov/sites/default/files/about-acl/2017-12/DDC-2017.pdf>.

⁶⁵ E.g., <https://www.acl.gov/sites/default/files/about-acl/2017-06/PADD-2017.pdf>.

subject to at least one of the additional Federal laws that this revision of part 88 proposes to enforce. This overlap occurs because such persons and entities should already be subject to 45 CFR part 88 by virtue of their coverage by the Weldon Amendment, Coats-Snowe Amendment, or Church Amendments (or a combination thereof), the coverage of which the Department explained in the immediately preceding part – Part XI.C.2.i. Because of this overlap, the Department estimates that the proposed delegation of authority to OCR to enforce the following laws would not add any new persons and entities to the coverage of part 88:

Provider conscience laws related to abortion (the Weldon Amendment for Medicare Advantage, *e.g.* Pub. L. 115-31, Div. H, sec. 209, 131 Stat. 135, 539 (2017));

Certain provisions of the Affordable Care Act applying Federal conscience protections of providers with respect to abortion (42 U.S.C. 18023(b)(4)), regarding assisted suicide (42 U.S.C. 18113), and providing a conscience exemption to the individual mandate (26 U.S.C. 5000A(d)(2));

Certain laws governing provider counseling, referral, and implementation of directives (counseling and referral in Medicare Advantage ((42 U.S.C. 1395w-22(j)(3)(B))), counseling and referral in Medicaid (42 U.S.C. 1396u-2(b)(3)(B)), and performance of advanced directives in the Medicare and Medicaid programs (42 U.S.C. 1396a(w)(3), and 14406));

Laws providing for patient objections to receiving health care services, including medical screening, examination, diagnosis, treatment, or other health care (42 U.S.C. 1396f), occupational illness testing (29 U.S.C. 669(a)(5)), pediatric

vaccination (42 U.S.C. 1396s(c)(2)(B)(ii)), youth suicide prevention and treatment (42 U.S.C. 290bb-36(f)), and newborn health screening (42 U.S.C. 280g-1(d)); and

Laws protecting religious nonmedical health care, by exempting religious non-medical institutions from 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)).

The Department estimates that the proposed delegation of authority to OCR to enforce the following laws would probably add new persons and entities to the coverage of part 88:

- Global Health Programs for HIV/AIDS Prevention, Treatment, or Care (22 U.S.C. 7631(d)), and
- The Helms Amendment (*e.g.*, Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. J, sec. 7018).

The persons and entities subject to 22 U.S.C. 7631(d) and the Helms Amendment may not be currently subject to part 88 because the persons and entities are recipients and sub-recipients of funds that HHS administers for Global Health programs where those funds are appropriated to the U.S. Department of State and USAID but awarded from HHS. Thus, the financing streams to which these laws apply likely do not overlap with the financial streams to which the Weldon,

Coats-Snowe, and Church Amendments apply. However, paragraph (d) of the Church Amendments applies to a “health service program or research activity funded in whole or in part under a program administered by the Secretary.”

Paragraph (d) 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 Secretary.” Consequently, paragraph (d) of the Church Amendments (and, thus, part 88) would arguably apply to recipients and sub-recipients of Federal funds from (or administered by) the Department with respect to such Global Health programs because if the Department administers the funds, it administers the program.

(iii) Methodology

Although the Department has qualitatively summarized the new persons and entities covered by this proposed rule, the Department has also quantitatively estimated those persons and entities to understand the likely impact of the proposed rule. To do so, the Department primarily relied on the latest data available from the U.S. Census Bureau’s Statistics of U.S. Businesses,⁶⁶ supplemented with other sources. The Department determined that no one data source could supply an unduplicated count of the persons or entities that receive an award through an instrument covered within the scope of this proposed rule. But in assessing the available methodologies, the Department concluded that the U.S. Census Bureau

⁶⁶ <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.*

data, supplemented with other sources, was the most reasonable way to estimate the number of persons and entities that this proposed rule would affect.

The U.S. Census Bureau's Statistics of U.S. Businesses is based on the North American Industry Classification System (NAICS).⁶⁷ The NAICS classifies all economic activity into 20 sectors and breaks that information down into sub-sectors and industries.⁶⁸ Essentially, the NAICS groups physical business establishments together based on how similar the locations' processes are for producing goods or services.⁶⁹ The NAICS provides information on how many singular physical locations exist for a particular business or industry (called an "establishment"),⁷⁰ how many of those establishments are under common ownership or control of a business organization or entity (called a "firm"),⁷¹ 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 assumes that only a portion of the industry captured in the Statistics of U.S. Businesses receives Federal funds. For instance, not all physician offices accept Medicare, Medicaid, or both. In fact, about 68.9% of physician offices accepted new Medicaid patients based on 2013 data from the National Electronic Health Records

⁶⁷ <https://www.census.gov/programs-surveys/susb/technical-documentation/methodology.html>.

⁶⁸ FAQ 5, <https://www.census.gov/eos/www/naics/faqs/faqs.html#q5>.

⁶⁹ FAQ 1, <https://www.census.gov/eos/www/naics/faqs/faqs.html#q1>.

⁷⁰ <https://www.census.gov/eos/www/naics/faqs/faqs.html#q2>.

⁷¹ https://www.census.gov/glossary/#term_Firm.

Survey.⁷² Approximately 83.7% of physicians accepted new Medicare patients based on the same data.⁷³ Because current part 88 applies to physicians receiving reimbursement for Medicare Part B and to physicians participating in Medicaid, the Department assumed that the lower of these two percentages (69%) represents the lower-bound of physicians nationwide subject to current part 88. In the absence of evidence with which to generate a refined upper-bound estimate, the Department assumed that current part 88 covers all physicians nationwide as the upper-bound.

The Department used this same percentage range (69% to 100%) 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% as the lower-bound and 100% as the upper-bound to cover 62.5% of the industry on average).

To estimate the number of local governments and educational institutions, the Department supplemented its use of data from the U.S. Census Bureau's Statistics of U.S. Businesses with Census data from other statistical programs or with available award data available through the HHS Tracking Accountability in Government Grants System (TAGGS).⁷⁴ For instance, in estimating the number of

⁷² 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).

⁷³ *Id.*

⁷⁴ <http://taggs.hhs.gov> (last visited Aug. 24, 2017).

counties nationwide, the Department relied on 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.⁷⁵

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 wanted a lower-bound estimate to reflect that assumption.

Using the “Advanced Search” function in TAGGS, HHS identified all awards to Junior Colleges, Colleges, and 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, a satellite campus is one location of a university system with common ownership and control of 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.

⁷⁵ https://www.census.gov/geo/maps-data/data/tallies/all_tallies.html.

Census Bureau's Statistics of U.S. Businesses.⁷⁶ This ratio is 51.32% (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 X 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.

The Department considered other methodologies for estimating the number of impacted persons and entities. For instance, the Department considered primarily relying on award data from TAGGS in lieu of using it as a supplemental data source. In addition, the Department also considered adding together the number of awards to States, local governments, private entities, nonprofit entities, etc., that Department components commonly report on a program-by-program basis on the Web, in ad hoc reports on topic-specific matters, and in their annual Justifications of Estimates to the Appropriations Committees as part of the President's annual budget request to Congress.

The Department rejected those methodological approaches. In particular, the Department was concerned that those approaches would double-count a substantial number of persons and entities that receive an award from more than one Department component or that receive multiple awards from the same component. Primarily relying on TAGGS would not only double-count some persons and entities

⁷⁶ U.S. Census Bureau, Statistics of U.S. Businesses, 2015, NAICS code 611310 (Colleges, Universities, and Professional Schools).

but would under-count others because TAGGS does not capture the number of sub-recipients receiving awards from a recipient. Given these considerations, NAICS information, supplemented with Census data from other statistical programs or with publicly available award data from TAGGS, was the best reasonably obtainable source of economic and technical information on which the Department could rely.

The Department seeks comment on the methodology used and whether there are other methodologies that the Department could consider to refine the scope of persons and entities affected by this proposed rule.

(iv) Quantitative Estimate of Persons and Entities Covered by NPRM

Table 1 lists each type of recipient and the estimated number of recipients that this proposed rule covers. Because there is uncertainty as to the universe of persons and entities currently covered by 45 CFR part 88 and the incremental number of new persons and entities that the Department expects this proposed rule will cover, Table 1 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.

Table 1: Estimated Number of Persons and Entities Covered by NPRM

	Type	Covered by current 45 CFR 88?	Covered by NPRM?	Estimated number (Low)	Estimated number (High)
1	State and Territorial Governments ⁷⁷	Yes	Yes	58	58
2	Federally recognized Tribes ⁷⁸	Yes	Yes	567	567

⁷⁷ Assumes coverage of the 50 States, D.C., Puerto Rico, 6 U.S. Territories, and the Island Areas.

⁷⁸ Assumes all Federally-recognized Tribes get HHS funds. Indian Health Service, FY 2018 Justification of Estimates to the Appropriations Committees CJ-1 (2017),

3	Counties ⁷⁹	Yes	Yes	3,234	3,234
Hospitals					
4	General and Medical Surgical Hospitals ⁸⁰	Yes	Yes	1,859	2,694
5	Specialty Hospitals (e.g. psychiatric, substance abuse, rehabilitation, cancer, maternity) ⁸¹	Yes	Yes	553	801
Nursing and Residential Care Facilities					
6	Skilled Nursing Facilities ⁸²	Yes	Yes	6,316	9,153
7	Residential Intellectual and Developmental Disability Facilities ⁸³	Yes	Yes	4,310	6,246
8	Continuing Care Retirement Communities ⁸⁴	Yes	Yes	2,605	3,775
9	Other Residential Care Facilities (e.g., group homes) ⁸⁵	Yes	Yes	2,247	3,256
10	Entities providing Home Health Care Services ⁸⁶	Yes	Yes	15,062	21,829
Entities Providing Ambulatory Health Care Services					
11	Offices of Physicians (except Mental Health Specialists) ⁸⁷	Yes	Yes	115,673	167,642

https://www.ihs.gov/budgetformulation/includes/themes/responsive2017/display_objects/documents/FY2018CongressionalJustification.pdf.

⁷⁹ 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 sub-recipient.

⁸⁰ 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). Assumes coverage for 69%-100% of the industry.

⁸¹ *Id.* (sum of the nationwide count of firms for NAICS Codes 622210 and 622310). Assumes 69%-100% of industry is covered.

⁸² *Id.* (relying on the nationwide count of firms for NAICS Code 623110). Assumes 69%-100% of industry is covered.

⁸³ *Id.* (nationwide count of firms for NAICS Code 623210). Assumes 69%-100% of industry is covered.

⁸⁴ *Id.* (nationwide count of firms for NAICS Code 623311). Assumes 69%-100% of industry is covered.

⁸⁵ *Id.* (nationwide count of firms for NAICS Code 623990). Assumes 69%-100% of industry is covered.

⁸⁶ *Id.* (nationwide count of firms for NAICS Code 621610). Assumes 69%-100% of industry is covered.

12	Offices of Physicians (Mental Health Specialists) ⁸⁸	Yes	Yes	7,324	10,614
13	Offices of Mental Health Practitioners (except Physicians) ⁸⁹	Yes	Yes	14,340	20,782
14	Offices of Dentists ⁹⁰	Yes	Yes	86,874	125,904
15	Offices of Chiropractors ⁹¹	Yes	Yes	26,725	32,535
16	Offices of Optometrists ⁹²	Yes	Yes	13,775	19,964
17	Offices of Physical, Occupational and Speech Therapists, and Audiologists ⁹³	Yes	Yes	17,623	25,540
18	Offices of Podiatrists ⁹⁴	Yes	Yes	5,314	7,701
19	Family Planning Centers ⁹⁵	Yes	Yes	999	1,448
20	Freestanding Ambulatory Surgical and Emergency Centers ⁹⁶	Yes	Yes	2,908	4,214
21	HMO Medical Centers ⁹⁷	Yes	Yes	78	113
22	Kidney Dialysis Centers ⁹⁸	Yes	Yes	305	442
23	Outpatient Mental Health and Substance Abuse Centers ⁹⁹	Yes	Yes	3,776	5,472

⁸⁷ *Id.* (nationwide count of firms for NAICS Code 621111). Assumes 69%-100% of industry is covered.

⁸⁸ *Id.* (nationwide count of firms for NAICS Code 621112). Assumes 69%-100% of industry is covered.

⁸⁹ *Id.* (nationwide count of firms for NAICS Code 621330). Assumes 69%-100% of industry is covered.

⁹⁰ *Id.* (nationwide count of firms for NAICS Code 621210). Assumes 69%-100% of industry is covered.

⁹¹ *Id.* (nationwide count of firms for NAICS Code 621310). Assumes 69%-100% of industry is covered.

⁹² *Id.* (nationwide count of firms for NAICS Code 621320). Assumes 69%-100% of industry is covered.

⁹³ *Id.* (nationwide count of firms for NAICS Code 621340). Assumes 69%-100% of industry is covered.

⁹⁴ *Id.* (nationwide count of firms for NAICS Code 621391). Assumes 69%-100% of industry is covered.

⁹⁵ *Id.* (nationwide count of firms for NAICS Code 621410). Assumes 69%-100% of industry is covered.

⁹⁶ *Id.* (nationwide count of firms for NAICS Code 621493). Assumes 69%-100% of industry is covered.

⁹⁷ *Id.* (nationwide count of firms for NAICS Code 621491). Assumes 69%-100% of industry is covered.

⁹⁸ *Id.* (nationwide count of firms for NAICS Code 621492). Assumes 69%-100% of industry is covered.

24	Diagnostic Imaging Centers ¹⁰⁰	Yes	Yes	3,209	4,651
25	Medical Laboratories ¹⁰¹	Yes	Yes	2,278	3,302
26	Ambulance Services ¹⁰²	Yes	Yes	2,185	3,167
27	All Other Outpatient Care Centers (e.g. centers and clinics for pain therapy, community health, and sleep disorders) ¹⁰³	Yes	Yes	3,880	5,623
28	Entities providing All Other Ambulatory Health Care Services (health screening, smoking cessation, hearing testing, blood banks) ¹⁰⁴	Yes	Yes	2,391	3,465
Insurance Carriers					
29	Direct Health and Medical Insurance Carriers ¹⁰⁵	Yes	Yes	607	880
Entities Providing Social Assistance Services					
30	Entities Serving the Elderly and Persons with Disabilities (provision of nonresidential social assistance services to improve quality of life) ¹⁰⁶	Yes	Yes	9,051	36,205
31	Entities providing Other Individual Family Services (e.g., marriage counseling, crisis intervention centers, suicide crisis centers) ¹⁰⁷	Yes	Yes	5,310	21,240
32	Entities providing Child and	Yes	Yes	2,169	8,674

⁹⁹ *Id.* (nationwide count of firms for NAICS Code 621420). Assumes 69%-100% of industry is covered.

¹⁰⁰ *Id.* (nationwide count of firms for NAICS Code 621512). Assumes 69%-100% of industry is covered.

¹⁰¹ *Id.* (nationwide count of firms for NAICS Code 621511). Assumes 69%-100% of industry is covered.

¹⁰² *Id.* (nationwide count of firms for NAICS Code 621910). Assumes 69%-100% of industry is covered.

¹⁰³ *Id.* (nationwide count of firms for NAICS Code 621498). Assumes 69%-100% of industry is covered.

¹⁰⁴ *Id.* (nationwide count of firms for NAICS Code 62199). Assumes 69%-100% of the industry is covered.

¹⁰⁵ *Id.* (nationwide count of firms for NAICS Code 524114). Assumes 69%-100% of industry is covered.

¹⁰⁶ *Id.* (nationwide count of firms for NAICS Code 624120). Assumes 69%-100% of industry is covered.

¹⁰⁷ *Id.* (nationwide count of firms for NAICS Code 624190). Assumes 69%-100% of industry is covered.

	Youth Services (e.g., adoption agencies, foster care placement services) ¹⁰⁸				
33	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) ¹⁰⁹	Yes	Yes	805	3,219
34	Emergency and Other Relief Services (e.g., medical relief, resettlement, and counseling to victims of domestic or international disasters or conflicts) ¹¹⁰	Yes	Yes	169	675
Other Entities					
35	Pharmacies and Drug Stores ¹¹¹	Yes	Yes	13,490	19,550
36	Research and Development in Biotechnology ¹¹²	Yes	Yes	2,347	3,402
37	Colleges, Universities, and Professional Schools ¹¹³	Yes	Yes	<u>316</u>	<u>2,457</u>
Subtotal , subject to current part 88				364,575	571,282
38	HHS awarded funds appropriated to the U.S. Department of State & USAID ¹¹⁴	No	Yes	<u>65</u>	<u>130</u>

¹⁰⁸ *Id.* (nationwide count of firms for NAICS Code 624110). As described *supra* Part XI.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%-100% of industry is covered.

¹⁰⁹ *Id.* (nationwide count of firms for NAICS Code 624221). As described *supra* Part XI.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%-100% of industry is covered.

¹¹⁰ *Id.* (nationwide count of firms for NAICS Code 624230). As described *supra* Part XI.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%-100% of industry is covered.

¹¹¹ *Id.* (nationwide count of firms for NAICS Code 44610). Assumes 69%-100% of industry is covered.

¹¹² *Id.* (nationwide count of firms for NAICS Code 541711). Assumes 69%-100% of industry is covered.

¹¹³ *Id.* (nationwide count of firms for NAICS Code 611310). As described *supra* Part XI.C.2.iii (methodology), the Department assumes 13%-100% of institutions of higher-education are covered. *See supra* 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.

¹¹⁴ 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

Subtotal , incremental increase in entities			65	130
TOTAL , estimated entities subject to NPRM			364,640	571,412

Approximately 364,575 to 571,282 persons and entities are currently subject to part 88 by virtue of the Weldon Amendment, the Coats-Snowe Amendment, and the Church Amendments. The Department estimated that the universe of incremental new persons and entities subject to 22 U.S.C. 7631(d) and the Helms Amendment that this proposed rule would cover is small and, possibly, non-existent. This proposed rule may add 65 to 130 new persons and entities to part 88's coverage.¹¹⁵ With this incremental increase, this proposed rule would cover a total of 364,640 to 571,412 entities.

(A) Estimated Persons and Entities Required to Sign an Assurance and Certification of Compliance

Relative to the persons and entities shown in Table 1, a smaller subset will be subject to proposed 88.4, which requires certain recipients to submit an assurance and certification of compliance. The Department began calculating that subset by removing sub-recipients from the total because proposed 88.4 would apply only to recipients, not sub-recipients. OCR has not found a reliable way to estimate the total

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.

¹¹⁵ *But see supra* Part XI.C.2.ii (discussing the application of paragraph (d) of the Church Amendments to such grantees).

number of sub-recipients. For purposes of this calculation, the Department assumed that every county is a sub-recipient but not a recipient and accordingly excluded all 3,234 counties from the total number that must comply with the assurance and certification of compliance requirement. The Department requests information, data sources, studies, or reports that could assist in identifying the number of sub-recipients under this proposed regulation excluded from § 88.4.

The Department next sought to estimate and remove exempted entities from the total. The Department assumed that all physicians would meet the proposed criteria for exemption from the requirement in proposed § 88.4(c)(1).¹¹⁶ Consequently, the Department excluded 255,684 to 370,557 entities, representing the lower and upper-bounds, from the estimate. To the degree that some physicians are recipients of the Department through an instrument other than reimbursement for their participation in Medicare Part B, then the Department overestimated the impact of the exemption.

The Department removed 11,220 to 44,879 persons and entities that provide child and youth services and services for the elderly and persons with disabilities based on the proposed exemption for recipients awarded under grant programs administered by the Administration for Children and Families or the Administration for Community Living. 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. *See* proposed § 88.4(c)(2)-(3).

¹¹⁶ Sum of rows 11, 12, 14-18 of Table 1.

The Department reasonably anticipated 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 anticipated 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 considered exempting entities providing Other Individual Family Services (e.g., marriage counseling, crisis intervention centers, suicide crisis centers), but decided not to do so. Although the provision of these services may not involve health care providers, there is a significant likelihood of referral for the provision of health care at crisis intervention centers and suicide crisis centers.

Finally, the Department excluded 223 Tribes and Tribal Organizations from the total. The number reflects the proposed Tribal exemption. *See* proposed § 88.4(c)(4). The Department has identified 223 Tribes and Tribal Organizations that operate Title contracts under Title I of the ISDEA Act.

The Department seeks comment on the methods used to estimate the scope of exempted recipients under proposed § 88.4(c)(1)-(4).

Table 2: Range of Recipients Subject to the Proposed Assurance and Certification Requirements (§ 88.4)

	Low-End Estimate	Upper-Bound Estimate
Range of Persons or Entities Subject to the NPRM	364,640	571,412
Range of Recipients Excepted from Proposed § 88.4	<u>-270,361</u>	<u>-418,893</u>
Total, Recipients Subject to the Assurance and Certification Requirements	94,279	152,519

(B) Estimated Number of Recipients Required to Provide Notice (§ 88.5)

More persons and entities would be subject to the notice requirement than to the assurance and certification requirements under the proposed rule. Although the Department proposes to exclude certain recipients from the assurance and certification requirements, the Department proposes to require all recipients and the Department to comply with the notice requirement. The Department proposes this policy approach because persons, entities, and health care entities who do not know their rights may not exercise them. The notice is designed to be seen by workforce members of the Department or recipients, beneficiaries of covered programs and activities, and the public. In contrast, assurance and certification documents are internal facing documents that certain recipients would sign and the public would likely never see.

In an effort to reduce the burden on sub-recipients, proposed § 88.5, similar to proposed § 88.4, does not require sub-recipients, to post a notice. The Department requests comment on whether its proposed policy strikes the right balance between reducing the burden on sub-recipients and providing notice of important rights. OCR employed the methods from *supra* Part XI.C.2.iv.A to estimate the total number of sub-recipients (3,234 counties) to exclude from the total count of persons and entities subject to the notice requirement.

The Department counted the number of establishments associated with each recipient type. Unlike the assurance and certification requirements, which will be implemented at the “firm” level, the Department expects that the notice

requirement will be implemented at the “establishment” level because proposed § 88.5 requires recipients to post the notice in all physical locations where notices are commonly posted for members of the workforce or for the public. For instance, a hospital system that has common ownership and control over multiple hospital facilities (a firm) would implement § 88.4 but each hospital facility (an establishment) would implement § 88.5 to display physical notices.

Table 3 employs the same methodology for calculating the number of entities but uses the U.S. Census Bureau’s Statistics of U.S. Businesses data for establishments rather than firms.

Table 3: Number of Physical Establishments of Each Recipient Type Required to Provide Notice (§ 88.5)

	Type	Estimated number (Low)	Estimated number (High)
1	State and Territorial Governments ¹¹⁷	58	58
2	Federally recognized Tribes ¹¹⁸	567	567
3	Counties ¹¹⁹ (assumed sub-recipient category to which the notice requirement does not apply)	n/a	n/a
4	General and Medical Surgical Hospitals ¹²⁰	3,699	5,361

¹¹⁷ Assumes coverage of the 50 States, D.C., Puerto Rico, 6 U.S. Territories, and the Island Areas.

¹¹⁸ Assumes all Federally-recognized Tribes get HHS funds. Indian Health Service, FY 2018 Justification of Estimates to the Appropriations Committees CJ-1 (2017), https://www.ihs.gov/budgetformulation/includes/themes/responsive2017/display_objects/documents/FY2018CongressionalJustification.pdf.

¹¹⁹ 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 is a recipient or a sub-recipient.

5	Specialty Hospitals (e.g. psychiatric, substance abuse, rehabilitation, cancer, maternity) ¹²¹	1,139	1,651
6	Skilled Nursing Facilities ¹²²	11,789	17,085
7	Residential Intellectual and Developmental Disability Facilities ¹²³	22,611	32,770
8	Continuing Care Retirement Communities ¹²⁴	3,668	5,316
9	Other Residential Care Facilities (e.g., group homes) ¹²⁵	3,627	5,256
10	Entities providing Home Health Care Services ¹²⁶	21,377	30,981
11	Offices of Physicians (except Mental Health Specialists) ¹²⁷	147,817	214,228
12	Offices of Physicians (Mental Health Specialists) ¹²⁸	7,498	10,867
13	Offices of Mental Health Practitioners (except Physicians) ¹²⁹	15,022	21,771
14	Offices of Dentists ¹³⁰	92,895	134,631

¹²⁰ 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). Assumes coverage for 69%-100% of the industry.

¹²¹ *Id.* (sum of the nationwide count of firms for NAICS Codes 622210 and 622310). Assumes 69%-100% of industry is covered.

¹²² *Id.* (relying on the nationwide count of firms for NAICS Code 623110). Assumes 69%-100% of industry is covered.

¹²³ *Id.* (nationwide count of firms for NAICS Code 623210). Assumes 69%-100% of industry is covered.

¹²⁴ *Id.* (nationwide count of firms for NAICS Code 623311). Assumes 69%-100% of industry is covered.

¹²⁵ *Id.* (nationwide count of firms for NAICS Code 623990). Assumes 69%-100% of industry is covered.

¹²⁶ *Id.* (nationwide count of firms for NAICS Code 621610). Assumes 69%-100% of industry is covered.

¹²⁷ *Id.* (nationwide count of firms for NAICS Code 621111). Assumes 69%-100% of industry is covered.

¹²⁸ *Id.* (nationwide count of firms for NAICS Code 621112). Assumes 69%-100% of industry is covered.

¹²⁹ *Id.* (nationwide count of firms for NAICS Code 621330). Assumes 69%-100% of industry is covered.

15	Offices of Chiropractors ¹³¹	26,999	39,129
16	Offices of Optometrists ¹³²	15,101	21,885
17	Offices of Physical, Occupational and Speech Therapists, and Audiologists ¹³³	25,213	36,541
18	Offices of Podiatrists ¹³⁴	5,769	8,361
19	Family Planning Centers ¹³⁵	1,584	2,295
20	Freestanding Ambulatory Surgical and Emergency Centers ¹³⁶	4,609	6,679
21	HMO Medical Centers ¹³⁷	560	812
22	Kidney Dialysis Centers ¹³⁸	5,144	7,455
23	Outpatient Mental Health and Substance Abuse Centers ¹³⁹	7,227	10,474
24	Diagnostic Imaging Centers ¹⁴⁰	4,553	6,598
25	Medical Laboratories ¹⁴¹	7,360	10,667

¹³⁰ *Id.* (nationwide count of firms for NAICS Code 621210). Assumes 69%-100% of industry is covered.

¹³¹ *Id.* (nationwide count of firms for NAICS Code 621310). Assumes 69%-100% of industry is covered.

¹³² *Id.* (nationwide count of firms for NAICS Code 621320). Assumes 69%-100% of industry is covered.

¹³³ *Id.* (nationwide count of firms for NAICS Code 621340). Assumes 69%-100% of industry is covered.

¹³⁴ *Id.* (nationwide count of firms for NAICS Code 621391). Assumes 69%-100% of industry is covered.

¹³⁵ *Id.* (nationwide count of firms for NAICS Code 621410). Assumes 69%-100% of industry is covered.

¹³⁶ *Id.* (nationwide count of firms for NAICS Code 621493). Assumes 69%-100% of industry is covered.

¹³⁷ *Id.* (nationwide count of firms for NAICS Code 621491). Assumes 69%-100% of industry is covered.

¹³⁸ *Id.* (nationwide count of firms for NAICS Code 621492). Assumes 69%-100% of industry is covered.

¹³⁹ *Id.* (nationwide count of firms for NAICS Code 621420). Assumes 69%-100% of industry is covered.

¹⁴⁰ *Id.* (nationwide count of firms for NAICS Code 621512). Assumes 69%-100% of industry is covered.

¹⁴¹ *Id.* (nationwide count of firms for NAICS Code 621511). Assumes 69%-100% of industry is covered.

26	Ambulance Services ¹⁴²	3,271	4,740
27	All Other Outpatient Care Centers (e.g. centers and clinics for pain therapy, community health, and sleep disorders) ¹⁴³	8,054	11,672
28	Entities providing All Other Ambulatory Health Care Services (health screening, smoking cessation, hearing testing, blood banks) ¹⁴⁴	3,670	5,319
29	Direct Health and Medical Insurance Carriers ¹⁴⁵	3,712	5,379
30	Entities Serving the Elderly and Persons with Disabilities (provision of nonresidential social assistance services to improve quality of life) ¹⁴⁶	10,475	41,899
31	Entities providing Other Individual Family Services (e.g., marriage counseling, crisis intervention centers, suicide crisis centers) ¹⁴⁷	7,184	28,736
32	Entities providing Child and Youth Services (e.g., adoption agencies, foster care placement services) ¹⁴⁸	2,901	11,604
33	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) ¹⁴⁹	1,013	4,053

¹⁴² *Id.* (nationwide count of firms for NAICS Code 621910). Assumes 69%-100% of industry is covered.

¹⁴³ *Id.* (nationwide count of firms for NAICS Code 621498). Assumes 69%-100% of industry is covered.

¹⁴⁴ *Id.* (nationwide count of firms for NAICS Code 62199). Assumes 69%-100% of the industry is covered.

¹⁴⁵ *Id.* (nationwide count of firms for NAICS Code 524114). Assumes 69%-100% of industry is covered.

¹⁴⁶ *Id.* (nationwide count of firms for NAICS Code 624120). Assumes 69%-100% of industry is covered.

¹⁴⁷ *Id.* (nationwide count of firms for NAICS Code 624190). Assumes 69%-100% of industry is covered.

¹⁴⁸ *Id.* (nationwide count of firms for NAICS Code 624110). As described *supra* Part XI.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%-100% of industry is covered.

¹⁴⁹ *Id.* (nationwide count of firms for NAICS Code 624221). As described *supra* Part XI.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%-100% of industry is covered.

34	Emergency and Other Relief Services (e.g., medical relief, resettlement, and counseling to victims of domestic or international disasters or conflicts) ¹⁵⁰	309	1,236
35	Pharmacies and Drug Stores ¹⁵¹	30,450	44,130
36	Research and Development in Biotechnology ¹⁵²	2,505	3,631
37	Colleges, Universities, and Professional Schools ¹⁵³	615	4,788
38	HHS awarded funds appropriated to the U.S. Department of State & USAID ¹⁵⁴	65	130
	TOTAL, Subject to the Notice Requirement	476,539	746,206

Public Comment Requested on Scope of Entities

Given the uncertainty as to the number of recipients covered by this NPRM, the Department in particular seeks public comment on ways that HHS could improve the accuracy of the estimates contained in this RIA. Please specifically provide data, studies, reports, or other documentation to support your comments.

Estimated Burdens

There are six categories of estimated burdens for this proposed rule, as summarized in Table 4.

¹⁵⁰ *Id.* (nationwide count of firms for NAICS Code 624230). As described *supra* Part XI.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%-100% of industry is covered.

¹⁵¹ *Id.* (nationwide count of firms for NAICS Code 44610). Assumes 69%-100% of industry is covered.

¹⁵² *Id.* (nationwide count of firms for NAICS Code 541711). Assumes 69%-100% of industry is covered.

¹⁵³ *Id.* (nationwide count of firms for NAICS Code 611310). As described *supra* Part XI.C.2.iii (methodology), the Department assumes 13%-100% of institutions of higher-education are covered.

¹⁵⁴ 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 4: Summary of Costs

	Cost Category	Year 1: Initial Costs		Years 2 to 5: Annual Recurring Costs	
		Total Cost	% Affected	Total Cost	% Affected
1	<u>Familiarization (one-time burden)</u>	\$62.9 M	100%	--	--
2	<u>Assurance and Certification</u>				
	Signing Documents	\$72.8 M	26%	\$72.8 M	26%
	Reviewing Policies and Procedures	\$36.4 M	13%	\$36.4 M	13%
	Update Policies, Procedures, Training	\$13.8 M	5%	\$1.4 M	0.5%
	Subtotal, Assurance and Cert.	\$123.0 M		\$110.6 M	
3	<u>Notice requirement</u>				
	Mandatory, one-time, posting	\$ 92.9 M	99%	--	--
	Voluntary Posting	<u>\$25.2 M</u>	50%	<u>\$6.7 M</u>	24.9%
	Subtotal, Notice	\$118.1 M		\$6.7 M	
4	<u>Compliance Procedures</u>	0.6 M	0.01%	\$0.6 M	.01%
5	<u>Voluntary Remedial Efforts</u>	<u>\$6.8 M</u>	0.5%	<u>\$6.8 M</u>	0.5%
	Subtotal, Non-HHS Costs	\$311.4 M		\$124.6 M	
6	<u>OCR Enforcement</u>	<u>\$0.9 M</u>	N/A	<u>\$0.9 M</u>	N/A
	TOTAL	\$312.3 M		\$125.5 M	

Familiarization Costs

The Department estimates that all persons and entities subject to the proposed rule would spend approximately one hour on average familiarizing themselves with the content of the proposed rule and its requirements. One fundamental reason that the Department publishes this proposed rule is the lack of awareness of obligations under Federal health care conscience and associated anti-discrimination laws and individuals rights. This burden is a one-time opportunity cost of staff time to review the proposed rule. The mean hourly wage (including

benefits and overhead) for a lawyer (occupation code 23-1011) is \$134.50 per hour (\$67.25 per hour X 2).¹⁵⁵ The labor cost is approximately \$62.9 million in the first year (\$134.50 per hour X 1 hour X 468,123 entities) and zero dollars in the out-years.

Assurance and Certification (Proposed § 88.4)

The burden for the assurance and certification is the opportunity cost of recipient staff time (1) to review the HHS-690 Form (assurance), and HHS-5161-1 Form (certification language) as well as the requirements of the underlying Federal health care conscience and associated 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 health care conscience and associated anti-discrimination laws, and (3) to implement any actions necessary to come into compliance. Examples of actions a recipient may need to take to come into compliance include updating policies and procedures, implementing staffing or scheduling practices that respect an exercise of conscience rights under Federal law, and training staff on relevant Federal laws or the recipient's policies and procedures. Table 5 *infra* summarizes these costs.

The Department estimates that each recipient not excepted will spend an average of 4 hours reviewing the assurance and certification language as well as the requirements of the underlying Federal health care conscience and associated anti-discrimination laws referenced or incorporated through a Web link. In the 2008

¹⁵⁵ Bureau of Labor Statistics, Occupational and Employment Statistics, Occupational Employment and Wages, May 2016, https://www.bls.gov/oes/current/oes_nat.htm.

Rule, the Department estimated that it would take 30 minutes to certify compliance with three laws: the Church, Weldon, and Coats-Snowe Amendments. 73 FR 78072, 78095 (2008 Rule). In this proposed rule, there are almost two dozen additional laws included. Using the rough guide of 10 minutes per law, the Department estimates that it would take 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 a chief executive spending one hour to review and sign, as proposed § 88.4(b)(2) requires a signature by an individual authorized to bind the recipient. The mean hourly wage (including benefits and overhead) for these occupations is \$134.50 per hour for the lawyer (occupation code 23-1011) (\$67.25 per hour X 2) and \$186.88 for the chief executive (occupation code 11-1011) (\$93.44 per hour X 2).¹⁵⁶ The weighted mean hourly wage (including benefits and overhead) of these two occupations is \$147.60 per hour ((134.50 X .75) + (186.88 X .25)). The labor cost is \$72.8 million each year for the first five years (\$147.60 per hour X 4 hours X 123,302 entities).

The Department estimates that 61,652 recipients, which is half of all recipients required to assure and certify compliance (123,302 entities / 2) will review policies and procedures or take other actions to self-assess compliance with

¹⁵⁶ Bureau of Labor Statistics, Occupational and Employment Statistics, Occupational Employment and Wages, May 2016, https://www.bls.gov/oes/current/oes_nat.htm.

applicable Federal health care conscience and associated anti-discrimination laws each year for the first five years of publication. The Department reasonably estimates such action because § 88.4(c)(4) states that the submission of an assurance and certification will not relieve a recipient of the obligation to take and complete actions to come into compliance prior to or after submission of such assurance or certification. The first step to such actions is reviewing organization-wide safeguards that are, or should be, in place.

The Department estimates that recipients that review policies and procedures or otherwise self-assess compliance will spend an average of 4 hours doing so. Some entities will spend more time and others will spend less time. The labor cost is a function of a lawyer spending 3 hours and a chief executive spending one hour, which produces the weighted mean hourly wage of \$147.60 per hour. The labor cost for self-assessing compliance, such as reviewing policies and procedures, is a total of \$36.4 million each year for the first five years ($\$147.60 \text{ per hour} \times 4 \text{ hours} \times 61,652 \text{ entities}$).

The Department estimates that approximately 5% of entities will take an organization-wide action to improve compliance in the first year and 0.5% will take a similar action annually each year in years two through five. This percentage equates to 23,406 recipients in year 1 and 2,341 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 train staff on relevant Federal law or the recipient's policies and procedures. The labor cost is a function of a lawyer spending 3 hours and a chief executive spending one hour, which produces a weighted mean hourly wage of \$147.60 per hour. The labor cost is \$13.8 million in year one (\$147.60 per hour X 4 hours X 23,406 entities) and approximately \$1.4 million annually for years two through five (\$147.60 per hour X 4 hours X 2,341 entities).

The Department is committed to leveraging existing grant, contract, and other Departmental forms where possible rather than creating additional, separate forms for recipients to sign. Sub-recipients are not subject to this requirement; as described in the preamble, the Department seeks comment on this approach taken to reduce burden on small entities.

Table 5: Summary of Assurance and Certification Costs

Cost Categories	Year 1: Initial Costs		Years 2 - 5: Recurring Costs	
	Total Cost	Per entity	Total Cost	Per entity
Review and Sign	\$72.8 M	\$590 dollars	\$72.8 M	\$590 dollars
Review Policies and Procedures	\$36.4 M	\$590 dollars	\$36.4 M	\$590 dollars
Update Policies and Procedures; Train Workforce	\$13.8 M	\$590 dollars	\$1.4 M	\$590 dollars
Total Costs	\$123.0 M	\$998 dollars	\$110.6 M	\$897 dollars

Notice Requirement (Proposed § 88.5)

Proposed § 88.5 requires recipients and the Department to provide notice. Section 88.5 includes a mandatory posting requirement and incentives additional posting. The mandatory posting requirement is a one-time burden with no recurring costs. The Department does not intend for recipients to incur any costs in developing the notice; indeed, proposed § 88.5 would require recipients to post the

text of the notice in appendix A to this proposed part. This approach leverages economies of scale by requiring recipients to post the exact text from the notice in Appendix A. The Department is mindful that Executive Order 13562 asks agencies, if feasible, to specify performance objectives for persons and entities rather than the behavior or manner of compliance. The Department has determined that providing a pre-written notice is the most efficient and effective way to provide information to persons, entities, and health care entities while reducing the burden on a recipient. The Department acknowledges that the trade-off regarding this approach is that it limits a recipient's flexibility. On the other hand, the decreased flexibility may be a worthwhile trade-off because, with a pre-written notice from OCR, a recipient need not spend time with counsel or executives in developing the text.

The Department estimates that the burden for the notice is represented in terms of opportunity costs of staff time to download, print, and post the notice, combined with material costs for paper and ink. These costs are a one-time, upfront burden in the first year of implementation. The Department estimates that it will take 1/3 of an hour for an administrative assistant to download the notice, print notice(s) and post them in physical locations of the establishment where notices are commonly posted. 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 to post the notice online. For some establishments, it may take an administrative assistant or Web developer longer to perform this function; for other establishments, it may take less time. The mean hourly wage (including benefits and overhead) for an administrative assistant is \$38.78 per hour (occupation code 43 -

6010) (\$19.39 per hour X 2).¹⁵⁷ The mean hourly wage (including benefits and overhead) for a Web developer is \$69.38 per hour (occupation code 15-11134) (\$34.69 per hour X 2).¹⁵⁸ This labor cost is approximately \$92.7 million ((1/3 hr. X \$38.78 per hour X 611,372 establishments) + (2 hours X \$63.38 per hour X 611,372 establishments)).

A key uncertainty with respect to this labor cost is the degree to which each establishment maintains its own Web site and thus would bear the labor cost for a Web developer to post the notice on the establishment's Web site. For the purpose of this RIA, the Department has erred on the side of overestimating the burden. Therefore, the Department assumed that a Web developer at each physical location will spend 2 hours to post the notice.

If, however, recipients maintain one Web site for all of its establishments, a Web developer at the firm-level, rather than Web developers at each establishment, would bear the labor costs to post the notice online. In contrast to 611,372 establishments bearing the labor costs of the Web developer, about 464,792 recipients at the firm-level would bear this cost. This number results from subtracting 3,324 counties from the total number of entities on average subject to the NPRM (468,026 entities). For the purpose of this calculation, the Department assumed all counties are sub-recipients.

The labor costs are the sum of (1) the costs for an administrative assistant at each establishment to post the notice in physical locations (1/3 hr. X \$38.78 per

¹⁵⁷ Bureau of Labor Statistics, Occupational and Employment Statistics, Occupational Employment and Wages, May 2016, https://www.bls.gov/oes/current/oes_nat.htm.

¹⁵⁸ *Id.*

hour X 611,372 establishments) and (2) the costs for a Web developer at each firm to post the notice on the entity's Web site (2 hours X \$63.38 per hour X 464,792), which equals \$72.4 million. This labor cost is \$20 million less, or approximately 22% less, than the labor cost of a Web developer at each establishment of a recipient, rather than at the firm-level, to post the notice on the Web sites of each recipient establishment.

Another key uncertainty with respect to the estimated burden of the notice requirement is the number of locations where notices are commonly posted in an establishment; the number will vary based on multiple factors. These factors may 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; larger entities might post more and smaller entities post fewer. The Department also 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 \$152,843 (611,372 establishments X \$.05 per page X 5 pages). Because the Department assumes that this cost is a one-time cost during the first year of this proposed rule's implementation, the cost will not recur in years 2 through 5. The total labor and materials costs for implementing the mandatory component of the notice requirement is \$8 million (\$7.9 million in labor costs and \$152,843 for materials) in year one with zero recurring costs.

Because societal goals for assuring nondiscrimination are often realized through individuals' persistent exercise of protected rights, this proposed rule's notice requirement serves as a gateway to achieve those goals. Section 88.5 intends to incentivize recipients to include the OCR-drafted notice in certain types of documents or publications by rendering such posting as a factor that the OCR Director would consider if the Director investigates or initiates a compliance review of a recipient.

For instance, OCR would take into account whether a recipient has provided the notice in a personnel manual for the recipient's workforce, in applications for membership in the recipient's workforce or to receive a service or benefit, or in a student handbook for students participating in a program for training or study. Because this provision is permissive, the Department assumes that 305,686 establishments will undertake such action in the first year, which is half of all establishments subject to the notice requirement (611,372 establishments X 50%). Approximately 152,843 establishments (305,686 establishments / 2) will annually undertake such voluntary posting in years 2 through 5. The Department assumes that an administrative assistant paid at \$19.39/hour would identify documents in which to include the notice, revising the documents or their layouts to include the notice, or otherwise printing an insert to include with paper documents. The assistant may spend a total of 2 hours in year one and 1 hour annually in years 2 through 5. The labor cost, adjusted upward for benefits and overhead is \$23.7 million (2 X \$19.39 per hour X 2 hours X 305,686 establishments) in year one and

\$5.9 million annually in years 2 through 5 (2 X \$19.39 X 1 X 152,843 establishments).

The Department anticipates that there may be some additional printing costs where inclusion of the notice adds a page to the underlying document. There is a high degree of uncertainty as to the average number of documents in which a recipient may proactively include the notice. There is also uncertainty as to whether a recipient would provide hard-copy publications or house them online.

A recipient that voluntarily includes the notice in certain publications probably would provide some in hard-copy and others online. On balance, a recipient might print approximately 100 extra pages. Given these assumptions, the cost of voluntarily included notices, as proposed § 88.5(c) incentivizes, will cost approximately \$1.5 million in the first year (305,686 entities X 100 pages X \$.05 per page) and \$764,215 annually in years two through five.

In sum, total first-year costs to implement the mandatory and voluntary components of the notice requirement is estimated at \$118.1 million and \$6.7 million annually in years 2 through 5, which is a 94% decrease in cost from the one-time cost to implement the notice requirement in year 1.

Compliance Procedures (§ 88.6(d))

The information promptly informs applicable Departmental components of OCR's pending investigation to ensure appropriate coordination within the Department during the pendency of the investigation and the obligation to report complaints if the Department modifies existing applications for grants, or in a separate writing with the applications, for five years. OCR estimates that there are

30 recipients on average per year that OCR may investigate and investigate. Thirty recipients is the average between the lower-bound estimate (10 recipients) and the upper-bound estimate (50 recipients).

The Department estimates that the burden is the opportunity cost that recipients and sub-recipients would incur to email the appropriate grants management official(s). The Department assumes that this email would inform the Department component and could also be used as the separate writing to accompany new or renewed applications. This burden is the labor cost associated with an administrative assistant spending approximately 15 minutes to draft and transmit the email. The mean hourly wage for the administrative assistant (occupation code 43-6010) (\$19.39 per hour) (adjusted for benefits and overhead) is \$38.78 per hour. The Department estimates that the administrative assistant would incur this labor cost for each award action for which the recipients applied, including new funding opportunities, supplemental funding, and non-competing continuations, among others.

Because OCR had no publicly available and reliable data source to know how many total applications for new or renewed funding in a fiscal year a recipient might make to the Department or its component, OCR used actual award data from HHS TAGGS as a proxy. The Department looked at 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 a couple of awards per fiscal year and others receive 80 awards per fiscal year.

The Department erred on the side of overestimating the burden and assumed that each of the 30 recipients would apply for new or renewed funding 2,000 times per year. The annual labor cost is \$0.6 million across all 30 entities (30 recipients X \$39.78 per hour X 0.25 hours X 2,000).

Voluntary Remedial Efforts

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 proposed 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 anticipates 0.5% of entities, or 2,340 recipients or sub-recipients, (0.005 X 468,026 recipients), would conduct such internal investigations should complaints come to the recipient's or sub-recipient's attention or undertake remedial efforts.

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 per year. On average, the Department anticipates entities spending 20 hours annually: 16 hours of a lawyer's time and 4 hours of a chief executive's time. The mean hourly wage (including benefits and overhead) for these occupations is \$134.50 per hour for the lawyer (occupation code 23-1011) (\$67.25 per hour X 2 to adjust upward for

benefits and overhead) and \$186.88 for the chief executive (occupation code 11-1011) (\$93.44 per hour X 2 to adjust upward for benefits and overhead).¹⁵⁹ The weighted mean hourly wage (including benefits and overhead) is \$72.49 per hour $((\$67.25 \times .80) + (\$93.44 \times .20))$. The labor cost is \$6.8 million (\$144.98 per hour X 20 hours X 2,341 entities).

Some recipients may spend more than 20 hours, 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.

OCR Enforcement

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 to address those rights through the administrative complaint process; and an increase in the number of Federal health care conscience and associated anti-discrimination laws for which the rule proposes to enforce. The Department expects that after 5 years following publication of the final rule, the number of complaints probably will plateau, but uncertainty exists in this estimated timeframe. The Department hopes that over time, recipients' awareness of their obligations will equate to fewer violations of law and consequently fewer complaints to OCR to address such violations.

¹⁵⁹ Bureau of Labor Statistics, Occupational and Employment Statistics, Occupational Employment and Wages, May 2016, https://www.bls.gov/oes/current/oes_nat.htm.

OCR will bear the increased cost in the form of the opportunity cost of staff resources for enforcement. In the first five years following publication of the rule, the Department anticipates that the impact of this proposed rule on enforcement is equivalent to an additional 4.5 FTE. The fully loaded labor cost (which includes benefits and overhead) is about \$201,000 per FTE. With these variables, the Department expects OCR's staff costs would increase by \$904,500 annually in years one through five (4.5 FTE X \$201,000 / FTE).

Request for Comment on Burden Analysis

The Department seeks public comment on improving the accuracy of the best estimates contained in this RIA. To the extent that more entities are covered or an entity spends more staff time executing or implementing required and/or voluntary actions, the costs will be higher than estimated. Similarly, to the extent that fewer persons and entities are covered, or an entity spends less staff time executing or implementing required and/or voluntary actions, the costs will be lower than estimated.

In particular, the Department would appreciate comment on areas where the public has documentation, data, or other information to support a belief that this RIA over-estimates or under-estimates the implementation costs. For instance, the Department assumes that recipients and sub-recipients maintain records in the course of evidencing compliance with the terms and conditions of a Federal award, which would include not only financial requirements but all applicable Federal laws, including Federal health care conscience and associated anti-discrimination laws. Consequently, the Department has not identified record keeping as a separate

burden resulting from this proposed rule because the Department understands that recipients and sub-recipients must document such compliance in the course of receiving a Federal award. To the extent that this assumption does not represent the existing record keeping requirements or practices, please provide comments to inform this assumption.

Moreover, the Department would appreciate information, data, studies, reports, or other documentation to that support what costs, if any, result from ancillary effects of this proposed rule, such as the monetary impact of certain health outcomes that may arise from the increase protection of conscience of medical providers as set forth in the proposed rule.

Estimated Benefits

This proposed rule is expected to remove barriers to the entry of certain health professionals, and to delay the exit of certain types of health professionals from the field, due to discrimination or coercion anticipated or experienced. Second, in supporting a more diverse medical field, the proposed rule would create ancillary benefits for patients. Third, the Department expects that the proposed rule would generate benefits by securing a public good—a society free from discrimination, which permits more personal freedom and removes unfairness. The proposed rule would promote protection of religious beliefs and moral convictions, which is a societal good based on fundamental rights.

Historical Support for Conscience Protections

The people of the United States of America have valued conscience protections since the country's founding. James Madison, the fourth President of the

United States and often hailed as the “father of the Constitution” said, “[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.”¹⁶⁰ 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.”¹⁶¹ Some scholars have argued that “[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.”¹⁶²

Recruitment and Maintenance of Health Care Professionals

This proposed rule is expected to remove barriers to the entry of certain health professionals, and to delay the exit of certain types of health professionals from the field, due to discrimination or coercion anticipated or experienced. The Department has a significant interest in removing unlawful barriers to careers in the health care field. As numerous studies and comments establish, failure to protect conscience is one such barrier.

¹⁶⁰ James Madison, Property, The Founders’ Constitution (March 29, 1792), <http://press-pubs.uchicago.edu/founders/documents/v1ch16s23.html>.

¹⁶¹ Letter from George Washington, to The Society of Quakers (October 13, 1789), <https://founders.archives.gov/documents/Washington/05-04-02-0188>.

¹⁶² Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals*, 49 Ariz. St. L.J. 549, 561 (2017).

A 2011 study released by the American College of Obstetrics and Gynecology revealed that, “while 97% of ob-gyns reported having encountered women seeking an abortion, only 14% said they were willing to perform the service.”¹⁶³ Only 1.2% of Evangelical Protestant, 9% of Catholic or Eastern Orthodox, 10.1% of Non-Evangelical Protestant, 20% of Hindu, 26.5% with no religious affiliation, and 40.2% of Jewish doctors said they would provide abortion.¹⁶⁴ Yet one in six patients is cared for in Catholic hospitals, and Catholic Hospitals employed 523,040 full-time and 216,487 part-time workers in 2015.¹⁶⁵ Another pro-life organization, the Christian Medical & Dental Associations (“CMDA”), boasts 19,000 members.¹⁶⁶ And the American Association of Pro-Life Obstetricians and Gynecologists (“AAPLOG”), which boasts 2,500 members and associates,¹⁶⁷ 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

¹⁶³ *Abortion is Legal, but What Percentage of Ob-Gyns Will Provide One?*, Freakonomics (August 24, 2011, 1:57 PM), <http://freakonomics.com/2011/08/24/abortion-is-legal-but-what-percentage-of-ob-gyns-will-provide-one/>.

¹⁶⁴ *Id.*

¹⁶⁵ *U.S. Catholic Health Care: The Nation’s Largest Group of Not-for-Profit Health Care Providers*, Catholic Health Association of the United States (2017), available at https://www.chausa.org/docs/default-source/default-document-library/cha_2017_miniprofile.pdf?sfvrsn=0.

¹⁶⁶ *History of Our Ministry*, Christian Medical & Dental Associations, <https://www.cmda.org/library/doclib/history-of-cmda.pdf>.

¹⁶⁷ *About Us*, American Association of Pro-Life Obstetricians and Gynecologists, <http://aaplog.org/about-us>.

would accept coercion to participate or assist in procedures that violate their consciences.”¹⁶⁸

Protecting the conscience rights of persons, entities, and health care entities is expected to result in the recruitment of diverse health care professionals and the maintenance of such professionals in the field. The medical community and American people as a whole might also benefit from the willing and enthusiastic participation in the field of people with a variety of moral, religious, and philosophical backgrounds. The Department expects that its proposed rule will protect existing participants in the profession and promote more diverse participation over time as the institutional culture at health facilities, and in health-professions training programs, changes.

Patient Benefits from Conscience Protections

In supporting a more diverse medical field, the proposed rule would create ancillary benefits for patients. The proposed rule would assist patients in seeking counselors and other health-care providers who share their deepest held convictions. Some patients will appreciate the ability to speak frankly about their own convictions concerning questions that touch upon life and death and treatment 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. A pro-vaccination parent may seek a pediatrician who shares

¹⁶⁸ Letter from Lawrence J. Joseph, on behalf of the American Association of Pro-Life Obstetricians and Gynecologists, to the Office of Public Health & Science, Department of Health & Human Services 2 (April 9, 2009), available at <http://downloads.frc.org/EF/EF09D50.pdf>.

his views. Open communication in the doctor-patient relationship will foster better over-all 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.”¹⁶⁹ But poor communication negatively affects continuity of care and undermines the patient’s health goals. 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 minorities. Because positions of conscience are often grounded in religious influence, “[d]eny[ing] the aspect of spirituality and religion for some patients can act as a barrier. These influences can greatly affect the well-being of people. These influences 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.”¹⁷⁰ It is important for patients seeking care to feel assured that their faith, and the principles of conscience grounded in their faith, will

¹⁶⁹ Fallon E. Chipidza, et al., *Impact of the Doctor-Patient Relationship*, 17(5) *The Primary Care Companion for CNS Disorders* (2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4732308/>.

¹⁷⁰ Emmanuel Scheppers, et al., *Potential Barriers to the Use of Health Services Among Ethnic Minorities: A Review*, 23 *Family Practice* 325, 343 (2006), available at <https://academic.oup.com/fampra/article/23/3/325/475515>.

be honored. This will ensure that they feel they are being treated fairly.¹⁷¹ And for some, being able to find health care providers that share the same moral convictions can be a source of personal healing. *See Gonzales v. Carhart*, 550 U.S. 124, 159 (2007) (“Respect for human life finds an ultimate expression in the bond of love the mother has for her child. . . . it seems unexceptionable to conclude some women come to regret their choice to abort the infant life they once created and sustained.”). The patient benefits that will accrue from respect for provider conscience protections may take time to develop, but the Department anticipates that such benefits will be individualized and long-lasting.

Societal Benefits from Conscience Protections

The proposed rule will also yield lasting societal benefits. The rule will mitigate current misunderstanding about what conduct the Federal government is legally able to support and fund, and it will educate individuals about their Federal health care conscience rights. The proposed rule would provide an enforcement mechanism for individuals and institutions to file complaints with the Department when such individuals and institutions believe that their rights have been curtailed. The Department expects that, as a result of this proposed rule, more individuals, having been apprised of those rights, would assert them, and such assertions would contribute to the general public’s knowledge and appreciation of these protections.

Fostering respect for the existing Federal health care conscience and associated anti-discrimination laws also fosters lawfulness more generally. As one author stated,

¹⁷¹ *Id.*

[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.¹⁷²

Because fostering conscience in individuals contributes to a more lawful and virtuous society, governments and their subdivisions have a significant interest in encouraging expressions of, and fidelity to, conscience. 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 respect for conscience to the individual and society as a whole, but the benefit is 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.

United States v. Seeger, 380 U.S. 163, 169 (1965) quoting Harlan Fisk Stone, *The Conscientious Objector*, 21 Col. Univ. Q. 253, 269 (1919).

¹⁷² Lynn Stout, *Cultivating Conscience: How Good Laws Make Good People* 17 (2011).

The Department seeks comment regarding the benefits of this proposed rule, and how they might be quantified or monetized and specifically seeks supporting data, studies, reports, or other documentation.

Analysis of Regulatory Alternatives

The Department carefully considered alternatives to this proposed rule, but concluded that none struck the appropriate balance between the Administration's goal of robust enforcement of existing Federal statutory protections for conscience in the health care field without unduly burdening entities in that field.

First, the Department considered maintaining the status quo, enforcing part 88 as it current exists and largely deferring to States to enact and enforce their respective conscience laws, but such an approach would create a significant risk of unaddressed violations of the conscience rights of persons, entities, and health care entities. Specifically, it would leave OCR's minimal administrative enforcement scheme as the only remedy for alleged violations of the Weldon, Coats-Snowe or Church Amendments. *See supra* Part VI (reasons for the proposed rule). That minimalistic scheme, so different from those that pertain to other civil rights laws, undermines both OCR's authority and public perception of the value of these protections. And it fails to allow for strategic coordination with respect to the compliance and enforcement of the many Federal health care conscience and associated anti-discrimination protections that exist outside the Weldon, Coats-Snowe or Church Amendments.

Second, the Department also considered alternative approaches to the policies enunciated in the proposed rule. The Department considered developing a

rule that specifies performance objectives rather than the manner of compliance to allow persons and entities more flexibility. For instance, instead of providing the text of a notice in Appendix A for recipients to post, the Department considered allowing recipients to develop the text of their own notices, so long as such notices achieved certain substantive objectives. But the Department was sensitive to the time it might take each entity to draft a notice and to obtain the proper legal consultation and executive sign-off. In lieu of requiring, or permitting, each entity to re-create the wheel, the Department proposes that entities use the notice in Appendix A to reduce burden. The Department also considered requiring fewer recipients to execute the assurance and certify compliance, and /or to post notices of individuals' conscience and anti-coercion rights and the recipients' corresponding obligations.

The Department invites comment on our proposed approach, as well as other approaches to achieve robust enforcement of Federal health care conscience laws with minimal regulatory burden.

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 proposed rule is a significant regulatory action as defined by Executive Order 12866. If this rule is finalized as proposed, it would be considered a regulatory action under Executive Order 13771. Excluding any ancillary costs attributed to this proposed rule that result from health outcomes or

other effects of protecting conscience rights (as this RIA seeks comment on such costs, which have not yet been quantified), the Department estimates that this rule generates \$112 million in annualized costs at a 7% discount rate, discounted relative to year 2016, over a perpetual time horizon.

Regulatory Flexibility Act

HHS has examined the economic implications of this proposed 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 proposed rulemaking on small entities by providing an initial regulatory flexibility analysis unless the agency expects that the proposed rule will not have a significant impact on a substantial number of small entities, provides a factual basis for this determination, and proposes to certify the statement. 5 U.S.C. 603(a), 605(b). If an agency must provide 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 preliminarily concluded that this proposed rule does not have a significant economic impact on a substantial number of small entities. The entities that would be affected by the proposed rule, in industries described in detail in the RIA, are considered small by virtue of either nonprofit status or having revenues of less than between \$7.5 million and \$38.5

million in average annual revenue, with the threshold varying by industry.¹⁷³

Persons and States are not included in the definition of a small entity. The Department assumes that most, if not all, of the entities affected meet the threshold of a small entity.

Although the proposed rule will apply to and thus affect small entities, the proposed rule's per-entity effects are relatively small. The Department estimates that this rule would impose an average cost of \$665 in the first year of compliance following publication of the final rule and about \$266 per year in subsequent years. Furthermore, these costs would generally be proportional to the size of an entity, suggesting that the smallest affected entities will face lower average costs. Given thresholds discussed above, we believe these average costs are well below those required to have a significant impact on a substantial number of small entities.

Despite this determination, the proposed rule attempts to minimize costs imposed on small entities. For example, the assurance and certification requirements in proposed § 88.4 contain exceptions to relieve many small entities of the requirement to submit an assurance and certification. 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, in an effort to reduce economic burden imposed by the notice requirements in proposed § 88.5, HHS has drafted a notice in Appendix A for recipients to use so that the recipients do not have to bear the labor costs of consulting with counsel and executives. In light of this determination, the

¹⁷³ https://www.sba.gov/sites/default/files/files/Size_Standards_Table_2017.pdf.

Secretary proposed to certify that this rule will not result in a significant impact on a substantial number of small entities.

Unfunded Mandates Reform Act

HHS similarly concludes that the requirements of the Unfunded Mandates Reform Act of 1995 are not triggered by the proposed rule. Section 202(a) of that Act requires us 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 \$148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. As discussed in this Regulatory Impact Analysis, if finalized as proposed, this rule would 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.

Executive Order 13132—Federalism

The Secretary has also preliminarily determined that this proposed rule does not implicate the requirements of Executive Order 13132. That Executive Order requires an agency to meet certain requirements when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct effects on (1) States, including political subdivisions thereof, (2) the relationship between the Federal government and the States, or (3) the distribution of power and responsibilities

among the various levels of government. Although this rulemaking is expected to affect State and local governments, the anticipated affect is not substantial.

First, this rulemaking does not impose substantial direct effects on States or political subdivisions of States. The substantive prohibitions and requirements in Federal health care conscience and associated anti-discrimination laws already apply to State and local governments. Moreover, State and local government agencies who are recipients of HHS awards must already assure compliance with applicable Federal laws and certify compliance with them in the normal course of receiving such awards. And although proposed § 88.5 imposes a new requirement to post a notice about rights and obligations under Federal health care conscience and associated anti-discrimination laws, this requirement involves a minimal one-time opportunity cost on staff time, attaches only to recipients, and is similar to notice requirements already in force for other civil rights laws. Under such circumstances, the notice requirement cannot be understood to impose substantial direct effects on States or their political subdivisions.

Second, this proposed rulemaking does not have substantial direct effects on the relationship between the Federal government and the States. The proposed rule would be promulgated under longstanding Federal laws that leave room for State activity. For example, 42 U.S.C. 280g-1(d) authorizes the Department to provide grants and cooperative agreements for newborn and infant hearing screening, but makes clear that such grants do not preempt or prohibit any State law, including State laws that allow parents to assert religious objections to such screening. Similarly, 42 U.S.C. 1396f clarifies that nothing in that subchapter shall be construed

to require a State to compel a person to undergo medical screenings, examination, diagnosis, treatment, health care or services if a person objects on religious grounds (except for discovering and preventing the spread of infection or contagious disease or protecting environmental health). And the requirement in 42 U.S.C. 1396s(c)(2)(B)(ii) for providers to offer pediatric vaccines is subject to applicable State law, including any law relating to any religious or other exemption. Given these provisions, it is no surprise that, as described *supra*, in Part VIII, all fifty States have some protections in place for conscientious objectors to certain health or medical services.¹⁷⁴

The proposed rule makes clear that it is not intended to interfere with the operation of State law, except as required by existing Federal health conscience protections. Thus, proposed § 88.8 states that this proposed rule does not preempt any Federal, State, or local law that is equally as protective of the rights of conscience and against coercion as the regulation. And the proposed § 88.7 borrows from enforcement mechanisms already available to OCR to enforce similar civil rights laws. States are familiar with such mechanisms from decades of investigations, compliance reviews, and remedial actions taken pursuant to existing civil rights laws (e.g. Title VI, Section 504 of the Rehabilitation Act, and Title II of the Americans with Disabilities Act). HHS believes that this approach does not alter or have any substantial direct effects on the relationship between the Federal government and the States.

¹⁷⁴ See Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals*, 49 Ariz. St. L.J. 549, 575-76, app. I, 587-600 (2017) (summarizing State laws).

The Department invites comments from States and local governments on whether provisions of this proposed rule implicate federalism concerns not identified and ways to minimize any such burden, consistent with meeting the Department's objectives of ensuring (1) knowledge of the obligations imposed, and the rights and protections afforded, by Federal health care conscience and associated anti-discrimination laws; and (2) compliance with their nondiscrimination provisions.

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 proposed rule under Executive Order 12866, the Department deems that this proposed rule is a major rule for purposes of the Congressional Review Act.

Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999, Pub. L. 105-277, section 654, 112 Stat. 2681 (1998) (codified at 5 U.S.C. 601

(note)), requires Federal departments and agencies to determine whether a proposed policy or regulation could affect family well-being.¹⁷⁵

Agencies must assess whether the proposed 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 financially impacts families, are 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 and personal responsibility of youth and the norms of society.¹⁷⁶

It is unlikely that this proposed rule will negatively impact the stability of the family or impact parental authority. In addition, the proposed rule has no bearing on the disposable income or poverty of families and children, and none of the rule's proposed provisions concern the relationship between the behavior and personal responsibility of youth and the norms of society. Finally, the action taken in this proposed rule cannot be carried out by State or local government or by the family because the rule pertains to the enforcement of certain Federal laws. Therefore, this proposed rule probably will have minimal to no impact on family well-being.

¹⁷⁵ This section discusses the assessment required in Executive Order 12606, The Family, which was revoked on April 21, 1997. Memorandum from Jacob Lew, Dir., Office Of Mgmt. & Budget, Exec. Office of the President, To Heads of Exec. Dep'ts, Agencies, & Independent Establishments Assessment of Federal Regulations and Policies on Families (Jan. 26, 1999) <https://www.fws.gov/policy/library/rglew.pdf>.

¹⁷⁶ Treasury and General Government Appropriations Act of 1999, Pub.L. 105-277, sec. 654, 112 Stat. 2681 (1998).

If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law. The Secretary proposes to certify that this proposed rule has been assessed in accordance with Section 654 of the Treasury and General Government Appropriations Act of 1999, Pub. L. 105-277, section 654, 112 Stat. 2681 (1998), and will not negatively affect family well-being.

Paperwork Reduction Act

This notice of proposed rulemaking would call for 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 collections of information required by the proposed rule relate to § 88.4 (Assurance and Certification), § 88.5 (Notice), and § 88.6(d) (Compliance Requirements).

Information Collection for Proposed § 88.4 (Assurance and Certification)

Summary of the Collection of Information: The proposed rule requires each recipient (or applicant to become a recipient), with limited exception, to assure and certify compliance with Federal conscience and associated anti-discrimination laws. Specifically, proposed § 88.4(a) 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 health care conscience and associated anti-discrimination laws. The Federal laws with which recipients would be required to assure compliance, if applicable, are:

Provider conscience laws related to abortion (the Weldon Amendment for Medicare Advantage, *e.g.* Pub. L. 115-31, Div. H, sec. 209, 131 Stat. 135, 539 (2017));

Certain provisions of the Affordable Care Act applying Federal conscience protections (42 U.S.C. 18023(b)(4)), regarding assisted suicide (42 U.S.C. 18113), and providing a conscience exemption to the individual mandate (26 U.S.C. 5000A(d)(2));

Certain laws governing provider counseling, referral, and implementation of directives (counseling and referral in Medicare Advantage ((42 U.S.C. 1395w-22(j)(3)(B))), counseling and referral in Medicaid (42 U.S.C. 1396u-2(b)(3)(B)), and performance of advanced directives in the Medicare and Medicaid programs (42 U.S.C. 1396a(w)(3), and 14406);

Conscience and anti-coercion laws applicable to Global Health Programs for HIV/AIDS Prevention, Treatment, or Care (22 U.S.C. 7631(d)) and certain funds appropriated to the U.S. Department of State and USAID (the Helms Amendment (*e.g.*, Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. J, sec. 7018));

Laws providing for patient objections to receiving health care services, including medical screening, examination, diagnosis, treatment, or other health care (42 U.S.C. 1396f), occupational illness testing (29 U.S.C. 669(a)(5)), pediatric

vaccination (42 U.S.C. 1396s(c)(2)(B)(ii)), youth suicide prevention and treatment (42 U.S.C. 290bb-36(f)), and newborn health screening (42 U.S.C. 280g-1(d)); and

Laws protecting religious nonmedical health care by exempting religious non-medical institutions from 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 from utilization review plan requirements (42 U.S.C. 1396b(i)(4)), and 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)).

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 health care conscience and associated anti-discrimination laws. Second, a recipient's or applicant's awareness of its obligation 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. Because of this awareness, the Department anticipates that this rule may generate changes in the policies, procedures, and operations of the entities that this proposed rule covers.

Proposed Use of Information: The Department and its components awarding Federal funds and OCR would use the signed assurance and certification as

documentation of: (1) a recipient's or applicant's awareness of its obligations under the Federal health care conscience and associated anti-discrimination laws and the proposed rule, and (2) a recipient's commitment to comply with such statutes and the proposed rule. This use would most likely occur during an OCR investigation of the recipient's compliance with Federal health care conscience and associated anti-discrimination laws and this proposed rule.

Description of the Respondents: The respondents are applicants or recipients for Federal financial assistance or Federal funds from the Department to which the proposed § 88.3 applies. 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.

Number of Respondents: The Department estimates the number of respondents at 123,302 persons or entities. This estimate represents the average between the lower-bound (94,214) and upper-bound (152,389) estimates of entities that will have to sign an assurance or a certification. These figures appear *supra* in Table 2.

Respondents are a subset of the recipients subject to the relevant Federal health care conscience and associated anti-discrimination laws and the proposed rule because proposed § 88.4(c)(1) through (4) excludes certain categories of recipients. Specifically, the proposed rule excludes physicians, as defined in 42 U.S.C. 1395x(r), physician offices, or other health care practitioners who are recipients, as defined in proposed § 88.2, only in the form of reimbursements for participation

Medicare Part B. *See* proposed § 88.4(c)(1). The proposed 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* proposed § 88.4(c)(2) and (3). Finally, the proposed rule excludes Indian Tribes and Tribal Organizations when contracting with the Indian Health Service under the Indian Self-Determination and Education Assistance Act. *See* proposed § 88.4(c)(4).

Burden of Response: The Department is committed to leveraging existing grant, contract, and other Departmental forms where possible rather than creating additional, separate forms for recipients to sign. The Department intends to update the HHS-690 Form , which includes several Federal civil rights authorities with which applicants and recipients must assure compliance.¹⁷⁷ The Department would update the form to include a reference to Federal health care conscience and associated anti-discrimination laws, as well as a Web link to information about the

¹⁷⁷ HHS regulations implementing each of the following civil rights laws require recipients to assure compliance with applicable implementing regulations: Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, and Section 1557 of the Affordable Care Act. *See* 45 CFR 80.4 (requiring recipients to assure compliance with HHS Title VI regulations), 84.5 (requiring recipients to assure compliance with HHS Section 504 regulations), 86.4 (requiring recipients to assure compliance with HHS Title IX regulations), 91.33 (requiring recipients to assure compliance with the Age Act and HHS implementing regulations), 92.5 (requiring recipients and entities created under Title I of the Affordable Care Act to assure compliance with Section 1557 and the HHS implementing regulation).

requirements. The Department also intends to update HHS-5161-1 Form, OMB No. 0930-0367 (Certification of Compliance).

The burden for the assurance and certification is the opportunity cost of recipient staff time (1) to review the assurance and certification language as well as the requirements of the underlying Federal health care conscience and associated anti-discrimination laws referenced or incorporated, (2) to review entity-wide policies and procedures or take other actions to self-assess compliance with applicable Federal health care conscience and associated anti-discrimination laws, and (3) to implement any actions to come into compliance.

The methods that the Department uses are outlined *supra* in the Assurance and Certification section of this RIA. The only adjustment to those methods for this information collection analysis is to adjust the mean hourly wage downward to exclude benefits and overhead. In doing so, the Department calculates the following labor costs.

The labor cost is a function of a lawyer spending 3 hours reviewing the assurance and certification and a chief executive spending one hour to review and sign, as proposed § 88.4(b)(2) requires a signature by an individual authorized to bind the recipient. The mean hourly wage (not including benefits and overhead) for these occupations is \$67.25 per hour for the lawyer (occupation code 23-1011) and \$93.44 for the chief executive (occupation code 11-1011).¹⁷⁸ The weighted mean hourly wage (not including benefits and overhead) of these two occupations is

¹⁷⁸ Bureau of Labor Statistics, Occupational and Employment Statistics, Occupational Employment and Wages, May 2016, https://www.bls.gov/oes/current/oes_nat.htm.

\$73.80 per hour $((\$67.25 \times .75) + (\$93.44 \times .25))$. The labor cost is \$36 million each year for the first five years $(\$73.80 \text{ per hour} \times 4 \text{ hours} \times 123,302 \text{ entities})$.¹⁷⁹

The Department estimates that 61,652 recipients, which is half of all respondents to this information collection $(123,302 \text{ entities} / 2)$ will review entity-wide policies and procedures or take other actions to self-assess compliance with applicable Federal health care conscience and associated anti-discrimination laws each year for the first five years of publication, spending an average of 4 hours doing so. The labor cost is a function of a lawyer spending 3 hours and a chief executive spending one hour, which produces the same weighted mean hourly wage of \$73.80 per hour. The labor cost for self-assessing compliance, such as reviewing policies and procedures, is a total of \$18.2 million each year for the first five years $(\$73.80 \text{ per hour} \times 4 \text{ hours} \times 61,652 \text{ entities})$.¹⁸⁰

The Department estimates that approximately 5% of entities will take an organization-wide action to improve compliance in the first year and 0.5% will act each year in years two through five. This percentage equates to 23,406 entities in year 1 and 2,341 entities annually in years two through five. The Department estimates that each year, the entities that engage in this voluntary compliance will spend 4 hours annually, on average. The labor cost is a function of a lawyer spending 3 hours and a chief executive spending one hour, which produces a weighted mean hourly wage of \$73.80 per hour. The labor cost is \$6.9 million in

¹⁷⁹ 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.

¹⁸⁰ 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.

year one (\$73.80 X 4 X 23,406 entities) and approximately \$690,783 annually for years two through five (\$73.80 X 4 X 2,341 entities).¹⁸¹

The Department asks for public comment on the proposed information collection, including the particular issues below.

- Whether the proposed collection of information is necessary for the proper performance of OCR's functions and the Department's and its components' functions to enforce Federal laws on which Federal funding is conditioned, including whether the information will have practical utility.

- 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 health care conscience 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.

¹⁸¹ 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.

- 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.

Information Collection for Proposed § 88.5 (Notice)

Summary of the Collection of Information: Under the proposed rule, each recipient and the Department must post a notice that appraises persons, entities, and health care entities of their rights under Federal health care conscience and associated anti-discrimination laws and this proposed part.

Need for Information: Notice serves three primary purposes. First, persons become apprised of their rights under the applicable Federal health care conscience and associated anti-discrimination laws, including the right to file a complaint with HHS OCR. Second, a person's awareness of his or her rights increases the likelihood that the person will exercise those rights. Third, recipients and their managers and employees will be reminded and be made aware of their own obligations under these laws.

Proposed Use of Information: In the event that the OCR Director investigates or initiates a compliance review of a recipient, the OCR Director will consider as one of many factors whether the recipient posted the notice in the documents described in § 88.5(c)(1) through (3), as applicable.

Description of the Respondents: The respondents are recipients. Respondents include, but are not limited to, 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.

Number of Respondents: The number of respondents is estimated at 611,372 establishments. This estimate represents the average between the lower and upper-bound estimates of how many recipient establishments must post notices.

Respondents are a subset (99.5%) of the total scope of entities subject to this proposed rule because the notice requirement does not apply to sub-recipients.

Burden of Response: The Department estimates that the burden for the notice is represented in terms of opportunity costs of staff time to download, print, and post the notice, combined with material costs for paper and ink. These costs are a one-time burden in the first year of this proposed rule's implementation.

The Department estimates that it would take 1/3 of an hour for an administrative assistant to download the notice, print notice(s) and post them in physical locations of the establishment where notices are commonly posted. 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 to post the notice online. For some establishments, it may take an administrative assistant or Web developer longer to perform these functions; for other establishments, it may take less time.

The Department uses the same method for calculating the cost of this requirement *supra* in the RIA but adjusts the hourly wage downward to exclude benefits and overhead. The mean hourly wage (not including benefits and overhead)

for an administrative assistant is \$19.39 per hour (occupation code 43-6010).¹⁸²

The mean hourly wage (not including benefits and overhead) for a Web developer is \$34.69 per hour (occupation code 15-11134). This labor cost is approximately \$46.4 million ((1/3 hour X \$19.39/hr. X 611,372 establishments) + (2 hours X \$34.69/hr. X 611,372 establishments)).¹⁸³

The number of locations where notices are commonly posted in an establishment will vary based on multiple factors. The Department also 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 (611,372 establishments X \$0.05 per page X 5 pages), which amounts to about \$152,843. Because the Department assumes that this cost is a one-time, upfront cost, it will not recur in the out-years.

The proposed notice provision at § 88.5(c)(1) through (3) includes language designed to incentivize recipients to include the OCR-drafted notice in certain types of documents or publications. Because this provision is permissive, the Department assumes that 305,686 establishments will undertake such action in the first year, which is half of all establishments subject to the notice requirement (611,372 establishments X 50%). Approximately 152,843 establishments (305,686 establishments / 2) will annually undertake such voluntary posting in years 2 through 5. The Department assumes that an administrative assistant paid at

¹⁸² Bureau of Labor Statistics, Occupational and Employment Statistics, Occupational Employment and Wages, May 2016, https://www.bls.gov/oes/current/oes_nat.htm.

¹⁸³ 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.

\$19.39/hour would identify documents in which to include the notice, revising the documents or their layouts to include the notice, or otherwise printing an insert to include with paper documents. The assistant may spend a total of 2 hours in year one and 1 hour annually in years 2 through 5. The labor cost in year 1 is \$11.9 million ($\$19.39 \times 2 \times 305,686$ establishments) and \$3 million annually in years 2 through 5 ($\$19.39 \times 1 \times 152,843$ establishments).

The Department anticipates that there may be some additional printing costs where inclusion of the notice adds a page to the underlying document. There is a high degree of uncertainty as to the average number of documents in which a recipient may proactively include the notice. There is also uncertainty as to whether a recipient would print the publications or house them online. The Department estimates that a recipient that voluntarily includes the notice in publications may print some publications and house others online; on balance, the recipient might print approximately 100 extra pages. With these assumptions, the cost of voluntarily included notices, as proposed § 88.5(c) incentivizes, will cost approximately \$1.5 million in the first year ($305,686$ entities \times 100 pages \times $\$.05$ per page) and \$764,216 annually in years two through five.

Total first-year costs (mandatory plus voluntary) for the notice requirement are estimated at \$59.9 million and \$3.7 million annually in years 2 through 5.

The Department asks for public comment on the proposed information collection, including the particular issues below.

- Whether the proposed collection of information is necessary for the proper performance of OCR's functions and the Department's and its components' functions

to enforce Federal laws on which Federal funding is conditioned, including whether the information will have practical utility.

- Feedback on the assumptions that form the basis of our cost estimates for the notice provision.

- How the manner of compliance with notice provision could be improved, including through the use of automated collection techniques or other forms of information technology.

Compliance Procedures (§ 88.6(d))

Summary of the Collection of Information: Proposed § 88.6(d) requires any recipient that receives a notice of investigation or compliance review letter from OCR concerning Federal health care conscience and associated anti-discrimination laws to report this fact to each of the Departmental components from which the recipient receives Federal funds. Additionally, this requirement applies to complaints filed with OCR such that the recipient must disclose to the applicable Departmental funding component the existence of the complaint for five years from the date of the filing of the complaint whenever it applies for new or renewed Federal financial assistance or other Federal funds from the Department.

Need for Information: The information promptly informs applicable Departmental components of OCR's pending investigation and historical complaints to ensure appropriate coordination within the Department during the pendency of the investigation and to inform funding decision-making.

Proposed Use of Information: At a minimum, this requirement puts the Departmental component on notice of OCR's investigation and facilitates

coordination between the component and OCR on technical or factual matters underlying the recipient's or sub-recipient's extension of Federal funds. The Department component may also use the information to monitor the status of the investigation and history of complaints to incorporate these facts into the component's decision-making when deciding whether to approve or renew or modify Federal funding to the recipient.

Description of the Respondents: The respondents are a subset of recipients and sub-recipients subject to an HHS OCR investigation of Federal health care conscience and associated anti-discrimination laws and this proposed rule. Respondents include State and local governments, physicians, hospitals, research institutions, health professions training programs, qualified health plan issuers, Health Insurance Marketplaces, home health agencies, educational institutions, community mental health centers, and skilled nursing facilities, among others.

Number of Respondents: The number of respondents on average is 30 recipients per year, which is the average between the lower-bound (10 recipients) and upper-bound (50 recipients) estimate.

Burden of Response: The Department estimates that the burden is the opportunity cost that recipients will incur to spend 15 minutes to email the appropriate grants management official(s). The Department uses the same methodology used when calculating these costs in the RIA but adjusts the hourly wage down to exclude benefit and overhead. The mean hourly wage for the administrative assistant (not adjusted for benefits and overhead) is \$19.39 per hour.

The annual labor cost is \$0.3 million across all 30 entities (30 entities X \$19.39 per hour X 0.25 hours X 2,000 applications or renewals).

The Department asks for public comment on the proposed information collection, including the particular issues below.

- Whether the proposed collection of information is necessary for the proper performance of OCR's functions and the Department's and its components' functions to enforce Federal laws on which Federal funding is conditioned, including whether the information will have practical utility.

- Feedback on the assumptions that form the basis of our cost estimates.

- The automated collection techniques or other forms of information technology that could improve the efficiency of this collection of information.

Comments regarding the collection of information proposed in this rule must refer to the proposed rule by name and docket number and must be submitted to both OMB and the Docket Management Facility where indicated under ADDRESSES by the date specified under DATES.

When it issues a final rule, the Department plans to publish in the Federal Register the control numbers assigned by the Office of Management and Budget (OMB). Publication of the control numbers notifies the public that OMB has approved the final rule's information collection requirements under the Paperwork Reduction Act of 1995.

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, Students, Technical assistance, Tribal Organizations.

PROPOSED RULE

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to revise 45 CFR part 88 to read as follows:

PART 88—ENSURING THAT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES DOES NOT FUND OR ADMINISTER PROGRAMS OR ACTIVITIES THAT VIOLATE CONSCIENCE AND ASSOCIATED ANTI-DISCRIMINATION LAWS

Sec.

88.1 Purpose.

88.2 Definitions.

88.3 Applicable requirements and prohibitions.

88.4 Assurance and certification of compliance requirements.

88.5 Notice requirement.

88.6 Compliance requirements.
88.7 Enforcement authority.
88.8 Relationship to other laws.
88.9 Rule of construction.
88.10 Severability.
Appendix A to Part 88—Notice Concerning Federal Health Care Conscience and Associated Anti-Discrimination Protections

Authority: The Weldon Amendment (*e.g.*, Consolidated Appropriations Act, 2017, Pub. L. 115-31, sec. 507(d); Div. H, sec. 209); the Helms Amendment (*e.g.*, Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. J, sec. 7018); 22 U.S.C. 7631(d); 26 U.S.C. 5000A(d)(2); 29 U.S.C. 669(a)(5); 42 U.S.C. 300a-7 (the Church Amendments), 42 U.S.C. 238n (Coats-Snowe Amendment); 18113 (Section 1553 of the Affordable Care Act), 18023(c)(2)(A)(i)-(iii), 18023(b)(1)(A), 18023(b)(4); 280g-1(d)), 290bb-36(f), 1320a-1, 1320c-11, 1395cc(f), 1395i-5, 1395w-22(j)(3)(B), 1395x(e), 1395x(y)(1), 1396a(a), 1396a(w)(3), 1396f, 1396s(c)(2)(B)(ii), 1396u-2(b)(3)(B), 1397j-1(b), 5106i(a), 14406.

§ 88.1 Purpose.

The purpose of this part is to provide for the implementation and enforcement of the Federal health care conscience and associated anti-discrimination laws. Such laws, for example, protect the rights of persons, entities, and health care entities to refuse to perform, assist in the performance of, or undergo health care services or research activities to which they may object for religious, moral, ethical, or other reasons. Such laws, for example, also protect patients from being subjected to certain health care or services over their conscientious objection. Consistent with their objective to comprehensively protect the conscience and associated anti-discrimination rights of persons, 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:

Administered by the Secretary means to be subject to the responsibility of the Secretary of the U.S. Department of Health and Human Services, as established via statute or regulation, for the administration of Federal funds available to any program or activity.

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. This includes but is not limited to counseling, referral, training, and other arrangements for the procedure, health service, health program, or research activity.

Department means the Department of Health and Human Services and any component thereof.

Discriminate or Discrimination means, as applicable and as permitted by the applicable statute:

(1) To withhold, reduce, exclude, terminate, restrict, or otherwise 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, terminate, restrict, or otherwise make unavailable or deny any benefit or privilege;

(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 tends to subject individuals or entities protected under this part to any adverse effect described in this definition, or have the effect of defeating or substantially impairing accomplishment of a health program or activity with respect to individuals, entities, or conduct protected under this part; or

(4) To otherwise engage in any activity reasonably regarded as discrimination including intimidating or retaliatory action.

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.

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 Federal agreement, arrangement, or other contract which has as one of its purposes the provision of assistance.

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. It may also include components of State or local governments.

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.

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.

Individual means a member of the workforce of an entity or health care entity.

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 foreign or international organizations (such as agencies of the United Nations).

Referral or refer for includes 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, where 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.

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.

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).

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 §§ 88.5 and 88.6 of this part.

(ii) Any State or local government or subdivision thereof and any other public entity are 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, 88.5, 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, 88.5, and 88.6 of this part.

(v) Any entity that carries out any part of any health service program or research activity funded in whole or in part under a 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, 88.5, 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, 88.5, and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Pursuant to 42 U.S.C. 300a-7(b)(1), entities to whom this paragraph (a)(2)(i) applies shall not require any individual who receives a grant, contract, loan, or loan guarantee under the Public Health Service Act 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), entities to whom this paragraph (a)(2)(ii) applies shall not require any entity funded under the Public Health Service Act 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 entity on the basis of religious beliefs or moral convictions.

(iii) Pursuant to 42 U.S.C. 300a-7(b)(2)(B), entities to whom this paragraph (a)(2)(iii) applies shall not require any entity funded under the Public Health Service Act 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 whom this paragraph (a)(2)(iv) applies shall not discriminate against any physician or other health care personnel in the employment, promotion, termination, or extension of staff or other privileges because such physician or other health care personnel performed or assisted in the performance, or refused to perform or assist in the performance of a lawful sterilization procedure or abortion on the grounds that doing so would be contrary to his or her religious beliefs or moral convictions, or because of his or her religious beliefs or moral convictions concerning abortions or sterilization procedures themselves.

(v) Pursuant to 42 U.S.C. 300a-7(c)(2), entities to whom 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 or refused to perform or assist in the performance of such service or activity on the grounds that doing so would be contrary to his or her religious beliefs or moral convictions, or because of his or her religious beliefs or moral convictions.

(vi) Pursuant to 42 U.S.C. 300a-7(d), entities to whom 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 if such

performance or assistance would be contrary to the individual's religious beliefs or moral convictions.

(vii) Pursuant to 42 U.S.C. 300a-7(e), entities to whom this paragraph (a)(2)(vii) applies shall not deny admission to or otherwise discriminate against any applicant for training or study because of 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 Federal government, including the Department, is required to comply with paragraphs (b)(2)(i) through (ii) of this section and §§ 88.5, 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, 88.5, 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 whom this paragraph (b)(2)(i) applies shall not subject any individual or institutional health care entity to discrimination on the basis that the individual or institutional 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 require attendees to 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 whom 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 an accreditation standard or standards that require an entity to perform an induced abortion or 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.

(c) *Weldon Amendment (See, e.g., Pub. L. 115-31, Div. H, sec. 507(d))*—(1) *Applicability.* (i) The Department, while operating under an appropriations act that contains the Weldon Amendment, is required to comply with paragraph (c)(2) of this section and §§ 88.5, 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, 88.5, and 88.6 of this part;

(iii) Any entity that receives funds through a program administered by the Secretary or 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, 88.5, and 88.6 of this part.

(2) *Prohibition.* 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.

(d) *Medicare Advantage, Consolidated Appropriations Act of 2017, Pub. L. 115-31, Div. H, Tit. II, sec. 209—(1) Applicability.* The Department, while operating under an appropriations act that contains a provision under the Medicare Advantage program as set forth by Pub. L. 115-31, Div. H, Tit. II, sec. 209, is required to comply with paragraph (d)(2) of this section and §§ 88.5, and 88.6 of this part.

(2) *Prohibition.* The entities to whom 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 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 §§ 88.5, 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 any amendment made by the Act) is required to comply with paragraph (e)(2) of this section and §§ 88.4, 88.5, 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 any amendment made by the Act) is required to comply with paragraph (e)(2) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(iv) Any health plan created under the Patient Protection and Affordable Care Act (or under any amendment) is required to comply with paragraph (e)(2) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) *Prohibition.* The entities to whom 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; provided, that 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 §§ 88.5, and 88.6 of this part.

(ii) Qualified health plans, as defined under 42 U.S.C. 18021, offered on any Exchange created under the Affordable Care Act, are required to comply with paragraph (f)(2)(ii) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) Requirements and prohibitions. (i) Pursuant to 42 U.S.C. 18023(b)(1)(A)(i), entities to whom this paragraph (f)(2)(i) applies shall not 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) as part of its essential health benefits for any plan year.

(ii) Pursuant to 42 U.S.C. 18023(b)(4), entities to whom 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 §§ 88.5, 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 Affordable Care Act to:

(i) Any individual who is a member of a recognized religious sect or division thereof and is an adherent of established tenets or teachings of such sect or division by reason of which he is conscientiously opposed to acceptance of the benefits of any private or public insurance which, among other things, 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); and

(ii) Any individual for the month for which such individual is a member of a “health care sharing ministry,” as defined in 26 U.S.C. 5000A(2)(B)(ii).

(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) through (ii) of this section and §§ 88.5 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, 88.5, and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Pursuant to 42 U.S.C. 1395w-22(j)(3)(B), entities to whom this paragraph (h)(2)(i) applies shall not require a Medicare Advantage organization to offer a plan that provides, reimburses for, or provides coverage of, a counseling or referral service if the organization objects to the provision of such service on moral or religious grounds.

(ii) Pursuant to 42 U.S.C. 1396u-2(b)(3)(B), entities to whom this paragraph (h)(2)(ii) applies shall not require a Medicaid managed care organization to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization objects to the provision of such service on moral or religious grounds.

(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 §§ 88.5 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, 88.5, and 88.6 of this part with respect to its Medicaid program.

(2) *Prohibitions.* The entities to whom this paragraph (i)(2) applies shall not:

(i) Construe 42 U.S.C. 1395cc(f) or 1395a(w) 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 any applicable 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 §§ 88.5 and 88.6 of this part.

(ii) Any entity that receives Federal financial assistance for HIV/AIDS prevention, treatment, or care to the extent administered by the Secretary 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, is required to comply with paragraph (j)(2) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) *Prohibitions.* The entities to whom this paragraph (j)(2) applies shall not:

(i) To the extent administered by the Secretary 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, require applicants for assistance for HIV/AIDS prevention, treatment, or care to:

(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 applicant has a religious or moral objection, as a condition of assistance.

(ii) Discriminate against applicants in the solicitation or issuance of grants, contracts, or cooperative agreements under such provisions of law for refusing to meet any requirement described in this paragraph (j)(2).

(k) *The Helms Amendment (e.g., Consolidated Appropriations Act of 2017, Pub. L. 115-31, Div. J, Tit. VII, sec. 7018) (codified at 22 U.S.C. 2151b(f))*—(1) *Applicability.* The Department is required to comply with paragraph (k)(2)(i) of this section and §§ 88.5 and 88.6 of this part.

(ii) 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, 88.5, and 88.6 of this part.

(2) *Prohibitions.* (i) The entities to whom this paragraph (k)(2)(i) applies shall not:

(A) Permit Federal financial assistance identified in (k)(1)(ii) to be used in an manner that would violation 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 to 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 whom this paragraph (k)(2)(ii) applies shall not:

(A) Use such Federal financial assistance identified in (k)(1)(ii) 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 sterilization as a method of family planning;

(4) Coerce or provide any financial incentive to any person to undergo sterilizations;

(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 to 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.

(1) *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 §§ 88.5 and 88.6 of this part.

(2) *Requirement.* The Department shall not construe 42 U.S.C. 280g-1(d) to preempt or prohibit State laws that do not require screening for hearing loss of newborn infants or young children when their parents 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 §§ 88.5 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 §§ 88.5 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, 88.5, and 88.6 of this part.

(2) *Requirements.* With respect to occupational illness examinations and tests, the entities to whom 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 §§ 88.5 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, 88.5, and 88.6 of this part.

(2) *Requirement.* The entities to whom this paragraph (o)(2) applies shall comply with applicable State law, including any such law relating to any religious or other exemption.

(p) *Specific Assessment, Prevention and Treatment Services, 42 U.S.C. 290bb-36(f), 5106i—(1) Applicability.* (i) The Department is required to comply with paragraphs (p)(2)(i) through (iii) of this section and §§ 88.5 and 88.6 of this part.

(ii) Any State; part of any State; public organization; or private nonprofit organization, such as a school, educational institution, juvenile justice system, substance use disorder program, mental health program, foster care system, or other child and youth support organization, 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, 88.5, 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 and §§ 88.4, 88.5, and 88.6 of this part.

(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, 88.5, and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Entities to whom 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 whom 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 whom this paragraph (p)(2)(iii) applies shall not 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, 1320c-11, 1395i-5, 1395x(e), 1395x(y)(1), 1396a(a), 1397j-1(b), and 5106i(a)(2)*—(1) *Applicability.* (i) The Department is required to comply with paragraphs (q)(2)(i), through (iii) of this section and §§ 88.5 and 88.6 of this part.

(ii) Any State agency that administers a Medicaid or CHIP program is required to comply with paragraph (q)(2)(ii) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(iii) Any entity, including a State or local government or subdivision thereof, receiving Federal financial assistance from Social Services Block Grant is required to comply with paragraphs (q)(2)(i) and (iv) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(iv) Any entity, including a State or local government or subdivision thereof, receiving Federal financial assistance from the Elder Justice Block Grants is required to comply with paragraph (q)(2)(iii) of this section and §§ 88.4, 88.5, and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) The entities to whom this paragraph (q)(2)(i) applies shall not fail or refuse to exempt a religious nonmedical health care institution from the Medicare requirement for peer review under 42 U.S.C. 1320cc and the Medicare requirements under 42 U.S.C. 1320a-1, for evaluation by advisory boards on capability to provide comprehensive health care services.

(ii) The entities to whom this paragraph (q)(2)(ii) applies shall not fail or refuse to exempt a religious nonmedical health care institution from the Medicaid requirements to:

(A) Meet State medical standards, under 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 medical 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) Establish a utilization review plan under 42 U.S.C. 1395x(k); or the Medicare, Medicaid, and Children's Health Insurance Program requirements, under 42 U.S.C. 1320a-1, for evaluation by advisory boards on capability to provide comprehensive health services.

(iii) Pursuant to 42 U.S.C. 1397j-1(b), the entities to whom this paragraph (q)(2)(iii) applies shall not 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.

(iv) Pursuant to 42 U.S.C. 1395i-5, the entities to whom this paragraph (q)(2)(iv) applies shall not prohibit coverage of inpatient hospital services or post-hospital extended care services furnished an individual in a religious nonmedical

health care institution or home health services furnished an individual by a religious nonmedical health care institution if an individual makes an election providing that:

(A) Such individual is conscientiously opposed to acceptance of conventional or unconventional medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs); and

(B) Acceptance of such medical treatment would be inconsistent with such individual's sincere religious beliefs.

§ 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 health care conscience and associated 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 health care conscience and associated anti-discrimination laws and this part.

(b) *Specific requirements—(1) Timing.* Applicants or recipients who are already recipients as of the effective date of this part 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 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 the applicant or recipient fails to meet a requirement of this part.

(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 health care

conscience and associated anti-discrimination laws and this part prior to, or 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 in applications.* An applicant or recipient may incorporate the assurances by reference in subsequent applications to the Department or Department component if prior assurances are initially provided in the same year.

(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 remedies 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, 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 requirement.

(a) *In general.* The Department and each recipient shall post the notice text located in Appendix A to this part in accordance with paragraph (b) of this section

by [DATE 90 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], or with respect to new recipients, within 90 days after becoming a recipient.

(b) *Specific requirements.* The notice text required in paragraph (a) of this section shall appear:

(1) On the Department's and each recipient's website(s), and

(2) In a prominent and conspicuous physical location in every Department and recipient establishment where notices to the public and notices to their workforce are customarily posted to permit ready observation. The text of the notice shall be large enough to be easily read. The Department and each recipient shall take steps to ensure that such notices are not altered, defaced, or covered by other material.

(c) *Factors in evaluation of compliance.* In evaluating a recipient's compliance with the requirements of this part, OCR will take into account whether the recipient has provided the notice text in paragraph (a) of this section:

(1) In a personnel manual or other substantially similar document for members of the recipient's workforce;

(2) In applications for membership in the recipient's workforce or for participation in a service, benefit, or other program, including for training or study; and

(3) In a 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.

(d) *Combined nondiscrimination notices.* The Department and each recipient may post the notice text provided in appendix A of this part along with the content of other notices only if it retains all of the language provided in appendix A of this part in an unaltered state.

§ 88.6 Compliance requirements.

(a) *In general.* The Department and each recipient has primary responsibility to ensure that it is in compliance with Federal health care conscience and associated anti-discrimination laws and this part, and shall take steps to eliminate any violations of the Federal health care conscience and associated anti-discrimination laws and this part. If a sub-recipient is found to have violated the Federal health care conscience and associated anti-discrimination laws, 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.

(b) *Records and information.* The Department, each recipient, and each sub-recipient shall maintain complete and accurate records evidencing compliance with Federal health care conscience and associated anti-discrimination laws and this part, and afford OCR, upon request, reasonable access to such records and information in a timely manner to the extent OCR finds necessary to determine compliance with the Federal health care conscience and associated anti-discrimination laws and this part.

(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 the production of documents, the

participation in interviews, the response to data requests, and the making available of premises for inspection where relevant. Failure to cooperate may result in an OCR referral to the Department of Justice for further enforcement in Federal court or otherwise.

(d) *Reporting requirement.* If a recipient or sub-recipient is subject to an OCR compliance review, investigation, or complaint filed with OCR regarding the recipient's or sub-recipient's compliance with Federal health care conscience and associated anti-discrimination laws, the recipient or sub-recipient must inform any Departmental funding component of such review, investigation, or complaint and must, in any application for new or renewed Federal financial assistance or Departmental funding, disclose the existence of such compliance review or investigation, and must also report on such applications, or in a separate writing with such applications, the existence of any such complaints filed with OCR for five years from such complaints' filing.

(e) *Intimidating or retaliatory acts prohibited.* Neither the Department nor any recipient or sub-recipient shall intimidate, threaten, coerce, or discriminate against any person, entity, or health care entity for the purpose of interfering with any right or privilege under the Federal health care conscience and associated anti-discrimination laws or this part, or because such person, entity, or health care entity has made a complaint or participated in any manner in an investigation or review under the Federal health care conscience and associated anti-discrimination laws or this part.

§ 88.7 Enforcement authority.

(a) *In general.* OCR has been delegated the authority to enforce the Federal health care conscience and associated anti-discrimination laws, which includes the authority to:

- (1) Receive and handle complaints;
- (2) Initiate compliance reviews;
- (3) Conduct investigations;
- (4) Supervise and coordinate compliance within the Department;
- (5) In coordination with the relevant component or components of the Department, make enforcement referrals to the Department of Justice; and
- (6) In coordination with the relevant component or components of the Department, take other appropriate remedial action as the Director of OCR deems necessary and as allowed by law to overcome the effects of violations of Federal health care conscience and associated anti-discrimination laws and this part.

(b) *Complaints.* Any entity, health care entity, or any person, 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 health care conscience and associated anti-discrimination laws or this part. OCR shall coordinate handling of complaints with the relevant Department component. The complaint filer is not required to be the person, entity, or health care entity whose rights under the Federal health care conscience and associated anti-discrimination laws or this part have been potentially violated.

(c) *Periodic compliance reviews.* OCR may from time to time 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 health care conscience and associated anti-discrimination laws and this part. OCR may conduct these reviews in the absence of a complaint.

(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 health care conscience and associated anti-discrimination laws or this part. The investigation should include, where appropriate, a review of the pertinent practices, policies, communications, documents, compliance history, the 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, but not limited to, site visits, interviews with complainants, the Department component, recipients, sub-recipients, or third-parties, and written data or discovery requests. OCR may seek the assistance of any State agency.

(e) *Destruction of evidence.* Consistent with § 88.6(b) and (c), a Department component, recipient, or sub-recipient that knowingly or recklessly destroys evidence potentially relevant to an OCR investigation or compliance review that is ongoing or reasonably anticipated shall be in violation of this part.

(f) *Failure to respond.* Absent good cause, a party's failure to respond to a request for information or a data or document request within 45 days of OCR's request, shall constitute a violation of this part.

(g) *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.

(h) *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 health care conscience and associated 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 delegate to officials of the Department responsibilities in connection with the effectuation of Federal health care conscience and associated anti-discrimination laws and this part, including the achievement of effective coordination and maximum uniformity within the Department.

(i) *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 health care conscience and associated anti-discrimination laws or this part, OCR may, in coordination with the relevant Department component make referrals to the Department of Justice for further enforcement in Federal court or otherwise.

(j) *Resolution of matters.* (1) If an investigation or compliance review reveals that no action is warranted, OCR will so inform the subject of the complaint or review and complainant, if any, in writing.

(2) If an investigation or compliance review indicates a failure to comply with Federal health care conscience and associated 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 § 88.7(j)(3).

(3) If there appears to be a failure or threatened failure to comply with Federal health care conscience and associated 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:

(i) Temporarily withholding cash payments, 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) Withholding new Federal financial assistance or other Federal funds from the Department, in whole or in part, 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) 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, created by Federal law; and

(vii) Taking any other remedies that may be legally available.

§ 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 free exercise of religious beliefs and moral convictions, to the maximum extent permitted by the terms of the Federal health care conscience and associated antidiscrimination statutes implemented by the Constitution.

§ 88.10 Severability.

Any provision of this part held to be invalid or unenforceable either by its terms or as applied to any person, 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—Notice Concerning Federal Health Care Conscience and Associated Anti-Discrimination Protections

[Name of recipient, the Department, or Department component] complies with Federal health care conscience and associated anti-discrimination laws and does not exclude, treat adversely, coerce, or otherwise discriminate against persons or entities on the basis of their religious beliefs or moral convictions. You have the right to decline to participate in, refer for, undergo, or pay for certain health care-related treatments, research, or services (such as abortion or assisted suicide, among others) which violate your conscience, religious beliefs, or moral convictions under Federal law.

If you believe that [Name of recipient, the Department, or Department component] has failed to accommodate your conscientious, religious, or moral objection, or has unlawfully 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, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms and more information about Federal health care conscience and associated anti-discrimination laws are available at <http://www.hhs.gov/conscience>.

Dated: January 18, 2018.

Eric D. Hargan

Acting Secretary.

Department of Health and Human Services.

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