

XAVIER BECERRA
Attorney General of California
MICHAEL L. NEWMAN
Senior Assistant Attorney General
KATHLEEN BOERGERS, State Bar number 213530
Supervising Deputy Attorney General
NELI PALMA
STEPHANIE YU
KARLI EISENBERG
Deputy Attorneys General
1515 Clay Street, 20th Floor
P.O. Box 70550
Oakland, CA 94612-0550
Telephone: 510-879-0011
Fax: 510-622-2270
E-mail: Kathleen.Boergers@doj.ca.gov
*Attorneys for State of California, by and through
Attorney General Xavier Becerra*

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

**CITY AND COUNTY OF SAN
FRANCISCO,**

Plaintiff,

v.

**ALEX AZAR, in his OFFICIAL
CAPACITY as SECRETARY of the U.S.
DEPARTMENT of HEALTH & HUMAN
SERVICES; ROGER SEVERINO,
Director, Office for Civil Rights,
Department of Health and Human Services;
U.S. DEPARTMENT of HEALTH &
HUMAN SERVICES; and DOES 1-25,**

Defendants.

3:19-cv-2405-JCS

**CALIFORNIA'S ADMINISTRATIVE
MOTION TO CONSIDER WHETHER
CASES SHOULD BE RELATED**

[N. D. CAL. CIVIL L.R. 3-12 & 7-11]

Judge: Chief Magistrate Judge Joseph
C. Spero
Trial Date: None set.
Action Filed: May 2, 2019

I. INTRODUCTION & BACKGROUND

The State of California seeks an order to relate three cases—*City and County of San Francisco v. Azar, et al.*, Case No. 3:19-cv-2405, *State of California v. Azar, et al.*, Case No. 3:19-cv-02769, and *County of Santa Clara et al. v. U.S Dep’t of Health and Human Svcs., et al.*, Case No. 5:19-cv-2916 (N.D. Cal. May 28, 2019)—under Civil Local Rules 3-12 and 7-11 because all three cases: (1) involve the same parties, property, transactions, or events; (2) call for determination of the same or substantially related questions of law; and (3) entail substantial duplication of labor and the risk of inconsistent rulings if heard by different judges. See Civil L.R. 3-12.

In separate cases, Plaintiffs the State of California, the City and County of San Francisco, and County of Santa Clara, Trust Women Seattle, Los Angeles LGBT Center, Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health, Bradbury-Sullivan LGBT Community Center, Center On Halsted, Hartford Gyn Center, Mazzoni Center, Medical Students For Choice, AGLP: The Association Of LGBTQ+ Psychiatrists, American Association of Physicians for Human Rights d/b/a Glma: Health Professionals Advancing LGBTQ Equality, Colleen McNicholas, Robert Bolan, Ward Carpenter, Sarah Henn, and Randy Pumphrey, challenge the U.S. Health and Human Services’ Refusal Rule, which allows healthcare providers and workers to refuse to comply with program rules and applicable state and federal laws on the basis of religious, ethical, or other beliefs. 84 Fed. Reg. 23170, 23264 (May 21, 2019) (the Refusal Rule). In May 2019, the City and County of San Francisco, California, and the County of Santa Clara and co-plaintiffs filed suits challenging the Rule. *City and County of San Francisco v. Azar, et al.*, Case No. 3:19-cv-2405 (N.D. Cal. May 2, 2019); *State of California v. Azar, et al.*, Case No. 3:19-cv-02769 (N.D. Cal. May 21, 2019) (Declaration of Kathleen Boergers (“Boergers Decl.”), Ex. A); and *County of Santa Clara et al. v. U.S Dep’t of Health and Human Svcs., et al.*, Case No. 5:19-cv-2916 (N.D. Cal. May 28, 2019) (Boergers Decl., Ex. B) (collectively, the Refusal Rule cases).

Due to the common and overlapping issues, a failure to relate the Refusal Rule cases may result in inconsistent outcomes and the burdensome duplication of labor and expense addressing related issues. Therefore, California respectfully requests that the Court relate the cases.

II. ARGUMENT

The State of California moves pursuant to Local Rule 3-12 for a determination that the Refusal Rule cases are related. Under Rule 3-12, actions are related when:

- (1) The actions concern substantially the same parties, property, transaction, or event; and
- (2) It appears likely that there will be an unduly burdensome duplication of labor and expense or conflicting results if the cases are conducted before different judges.

The Refusal Rule cases should be related because they involve the same defendants, similar plaintiffs and claims, and relation will promote judicial economy and avoid inconsistent rulings.

First, the cases involve the same or similar parties. All three cases have the same or overlapping defendants: Secretary Azar and HHS (San Francisco also included the HHS Director of the Office for Civil Rights, Roger Severino). *See* Dkt. No. 1 (Complaint).

Second, the Refusal Rule cases concern substantially the same event, claims, and subject matter. The cases involve the exact same event, the promulgation of the Refusal Rule by the defendants. And the cases involve similar claims. The Refusal Rule cases challenge the Rule on the grounds that the rule is in violation of the APA, the Spending and the Establishment Clause of the U.S. Constitution. *Id.* at ¶¶ 106-126, 130-132; *see also* Boergers Decl. Exh. A, ¶¶ 127-186, and Exh. B, ¶¶ 202-225, 253-254. San Francisco and Santa Clara also allege that the Refusal Rule violates separation of powers. Dkt. No. 1, ¶¶ 127-129; Boergers Decl. Exh. B, at ¶¶ 255-260.

The cases also involve similar subject matter. California alleges that the rule impedes access to basic healthcare, including reproductive and emergency care; threatens billions of dollars in federal funding for California's public healthcare and other federally funded programs; and encourages discrimination against vulnerable patients, including women; lesbian, gay, bisexual, and transgender (LGBT) individuals and other vulnerable populations. Boergers Decl., Ex. A, ¶ 1. Similarly, San Francisco alleges that the rule will compromise patient care and put patients' health at risk; harm vulnerable patients, including LGBT people by harming their access to care; and that the loss of federal funds would devastate San Francisco's health care system and its ability to provide critical health care services for diseases like HIV, STDs, TB, Hepatitis C, and other communicable diseases. Dkt. No. 1, ¶¶ 2-5, 86-105. And the County of Santa Clara *et*

1 *al.* make substantially similar allegations. For example, that the Refusal Rule invites refusals to
 2 provide care to women seeking reproductive healthcare and transgender and gender-
 3 nonconforming patients seeking gender-affirming care, adversely affecting the healthcare entities
 4 that provide reproductive healthcare services and that serve LGBT community, as well as
 5 stigmatizing and shaming these patients, depriving them of their constitutionally protected rights
 6 of access to healthcare and their dignity and autonomy in seeking medically necessary healthcare
 7 central to their self-determination. Boergers Decl., Exh. B, ¶ 4.

8 Third, presenting the overlapping legal questions in the Refusal Rule cases to different
 9 judges of this Court would involve unnecessary duplication of efforts and a waste of judicial
 10 resources, while also creating a risk of inconsistent results. The plaintiffs in these cases ask the
 11 Court to evaluate the procedures, bases, reasoning, and record supporting the Refusal Rule and
 12 whether it comports with the requirements of the law, including whether the challenged agency
 13 action is arbitrary and capricious. Further, the plaintiffs ask the Court to evaluate whether the
 14 agency acted in excess of authority and contrary to numerous laws, including Section 1554 of the
 15 Affordable Care Act (42 U.S.C. § 18114) and the Emergency Medical Treatment and Labor Act,
 16 which requires hospitals to provide emergency care (42 U.S.C. § 1395dd).

17 Without relation, there is a risk of inconsistent rulings that may result in confusion as to the
 18 legality of the Refusal Rule. Relation will ensure that the Court can provide consistent
 19 enforcement of its orders. Finally, if the cases are related, only one judge and chambers staff will
 20 be burdened with reviewing the voluminous administrative record and conducting the required
 21 fact-finding, including details about the specific healthcare programs at issue, sources of funding,
 22 and the extensive harm that will be caused by the Refusal Rule. This will conserve judicial
 23 resources and ensure that the same court is able to enforce any relief afforded.

24 **III. CONCLUSION**

25 Plaintiff respectfully requests that this Court relate *City and County of San Francisco v.*
 26 *Azar, et al.*, Case No. 3:19-cv-2405, *State of California v. Azar, et al.*, Case No. 3:19-cv-02769,
 27 and *County of Santa Clara et al. v. U.S Dep't of Health and Human Svcs., et al.*, Case No. 5:19-
 28 cv-2916 (N.D. Cal. May 28, 2019).

1 Dated: June 3, 2019

Respectfully Submitted,

2 XAVIER BECERRA
3 Attorney General of California

4 *s/ Kathleen Boergers*

5 KATHLEEN BOERGERS
6 Supervising Deputy Attorney General
7 *Attorneys for State of California, by and
through Attorney General Xavier Becerra*

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XAVIER BECERRA
Attorney General of California
MICHAEL L. NEWMAN
Senior Assistant Attorney General
KATHLEEN BOERGERS, State Bar number 213530
Supervising Deputy Attorney General
NELI PALMA
STEPHANIE YU
KARLI EISENBERG
Deputy Attorneys General
1515 Clay Street, 20th Floor
P.O. Box 70550
Oakland, CA 94612-0550
Telephone: 510-879-0011
Fax: 510-622-2270
E-mail: Kathleen.Boergers@doj.ca.gov
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Plaintiff,

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**ALEX AZAR, in his OFFICIAL
CAPACITY as SECRETARY of the U.S.
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Defendants.

3:19-cv-2405-JCS

**[PROPOSED] ORDER IN SUPPORT OF
CALIFORNIA'S ADMINISTRATIVE
MOTION TO CONSIDER WHETHER
CASES SHOULD BE RELATED**

[N. D. CAL. CIVIL L.R. 3-12 & 7-11]

Judge: Judge Spero
Trial Date: None set.
Action Filed: May 2, 2019

[PROPOSED] ORDER

The Motion of the State of California, by and through Attorney General Xavier Becerra, to consider whether cases should be related was filed on June 3, 2019. Having read the parties' papers, the Court GRANTS California's motion and relates the following cases with the *City and County of San Francisco v. Azar, et al.*, Case No. 3:19-cv-2405:

- *State of California v. Azar, et al.*, Case No. 3:19-cv-02769
- *County of Santa Clara et al. v. U.S Dep't of Health and Human Svcs., et al.*, Case No. 5:19-cv-2916 (N.D. Cal. May 28, 2019)

The parties are instructed that all future filings in any reassigned case are to bear the initials of the newly assigned judge immediately after the case number. Any case management conference in any reassigned case will be rescheduled by the Court. The parties shall adjust the dates for the conference, disclosures, and report required by Fed. R. Civ. P. 16 and 26 accordingly. Unless otherwise ordered, any dates for hearing noticed motions are vacated and must be re-noticed by the moving party before the newly assigned judge; any deadlines set by the ADR Local Rules remain in effect; and any deadlines established in a case management order continue to govern, except dates for appearance in court, which will be rescheduled by the newly assigned judge.

IT IS SO ORDERED.

Dated:

Hon. Joseph C. Spero
United States Magistrate Judge

XAVIER BECERRA
Attorney General of California
MICHAEL L. NEWMAN
Senior Assistant Attorney General
KATHLEEN BOERGERS, State Bar number 213530
Supervising Deputy Attorney General
NELI PALMA
STEPHANIE YU
KARLI EISENBERG
Deputy Attorneys General
1515 Clay Street, 20th Floor
P.O. Box 70550
Oakland, CA 94612-0550
Telephone: 510-879-0011
Fax: 510-622-2270
E-mail: Kathleen.Boergers@doj.ca.gov
*Attorneys for State of California, by and through
Attorney General Xavier Becerra*

IN THE UNITED STATES DISTRICT COURT
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**CITY AND COUNTY OF SAN
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Plaintiff,

v.

**ALEX AZAR, in his OFFICIAL
CAPACITY as SECRETARY of the U.S.
DEPARTMENT of HEALTH & HUMAN
SERVICES; ROGER SEVERINO,
Director, Office for Civil Rights,
Department of Health and Human Services;
U.S. DEPARTMENT of HEALTH &
HUMAN SERVICES; and DOES 1-25,**

Defendants.

3:19-cv-2405-JCS

**DECLARATION OF KATHLEEN
BOERGERS IN SUPPORT OF
CALIFORNIA'S ADMINISTRATIVE
MOTION TO CONSIDER WHETHER
CASES SHOULD BE RELATED**

[N. D. CAL. CIVIL L.R. 3-12 & 7-11]

Judge: Judge Spero
Trial Date: None set.
Action Filed: May 2, 2019

1
2 I, Kathleen Boergers, declare as follows:

3 1. I am a member of the California State Bar, admitted to practice before this Court,
4 employed by the Office of the California Attorney General as a Supervising Deputy Attorney
5 General, and counsel to Plaintiff in *State of California v. Azar, et al.*, Case No. 3:19-cv-02769
6 (N.D. Cal. May 21, 2019). I have personal knowledge of the facts set forth herein, and if called upon
7 as a witness, I could testify to them competently under oath.

8 2. Attached as **Exhibit A** is a true and correct copy of the complaint in *State of*
9 *California v. Azar, et al.*, Case No. 3:19-cv-02769 (N.D. Cal. May 21, 2019).

10 3. Attached as **Exhibit B** is a true and correct copy of the complaint in *County of Santa*
11 *Clara et al. v. U.S Dep't of Health and Human Svcs., et al.*, Case No. 5:19-cv-2916 (N.D. Cal.
12 May 28, 2019).

13 I declare under penalty of perjury under the laws of the United States that the foregoing is true
14 and correct and that this declaration was executed on June 3, 2019 in Oakland, California.

15
16 /s/ Kathleen Boergers
17 KATHLEEN BOERGERS
18 Supervising Deputy Attorney General
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EXHIBIT A

XAVIER BECERRA, State Bar No. 118517
Attorney General of California
MICHAEL NEWMAN, State Bar No. 222993
Senior Assistant Attorney General
KATHLEEN BOERGER, State Bar No. 213530
Supervising Deputy Attorney General
NELI N. PALMA, State Bar No. 203374
KARLI EISENBERG, State Bar No. 281923
STEPHANIE YU, State Bar No. 294405
Deputy Attorneys General
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 445-2482
Fax: (916) 322-8288
E-mail: Neli.Palma@doj.ca.gov
*Attorneys for Plaintiff State of California, by and
through Attorney General Xavier Becerra*

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

**STATE OF CALIFORNIA, BY AND THROUGH
ATTORNEY GENERAL XAVIER BECERRA,**

Plaintiff,

v.

**ALEX M. AZAR, IN HIS OFFICIAL CAPACITY
AS SECRETARY OF THE U.S. DEPARTMENT OF
HEALTH & HUMAN SERVICES; U.S.
DEPARTMENT OF HEALTH AND
HUMAN SERVICES; DOES 1-100,**

Defendants.

**COMPLAINT FOR DECLARATORY
AND INJUNCTIVE RELIEF**

Administrative Procedure Act Case

INTRODUCTION

1. The State of California, by and through Attorney General Xavier Becerra, challenges the final rule titled “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority,” RIN 0945-AA10, issued by the U.S. Department of Health and Human Services

(HHS) on May 2, 2019 (Rule), and published in the Federal Register on May 21, 2019.¹ 84 Fed. Reg. 23170 (May 21, 2019). The State seeks to have the Rule set aside because the Rule, in violation of the Administrative Procedure Act (APA), the Spending Clause, and the Establishment Clause of the United States Constitution, impedes access to basic healthcare, including reproductive and emergency care; threatens billions of dollars in federal funding for California’s public healthcare and other federally funded programs; and encourages discrimination against vulnerable patients, including women; lesbian, gay, bisexual, transgender, and queer or questioning (LGBTQ) individuals; and other vulnerable populations.

2. The Rule creates a broad exemption that permits any individual, entity, or provider—from doctors to front office staff—to deny patients basic healthcare, including reproductive and emergency care, not just on the basis of federally protected conscience protections, but also on the basis of “ethical or other reasons.” 84 Fed. Reg. at 23264. A provider can therefore deny service on the basis of a hunch or prejudice, without any supporting evidence, without notifying a supervisor of the denial of service, and without providing notice or alternative options and/or referrals to patients in need.² *Id.* (broadly defining “referral or referral for”).

3. Allowing such denial of service would be contrary to federal and state laws enacted to ensure patient safety and nondiscriminatory access to care, and contrary to medical ethics. Further, the Rule will create rampant confusion about basic patient rights and federally entitled healthcare services, such as Medicaid and Medicare, while discouraging providers from offering safe, legal medical care to their patients.

4. In promulgating the Rule, Defendants failed to engage in reasoned decisionmaking, and there is no evidence that HHS considered the impact on patients. 84 Fed. Reg. at 23230-23239 (failing to quantify the impact of this Rule on patients). Moreover, the effects of the Rule would be widespread as it implicates “an action that has a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program or research activity

¹ Available at <https://www.govinfo.gov/content/pkg/FR-2019-05-21/pdf/2019-09667.pdf>.

² See American Medical Association, Policy E-1.1.1, “Patient-Physician Relationships,” 1.1.2, “Prospective Patients,” 1.1.3., “Patient Rights,” 1.1.6, “Quality,” and 1.1.7, “Physician Exercise of Conscience,” available at https://www.ama-assn.org/system/files/2019-01/code-of-medical-ethics-chapter-1_0.pdf.

undertaken by or with another person or entity.” 84 Fed. Reg. at 23263. The consequences of this broad, vague Rule will disproportionately affect vulnerable populations, and will have a chilling effect on those seeking to exercise their constitutionally protected healthcare rights.

5. The Rule is also unlawful because it threatens the termination of billions of dollars (over half a trillion dollars) in federal funds to California for labor, education, health, and human services programs unless the State surrenders to the Rule’s unlawful, vague provisions. Its notice, assurance and certification, recordkeeping, and reporting requirements needlessly impose administrative burdens and onerous costs of implementation on the State. As such, the Rule is an assault on California’s sovereignty, which is directly targeted by the Rule, and poses a real risk to the health and welfare of all Californians.

6. The State also seeks injunctive, declaratory, and other appropriate relief against HHS to remedy HHS’s violations of the Freedom of Information Act (FOIA), 5 U.S.C. § 552.

JURISDICTION AND VENUE

7. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the laws of the United States), 28 U.S.C. § 1346 (civil action against the United States founded upon the Constitution, an Act of Congress, or an executive regulation), 28 U.S.C. § 1361 (action to compel officer or agency to perform duty owed to Plaintiff), and 5 U.S.C. §§ 701-706 (Administrative Procedure Act). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 2201-2202 and 5 U.S.C. §§ 705-706.

8. Defendants’ issuance of the Rule on May 21, 2019, constitutes a final agency action and is therefore judicially reviewable within the meaning of the Administrative Procedure Act. 5 U.S.C. §§ 704, 706.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e), because this is a judicial district in which the State of California resides and this action seeks relief for the State against federal agencies and officials acting in their official capacities.

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INTRADISTRICT ASSIGNMENT

10. Pursuant to Civil Local Rules 3-2(c) and 3-5(b), there is no basis for assignment of this action to any particular location or division of this Court.

PARTIES

11. Plaintiff, the State of California, by and through Attorney General Xavier Becerra, brings this action. The Attorney General is the chief law officer of the State and has the authority to file civil actions in order to protect public rights and interests. Cal. Const., art. V, § 13; Cal. Bus. & Prof. Code § 321. This challenge is brought pursuant to the Attorney General's independent constitutional, statutory, and common law authority to represent the public interest.

12. The State of California has an interest in ensuring that all healthcare is accessible to all those within its borders. Regulating healthcare is within the police power of the States. California is aggrieved by the actions of Defendants and has standing to bring this action because of the injury to its state sovereignty caused by Defendants' issuance of the illegal Rule, and by Defendants' threat to terminate billions of dollars in federal funding, including immediate and irreparable injuries to its sovereign, quasi-sovereign, and proprietary interests. California is also harmed by the Rule because it requires the State to establish a costly and onerous bureaucratic structure to ensure that the Rule's expansive and unlawful provisions are complied with, including compliance by any downstream sub-recipients. California will suffer concrete and substantial harm because the Rule frustrates California's public health interests by, among other things, curtailing access to contraceptive care, abortion, and other healthcare services. The Rule will also burden the State with increased costs—for example, increased costs resulting from unintended pregnancies and untreated medical conditions. The Rule's position on vaccinations and its possible sanctioning of doctors opposed to efforts to ensure that all children and their families follow the recommended childhood vaccination schedule could also adversely affect California's public health efforts to control the spread of preventable diseases such as measles. Additionally, the Rule will chill many Californians' (for example, transgender individuals' and other LGBTQ community members') ability to access healthcare, further exacerbating long-term health problems.

13. States have a sovereign interest in the power to create and enforce a legal code. Pursuant to that interest, California has an interest in challenging (1) HHS’s assertions of authority to regulate matters within California’s police power, and (2) HHS’s interference with the enforcement of state law—particularly California’s laws regulating behavior of and providing for the administration and regulation of state licensed professionals.

14. Defendant Alex M. Azar is Secretary of U.S. Department of Health and Human Services (HHS) and is sued in his official capacity. Secretary Azar has responsibility for implementing and fulfilling HHS’s duties under the Constitution and other federal law, including the Patient Protection and Affordable Care Act (ACA) and the APA.

15. Defendant HHS is an agency of the United States government and bears responsibility, in whole or in part, for the acts complained of in this Complaint. The Office for Civil Rights (OCR) is an entity within HHS.

FACTUAL AND PROCEDURAL BACKGROUND

I. CALIFORNIA LAWS AND REGULATIONS

A. Laws Protecting Religious Freedoms

16. Ensuring access to healthcare is a key element in shaping overall health and well-being of California residents, and is therefore a critical component of the State’s public health programs and laws. At the same time, and in enacting the California Religious Freedom Act in 2017,³ California Government Code section 8310.3, the California Legislature found and declared that “California must uphold the protection of religious freedom enshrined in the United States Constitution for all of its people, and the state has a moral obligation to protect its citizens from religious persecution.”

17. But the California Supreme Court has concluded that the right to freely exercise one’s religious rights is not violated by laws ensuring full and equal access to healthcare. *N. Coast Women’s Care Med. Group, Inc. v San Diego Cty. Superior Court*, 44 Cal.4th 1145 (2008);

³ Generally, the California Religious Freedom Act prohibits California state and local governments from initiating, participating in, or assisting with any program to create a religious list, registry, or database, or using information about people’s national origin or ethnicity to achieve the same basic purpose.

1 *Catholic Charities of Sacramento, Inc. v. Superior Court*, 32 Cal.4th 527 (2004). Toward this
2 end, California has struck a careful balance between the provision of healthcare and conscience
3 protections.

4 18. Under California law, a healthcare provider—defined as a person who is licensed,
5 certified, or otherwise authorized by state law to provide health care—may decline to comply with
6 an individual healthcare instruction or healthcare decision for reasons of conscience (but not on the
7 basis of discrimination). Cal. Prob. Code §§ 4621, 4734(a). Also, a healthcare institution—defined
8 as an institution, facility, or agency licensed, certified, or otherwise authorized by law to provide
9 healthcare—may decline to comply with an individual healthcare instruction if that is contrary to a
10 policy of the institution that is expressly based on reasons of conscience, if the policy was timely
11 communicated to the patient. Cal. Prob. Code §§ 4619, 4734(b). However, a healthcare provider
12 or institution that declines to comply with an individual healthcare instruction must (1) promptly so
13 inform the patient; (2) immediately make all reasonable efforts to assist in the transfer of the patient
14 to another provider or institution that is willing to comply with the instruction; and (3) provide
15 continuing care to the patient until the transfer is accomplished or until it appears that a transfer
16 cannot be accomplished. Cal. Prob. Code § 4736.

17 19. California laws also carefully balance protections for conscience protections and a
18 woman’s right to reproductive health. For example, California law provides that no employer or
19 other person shall require a physician, a registered nurse, a licensed vocational nurse, or any other
20 person employed or with staff privileges at a hospital, facility, or clinic to directly participate in
21 the induction or performance of an abortion “if the employee or other person has filed a written
22 statement with the employer or the hospital, facility, or clinic indicating a moral, ethical, or
23 religious basis for refusal to participate.” Cal. Health & Safety Code § 123420(a). No employee
24 or person shall be subject to any penalty or discipline for refusing to participate in the induction
25 or performance of an abortion. *Id.*

26 20. However, to balance the needs of the patient who may be in urgent need of care and
27 in recognition that emergency medical care is a vital public service, this provision does not apply
28 to “medical emergency situations and spontaneous abortions” (also known as miscarriages,

1 *People v. Davis*, 7 Cal. 4th 797, 840 n.14 (1994) (en banc)). Cal. Health & Safety Code
 2 § 123420(d); *see also* Cal. Health & Safety Code § 1317(a) & (e) (requiring that emergency
 3 services be provided to a patient for any condition in which the person is in danger of loss of life,
 4 or serious injury or illness, at any health facility that maintains and operates an emergency
 5 department; or if the facility does not maintain an emergency department, “its employees shall
 6 nevertheless exercise reasonable care to determine whether an emergency exists and shall direct
 7 the persons seeking emergency care to a nearby facility that can render the needed services, and
 8 shall assist the persons seeking emergency care in obtaining the services, including transportation
 9 services, in every way reasonable under the circumstances”).

10 21. California law requires that a female survivor of sexual assault shall be provided with
 11 “the option of postcoital contraception by a physician or other health care provider” and that
 12 “[p]ostcoital contraception . . . be dispensed by a physician or other health care provider upon the
 13 request of the victim at no cost to the victim.” Cal. Penal Code §§ 13823.11(e)(1), (e)(2),
 14 (g)(4)(A), (g)(4)(B). If a hospital is unable to comply, hospitals must adopt a protocol for the
 15 immediate referral of these individuals to a local hospital that complies with these requirements,
 16 and notify local law enforcement agencies, the district attorney, and local victim assistance
 17 agencies of the adoption of the referral protocol. Cal. Health & Safety Code § 1281.

18 22. Moreover, a California healthcare licentiate “shall not obstruct a patient in obtaining a
 19 prescription drug or device that has been legally prescribed or ordered for that patient.” Cal. Bus.
 20 & Prof. Code § 733(a); *see also Stormans, Inc. v. Wiesman*, 794 F.3d 1064, 1076-1088 (9th Cir.
 21 2015) (rejecting First Amendment challenge to state regulation that requires pharmacists to timely
 22 dispense all prescription medications, even if the pharmacist has a religious objection), *cert.*
 23 *denied* 136 S.Ct. 2433 (2016). But a licentiate may decline to dispense a prescription drug or
 24 device on the basis of an ethical, moral, or religious objection, but only if the licentiate has
 25 previously notified his or her employer, in writing, of the drug or class of drugs to which he or
 26 she objects, and the licentiate’s employer can, without creating undue hardship, provide a
 27 reasonable accommodation and establish protocols to address the licentiate’s objection and also
 28

1 ensure that the patient has timely access to the prescribed drug or device. Cal. Bus. & Prof. Code
2 § 733(b)(3).

3 23. In keeping with the careful balance that California has struck, California laws protect
4 employees from discrimination based on religious beliefs, unless accommodation of those beliefs
5 would result in undue hardship to the employer.⁴ FEHA (which applies to employers with five or
6 more workers) requires that an employer reasonably accommodate an employee's bona fide
7 religious beliefs, including moral and ethical beliefs about what is right and what is wrong. Cal.
8 Gov't Code § 12926 (d) & (q); 29 C.F.R. § 1605.1, *Friedman v. So. Calif. Permanente Med.*
9 *Group*, 102 Cal.App. 4th 39, 45 (2002). Depending on the circumstances, "reasonable"
10 accommodation could include schedule changes, reassignment, and modification of work
11 practices, among other options. 29 C.F.R. § 1605.2(d)(1); 2 C.C.R. § 11062(a). Undue hardship
12 is defined as "an action requiring significant difficulty or expense" and the calculus requires that
13 the employer consider a variety of factors, including the nature and cost of accommodation, the
14 facility's financial resources, the number of employees, operational impacts, the type of
15 operations, and the employer's overall financial resources and size. Cal. Gov't Code § 12926(u).
16 However, a religious accommodation cannot cause the employer to violate other laws prohibiting
17 discrimination or protecting civil rights, including, for example, California Civil Code § 51(b)
18 (the Unruh Act) and California Government Code § 11135 (concerning discrimination by state
19 agencies). Cal. Gov't Code § 12940(l)(3). Like Title VII, FEHA requires a dialogue, as needed,
20 between the employer and the employee that permits the consideration of an accommodation's
21 impact on a patient's right to care.

22 **B. Laws Guaranteeing Access to Healthcare**

23 24. Women have historically faced unfair and discriminatory insurance practices, such as
24 being denied coverage for services that only women need—for example, maternity care. For this
25 reason, California law requires that health care service and insurance plans provide coverage for

26 ⁴ In addition, for the purpose of Fair Employment and Housing Act or FEHA protections,
27 "sex" includes, but is not limited to, "pregnancy or medical conditions related to pregnancy" and
28 gender, which includes gender identity and gender expression ("gender-related appearance and
behavior whether or not stereotypically associated with the person's assigned sex at birth."). Cal.
Gov't Code § 12926(r).

1 maternity services. Cal. Health & Safety Code §§ 1345, 1367(i); Cal. Code Regs., tit. 28,
2 § 1300.67; Cal. Ins. Code §§ 10123.865, 10123.866.

3 25. In 1972, California voters amended the state Constitution to include a right of privacy
4 among the inalienable rights protected by article I, section 1. *Chico Feminist Women's Health*
5 *Ctr. v. Butte Glen Med. Soc'y*, 557 F. Supp. 1190, 1201-1202 (E.D. Cal. 1983) (citing *White v.*
6 *Davis*, 13 Cal. 3d 757 (1975)). Under article I, section 1, "all women in this state rich and poor
7 alike possess a fundamental constitutional right to choose whether or not to bear a child." *Comm.*
8 *to Defend Reprod. Rights v. Myers*, 29 Cal. 3d 252, 262 (1981). Under state law, private parties
9 cannot interfere with the right to procreative choice under article I, section 1. *Chico*, 557 Supp. at
10 1202-03; *Hill v. Nat'l Collegiate Athletic Ass'n*, 7 Cal. 4th 1, 20 (1994). In addition, the right of
11 procreative choice, guaranteed under article I, section 1, is protected from State interference.
12 *Chico*, 557 F. Supp. at 1202; *Myers*, 29 Cal. 3d at 284. Therefore, California law requires
13 coverage of all lawful abortions for enrollees and beneficiaries in both the Medi-Cal program and
14 commercial health coverage.

15 26. Echoing these constitutional protections, the Reproductive Privacy Act of 2002
16 (RPA) declares as state public policy that "[e]very woman has the fundamental right to choose to
17 bear a child or to choose and to obtain an abortion." Cal. Health & Safety Code § 123462(b).
18 The RPA expressly provides that: "The state may not deny or interfere with a woman's right to
19 choose or obtain an abortion" Cal. Health & Safety Code § 123466.

20 27. Contraceptives are among the most widely used medical services in the United States.
21 They are much less costly than the medical consequences of pregnancy, including maternal
22 deliveries, for patients, insurers, employers and states. The use of contraceptives has been shown
23 to result in net savings to women and their employers.

24 28. Starting in 2012, the Women's Health Amendment to the ACA gave women across
25 the country guaranteed access to preventive healthcare by requiring certain group health
26 insurance plans to cover preventive care, including all Food and Drug Administration (FDA)-
27 approved contraceptive methods and contraceptive counseling for women without cost-sharing
28

for beneficiaries. 42 U.S.C. § 300gg-13(a)(4).⁵ In addition, the Women’s Health Amendment requires coverage of other preventive care for women, including an annual well-woman preventive care visit, counseling and screening for HIV and domestic violence, and services for the early detection of reproductive cancers and sexually transmitted infections.

29. Under California law, it is unlawful for an insurance or health care service plan to refuse to enter into any contract, or to cancel or decline to renew or reinstate any contract, because of a person’s race, color, national origin, ancestry, religion, sex, marital status, sexual orientation, or age. Cal. Health & Safety Code § 1365.5(a);⁶ Cal. Ins. Code § 10140.2 (barring premium, price, or charge differentials due to insured’s sex, including gender identity and expression); Cal. Penal Code § 422.56 (“gender” means sex and includes a person’s gender identity and gender expression defined as a “person’s gender-related appearance and behavior whether or not stereotypically associated with the person’s assigned sex at birth”). It is also unlawful for an insurance or health care service plan to modify the terms of the contract or to impose any limitations, exceptions, exclusions, reductions, copayments, coinsurance, deductibles, reservations, or other modifications because of a person’s race, color, national origin, ancestry, religion, sex, marital status, sexual orientation, or age. Cal. Health & Safety Code § 1365.5(b); Cal. Ins. Code § 10140.2.

⁵ On October 6, 2017, HHS issued two interim final rules purporting to implement the ACA’s contraceptive coverage requirement. The regulations, which went into effect immediately, permit nearly any employer with any moral or religious objection to contraception to exempt themselves from the requirement. The rules thus transformed an important legal entitlement to no-cost contraceptive coverage into a conditional benefit subject to the employer’s veto. The States of California, Delaware, Maryland, New York, and Virginia immediately sought and received an injunction. *California v. HHS*, 281 F. Supp. 3d 806 (N.D. Cal. 2017); *California v. Azar*, 911 F.3d 558 (9th Cir. 2018) (largely affirming district court); see also *Pennsylvania v. Trump*, 281 F. Supp. 3d 553 (E.D. Pa. 2017), appeal pending (3rd Cir.). Final rules issued on November 15, 2018, have now also been enjoined. *California v. HHS*, 351 F. Supp. 3d 1267 (N.D. Cal. 2019); *Pennsylvania v. Trump*, 351 F. Supp. 3d 791 (E.D. Pa. 2019).

⁶ In enacting this provision as part of Assembly Bill 1586 (2005-2006), the California Legislature considered a 2002 report from the Transgender Law Center and the National Center for Lesbian Rights entitled “Trans Realities: A Legal Needs Assessment of San Francisco’s Transgender Communities,” in which nearly one in three respondents stated that they had experienced some form of healthcare-related gender identity discrimination, including routine denial of coverage by health insurers for transition-related procedures, and discriminatory or inappropriate behavior by healthcare providers and staff. See September 8, 2005 Assembly Floor Analysis available at http://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=200520060AB1586.

30. California, through its Department of Management Health Care (DMHC), also regulates licensed health plans under the Knox-Keene Health Care Service Plan Act of 1975. Cal. Health & Safety Code §§ 1340-1399.818. The Knox-Keene Act requires coverage of all FDA-approved contraceptive drugs, devices, and other products for women, including all FDA-approved contraceptive drugs, devices, and products available over the counter, as prescribed by the insured's provider; patient education and counseling on contraception; and any follow-up care for same, including, but not limited to, management of side effects, counseling for continued adherence, and device insertion and removal. Cal. Health & Safety Code § 1367.25. However, pursuant to Health and Safety Code section 1367.25(c), a religious employer may request a health care service plan contract without coverage for FDA-approved contraceptive methods that are contrary to the religious employer's religious tenets, and, if so requested, a health care service plan contract shall be provided without coverage for contraceptive methods.

31. California further regulates insurers through its Department of Insurance. Insurance Code section 10123.196(b)(1) requires coverage of all FDA-approved contraceptive drugs, devices, and other products for women, including all FDA-approved contraceptive drugs, devices, and products available over the counter, as prescribed by the insured's provider; patient education and counseling on contraception; and any follow-up care for same, including, but not limited to, management of side effects, counseling for continued adherence, and device insertion and removal. However, pursuant to Insurance Code section 10123.196(e), a religious employer may request an insurance policy without coverage for contraceptive methods that are contrary to the religious employer's religious tenets, and, if so requested, an insurance policy shall be provided without coverage for contraceptive methods.

32. To further access to family planning services, California offers such services to those eligible for Medicaid (known as Medi-Cal), administered by the Office of Family Planning (OFP). See Cal. Welf. & Inst. Code § 14501(a) (OFP is tasked with ensuring that citizens of childbearing age have comprehensive medical knowledge, assistance, and services relating to the planning of families). For those not eligible for Medicaid, OFP also administers the Family Planning, Access, Care, and Treatment (Family PACT) program for persons with incomes at or

below 200% of the federal poverty guidelines and who have no other source of healthcare coverage for family planning services. And while access to contraceptive coverage has increased under the ACA, the Rule's likely reversal of this progress⁷ will burden the State with increased costs of providing contraceptive care through programs like Family PACT and the increased costs resulting from unintended pregnancies.⁸

C. Regulation of Medical Professions

33. California regulates its medical professionals, including physicians, physician assistants, nurses, nurse practitioners, psychologists, midwives, and pharmacists, among others. Cal. Bus. & Prof. Code § 101 (composition of the Department of Consumer Affairs includes the Medical, Pharmacy, Nursing, Behavioral Sciences, and Psychology Boards, and the Physician Assistant Committee, among others); *see also* Cal. Bus. & Prof. Code § 101.6 (the purpose of the boards of the Department of Consumer Affairs is to ensure the public health, safety and welfare by establishing minimum qualifications and levels of competency, and to provide a means for redress of grievances by investigating allegations of unprofessional conduct, incompetence, fraudulent action, or unlawful activity and, as necessary, to institute disciplinary action against licensees).

34. California licensed doctors, as part of their continuing medical education, are required to meet cultural competency standards that include “understanding and applying cultural and ethnic data to the process of clinical care, including, as appropriate, information pertinent to the appropriate treatment of, and provision of care to, the lesbian, gay, bisexual, transgender, and intersex communities.” Cal. Bus. & Prof. Code § 2190.1(c)(1)(D).

⁷ The Rule's impact on California's family planning efforts only increases harms that will result from Defendants' recent Title X regulations, 84 Fed. Reg. 7714 (2019). *See California v. Azar*, No. 3:19-cv-01184-EMC, 2019 WL 1877392, *10-11 (N.D. Cal. Apr. 26, 2019).

⁸ In 2010, for example, 64% of the 393,000 unintended pregnancies in California were paid for by Medicaid and other public insurance programs, costing the State approximately \$689 million and the federal government approximately \$1.06 billion. Kathryn Kost, Unintended Pregnancy Rates at the State Level: Estimates for 2010 and Trends Since 2002, Guttmacher Institute (2015), 8, <https://www.guttmacher.org/report/unintended-pregnancy-rates-state-level-estimates-2010-and-trends-2002>. Adam Sonfield and Kathryn Kost, Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010, Guttmacher Institute (2015), 13, <https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy>.

35. A California licensed healthcare professional is subject to discipline “if, because of any characteristic listed or defined in subdivision (b) or (e) of Section 51 of the Civil Code [sex, race, color, religion, ancestry, national origin, disability, medical condition, genetic information, marital status, sexual orientation, citizenship, primary language, or immigration status], he or she refuses to perform the licensed activity or aids or incites the refusal to perform that licensed activity by another licensee, or if, because [of such characteristics], he or she makes any discrimination, or restriction in the performance of the licensed activity.” Cal. Bus. & Prof. Code § 125.6.

36. By promulgating the Rule, HHS has infringed upon California’s interest in the laws it has enacted to regulate matters concerning the health and safety of its residents and its medical professions, which are integral to ensuring Californians’ access to healthcare.

37. “[T]he structure and limitations of federalism . . . allow the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.” *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (internal quotation marks and citation omitted). But the Rule encourages California licensed physicians and other healthcare professionals to disregard their licensure requirements, and freely interfere with patients’ access to healthcare while disregarding anti-discrimination protections, thereby threatening California’s sovereign and quasi-sovereign interests in regulating healthcare and California licensed entities and professionals.

38. The Rule is a direct assault on California’s sovereign and quasi-sovereign interests in regulating healthcare and California licensed entities and professionals because it broadly defines “discriminate or discrimination” to include the acts of making unavailable or denying any license, certification, accreditation, title, or other similar interest. 84 Fed. Reg. at 23263.

39. The Rule has likely already impacted the provision of healthcare by encouraging healthcare professionals to refuse to provide care. In fall 2018, a pharmacy refused a Michigan woman a prescription to treat her miscarriage.⁹ In summer 2018, an Arizona transgender woman

⁹ <https://www.aclumich.org/en/press-releases/aclu-files-complaint-meijer-after-pharmacist-refused-fill-prescription-customer-who>.

1 was refused a prescription for hormone therapy.¹⁰ These incidents highlight discrimination that
 2 takes place even without this Rule, and that could be encouraged by the Rule's provisions.

3 40. California's Unruh Civil Rights Act, Civil Code sections 51 *et seq.*, bars business
 4 establishments from discriminating in the delivery of services and goods, including
 5 discrimination based on sex, which includes gender identity and gender expression. Cal. Civ.
 6 Code § 51(b);¹¹ *N. Coast*, 44 Cal.4th at 1145, 1158 (the Unruh Act furthers California's
 7 compelling interest in ensuring full and equal access to medical treatment irrespective of sexual
 8 orientation).

9 **II. HHS'S UNLAWFUL NEW RULE**

10 **A. Current Regulatory Scheme and Background**

11 41. On December 19, 2008, Defendants issued a final rule to "provide for the
 12 enforcement of the Church Amendments...the Public Health Service Act [Coats-Snowe
 13 Amendment] and the Weldon Amendment." 73 Fed. Reg. 78072, 78074 & 78098. The
 14 regulation purported to authorize HHS to terminate and/or compel the return of all HHS funds
 15 from state and local governments that violate its prohibition against "discrimination on the basis
 16 that the health entity does not provide, pay for, provide coverage of, or refer for abortion. *Id.* at
 17 78074 & 78098. The 2008 final rule went into effect on January 20, 2009 except that its
 18 certification requirement never took effect, as it was subject to information collection approval
 19 process under the Paperwork Reduction Act, which was never completed. 76 Fed. Reg. 9968,
 20 9971 (Feb. 23, 2011).

21 42. On March 10, 2009, HHS proposed a rule to rescind the 2008 rule. 74 Fed. Reg.
 22 10207 (Mar. 10, 2009). In it, HHS discussed that commenters of the previous rule "raised a
 23 number of questions that warrant[ed] further careful consideration." *Id.* In that proposed rule and
 24

25 ¹⁰ <https://www.aclu.org/blog/lgbt-rights/transgender-rights/my-pharmacist-humiliated-me-when-he-refused-fill-my-hormone>.

26 ¹¹ "For purposes of this section . . . 'Sex' includes, but is not limited to, pregnancy, childbirth, or
 27 medical conditions related to pregnancy or childbirth. 'Sex' also includes, but is not limited to, a
 28 person's gender. 'Gender' means sex, and includes a person's gender identity and gender
 expression. 'Gender expression' means a person's gender-related appearance and behavior
 whether or not stereotypically associated with the person's assigned sex at birth." Cal. Civ. Code
 § 51 (e)(5).

1 the resulting 2011 final (and current) rule, HHS also noted “[n]o statutory provision, however,
 2 requires promulgation of a rule.” *Id.*; 76 Fed. Reg. 9968, 9975 (Feb. 23, 2011) (the Church,
 3 Weldon, and Coat-Snowe Amendments do not require “promulgation of regulations for their
 4 interpretation.”).

5 43. The 2011 rule changed the 2008 rule by indicating that its purpose was to provide for
 6 the enforcement of Church, Weldon, and Coat-Snowe Amendments and by removing provisions
 7 containing definitions of terms, requirements, prohibitions, and a certification requirement. *See*
 8 73 Fed. Reg. 78072 and 76 Fed. Reg. 9968, generally. The 2011 rule also provided that the
 9 Office for Civil Rights (OCR) of HHS is designated to “receive complaints based on the Federal
 10 health care provider conscience protection statutes,” and is further directed to “coordinate the
 11 handling of complaints with [HHS] funding components from which the entity, to which a
 12 complaint has been filed, receives funding.” 76 Fed. Reg. at 9975, 9977. But the 2011 rule also
 13 made clear that “[f]ederal provider conscience statutes...were never intended to allow providers
 14 to refuse to provide medical care to an individual because the individual engaged in behavior the
 15 health care provider found objectionable.” *Id.* at 9973-74.

16 44. And since receiving the aforementioned designation on 2011, OCR had received a
 17 total of 44 complaints by the time Defendants issued their Notice of Proposed Rulemaking
 18 (NPRM) on January 26, 2018. 83 Fed. Reg. 3880, 3886 (Jan. 26, 2018).

19 **B. Proposed Rule and Public Comments**

20 45. In the January 26, 2018 NPRM, HHS proposed to revise the 2011 rule to ensure that
 21 “persons or entities are not subjected to certain practices or policies that violate conscience,
 22 coerce, or discriminate, in violation of such Federal laws.” 83 Fed. Reg. at 3880. The NPRM
 23 proposed a broad exemption to opt out of any healthcare service on the basis of “conscience,
 24 religious beliefs, or moral convictions” to medical providers but also to anyone with an
 25 “articulable connection” to the provision of that service, including helping to make a referral for
 26 that service. Specific scenarios included in the NPRM included abortion, sterilization,
 27 euthanasia, certain vaccinations if there is an “aborted fetal tissue” connection, contraception,
 28

gender transition/gender dysphoria, tubal ligations, hysterectomies, assisted suicide, and referrals for advanced directives, and “other health services.” 83 Fed. Reg. at 3903.

46. HHS also proposed to grant overall responsibility for ensuring that those who participate in HHS programs or activities comply with Federal conscience laws to its Office for Civil Rights by initiating compliance reviews, conducting investigations, supervising and coordinating compliance, and using enforcement tools otherwise available in civil rights law to address violations and resolve complaints, including:

- (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 subrecipient, created by Federal law; and
- (vii) Taking any other remedies that may be legally available.

84 Fed. Reg. at 23272.

47. In response to the NPRM, HHS received over 242,000 comments.¹² Comments opposed to the NPRM came from a broad array of individuals, medical associations, state and

¹²Comments are available at <https://www.regulations.gov/docketBrowser?rpp=50&so=DESC&sb=postedDate&po=0&dct=PS&D=HHS-OCR-2018-0002>. Although the website shows 72,417 comment submissions, some are batch comments comprising thousands of individual comments. The Rule provides a total of over 242,000 as of the date the Rule was published. 84 Fed. Reg. at 23180, n. 41.

1 local governments, reproductive rights organizations, children’s rights organizations, disease
2 advocates, and civil liberties organizations.

3 48. The nation’s trusted major medical organizations raised grave concerns about the
4 legality and reasonableness of the proposed regulation. For example, the American Medical
5 Association (AMA) commented that the proposed rule “would undermine patients’ access to
6 medical care and information, impose barriers to physicians’ and health care institutions’ ability
7 to provide treatment, impede advances in biomedical research, and create confusion and
8 uncertainty among physicians, other health care professionals, and health care institutions about
9 their legal and ethical obligations to treat patients.” The Association stated that the proposed rule
10 “would legitimize discrimination against vulnerable patients and in fact create a right to refuse to
11 provide certain treatments or services.”¹³

12 49. The American Academy of Family Physicians (AAFP), which represents 129,000
13 physicians and medical students across the country, noted it was “concerned that the [proposed
14 rule] could restrict access to care for vulnerable patients seeking the aid of their family physician
15 or other health care professionals.”¹⁴

16 50. The American Nurses Association (ANA) and the American Academy of Nursing
17 (AAN) stated that while they “strongly support the right and prerogative of nurses—and all
18 healthcare workers—to heed their moral and ethical values,” they had concerns that the proposed
19 rule would “lead to inordinate discrimination against certain patient populations—namely
20 individuals seeking reproductive health care services and lesbian, gay, bisexual, transgender, and
21 queer or questioning (LGBTQ) individuals.” This proliferation of discrimination could “result in
22 reduced access to crucial and medically necessary health care services and the further
23 exacerbation of health disparities between these groups and the overall population.”¹⁵

24
25
26 ¹³ AMA comment at 1, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70564>.

27 ¹⁴ AAFP comment at 1, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-34646>.

28 ¹⁵ ANA-AAN comment at 1-2, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-55870>.

51. The American Congress of Obstetricians and Gynecologists (ACOG) noted that under the American Medical Association's Code of Medical Ethics, responsibility to the patient is paramount for all physicians, and that providers with moral or religious objections should ensure that processes are in place to protect access to and maintain a continuity of care for all patients; but in an emergency in which referral is not possible or might negatively impact the patient's physical or mental health, providers have an obligation to provide medically indicated and requested care.¹⁶

52. The American College of Emergency Physicians (ACEP), on behalf of its 37,000 members, expressed concerns that the proposed rule failed to reflect the moral and legal duty of emergency physicians to treat everyone "who comes through our doors," stating that [b]oth by law and by oath, emergency physicians care for all patients seeking emergency medical treatment," and concluding that "[d]enial of emergency care or delay in providing emergency services on the basis of race, religion, sexual orientation, gender identity, ethnic background, social status, type of illness, or ability to pay, is unethical."¹⁷

53. The American Academy of Pediatrics (AAP), which represents 66,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists, urged HHS to ensure that children have appropriate access to needed healthcare in the areas of vaccines, mental health services, newborn hearing screening, reproductive health, medical neglect, treatment for sexual assault, including screening for sexually transmitted diseases and pregnancy prevention, and supportive care for LGBTQ youth.¹⁸

54. On behalf of more than 123,000 physician assistants, the American Academy of PAs (AAPA) expressed concerns that the proposed rule could have a negative impact on access to healthcare for patients, especially those who are most vulnerable and those who may live in rural

¹⁶ ACOG comment at 1-2, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70647>.

¹⁷ ACEP comment at 1, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71219>.

¹⁸ AAP comment at 4-14, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71022>.

1 or underserved areas, and that the new paperwork requirements related to the assurance and
 2 certification provisions could be excessively burdensome to healthcare providers.¹⁹

3 55. The American Health Care Association (AHCA) and National Center for Assisted
 4 Living (NCAL) expressed concerns that the increased regulatory burden of the proposed rule for
 5 long term and post-acute care providers could reduce time for providing high quality patient-
 6 centered care.²⁰

7 56. The American Physical Therapy Association (APTA) urged that the proposed rule not
 8 be finalized because discrimination under the guise of religion or morality runs counter to their
 9 Code of Ethics and the principle of patient-centered care, both of which are foundational to the
 10 physical therapy profession. In their view, the proposed rule also would severely compromise
 11 patient access to medically necessary healthcare services.²¹

12 57. Physicians for Reproductive Health (PRH) warned that the proposed rule unlawfully
 13 exceeds HHS's authority by impermissibly expanding federal conscience laws, creates barriers to
 14 healthcare and exacerbates already existing inequities, and will cause severe consequences for
 15 providers while undermining the provider-patient relationship.²²

16 58. The American Hospital Association (AHA)²³ and hospital associations from around
 17 the country, including the Wisconsin Hospital Association, Inc. (WHA),²⁴ the Greater New York
 18 Hospital Association (GNYHA),²⁵ the Texas Hospital Association (THA),²⁶ the Ohio Hospital
 19

20 ¹⁹ AAPA comment at 1, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-65085>.

21 ²⁰ AHCA-NCAL comment at 1, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-29924>.

22 ²¹ APTA comment at 2-3, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-28624>.

23 ²² PRH comment at 2-7; 9-11, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71284>.

24 ²³ AHA comment at 4, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-65761>.

25 ²⁴ WHA comment at 3-4, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-66144>.

26 ²⁵ GNYHA comment at 2; 4-5, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71154>.

27 ²⁶ THA comment at 1-2, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-67485>.
 28

Association (OHA),²⁷ and the Massachusetts Health and Hospital Association (MHA)²⁸ objected to the proposed rule imposing regulatory burdens on hospitals that should instead be focused on providing patient care; also the overbroad and expanded definitions further run the risk of creating unintended consequences for patient care and run counter to hospital policies not to discriminate in the delivery of emergency, urgent, and necessary care on the basis of a patient's race, color, national origin, citizenship, alienage, religion, creed, sex, sexual orientation, gender identity, age, or disability.

59. The Association of American Medical Colleges (AAMC) asked that the proposed rule be withdrawn because there is no demonstrable need for the proposed rule due to existing laws and protections. AAMC asserted that the paucity of complaints does not justify an expansion of enforcement authority, that the proposed rule is overly expansive in its reach and incongruous with medical professionalism, and that it will do harm to lower-income Americans, racial and ethnic minorities, the LGBTQ community, and patients in rural areas.²⁹

60. The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) opposed the proposed rule as unnecessary to protect the rights of providers, and noted that the existing rule issued in 2011 adequately protects the conscience of providers while also protecting patients; the proposed rule also undermines the Title X program.³⁰

61. Other major medical organizations also submitted comments, including the National Association of Councils on Developmental Disabilities,³¹ the National Association of Pediatric Nurse Practitioners,³² the National Community Pharmacists Association,³³ and the National Family Planning & Reproductive Health Association.³⁴

²⁷ OHA comment at 1, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70015>.

²⁸ MHA comment at 1-3, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71172>.

²⁹ AAMC comment at 1-2; 4-5, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-67592>.

³⁰ AWHONN comment at 1-2, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71214>.

³¹ Available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-66494>.

³² Available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71063>.

³³ Available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71176>.

³⁴ Available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70260>.

62. Numerous comments raised concerns regarding the proposed rule's impact on healthcare access, noting that refusal of care would be especially dangerous for those already facing barriers in healthcare, including patients in rural communities where there may be no other sources of health and life preserving medical care.³⁵ Others expressed similar concerns:

- "As a transgender individual, I have been refused important treatment at local doctors. I have to drive for 2 hours in order to receive basic medical care, because I cannot find a doctor who will help me in my town. Someday this very well might kill me if I need immediate, life-saving care."³⁶
- "Because I am gay and live in a rural area, my son (who is not gay) and I have been refused healthcare by our local clinic. As a result, we have been forced to seek a physician in another town rather than receive treatment from our local provider."³⁷
- "If a doctor can refuse to treat me, then I know I will be at my most vulnerable in emergency medicine situations....If this is passed, I will no longer feel safe traveling the 1700 miles between my home and where my family lives. My family is poor and can't afford to come see me. Effectively, I will be cut off from my loved ones for fear of what might happen to me in transit."³⁸
- "My wife was born intersexed. She is considered transgender and we rely on trans healthcare for her daily medications. We already drive 2 hours from Colorado Springs to Denver for qualified doctors that take our insurance. She needs this care to be able to function without pain at work. Reducing the number of doctors and prescriptions available will only make it harder for us to continue working and will further drain our time and money."³⁹
- "I live in an area where I have few health insurance options (currently two). If healthcare providers are allowed to opt out of providing care to me because I am a

³⁵ National Council of Jewish Women New York comment at 4-5, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-56027>.

³⁶ Available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-34687>.

³⁷ Available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-54505>.

³⁸ Available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-56725>.

³⁹ Available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71419>.

1 gay American, My chronic disease could become a much more expensive life
 2 threatening disease that would ultimately cost me, other tax payers and/or the
 3 government more money for treatment.”⁴⁰

- 4 • “When I was coming out as transgender, I had a difficult time finding a doctor who
 5 was willing to treat me, and I live in the San Francisco Bay Area. I cannot imagine
 6 how difficult it is for transgender people in more conservative areas of the country
 7 to find healthcare providers who are willing to treat them.”⁴¹

8 63. Several comments highlighted the negative impacts the proposed rule would have on
 9 the interests of Californians:

- 10 • The California Attorney General commented that the proposed rule violated the APA
 11 because it construed numerous terms, including “assist in the performance,” “health
 12 care entity,” and “referral or refer for,” so broadly as to materially alter well-
 13 established statutory language in the Church Amendments, the Coats-Snowe
 14 Amendment, and the Weldon Amendment. Further, California explained that the
 15 proposed rule violated several constitutional provisions, including the Spending
 16 Clause, and the Establishment Clause, and would result in significant negative
 17 impacts on California, its residents, and California state entities that receive federal
 18 funding.⁴²
- 19 • The California Insurance Commissioner’s comment letter emphasized that existing
 20 state and federal law provide healthcare provider conscience protections; however,
 21 these laws rightly do not allow objectors to interfere with patient access to care or
 22 civil rights protections that prohibit discrimination. In contrast, the proposed rule
 23 would harm patients and encourage discrimination against people on the basis of
 24

25
 26 ⁴⁰ Available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71960>.

27 ⁴¹ Available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72133>.

28 ⁴² California Attorney General comment at 2-6, available at
<https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70182>.

1 race, sex, sexual orientation, gender, gender identity, and almost any other kind of
 2 bias due to its overbroad scope.⁴³

- 3 • The California Medical Association, on behalf of its 43,000 physician members and
 4 medical students, cautioned that the proposed rule could lead to discrimination
 5 prohibited under federal and state law, insert politics into the patient-physician
 6 relationship, increase administrative burdens on doctors, and, due to its broad
 7 application, allow any entity or individual to use their personal beliefs to dictate
 8 patient care.⁴⁴
- 9 • The California Primary Care Association, which represents over 1,300 not-for-profit
 10 community clinics and health centers in California, expressed concern about the
 11 proposed rule's potential disparate impact on vulnerable groups such as those
 12 seeking end-of-life care, persons affected by HIV/AIDS, women, persons of color,
 13 and the LGBTQ community. The Association cautioned that the proposed rule is so
 14 broad and ambiguous that medical staff may interpret it to allow them to decline to
 15 tell a patient where s/he would be able to obtain lifesaving services, putting them
 16 and others at risk, and further, threatening patient informed consent.⁴⁵
- 17 • California county public safety-net healthcare providers, including the Santa Clara
 18 Valley Medical Center⁴⁶ and the San Francisco Department of Public Health,⁴⁷ also
 19 opposed the proposed rule due to its impermissible expansion of federal laws that
 20 could sanction discrimination against vulnerable communities, including the
 21
 22

23 ⁴³ California Insurance Commissioner comment at 1-2; 5-6, available at
 24 <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70956>.

24 ⁴⁴ CMA comment at 1-5, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71550>.

25 ⁴⁵ CPCA comment at 1-2, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70654>.

26 ⁴⁶ County of Santa Clara comment at 2-8, available at
 27 <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-54930>.

27 ⁴⁷ SFDPH comment at 2-3, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-69109>.
 28

LGBTQ community, and the proposed rule’s unnecessary new burdens on public healthcare providers.⁴⁸

- The California LGBT Health & Human Services Network, a coalition of 60 non-profit providers, community centers, and researchers, expressed that the proposed rule “tramples on California’s efforts to protect patients’ health and safety, including through the California Insurance Gender Nondiscrimination Act” and other rules that make clear that all people have the right to access coverage for necessary healthcare regardless of their gender identity or gender expression.⁴⁹
- The Latino Coalition for a Healthy California objected to the proposed rule’s broad and poorly defined language in comparison to existing law that already provides ample protections to healthcare workers that refuse to participate in a healthcare service to which they have a moral objection, and warned that the proposed rule could result in medical, behavioral and oral health care that fails to comply with established medical practice guidelines; also the proposed rule fails to account for the significant burden that will be imposed on patients, a burden that will fall disproportionately on women, people of color, persons with disabilities, and LGBTQ individuals, communities that already experience severe health disparities and discrimination.⁵⁰
- The American Civil Liberties Union Foundation of California cautioned that the proposed rule’s expansion of definitions, covered entities, and enforcement mechanisms invite violation of California laws that safeguard patients from substandard healthcare and ensure patients’ health, access, and choice. These include state laws that mandate minimum educational requirements for licensed medical professionals, medically necessary services in emergency situations,

⁴⁸ See also comments submitted by the National Association of County and City Health Officials; available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70228>.

⁴⁹ California LGBT Health and Human Services Network comment at 2-3, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-56435>.

⁵⁰ LCHC comment at 1-2, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-67994>.

managed care health plans' coverage of abortion as basic healthcare under the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act), and informing patients when they are not offered all medical options.⁵¹

64. On February 15, 2019, California representatives met with HHS's Office of Budget Management to discuss California's concerns regarding the proposed rule, including concerns that the proposed rule unfairly targets California and interferes with the State's policy making, encourages discrimination, impedes access to healthcare and information, violates various federal laws, and imposes administrative burdens and costs on states and other entities. The California representatives also raised California's outstanding FOIA request to HHS (discussed further below) and provided a copy of the FOIA request with the State's numerous follow-up communications.

C. HHS Issues a Largely Unchanged and Arbitrary and Capricious Rule

65. On May 21, 2019, HHS issued its final rule. Like the proposed rule, the final rule conflicts with existing law and impedes the provision of and access to medical information and healthcare by attempting to create limitless categories under which medical information and care can be refused. The final Rule (which did little to address the proposed rule's errors in this respect, notwithstanding the large volume of intervening comments) so conflicts by misconstruing and exceeding the bounds of federal statutes, including well-established statutory language and definitions.

66. Although the Rule states that it seeks to only clarify federal conscience protection laws—particularly the Church Amendments, 42 U.S.C. 300a-7; the Coats-Snowe Amendment, 42 U.S.C. 238n; and the Weldon Amendment in HHS's yearly appropriations acts, *e.g.*, the Consolidated Appropriations Act, 2018, Pub. L. 115-141 (H.R. 1625)—the Rule greatly expands the breadth of these laws, which (at most) address only exemptions to abortion and sterilization procedures. *See Chrisman v. Sisters of St. Joseph of Peace*, 506 F.2d 308, 312 (1974).⁵²

⁵¹ ACLU of California comment at 3-5; 10-11, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71871>.

⁵² Indeed, the case studies referenced in the Rule indicate that it is intended to include refusals for gender transition-related services (reference to *Minton v. Dignity Health*, San Francisco Superior

67. The Rule defines “assist in the performance” of an activity to encompass an action that has a “specific, reasonable, and articulable connection” to furthering a procedure, health service program, or research activity, including “counseling, referral, training, or otherwise making arrangements” for the procedure, health program, or research activity. 84 Fed. Reg. at 23263. Only the Church Amendments refer to “assist in the performance” of an activity, and nothing in that statutory scheme envisions the broad definition in the Rule. 42 U.S.C. § 300a-7. Congress’s specific references to “counsel[ing]” in a separate Church Amendment provision, “training” in the Coats-Snowe Amendment, and “refer for” in the Weldon Amendment evidence Congress’s intent to keep these actions separate in meaning from the performance of a procedure and confirm that the Rule’s expansive definition of “assist in the performance” should not include a panoply of additional activities.

68. Similarly, “health care entity” is defined in the Coats-Snowe Amendment and the Weldon Amendment, yet the Rule expands these definitions to include “health care personnel,” as distinct from a “health care professional,” such as a doctor, nurse or other licensed medical provider.⁵³ Thus, the Rule suggests significantly broader categories of personnel could refuse to

Court Case No. CGC 17-558259, 2017 WL 7733922 at 84 Fed. Reg. at 23176, n. 27) and circumstances that may involve California’s End of Life Option Act, California Health and Safety Code sections 443, *et seq.* (84 Fed. Reg. at 23177). But as discussed in section I, the Rule is unnecessary because the End of Life Option Act, like other California provisions, contains a conscience exemption: “Participation in activities authorized pursuant to this part shall be voluntary. Notwithstanding Sections 442 to 442.7, inclusive, a person or entity that elects, for reasons of conscience, morality, or ethics, not to engage in activities authorized pursuant to this part is not required to take any action in support of an individual’s decision under this part.” Cal. Health & Safety Code § 443.14 (e)(1). Moreover, the Act specifically provides that that a conscientious objector cannot be sanctioned, disciplined, or penalized “for refusing to inform a patient regarding his or her rights under this part, and not referring an individual to a physician who participates in activities authorized under this part.” Cal. Health & Safety Code § 443.14(e)(2).

⁵³ Compare 42 U.S.C. § 238n(c)(2) (defining “health care entity” to include “an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions”) and P.L. 115-141, the Consolidated Appropriations Act of 2018 (H.R. 1625), Div. H, sec. 507(d)(2) (defining “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”) with 84 Fed. Reg. at 23264 (defining “health care entity” to include “health care personnel” and describing listed entities included in the definition as “illustrative, not exhaustive”).

1 provide services—potentially including even a receptionist at a doctor’s office making an
 2 appointment for a patient, for example—based on his or her moral objections.

3 69. The Rule’s definition of “health care entity” is also overbroad, given that it includes “a
 4 plan sponsor, issuer, or third-party administrator, or any other kind of health care organization,
 5 facility, or plan.” 84 Fed. Reg. at 23264. Such a broad definition, well beyond the definition in
 6 the statutory text, could result in limitless categories of individuals and entities with absolutely no
 7 ethical obligation to the patient or involvement in direct patient care to sabotage and delay the
 8 provision of healthcare to patients.

9 70. The Rule’s definition of “referral or refer for” is particularly broad, including “the
 10 provision of information in oral, written, or electronic form (including names, addresses, phone
 11 numbers, email or web addresses, directions, instructions, descriptions, or other information
 12 resources), where the purpose or reasonably foreseeable outcome of provision of the information
 13 is to assist a person in receiving funding or financing for, training in, obtaining, or performing a
 14 particular health care service, program, activity, or procedure.” Thus, under the Rule, even the
 15 posting of notices, would be considered a “referral.” 84 Fed. Reg. at 23264.

16 71. Reading and interpreting these statutes in such an overly broad manner will permit
 17 unlawful refusals of any healthcare service by almost any individual, even those not at all
 18 involved in the provision of healthcare; whereas the Weldon, Church, and Coats-Snowe
 19 Amendments refer to only specific circumstances in which healthcare providers or certain
 20 enumerated healthcare entities may not be required to participate in abortions, sterilizations, or
 21 certain health service programs and research activities.

22 72. In addition, the Rule’s implementation of specific penalties for noncompliance is
 23 unmoored from any statutory text. Although the Weldon Amendment purports to strip
 24 noncompliant states of broad categories of federal funding (which raises its own legal problems),
 25 nothing in the Weldon Amendment, or elsewhere in federal law, supports the separate,
 26 discretionary enforcement mechanisms asserted in the Rule. P.L. 115-141, the Consolidated
 27 Appropriations Act of 2018 (H.R. 1625), Div. H, sec. 507(d)(1).

28 ///

73. Defendants justify the Rule in part on “presidential priority of protecting conscience and religious freedom.” 84 Fed. Reg. at 23227, *citing* Executive Order 13798, 82 FR 21675 (May 4, 2017). But the validity of the Rule depends on its relationship to legislative, not executive, action: if the underlying federal statutes do not support the Rule, additional executive action cannot change this basic fact.

74. The Rule also conflicts with several other federal statutes, and is written so broadly it implicates several others. For starters, the Rule clashes with the following provisions of the ACA:

- Section 1554, which prohibits the Secretary of HHS from promulgating any regulation that (1) creates unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to healthcare; (3) interferes with communications regarding a full range of treatment options; (4) restricts the ability of providers to provide full disclosure of all relevant information to patients making healthcare decisions; (5) violates the principles of informed consent and the ethical standards of medical professionals; or (6) limits the availability of treatment for the full duration of a patient’s medical needs (42 U.S.C. § 18116); and
- Section 1557, which prohibits discrimination in health programs or activities, including gender discrimination (42 U.S.C. § 18116).

75. The Rule further fails to address and acknowledge the employers’ legal obligations under Title VII of the Civil Rights Act of 1964. Title VII (which applies to employers with 15 or more employees) prohibits an employer from discriminating on the basis of religion, and absent undue hardship (*e.g.*, “more than a de minimis cost”), imposes a duty that an employer reasonably accommodate an employee’s religion, including all aspects of religious belief, observance and practices. 42 U.S.C. § 2000e (a); *Opuku-Boateng v. State of California*, 95 F.3d 1461, 1467-1468 (9th Cir. 1996). An undue hardship may also exist if accommodating the employee would result in the employer violating state or federal law or if it would have a discriminatory impact on the rights of other employees. *Sutton v. Providence St. Joseph Med. Ctr.*, 192 F.3d 826, 830 (9th Cir.

1999); *Peterson v. Hewlett Packard Co.*, 358 F.3d 599, 606-607 (9th Cir. 2004). Yet under the Rule, there is no workable requirement that there be dialogue between the employer and employee. The Rule’s requirement that an employer “may,” no more than once a year, require an employee to “inform it of objections to performing, referring for, participating in, or assisting in the performance of specific procedures, programs, research, counseling, or treatments, but only to the extent that there is a reasonable likelihood that the protected entity may be asked in good faith to perform, refer for, participate in, or assist in the performance of, any act or conduct just described,” 84 Fed. Reg. at 23263, fails to comport with the accommodation process under Title VII. The Rule thus suggests that an employee can simply opt out of providing comprehensive healthcare to a patient, depriving the patient of emergency medical care or of state- and federally entitled healthcare rights, without consequence and without considering alternatives that would accommodate both the employee’s religion and the patient’s needs. Such a deprivation creates unnecessary tension with state and federal laws barring discrimination on the basis of other protected categories, including sex and gender.⁵⁴

76. The Rule also contravenes Title X of the Public Health Service Act, 42 U.S.C. §§ 300-300a-6, which provides federal funding for family-planning services. Congress required Title X grantees to operate “voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services.” 42 U.S.C. § 300(a). Title X appropriations bills, e.g., 2019 Continuing Appropriations Act, Pub. L. No. 115-245, Div. B., Tit. II, 132 Stat. 2981, 3070-71 (2018), require that “all pregnancy counseling shall be nondirective”; in other words, funded projects are to offer pregnant women neutral, non-judgmental information and counseling regarding their options, including prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination.

77. In the preamble to the Rule, Defendants justify their action in part by explaining that they have “amended the Title X regulations to remove the requirements for abortion counseling, information, and referrals.” 84 Fed. Reg. at 23200. But Defendants’ attempted amendment to

⁵⁴ Title VII prohibits both discrimination on the basis of sex and gender. *Schwenk v. Hartford*, 204 F.3d 1187, 1202 (9th Cir. 2000) (Title VII extends protections to transgender individuals).

Title X regulations has, as of the date of this complaint, been rejected by three separate district courts on the grounds that it likely violates federal law and is an arbitrary and capricious exercise of agency authority. *See, e.g., California v. Azar*, No. 3:19-cv-01184-EMC, 2019 WL 1877392 (N.D. Cal. Apr. 26, 2019), appeal docketed, No. 19-15974 (9th Cir. May 6, 2019); *Oregon v. Azar*, 6:19-cv-00317-MC, 2019 WL 1897475 (D. Or. Apr. 29, 2019), appeal docketed, No. 19-35386 (9th Cir. May 6, 2019); *Washington v. Azar*, No. 1:19-cv-03040-SAB, 2019 WL 1868362 (E.D. Wash. Apr. 25, 2019), appeal docketed, No. 19-35394 (9th Cir. May 6, 2019) (all granting preliminary injunction of new rule regarding Title X).

78. Additionally, the Rule disregards the Emergency Medical Treatment & Labor Act (EMTALA) enacted by Congress in response to growing concern about the provision of adequate medical services to individuals, particularly the indigent and the uninsured, who seek care from hospital emergency rooms. 42 U.S.C. § 1395dd(a); *Jackson v. East Bay Hosp.*, 246 F.3d 1248, 1254 (9th Cir. 2001). In this case, the Rule places conscience protection over patient care without exception, even for emergencies. Defendants summarily dismissed these concerns, merely stating that “[w]ith respect to EMTALA, the Department generally agrees with its explanation in the preamble to the 2008 Rule that the requirement under EMTALA that certain hospitals treat and stabilize patients who present in an emergency does not conflict with Federal conscience and anti-discrimination laws.” 84 Fed. Reg. at 23183. By disregarding these concerns, Defendants failed to meaningfully respond to comments and “failed to consider an important aspect of the problem[.]” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

79. Defendants also minimize concerns regarding the Rule’s impact on patients in rural communities. While conceding that “patients in rural area are more likely than patients in urban areas to suffer adverse health outcomes as a result of being denied care, 84 Fed. Reg. at 23253, Defendants, without any actual evidence, conclude that rural residents would be better off because providers will enter and stay in the field due to the Rule’s protections; and in any event, rural resident are less likely to request potentially objectionable care and/or may share the same values with objecting providers. But this Court recently concluded that Defendants’ failure to

adequately consider the patient harms renders a rule arbitrary and capricious. *See California v. Azar*, 2019 WL 1877392, at *29-32 (N.D. Cal. Apr. 26, 2019) (also rejecting unsubstantiated assertions of providers waiting in the wings to enter the field as a result of Defendants' regulations).

80. Nor do the estimated costs of the Rule justify its benefits, revealing it to be greatly wasteful of public funds. Defendants admit in their NPRM that OCR received only 44 complaints over the last 10 years of alleged instances of violations of conscience rights. 83 Fed. Reg. at 3886.⁵⁵ Yet, as HHS further admits, it will cost nearly \$1.06 billion over the first years to implement the Rule, and for the affected entities to comply with the new assurance and certification requirements.⁵⁶ 84 Fed. Reg. at 23240. And these costs fail to account for cost to patients that will result from refusals of care. Meanwhile, HHS disclaims any ability to specifically quantify the benefits. *Id.* at 23227, 23246-23254.

III. CALIFORNIA'S SOVEREIGNTY AND FEDERAL FUNDING TARGETED BY RULE

81. California and its laws balancing conscience protections and patient rights are expressly targeted by the Rule. The Rule's suggestion that California laws "discriminate" is based on a faulty and biased read of these laws, meant to justify an unlawful expansion of federal laws. The threat to revoke California's federal health, education and labor federal funds is a direct assault on state sovereignty and puts the state in an illusory choice—comply with the Rule that conflicts with California's laws and policies or risk losing half a trillion dollars in funds for critical programs that help residents—it is not a choice at all.

82. The Rule states that the Rule resolves confusion caused by OCR's "sub-regulatory guidance" issued through OCR's "high-profile" closing of three Weldon Amendment complaints

⁵⁵ Although Defendants report receiving 343 complaints in fiscal year 2018, 84 Fed. Reg. at 23229, they have refused to comply with FOIA requests for records of complaints to OCR (as discussed further below).

⁵⁶ And as the California Medical Association correctly notes, the Departments' estimated costs of implementation fail to consider the significant time and resources it will take to continuously implement and enforce the Rule, as well as the numerous other administrative and regulatory burdens physicians and providers already face and the degree to which each additional burden detracts from actual care to patients and improving quality. CMA comment at 8, available at <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71550>. 84 Fed. Reg. at 23230-23246.

1 against California. 84 Fed. Reg. at 23178-23179. The three complaints,⁵⁷ which were filed by a
 2 religious organization, churches and a church-run school, and employees of a religiously
 3 affiliated university, alleged that the Department of Managed Health Care (DMHC) (the state
 4 agency responsible for regulating California’s managed care health plans) contacted seven health
 5 plans offering products without abortion coverage on August 22, 2014, and required those health
 6 plans to include abortion coverage.⁵⁸

7 83. On June 21, 2016, OCR closed the three complaints in favor of California, finding
 8 that the Weldon Amendment was not violated because the seven health plans that received the
 9 letter had not objected to providing such coverage on religious or moral grounds, a requirement
 10 for protection under the Weldon Amendment. Additionally, OCR noted that after receipt of
 11 DMHC’s August 22, 2014 letter, the health plans modified their health products, without
 12 objection.⁵⁹ Citing *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012)
 13 (*NFIB*), OCR also determined that this approach avoided a potentially unconstitutional
 14 application of Weldon, given Weldon’s threat to rescind “all funds appropriated under the
 15 Appropriations Act to the State of California – including funds provided to the State not only by
 16 HHS but also by the Departments of Education and Labor, as well as other agencies.”⁶⁰

17 84. In closing the complaints in favor of California, OCR also noted that one of the health
 18 plans, Blue Cross of California, subsequently sought and received from California an exemption
 19 to allow it to offer a plan product excluding abortion services for “religious employers” as defined
 20 under California law, specifically, California Health and Safety Code section 1367.25(c)(1).

21 85. Although litigation is still ongoing, California has been successful in challenges
 22 stemming from DMHC’s 2014 letters. See *Missionary Guadalupanas of the Holy Spirit, Inc., v.*
 23 *Rouillard*, Sacramento Superior Court Case No. 34-2015-80002226 (rejecting claim under the
 24 California APA because its provisions do not apply when the agency’s action merely confirms

25 ⁵⁷ OCR Complaint Nos. 14–193604, 15–193782, and 15–195665.

26 ⁵⁸ DMHC explained in its August 22, 2014 letter that the Knox-Keene Act requires the provision
 27 of basic healthcare services and the California Constitution prohibits health plans from
 28 discriminating against women who choose to terminate a pregnancy.

⁵⁹ Letter from OCR Director to Complainants (June 21, 2016), <https://perma.cc/G4WP-V69V>.

⁶⁰ *Id.*

1 law and the agency's application of the law is the only legally tenable interpretation), appeal
2 pending to the Third District Court of Appeal, Case No. C083232; *Skyline Wesleyan Church v.*
3 *Rouillard*, United States District Court for the Southern District of California, Case No. 3:16-cv-
4 00501 (granting defendants' motion for summary judgment because plaintiffs lacked standing and
5 claims were not ripe); Ninth Circuit appeal pending, Case No. 18-55451; *Foothill Church v.*
6 *Department of Health Care*, United States District Court for the Eastern District of California,
7 Case No. 2:15-cv-02165-KJM-EFB (granting defendants' motion to dismiss), Ninth Circuit
8 appeal pending, Case No. 19-15658.

9 86. The Rule states that, based on its review of OCR's previous closure of complaints
10 against California's August 22, 2014 letter, it has concluded that the aforementioned "sub-
11 regulatory guidance" previously issued by OCR with respect to interpretation of the Weldon
12 Amendment no longer reflects the current position of HHS, OCR, or the HHS Office of the
13 General Counsel. 84 Fed. Reg. at 23179. The Rule states that HHS "continues to hold the views
14 it expressed" in the NPRM, *Id.*, which noted that despite the constitutional concerns cited in
15 OCR's June 21, 2016 letter, HHS nonetheless remained obligated "to not make certain funding
16 available to covered entities that discriminate in violation of the Weldon Amendment." 83 Fed.
17 Reg. at 3890.

18 87. Starting on August 30, 2018, OCR sent a letter to California informing it that OCR
19 has reviewed a September 2017 complaint based on the previously closed complaints stemming
20 from the August 22, 2014 DMHC letter to health plans and determined that OCR has sufficient
21 authority and cause to investigate the allegations raised under the Weldon Amendment, the Coats-
22 Snowe Amendment, and the Church Amendments.

23 88. As noted *infra*, although "health care entity" is defined by the Weldon Amendment
24 (and the Coats-Snowe Amendment), the Rule includes a far broader definition that includes "a
25 plan sponsor, issuer, or third party administrator," thus allowing an employer, as expressly stated
26 by the Rule, to deny coverage for reproductive services to its employees. And the Rule also
27 expands Weldon protection to *any* reason for refusing such coverage, not just religious and moral
28 objections.

89. Both the promulgation of the proposed and final rule shows OCR’s intent to not only target the State of California and its residents, healthcare system and laws, but also sets up an unavoidable clash. Evidence of this has been demonstrated to California throughout the trajectory of this rulemaking.

90. And on January 17, 2019, OCR issued a letter, entitled a Notice of Violation, regarding California’s Reproductive FACT Act, and concluded that California violated the Weldon Amendment and the Coats-Snowe Amendment.⁶¹ In its letter, OCR claimed it investigated complaints by four California clinics. The letter concluded that California “engaged in impermissible discrimination” by subjecting the complainants to “potential fines” under the Reproductive FACT Act. But in light of the permanent court injunctions entered against the FACT Act and the State’s statement that it has no intention of enforcing the Act, OCR concluded that no further remedial action is warranted.

91. Thus although Defendants state in the Rule that they do “not opine upon, and [have] not yet made a judgment on the compatibility of California’s policy with the Weldon Amendment,” 84 Fed. Reg. at 23179, California has reason to believe its state sovereignty and federal funding are at risk under the Rule given the direct attack on California, the Rule’s impermissibly broad interpretation of Weldon which permits a non-covered entity to claim discrimination against the State, and the subsequent receipt of a letter from OCR finding California in violation. That is because section 88.6(d)(iii) of the Rule makes clear that an OCR “determination of noncompliance [will be used] to inform [HHS’s] decision whether to approve, renew, or modify Federal funding to the recipient,” and the Rule notes that OCR has already made a determination of noncompliance against California. 84 Fed. Reg. at 23177, 23262. These actions thus place California in the difficult position of either continuing to uphold its Constitution and state laws or risking loss of billions of dollars of critical federal funds.

92. California received billions of dollars in funds under the Public Law 115-245, the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (H.R. 6157)—and billions more under future

⁶¹ <https://www.hhs.gov/sites/default/files/california-notice-of-violation.pdf>.

1 appropriations acts—for labor, education, and health and human services. This crucial funding
 2 necessary for multiple state agencies and their programs is now at risk. Threatened funding
 3 includes:⁶²

- 4 • The Elementary and Secondary Education Act of 1965, Title I (funding for schools
 5 with a high percentage of students with low-income families, 20 U.S.C. § 6301 et.
 6 seq.); and Title II, part B, subpart 2 (federal support to states to develop, revise, or
 7 update comprehensive literacy, evidence-based, instruction plans, 20 U.S.C.
 8 § 6641);
- 9 • The Social Security Act, Title XIX, to operate and make payments for Medicaid
 10 which provides healthcare coverage for low-income adults, families and children,
 11 pregnant women, the elderly, and people with disabilities;
- 12 • The Social Security Act, the State Unemployment Insurance Program, to provide
 13 payments to laid-off workers;
- 14 • The Individuals with Disabilities Education Act to ensure free appropriate public
 15 education to children with disabilities, including special education and related
 16 services to those children;
- 17 • The Child Care and Development Block Grant Act of 1990 to help low-income
 18 parents obtain childcare so they are able to work or go to school;
- 19 • The Child Support Enforcement and Family Support Programs for child support
 20 enforcement and family support programs;

21
 22
 23
 24 ⁶² Section 507(d)(1) of Division B of H.R. 6157 states: “None of the funds made available in this
 25 Act may be made available to a Federal agency or program, or to a State or local government, if
 26 such agency, program, or government subjects any institutional or individual health care entity to
 27 discrimination on the basis that the health care entity does not provide, pay for, provide coverage
 28 of, or refer for abortions.” And as is specified in Section 3 of H.R. 1625, “[e]xcept as expressly
 provided otherwise, any reference to ‘this Act’ contained in any division of this Act shall be
 treated as referring only to the provisions of that division.” Public Law 115-245, the Department
 of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and
 Continuing Appropriations Act, 2019 (H.R. 6157), Division B,
<https://www.congress.gov/bill/115th-congress/house-bill/6157>.

- The Workforce Innovation and Opportunity Act, including grants to states for adult employment and training activities, youth activities, and dislocated worker employment and training activities;
- The Wagner-Peyser Act of 1933 to establish a nationwide system of public employment offices to assist individuals seeking employment;
- The Occupational Safety and Health Act, section 23(g), to assist states in administering and enforcing programs for occupational safety and health;
- The Jobs for Veterans State grants program under 38 U.S.C. 4102A(b)(5) to support disabled veterans' outreach program specialists;
- The National Apprenticeship Act to expand apprenticeship and on-the-job training programs;
- The Social Security Block Grant Program to assist states in delivering social services by helping reduce dependency, increase self-sufficiency, prevent abuse and neglect, and limit institutional care, if possible;⁶³
- The Older Americans Act of 1965, Section 361, for disease prevention and health promotion programs and activities;
- The 21st Century Cures Act, section 1003(c), and the State Opioid Response Grants Program to assist state response to the opioid crisis;
- The Ryan White HIV/AIDS Program to provide primary medical care and essential support for people with HIV/AIDS;
- The Rehabilitation Act of 1973 to ensure that disabled individuals have access to programs and activities that are funded by federal agencies and to federal employment;
- The Helen Keller National Center Act to assist deaf-blind persons; and
- The McKinney-Vento Homeless Assistance Act to provide assistance to the homeless, especially elderly persons, handicapped persons, and families with children.

⁶³ <https://www.benefits.gov/benefit/775>.

93. Specific programs at risk include, among many others: (1) the Public Health Emergency Preparedness Program, which coordinates preparedness and response activities for all public health emergencies, including natural disasters, acts of terrorism, and pandemic diseases and plans and supports surge capacity in the medical care and public health systems to meet needs during emergencies, (2) Chronic Disease Prevention and Health Promotion programs, which work to prevent and control chronic diseases, injuries, and violence, (3) the Health Facilities Licensing Program, which, among other functions regulates the quality of care in over 10,000 public and private health facilities, clinics, and agencies throughout the State, and (4) refugee social services programs for elder care, school impact services, and youth mentoring programs.

94. In addition, California's public universities receive hundreds of millions of dollars of grant funding for medical and scientific research from the National Institutes of Health and the Centers for Disease Control and Prevention, among other agencies within HHS. Institutions and their net amount in grant funding from HHS in fiscal year 2018 include:⁶⁴

- California Polytechnic State University, San Luis Obispo: \$1,352,184
- California State University, Bakersfield: \$356,689
- California State University, Northridge: \$8,895,002
- California State University, San Marcos: \$2,460,508
- San Francisco State University: \$8,501,370
- University of California, Berkeley: \$132,824,700
- University of California, Davis: \$251,243,608
- University of California, Irvine: \$155,496,306
- University of California, Los Angeles: \$435,373,496
- University of California, Merced: \$5,707,704
- University of California, Riverside: \$30,725,968
- University of California, San Diego: \$462,800,222
- University of California, San Francisco: \$694,071,148
- University of California, Santa Barbara: \$17,647,751

⁶⁴ Data from HHS TAGGS database, available at <https://taggs.hhs.gov/SearchRecip>.

- University of California, Santa Cruz: \$38,331,998

95. Yet despite the substantial amounts of funding and critical programs at risk, California, and other regulated entities, cannot reasonably anticipate what actions Defendants might deem a violation of the Rule. The Rule’s vague and subjective standards, based on overbroad definitions without regard to statutory definitions and ill-reasoned reversals of prior policy and determinations, invite inconsistent and biased enforcement by Defendants. Defendants’ previous recent enforcement efforts of federal conscience laws have been arbitrary and discriminatory, and targeted California unfairly.

96. And although the Rule says it “adopts the enforcement procedures” of Title VI of the Civil Rights Act of 1964, the Rule ignores many of that scheme’s procedural protections, including findings on the record after opportunity for hearing (45 C.F.R. § 80.7), and the Rule’s potential fund termination based on the conduct of sub-recipients seems unrestrained by the “pinpoint provision” in which Congress limited termination of funding to the “particular political entity, or part thereof, or other recipient as to whom such a finding has been made and, shall be limited in its effect to the particular program, or part thereof, in which such noncompliance has been so found” (42 U.S.C. § 2000d–1). Furthermore, whereas a complaint under Title VI “must be filed not later than 180 days from the date of the alleged discrimination” (unless extended), 45 C.F.R. § 80.7, the Rule seeks to re-adjudicate a complaint against California’s Department of Managed Health Care under the illegal Rule. 84 Fed. Reg. at 23179.

IV. THE RULE IMPOSES ADMINISTRATIVE BURDENS AND ONEROUS IMPLEMENTATION COSTS

97. The Rule includes burdensome assurance and certification, recordkeeping, and reporting requirements which will impose unreasonable costs of implementation on California. 84 Fed. Reg. at 23233-23246. The State must submit certifications and assurance, maintain detailed records, and ensure compliance with the Rule on an ongoing basis.

98. In order to be deemed in compliance, the Rule also requires that providers post lengthy notices on their website and in conspicuous physical locations, and to continuously take

steps to ensure that such notices are not altered, defaced, or covered by other material.⁶⁵ 84 Fed. Reg. at 23270. The Rule also appears to require inclusion of the notice in personnel manuals, applications, benefits material, training materials, and handbooks in order to be deemed in compliance. *Id.*

99. This Rule will result in further fiscal harm to California because it makes California responsible for policing others' compliance, including independent political entities, with the Rule. This would include, for example, ensuring compliance by California's 58 counties, which are separate legal entities from the State (Cal. Gov. Code § 23000, et seq.). Here, the Rule asserts "that recipients are responsible for their own compliance with Federal conscience and anti-discrimination laws and implementing regulations, *as well as for ensuring their sub-recipients comply with these laws.*" 84 Fed. Reg. at 23180 (emphasis added). The Rule also asserts that the State may be liable for the conduct of any entity it contracts with: "The Department notes, however, that the conduct and activities of contractors engaged by the Department, a Departmental program, or a State or local government is attributable to such Department, program, or government for purposes of enforcement or liability under the Weldon amendment." *Id.* at 23207.

100. Under the Rule, the term "sub-recipients" is defined to include "any State, political subdivision of any State, instrumentality of any State or political subdivision thereof, or any person or any public or private agency, institution, organization, or other entity in any State, including any successor, assign, or transferee thereof, to whom there is a pass-through of Federal financial assistance or Federal funds from the Department through a recipient or another sub-recipient, but such term does not include any ultimate beneficiary. The term may include a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies)." 84 Fed. Reg. at 23264.

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⁶⁵ Although the Rule states that the notice requirement is voluntary, it also states that "OCR will consider the posting of notices as "non-dispositive" evidence of compliance. 84 Fed. Reg. at 23270.

101. The Rule thus requires California to create a costly bureaucratic structure to ensure that the Rule's expansive and unlawful provisions are complied with, including compliance by any downstream sub-recipients, public or private.

102. The high costs of implementation and administrative burdens (which will also impact providers, patients, and insurers) are also unnecessary because existing laws already protect conscience rights, while also balancing patient rights to access lawful medical care.

102. California estimates that the costs of compliance will be well into the millions.

103. Indeed, the Rule itself estimates that compliance will cost affected entities a total of approximately \$1.06 billion in the first five years. 84 Fed. Reg. at 23240.

104. And the Rule makes clear that OCR will aggressively pursue all remedial actions, including temporarily withholding, suspending, denying, or terminating federal funds, "[i]f OCR determines that there is a failure to comply with Federal conscience and anti-discrimination laws." 84 Fed. Reg. at 23272.

FOIA STATUTORY FRAMEWORK AND FACTUAL BACKGROUND

I. STATUTORY FRAMEWORK

105. FOIA promotes open government by providing every person with a right to request and timely receive federal agency records. 5 U.S.C. § 552(a)(3)(A).

106. In furtherance of its purpose to encourage open government, FOIA imposes strict deadlines on agencies to provide responsive documents to FOIA requests. *Id.* § 552(a)(6)(A).

107. An agency must comply with a FOIA request by issuing a determination within 20 business days after receipt of the request. *Id.* § 552(a)(6)(A)(i).

108. The determination "must at least inform the requester of the scope of the documents that the agency will produce, as well as the scope of the documents that the agency plans to withhold under any FOIA exemptions." *Citizens for Responsibility & Ethics in Wash. v. Fed. Election Comm'n*, 711 F.3d 180, 186 (D.C. Cir. 2013).

109. An agency may be entitled to one ten-day extension of time to respond to a request if it provides written notice to the requester explaining "unusual circumstances" exist that warrant additional time. 5 U.S.C. § 552(a)(6)(B).

110. An agency must immediately notify the requester of its determination whether to comply with a request, and the reasons for it, and of the right of such person to appeal an adverse determination. *Id.* § 552(a)(6)(A)(i). Further, an agency shall make available a FOIA public liaison to aid the requestor in limiting the scope of the request so that it may be processed within the statutory time limit. *Id.* § 552(a)(6)(B)(ii).

111. An agency's failure to comply with any timing requirements is deemed constructive denial and satisfies the requester's requirement to exhaust administrative remedies. *Id.* § 552(a)(6)(C)(i).

112. A FOIA requester who exhausts administrative remedies may petition the court for injunctive and declaratory relief from the agency's continued withholding of public records. *Id.* § 552(a)(4)(B).

II. FOIA FACTUAL BACKGROUND

113. On April 25, 2018, California sent the Request by mail and via electronic submission to HHS.

114. By email and letter, on May 10, 2018, HHS confirmed receipt of the Request, which it had received on April 25, 2018. HHS assigned it Request Number 2018-00934-FOIA-OS. In its letter, HHS stated that it "may utilize a 10 working day extension to process your request, as permitted pursuant to the FOIA" if one of two "unusual and exceptional circumstances" applied.

115. In addition, the letter stated that HHS had "initiated a search to locate records falling within the scope of your request. If our searching units advise us that you have requested a voluminous amount of records that require extensive search and examination, my staff will contact you shortly to discuss your willingness to modify your request."

116. With regard to the fee waiver, the letter stated that HHS was "not addressing your request for a fee waiver at this time."

117. The letter further provided that any questions regarding the status of the Request should be directed to the HHS FOIA office.

118. On June 6, 2018, California reached out to the assigned HHS FOIA Public Liaison to discuss the status of the Request as suggested in the May 10, 2018 letter. California received no

1 response. California reached out to the HHS FOIA Public Liaison again on June 12, 2018, noting
2 that California had also called the number located on the May 10, 2018 letter and reached a
3 voicemail box that was full and no longer accepting messages. On June 19, 2018, California
4 again emailed the HHS FOIA Public Liaison, noting that California had reached someone at the
5 designated HHS phone number; however, California was told that all status requests should be
6 made via email to the HHS FOIA Public Liaison.

7 119. On June 26, 2018, California sent its fourth request for a status update. The HHS
8 FOIA Liaison responded that “HHS FOIA has not received any responsive records from the
9 program office tasked to search for responsive records pertaining to your request.” She stated
10 that she has “reached out once again to those offices (the Office for Civil Rights and the
11 Immediate Office of the Secretary) to ascertain when their records search will be completed.”
12 (See Exhibit D.) In response, California asked for clarification as to whether its request was
13 placed in the “simple” or complex” queue pursuant to 45 C.F.R. § 5.24(e). California sent a
14 follow-up email on July 16, 2018, requesting an update and received no response.

15 120. Then on February 15, 2019, California provided a duplicate copy of the FOIA request
16 and follow up correspondence at a meeting with OMB which was also attended by representatives
17 of OCR.

18 121. As of the date of this filing, HHS has not objected to the Request, provided any
19 detailed information regarding specific disclosure of the records sought, nor produced any
20 responsive documents in response to California’s April 25, 2018 Request.

21 122. Under FOIA, HHS was required to have provided California with a determination on
22 the scope of the documents it would produce and the exemptions it would claim within 20
23 working days of receiving the request. 5 U.S.C. § 552(a)(6)(A)(i). At no point has HHS
24 explicitly extended the 20-day time, nor has it provided details of any “unusual circumstances.”
25 *Id.* § 552(a)(6)(B). Under the statute, HHS could only extend the 20-day time period to 10
26 additional working days (for a total of 30 days) or else “make available its FOIA Public Liaison”
27 “[t]o aid the requestor” in “limit[ing] the scope of the request.” *Id.* § 552(a)(6)(B)(i)-(ii).
28

123. The 30-day period expired on May 30, 2018. HHS has never provided to California the determination required by statute, nor provided any documents, claimed any exemptions, or provided any reasonably segregable portions of records. The FOIA Public Liaison has failed to respond to California's communications to discuss processing of its Request in a timely manner.

124. Where Defendants have failed to provide any substantive responses to the Request within the statutory timeframe, they have constructively denied the Request. As such, California has exhausted its administrative remedies. *Id.* § 552(a)(6)(C)(i).

125. Because HHS failed to provide California with the determination required in the statutory timeframe, and has failed to respond to California's communications to discuss limiting the scope of its Request, FOIA prevents HHS from assessing search fees on California for records responsive to the Request. *Id.* § 552(a)(4)(A)(viii).

126. Because of HHS's violations of FOIA, California has been required to expend resources to prosecute this action.

FIRST CAUSE OF ACTION

(Violation of APA; 5 U.S.C. § 706—Contrary to Law)

127. Paragraphs 1 through 126 are realleged and incorporated herein by reference.

128. The Rule, constitutes "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." 5 U.S.C. §§ 551(4), (13), 704.

129. The APA requires courts to "hold unlawful and set aside" agency action that is "not in accordance with law." 5 U.S.C. § 706(2)(A).

130. The Rule is not in accordance with the law because it expands statutory definitions and conscience laws by allowing an overly broad range of individuals and entities to refuse to provide virtually any lawful healthcare service or coverage for any reason, not just due to religious and moral objections. In this way, the Rule goes far beyond what is permitted by the Weldon, Church, and Coats-Snowe Amendments, and other statutes the Rule purports to implement or enforce.

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131. The Rule also conflicts with several other federal statutes, including Title VII of the Civil Rights Act of the 1964, Title X of the Public Health Services Act and the nondirective counseling requirement, and the Emergency Medical Treatment & Labor Act.

132. The Rule also conflicts with Section 1554 of the ACA, which forbids the HHS Secretary from promulgating “any regulation” that:

creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; [or] (5) violates the principles of informed consent and the ethical standards of health care professionals.

42 U.S.C. § 18114. The Rule violates this provision by creating unreasonable barriers to medical care, including admittedly to patients in rural communities, among others.

132. The Rule further conflicts with Section 1557 of the ACA, which states that an “individual shall not . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity” on the basis of sex. 42 U.S.C. § 18116; 20 U.S.C. § 1681.

133. Defendants’ reversal of their interpretation of the Weldon Amendment as it relates to California’s abortion health plan coverage requirement is also unsupported by any legal authority, and is based on a distortion of existing law. Defendants’ unsupported reversal creates uncertainties for the future of the State’s entire healthcare system, from state programs, to hospitals, to patients.

134. Defendants’ violation causes ongoing harm to California and its residents and threatens much greater harm should massive amounts of federal funding to the State be revoked.

135. By promulgating the Rule, Defendants have acted contrary to law. In doing so, Defendants have taken action in violation of the APA. The Rule is therefore invalid and should be set aside as arbitrary and capricious under 5 U.S.C. § 706(2)(A).

SECOND CAUSE OF ACTION

(Violation of APA; 5 U.S.C. § 706—Exceeded Statutory Authority)

136. Paragraphs 1 through 135 are realleged and incorporated herein by reference.

137. HHS is an agency under the APA. 5 U.S.C. § 551(1).

138. The APA requires courts to “hold unlawful and set aside” agency action that is “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(C). The Rule is in excess of statutory jurisdiction, authority, and limitations in several respects.

139. HHS previously acknowledged that “[n]o statutory provision requires the promulgation of rules to implement the requirements of the Church Amendments, Public Health Service (PHS) Act Sec. 245, and the Weldon Amendment. 74 Fed. Reg. 10,207, 10209 (March 10, 2009).

140. Nevertheless, Defendants have acted in excess of statutory authority by granting themselves broad powers to expand statutory definitions in these and other federal laws, including in direct contravention to statutory text, and by granting themselves broad enforcement powers unmoored from any statutory scheme. *La. Pub. Serv. Comm’n v. FCC*, 476 U.S. 355, 374 (1986) (“[A]n agency literally has no power to act . . . unless and until Congress confers power upon it.”).

141. By promulgating this new Rule, Defendants have taken action in violation of the APA. The Rule is therefore invalid and should be set aside as arbitrary and capricious under 5 U.S.C. § 706(2)(A).

THIRD CAUSE OF ACTION

(Violation of APA; 5 U.S.C. § 706—Arbitrary, Capricious, and Abuse of Discretion)

142. Paragraphs 1 through 141 are realleged and incorporated herein by reference.

143. The Rule constitutes “[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court.” 5 U.S.C. §§ 551(4), (13), 704.

144. The APA requires courts to “hold unlawful and set aside” agency action that is “arbitrary,” “capricious,” or an “abuse of discretion.” 5 U.S.C. § 706(2)(A). In this case, the Rule is arbitrary and capricious for several reasons.

145. Defendants offer no reasoned explanation for misconstruing and straining well-established statutory language and definitions in federal conscience laws. Without substantial

1 justification, Defendants have created limitless categories of individuals, entities, and
2 circumstances under which medical information and care can be refused, and also created conflicts
3 with other federal laws, including the ACA, Title VII of the Civil Rights Act of the 1964, Title X
4 of the Public Health Services Act and the nondirective counseling requirement, and the
5 Emergency Medical Treatment & Labor Act.

6 146. Defendants offer no reasoned explanation for Defendants' reversal of their
7 interpretation of the Weldon Amendment as it relates to California's abortion health plan
8 coverage requirement. Defendants provide no reasonable justification for now ignoring previous
9 constitutional concerns cited by OCR in its June 21, 2016 letter that may result in the widespread
10 termination of federal funding to California, or California's substantial reliance interest on
11 Defendants' prior interpretation.

12 147. The Rule is also arbitrary and capricious because Defendants failed to consider
13 important aspects of the problem that were raised by California and others in public comments,
14 including patient harms, particularly to vulnerable patients, including women, LGBTQ
15 individuals, rural patients, and other vulnerable populations.

16 148. In promulgating the Rule, Defendants have offered ill-reasoned analysis for their
17 decision, which runs counter to the evidence in the administrative record, is based on outdated
18 data, and rests on speculative conclusions. Such speculative conclusions include the
19 unsubstantiated conclusion that the Rule will result in an increase in the number of providers and
20 better patient care because greater enforcement of federal conscience laws will cause more
21 providers to enter and stay in the field, and patients will benefit from more open and honest
22 communications with providers.

23 149. The Rule is also arbitrary and capricious because it disregards consequential costs of
24 compliance—including the costs to patients and regulated entities such as the State—and is based
25 on a flawed cost-benefit analysis because it relies on unsubstantiated and speculative benefits
26 such as purported increases in the number of providers and better patient care if medical
27 information and care can be broadly denied under the Rule.
28

150. Defendants' violation causes ongoing harm to California and its residents and threatens to inflict much greater harm by withdrawing or withholding massive amounts of federal funding to the State.

151. By promulgating the Rule, without a proper factual or legal basis, Defendants have acted arbitrarily and capriciously, have abused their discretion, have otherwise acted not in accordance with law, and have taken unconstitutional and unlawful action in violation of the APA.

152. For these reasons, the Rule is unlawful and should be set aside as arbitrary and capricious under 5 U.S.C. § 706(2)(A).

FOURTH CAUSE OF ACTION (Violation of the Spending Clause - Coerciveness)

153. Paragraphs 1 through 152 are realleged and incorporated herein by reference.

154. While the federal government may "create incentives for states to act in accordance with federal policies," it may not use its Spending Clause powers to coerce States to accept those policy changes without running afoul of our system of federalism. *NFIB*, 567 U.S. 519, 577-78.

155. Thus, when conditions on the receipt of federal funds takes the form of threats to terminate significant independent grants, "the conditions are properly viewed as a means of pressuring the States to accept policy changes." *Id.* at 580.

156. The Rule violates the Spending Clause because it crosses the line from pressure to compulsion. It leaves the State with no practical alternative but to surrender and comply with the Rule or risk the loss of a substantial portion of the State's budget.

157. The Rule is so severe that it forces the State and its entities adopt the Defendants' regulatory scheme and forego enforcement of its state laws and the exercise of its police powers, or risk the loss of billions of dollars in federal funds, including funds for Medicaid, and educational and labor programs.

158. The Rule is thus tantamount to "a gun to the head." *NFIB*, 567 U.S. 519, 581. If California opts out of complying with the Rule (or even "[i]f OCR determines that there is a failure to comply") 84 Fed. Reg. 23170, 23271 (May 21, 2019), California "would stand to lose

not a relatively small percentage” of its existing federal funding, but billions of dollars of critical funding for its healthcare, education, and labor programs. *NFIB*, 567 U.S. at 581.

159. As such, the Rule is an unconstitutional abuse of the Spending Clause of the United States Constitution, and is an additional basis to set aside the Rule under the APA.

FIFTH CAUSE OF ACTION

(Violation of the Spending Clause - Vagueness)

160. Paragraphs 1 through 159 are realleged and incorporated herein by reference.

161. The federal government’s spending powers are not unlimited, and a condition on the states’ receipt of federal funds must be done so unambiguously so as to enable the states to exercise their choice knowingly and cognizant of the consequences of their participation. *Pennhurst State Sch. and Hospital v. Halderman*, 451 U.S. 1, 17 (1981).

162. The Rule cannot be upheld under the Spending Clause because the Rule is vague and does not provide adequate notice of what specific action or conduct, if engaged in, will result in the withholding of federal funds. Because of the Rule’s vague and subjective standards, which are based on newly expanded definitions that pay no regard to statutory text, California cannot reasonably anticipate what actions Defendants might deem in violation of the Rule.

163. For example, because the Rule now includes such expansive definitions beyond those long-established by statute—allowing, for example, any medical provider or “health care personnel” to refuse medical care without any information about the patient’s medical condition or treatment options, not just on the basis of state and federally protected religious and conscience protections, but also on the basis of “ethical[] or other reasons,” and applying to any “action that has a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program or research activity undertaken by or with another person or entity”—the State cannot make a knowing choice as to whether it would be a violation of the Rule if it takes enforcement action against medical providers or programs that deny care and/or who discriminate against its most vulnerable residents.

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164. Also, the Rule is so broadly and vaguely written that it is nearly impossible to ascertain how California should communicate with its sub-recipients in order to obligate them to comply with the Rule in a manner that effectively protects California's own funding.

165. Terminating California's funding based on the conduct of third parties that California neither controls nor operates would be financially crippling for the State. For example, federal funding for the State and for all counties could be placed at risk based on the alleged violation of a single county under this vague rule.

166. Defendants’ reversal of their interpretation of the Weldon Amendment as it relates to California’s abortion health plan coverage requirement is also unsupported by any legal authority. This unsupported reversal creates uncertainties as to what additional state laws and policies may also now be deemed a violation of the Rule.

167. And the January 18, 2019 “Notice of Violation” issued against California, although it concluded that further remedial action against California was not warranted, could, under the Rule, be deemed a “determination” that could “inform funding decision-making.” 84 Fed. Reg. at 23177, 23262.

168. Yet despite the substantial amounts of funding and critical programs at risk and the evident set up for a direct confrontation between California and the OCR, California cannot reasonably anticipate what actions Defendants might deem a violation of the Rule. The Rule's vague and subjective standards, based on overbroad definitions without regard to statutory definitions and ill-reasoned reversals of prior policy and determinations, invite inconsistent and biased enforcement by Defendants.

169. As such, the Rule is an unconstitutional abuse of the Spending Clause of the United States Constitution, and is an additional basis to set aside the Rule under the APA.

SIXTH CAUSE OF ACTION

(Violation of the Spending Clause – Post-Acceptance Conditions on Federal Funds)

170. Paragraphs 1 through 169 are realleged and incorporated herein by reference.

171. The Rule cannot be upheld under the Spending Clause because the Rule constitutes post-acceptance conditions on federal funds. *Pennhurst*, 451 U.S. 1, 17 (“Though Congress’

power to legislate under the spending power is broad, it does not include surprising participating States with post acceptance or “retroactive” conditions.); *NFIB*, 567 U.S. 519, 584 (a state could hardly anticipate that the federal government’s reservation of the right to alter or amend Medicaid included the power to transform the program dramatically).

172. In this case, the Rule dramatically alters the scope of federal conscience laws, California’s ability to enforce its own laws (including laws previously found by OCR not to violate federal conscience laws) and compliance requirements, and threatens to withhold massive amounts of federal funding unless California capitulates to the provisions of the new Rule.

173. The Rule was published in the Federal Register on May 21, 2019. The Rule is set to go into effect on July 22, 2019.

174. In fact, even before the Rule was finalized, OCR contacted California to re-open its investigation. See Letter from Roger T. Severino, Dir., Dep’t of Health & Human Serv’s. Office for Civil Rights, to Xavier Becerra, Att’y. Gen., State of Cal. (Jan. 18, 2019), available at <https://www.hhs.gov/sites/default/files/california-notice-of-violation.pdf>.

175. As such, the Rule is an unconstitutional abuse of the Spending Clause of the United States Constitution, and is an additional basis to set aside the Rule under the APA.

SEVENTH CAUSE OF ACTION

(Violation of the Spending Clause - Unrelatedness)

176. Paragraphs 1 through 175 are realleged and incorporated herein by reference.

177. The Rule cannot be upheld under the Spending Clause because the Rule is not rationally related to the federal interest in the particular programs that receive federal funds. See *South Dakota v. Dole*, 483 U.S. 203 (1987); *Massachusetts v. United States*, 435 U.S. 444, 461 (1978) (plurality op.) (conditioning federal grants illegitimate if unrelated “to the federal interest in particular national projects or programs”).

178. The Rule places various federal grants at risk, including those for Medicaid, HIV prevention, emergency preparedness, education programs, such as those under Individuals with Disabilities Education Act, employment programs, including those under the State

Unemployment Insurance Program, and block grants to help low-income parents obtain childcare so they are able to work or go to school.

179. But the programs, and so many others, bear no rational relationship between the federal conscience laws Defendants seek to enforce and the federal interest in those programs.

180. As such, the Rule is an unconstitutional abuse of the Spending Clause of the United States Constitution, and is an additional basis to set aside the Rule under the APA.

EIGHTH CAUSE OF ACTION

(First Amendment–Violation of the Establishment Clause)

181. Paragraphs 1 through 180 are realleged and incorporated herein by reference.

182. The First Amendment provides that “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof.” U.S. Const., amend. I. “The clearest command of the Establishment Clause is that one religious denomination cannot be officially preferred over another.” *Larson v. Valente*, 456 U.S. 228, 244 (1982); *see also* *McCreary County, Kentucky v. ACLU*, 545 U.S. 844, 875 (2005) (“the government may not favor one religion over another, or religion over irreligion”).

183. Defendants have used their rule-making authority for the primary purpose of advancing and endorsing religious beliefs, and permitting same to be privileged over secular beliefs as a basis for denying medically necessary information, referrals, and services, including emergency healthcare and healthcare guaranteed under federal and state laws.

184. By promulgating the Rule, Defendants have also violated the Establishment Clause because the new Rule goes too far in accommodating an employee’s religious objections, placing an undue burden on third parties— i.e., patients who seek access to care. *Burwell v. Hobby Lobby Stores, Inc.* 134 S.Ct. 2751, 2781 n.37 (2014) (requiring consideration of the burden placed on third parties by a religious accommodation).

185. The Rule is not narrowly tailored and ignores the compelling interest of seamless access to healthcare and necessary medical information. This crosses the line from acceptable accommodation to religious endorsement and entanglement.

186. As such, the Rule violates the Establishment Clause of the First Amendment of the United States Constitution, and is an additional basis to set aside the Rule under the APA.

NINTH CAUSE OF ACTION

(FOIA)

Claim One (Failure to Conduct Adequate Search)

187. Paragraphs 1 through 186 are realleged and incorporated herein by reference.

188. California has a statutory right to have HHS process its FOIA Request in a manner that complies with FOIA. 5 U.S.C. § 552(a)(3). HHS violated California's rights in this regard when it unlawfully failed to undertake a search that is reasonably calculated to locate all records that are responsive to California's April 25, 2018 Request.

189. Unless enjoined and made subject to a declaration of California's legal rights by this Court, HHS will continue to violate California's rights to receive public records under FOIA.

Claim Two (Failure to Respond to Request Within Statutory Timeframe)

190. Paragraphs 1 through 189 are realleged and incorporated herein by reference.

191. Defendants failed to respond to the Request within the statutorily mandated timeframe, in violation of California's rights under FOIA, including but not limited to 5 U.S.C. § 552(a)(6)(A)(i) and (6)(B). Defendants also effectively failed to make available the FOIA Public Liaison to assist in narrowing the scope of California's Request to justify extending the statutorily-mandated timeline. *Id.* § 552(a)(6)(B)(ii).

192. Unless enjoined and made subject to a declaration of California's legal rights by this Court, HHS will continue to violate California's rights to receive public records under FOIA.

Claim Three (Failure to Disclose Non-Exempt Records)

193. Paragraphs 1 through 192 are realleged and incorporated herein by reference.

194. HHS violated FOIA by refusing to disclose records responsive to California's April 25, 2018 FOIA Request.

195. California has a statutory right to the records it seeks.

196. Unless enjoined and made subject to a declaration of California's legal rights by this Court, HHS will continue to violate California's rights to receive public records under FOIA.

Claim Four (Failure to Provide Reasonably Segregable Portions of Records)

197. Paragraphs 1 through 196 are realleged and incorporated herein by reference.

198. HHS violated FOIA by failing to provide California with reasonably segregable portions of records (after deletion of portions lawfully exempt under FOIA) that are responsive to California's April 25, 2018 FOIA Request, as required by 5 U.S.C. § 552(b).

199. Unless enjoined and made subject to a declaration of California's legal rights by this Court, HHS will continue to violate California's rights to receive reasonably segregable portions of records (after deletion of portions lawfully exempt under FOIA).

PRAYER FOR RELIEF

WHEREFORE, the State of California, by and through Attorney General Xavier Becerra, respectfully requests that this Court:

With regard to the Rule,

1. Issue a declaratory judgment that the Rule is arbitrary and capricious, not in accordance with law, and Defendants acted in excess of statutory authority in promulgating the Rule;
2. Issue an order vacating and setting aside the Rule in accordance with the APA;
3. Issue a declaratory judgment that the Rule violates the Spending Clause;
4. Issue a declaratory judgment that the Rule violates the Establishment Clause;
5. Issue an order enjoining Defendants from withholding, denying, suspending, and/or terminating federal funding from California in connection with the unlawful Rule, or otherwise unlawfully;
6. Issue a preliminary injunction prohibiting the implementation of the Rule;
7. Issue permanent injunction prohibiting the implementation of the Rule;
8. Award California costs, expenses, and reasonable attorneys' fees; and
9. Grant such other relief as the Court deems just and proper.

///.

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With regard to the FOIA claims,

1. Order HHS to conduct searches that are reasonably calculated to locate all records responsive to California's April 25, 2018 FOIA Request, with the cut-off date for such searches being the date the searches are conducted, and to provide California, by a date certain, with all responsive records and reasonably segregable portions of responsive records sought;

2. Declare that HHS's failure to make a timely determination regarding California's April 25, 2018 Request, as alleged above, is unlawful under FOIA, 5 U.S.C. § 552(a)(6)(A)(i) and (6)(B);

3. Declare that HHS's failure to search for and disclose to California all records that are responsive to California's Request, as alleged above, is unlawful under FOIA, 5 U.S.C. § 552(a)(3);

4. Declare that HHS's failure to provide California with reasonably segregable portions of records (after deletion of portions lawfully exempt under FOIA) that are responsive to California's Request, as alleged above, is unlawful under FOIA, 5 U.S.C. § 552(b);

5. Award California its reasonable litigation costs and attorney fees pursuant to 5 U.S.C. § 552(a)(4)(E).

6. Grant such other relief as the Court may deem just and proper.

Dated: May 21, 2019

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
MICHAEL NEWMAN
Senior Assistant Attorney General
KATHLEEN BOERGERS
Supervising Deputy Attorney General

/s/ Neli N. Palma

NELI PALMA
KARLI EISENBERG
STEPHANIE YU
Deputy Attorneys General
Attorneys for Plaintiff State of California, by
and through Attorney General Xavier
Becerra

EXHIBIT B

RICHARD B. KATSKEE*
AMERICANS UNITED FOR SEPARATION
OF CHURCH AND STATE
1310 L Street NW, Suite 200
Washington, DC 20005
Tel: (202) 466-3234; Fax: (202) 466-3234
katskee@au.org

GENEVIEVE SCOTT*
CENTER FOR REPRODUCTIVE RIGHTS
199 Water Street, 22nd Floor
New York, NY 10038
Tel: (917) 637-3605; Fax: (917) 637-3666
gscott@reprorights.org

JAMIE A. GLIKSBERG*
LAMBDA LEGAL DEFENSE AND
EDUCATION FUND, INC.
105 West Adams, 26th Floor
Chicago, IL 60603-6208
Tel: (312) 663-4413; Fax: (312) 663-4307
jglikberg@lambdalegal.org

JAMES R. WILLIAMS (SBN 271253)
GRETA S. HANSEN (SBN 251471)
LAURA S. TRICE (SBN 284837)
MARY E. HANNA-WEIR (SBN 320011)
SUSAN P. GREENBERG (SBN 318055)
H. LUKE EDWARDS (SBN 313756)
OFFICE OF THE COUNTY COUNSEL,
COUNTY OF SANTA CLARA
70 West Hedding Street, East Wing, 9th Fl.
San José, CA 95110-1770
Tel: (408) 299-5900; Fax: (408) 292-7240
mary.hanna-weir@cco.sccgov.org

LEE H. RUBIN (SBN 141331)
MAYER BROWN LLP
Two Palo Alto Square, Suite 300
3000 El Camino Real
Palo Alto, CA 94306-2112
Tel: (650) 331-2000; Fax: (650) 331-2060
lrubin@mayerbrown.com

*Counsel for Plaintiffs County of Santa Clara
et al.*

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

COUNTY OF SANTA CLARA, TRUST
WOMEN SEATTLE, LOS ANGELES LGBT
CENTER, WHITMAN-WALKER CLINIC,
INC. d/b/a WHITMAN-WALKER HEALTH,
BRADBURY-SULLIVAN LGBT
COMMUNITY CENTER, CENTER ON
HALSTED, HARTFORD GYN CENTER,
MAZZONI CENTER, MEDICAL STUDENTS
FOR CHOICE, AGLP: THE ASSOCIATION
OF LGBTQ+ PSYCHIATRISTS, AMERICAN
ASSOCIATION OF PHYSICIANS FOR
HUMAN RIGHTS d/b/a GLMA: HEALTH
PROFESSIONALS ADVANCING LGBTQ
EQUALITY, COLLEEN MCNICHOLAS,
ROBERT BOLAN, WARD CARPENTER,
SARAH HENN, and RANDY PUMPHREY,

Plaintiffs,

vs.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES and ALEX M. AZAR, II,
in his official capacity as SECRETARY OF
HEALTH AND HUMAN SERVICES,

Defendants.

Case No. 5:19-cv-2916

**COMPLAINT FOR DECLARATORY
AND INJUNCTIVE RELIEF**

INTRODUCTION

1
2 1. When people go to an emergency room, clinic, or public health program seeking
3 treatment for illness or injury, they expect and trust that they will receive care appropriate to meet
4 their health needs, without regard to their sex, gender identity, sexual orientation, disability status,
5 or religion, or the type of healthcare they seek. Healthcare providers have adopted nuanced policies
6 that respect healthcare workers' religious and moral beliefs; protect patients' access to information
7 and timely, high-quality care; and satisfy healthcare providers' legal and professional duties of care
8 to all patients.

9 2. Now, however, the U.S. Department of Health and Human Services has issued a
10 new regulation (the "Denial-of-Care Rule") that upsets this thoughtful approach. Although
11 purporting to implement long-standing healthcare statutes with specific provisions affording
12 protections for the religious or moral beliefs of certain individuals and entities ("religious
13 objections"), the Rule instead creates a wholly new regime that elevates religious objections over
14 all other interests and values. The Rule invites a much larger universe of healthcare workers to
15 decline to serve patients based on religious objections, defines with unprecedented breadth the types
16 of activities to which they may object, and fails to reconcile objections with the needs and rights of
17 patients—even though doing so is critical in any regulatory scheme administering these laws. And
18 the Rule does not include emergency exceptions. As a result, the Rule endangers patients' health
19 in the name of advancing the religious beliefs of those who are entrusted with caring for them—a
20 result sharply at odds with the stated mission of the Department of Health and Human Services
21 ("HHS"), which is to "enhance and protect the health and well-being of all Americans" and to
22 "provid[e] for effective health and human services."

23 3. The Rule applies to hospitals, medical schools, public- and community-health
24 programs, and state and local governments throughout the Nation that are recipients or
25 subrecipients of certain federal funds. These healthcare providers must comply with the Rule or
26 risk incurring draconian penalties, including the withdrawal or clawback of all federal funding. Yet
27 the Rule offers scant guidance on how healthcare providers might satisfy the Rule's extreme
28 obligations while still reliably delivering patient care. And the Rule places vague and unworkable

1 limits on the reasonable measures that are necessary to protect patients (and comply with the
2 applicable standards of care and medical ethics) when accommodating objections. By failing to
3 provide for emergency exceptions or to address an array of other issues about the Rule's
4 requirements, the agency's action leaves healthcare providers utterly in the dark about what they
5 may or may not do to protect patients consistent with the Rule. If they guess wrong, they could lose
6 federal funding, which would frustrate their ability to provide adequate care to their most needy
7 patients.

8 4. The Rule specifically invites refusals to provide care to women seeking reproductive
9 healthcare and transgender and gender-nonconforming patients seeking gender-affirming care,
10 adversely affecting the healthcare entities that provide reproductive healthcare services and that
11 serve the lesbian, gay, bisexual, and transgender ("LGBT") community. The Rule stigmatizes and
12 shames these patients, depriving them of their constitutionally protected rights of access to
13 healthcare and their dignity and autonomy in seeking medically necessary healthcare central to their
14 self-determination. The Rule will delay and deny the provision of care and information to many
15 patients. It also will deter patients from disclosing their medical histories, gender identities, or
16 transgender status as they seek care; chill patients from expressing themselves in a manner
17 consistent with their gender identities; and render them less likely to seek healthcare services at all,
18 detrimentally affecting not only individual patients' mental and physical health, but public health
19 generally.

20 5. In adopting the Rule, HHS acted arbitrarily and capriciously, in excess of its
21 statutory authority, and in conflict with other laws. Among other problems, HHS failed adequately
22 to consider significant factors, including the Rule's lack of workability and its impact on patients,
23 despite numerous comments raising these concerns; it defined key statutory terms in a manner that
24 is contrary to the underlying statutes; and it ignored limitations contained in other federal laws on
25 HHS's authority to limit patient access to information and care, including emergency care.

26 6. The Rule infringes the constitutional rights of patients by impermissibly advancing
27 the religious beliefs of individual employees over the constitutional rights of patients, including
28 patients' rights to liberty and privacy guaranteed by the Fifth Amendment; their right to equal

1 protection of the laws; and their rights to free speech and expression. The Rule also infringes the
 2 constitutional rights of healthcare providers and their patients not to be compelled by the
 3 government to live and act in accordance with religious beliefs to which they do not subscribe.

4 7. The Rule is ill-considered and dangerous, and it puts us all at risk. It should be
 5 declared unlawful and enjoined.

6 JURISDICTION AND VENUE

7 8. This Court has jurisdiction under 28 U.S.C. § 1331, as this case arises under the
 8 United States Constitution and the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.*, and
 9 challenges final agency action for which there is no other adequate remedy, 5 U.S.C. § 704.

10 9. The Court has the authority to issue declaratory and injunctive relief under the
 11 Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, and the Administrative Procedure Act,
 12 5 U.S.C. § 701 *et seq.*

13 10. Defendants are subject to suit in any federal jurisdiction in challenges to federal
 14 regulations, and no real property is involved in this action. 42 U.S.C. §1391(e)(1).

15 11. Venue is proper in the Northern District of California under 28 U.S.C. § 1391(b)
 16 and (e)(1) because at least one Plaintiff resides in this district and each defendant is an agency of
 17 the United States or an officer of the United States sued in his or her official capacity.

18 12. The challenged Rule is final and subject to judicial review under 5 U.S.C. §§ 702,
 19 704, and 706.

20 PARTIES

21 A. Plaintiffs

22 13. Plaintiffs include a governmental entity that owns healthcare facilities (the County
 23 of Santa Clara); five private healthcare facilities that provide reproductive-health services and
 24 healthcare services for LGBT individuals (Trust Women Seattle, the Los Angeles LGBT Center,
 25 Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health, Hartford Gyn Center, and Mazzoni
 26 Center) (“private-healthcare-provider Plaintiffs”); four individual physicians and a licensed
 27 counselor who work for these entities (“individual-provider Plaintiffs”); three national associations
 28 of medical professionals (Medical Students for Choice, AGLP: Association of LGBTQ

Psychiatrists, and American Association of Physicians for Human Rights d/b/a GLMA: Health Professionals Advancing LGBTQ Equality) (“medical-association Plaintiffs”); and two organizations that provide a wide range of services to the LGBT community (Bradbury-Sullivan LGBT Community Center and Center on Halsted) (“LGBT-services Plaintiffs”).

14. The private-healthcare-provider and individual-provider Plaintiffs assert claims on their own behalf and also on behalf of their patients and recipients of services, who face barriers to asserting their own claims and protecting their own interests. The medical-association Plaintiffs assert claims on behalf of themselves and their members.

15. Plaintiffs assert different but complementary interests, and share the common objective of maintaining an effective, functioning healthcare system, one that protects patients’ dignity and their rights of access to health services as well as the dignity of healthcare workers who raise religious objections. Plaintiffs also support the objective of providing informed access to comprehensive reproductive healthcare and gender-affirming and medically appropriate care to transgender and gender-nonconforming patients without discrimination based on a patient’s sex, gender identity, or transgender status and in accordance with medical and ethical standards of care.

16. Plaintiff **County of Santa Clara** is a charter county and political subdivision of the State of California, located in the Northern District of California. It is home to almost two million residents, is more populous than 14 States, and employs more than 20,000 people.

17. The County, as part of its governmental responsibilities, is tasked with providing critical safety-net and public health services. These core County functions are undertaken by a network of County departments and programs, including several County-owned and -operated hospitals, public pharmacies, a public health department, an emergency-medical-services department, a behavioral-health-services department, and a publicly run health-insurance plan. The County of Santa Clara Health System is the only public safety-net healthcare provider in Santa Clara County, and it is the second largest such provider in the State of California.

18. To operate this network, and because of the County’s focus on serving indigent and vulnerable populations whose insurance is paid through federally funded Medicare or Medicaid, the County is dependent on hundreds of millions of dollars of federal funding from HHS. The

1 County also receives funding through a variety of other funding streams that pass through HHS,
2 including under the Public Health Services Act (“PHSA”). Because it receives this federal funding,
3 the County is subject to the Denial-of-Care Rule in its entirety.

4 19. At the center of the County’s health system are the County’s three hospitals. The
5 County owns and operates Santa Clara Valley Medical Center (“Valley Medical Center”), an acute-
6 care hospital with over 6,000 employees providing emergency medical services, primary care,
7 hospital care, and reproductive-health services. The mission of Valley Medical Center and its
8 satellite clinics is to provide high-quality, accessible, and compassionate care to all, regardless of
9 their socio-economic status or ability to pay. Last year, Valley Medical Center had an average daily
10 census of 363 patients and handled 3,087 births and 88,856 emergency department visits.

11 20. Valley Medical Center also operates a Gender Health Center that provides
12 (1) resources and psychological support for people of all ages, including children, teens, and young
13 adults, who seek to understand and explore their gender identity; (2) medical care, including
14 hormone treatments; and (3) primary care, including HIV and STI testing. Patient services at the
15 Gender Health Center include standard primary care and acute care, as well as specialized care for
16 the psychological and biological elements of gender transition. Valley Medical Center also operates
17 a family-planning clinic, which provides contraception and abortion services, and it operates a
18 dedicated clinic for LGBT patients.

19 21. In March 2019, the County purchased three additional major health facilities in
20 danger of closing—O’Connor Hospital, St. Louise Regional Hospital, and De Paul Health Center—
21 adding these critical local facilities to its safety net. O’Connor Hospital is the home of one of the
22 only family-medicine residency programs in the Bay Area. It provides emergency medical services,
23 urgent-care services, primary care, hospital care, and reproductive-health services. Last year,
24 O’Connor Hospital handled an estimated 51,948 emergency visits, 4,311 surgical cases, and 1,631
25 births.

26 22. St. Louise Regional Hospital, located in the City of Gilroy, operates the only acute-
27 care hospital in the southern part of Santa Clara County and specializes in maternal child-health
28 services, emergency services, women’s health, breast-cancer care, imaging, surgical procedures,

1 and wound care. St. Louise Regional Hospital is the only hospital in reasonable proximity to many
2 County residents living in the vast rural areas to the north, east, and south of the City of Gilroy.

3 23. De Paul Health Center, located in the City of Morgan Hill, provides urgent-care
4 services and a breast cancer clinic, and is also one of the key healthcare clinics close to many of
5 the rural residents in the County. In 2018, De Paul Health Center provided care for approximately
6 8,858 patients.

7 24. The County also operates the local public health department, which is responsible
8 for providing immunizations; tracking disease outbreaks; offering long-term case management for
9 patients with conditions such as active tuberculosis; providing testing, prevention, and treatment
10 services for sexually transmitted diseases; operating a needle-exchange program; and planning for
11 health emergencies. The 15 cities within the County—including the City of San José, the nation's
12 tenth largest city—lack their own public health departments and depend on the County to provide
13 all public health services.

14 25. To support its hospitals and public health department, the County operates numerous
15 pharmacies that supply essential medicines and treatments, including those used for contraceptive
16 care, abortions, hormone therapy as part of gender-transition-related care, sexually transmitted
17 infections, and HIV/AIDS. One County pharmacy provides free, donated medicine to individuals
18 who cannot afford the retail cost of needed medications. Another specializes in serving patients
19 with HIV/AIDS, patients with tuberculosis, patients from the Public Health Department's STD
20 clinic, and patients being discharged from the County jail. Staff at these pharmacies supports
21 communicable-disease control by procuring, storing, maintaining, and distributing essential
22 medications and vaccines during outbreaks and by distributing state-funded influenza vaccines for
23 administration at no charge to low-income and elderly residents.

24 26. The County also operates the local emergency-medical-services system, overseeing
25 all 911 ambulance response countywide. The County is also the sole accreditor in the county for
26 emergency responders, such as ambulance workers and firefighters.

27 27. The Santa Clara County Behavioral Health Services Department serves County
28 residents in need of mental-health and substance-use-treatment services. It provides needed

1 emergency and crisis care, short-term and long-term inpatient psychiatric care, outpatient mental-
2 health care, medication support, case-management services, and substance-abuse treatment. These
3 services are provided to many County residents from vulnerable populations, with a focus on
4 providing non-stigmatizing care to support those affected by mental illness and substance use.

5 28. The County also operates the only local publicly operated insurance plan, Valley
6 Health Plan. As a health-maintenance organization, Valley Health Plan offers various healthcare-
7 coverage plans that give enrolled members access to a range of medical services from physicians
8 and other healthcare providers within Valley Health Plan's network.

9 29. Plaintiff **Trust Women Seattle**, located in Seattle, Washington, is a clinic that
10 provides full-spectrum reproductive-health services, including abortion and transgender-health
11 services. Its mission is to expand access to abortion, healthcare for LGBT people, and reproductive
12 healthcare in underserved communities throughout the United States. In serving this mission, Trust
13 Women strives to treat all patients with dignity and compassion. Trust Women Seattle is a
14 subrecipient of federal Medicaid funding through the State of Washington and therefore is subject
15 to the Denial-of-Care Rule.

16 30. Plaintiff **Dr. Colleen McNicholas** is the Medical Director for Trust Women,
17 overseeing medical practice at Trust Women's Seattle, Oklahoma, and Kansas clinics.
18 Dr. McNicholas is involved in all aspects of medical decision-making with respect to abortion,
19 contraception, and transgender care offered at Trust Women Seattle. She provides full-spectrum
20 reproductive healthcare to her patients, including contraceptive care and abortion care into the
21 second trimester. In her hospital practice, Dr. McNicholas has developed a program to incorporate
22 gender-affirming gynecologic treatment for transgender children and adults. And she trains other
23 providers to provide abortion, contraception, and gender-affirming care. Dr. McNicholas is the
24 Director of the Ryan Residency Collaborative between Oklahoma University and Washington
25 University School of Medicine in St. Louis, Missouri, which offers formal training in abortion and
26 family planning to residents in obstetrics/gynecology; the Assistant Director of the Fellowship in
27 Family Planning at Washington University School of Medicine; and an Associate Professor at
28

1 Washington University School of Medicine, in the Department of Obstetrics and Gynecology's
2 Division of Family Planning.

3 31. Plaintiff **Los Angeles LGBT Center** is located in Los Angeles, California. Its
4 mission is to build a world in which LGBT people thrive as healthy, equal, and complete members
5 of society. The LA LGBT Center offers programs, services, and advocacy spanning four broad
6 categories: health, social services and housing, culture and education, and leadership and advocacy.
7 The LA LGBT Center has more than 650 employees and provides services for more LGBT people
8 than any other organization in the world, with about 500,000 patient visits per year. LA LGBT
9 Center receives funds under the PHSA. Approximately 80 percent of the LA LGBT Center's
10 funding originates from the federal government, including, but not limited to, funding under the
11 Ryan White Comprehensive AIDS Resources Emergency Act of 1990, 42 U.S.C. § 300ff *et seq.*
12 ("Ryan White funding"); direct funding from the Centers for Disease Control and Prevention,
13 discounts under the 340B Drug Discount Program, grants under section 330 of the PHSA; grants
14 from HHS-HRSA-Bureau of Primary Health Care under which the LA LGBT Center is a Federally
15 Qualified Health Center; and Medicaid and Medicare reimbursements. The LA LGBT Center
16 therefore is subject to the Denial-of-Care Rule.

17 32. Plaintiff **Dr. Robert Bolan** is the Chief Medical Officer of the LA LGBT Center.
18 He oversees the delivery of healthcare for approximately 9,000 patients who come to the LA LGBT
19 Center and personally treats approximately 300 patients. Over 90% of these patients identify as
20 LGBT, many of them coming from different areas of California and other States to obtain services
21 in a safe and affirming environment. Dr. Bolan also oversees the LA LGBT Center's Research
22 Department. Dr. Bolan and the providers he supervises treat patients who identify as transgender
23 and who require gender-affirming treatment, including medically necessary healthcare for gender
24 dysphoria. Many of Dr. Bolan's patients and many of the patients of the providers he supervises at
25 the LA LGBT Center already have experienced traumatic and discriminatory denials of healthcare
26 based on their sexual orientation, gender identity, transgender status, or HIV status at the hands of
27 providers outside the LA LGBT Center, including by healthcare providers who have expressed
28

1 religious or moral objections to treating them. Such experiences will increase as a result of the
2 Denial-of-Care Rule.

3 33. Plaintiff **Dr. Ward Carpenter** is the Co-Director of Health Services at the LA
4 LGBT Center. Dr. Carpenter is a nationally recognized expert in the field of transgender medicine.
5 In his role as Co-Director of Health Services, Dr. Carpenter oversees the healthcare of over 17,000
6 patients who come to the LA LGBT Center and personally treats 150 patients. All of Dr.
7 Carpenter's patients identify within the LGBT community, and approximately 30% of them are
8 people living with HIV. These patients come from different areas of California and other States to
9 obtain services in a safe and affirming environment. Dr. Carpenter's patient population is
10 disproportionately low-income and experiences high rates of chronic medical conditions,
11 homelessness, unstable housing, and extensive trauma history. In addition, many of Dr. Carpenter's
12 patients, as well as those of the other medical providers he supervises at the Center, already have
13 experienced traumatic and discriminatory denials of healthcare based on their sexual orientation,
14 gender identity, transgender status, or HIV status at the hands of providers outside the LA LGBT
15 Center, including by healthcare providers who have expressed religious or moral objections to
16 treating them. Such experiences will increase as a result of the Denial-of-Care Rule.

17 34. Plaintiff **Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health**, located
18 in Washington, D.C., provides a range of services, including medical and community healthcare,
19 transgender care and services, behavioral-health services, dental-health services, legal services,
20 insurance-navigation services, and youth and family support. It has particular expertise in LGBT
21 and HIV care. The mission of Whitman-Walker is to offer affirming community-based health and
22 wellness services to all with a special expertise in LGBT and HIV care. Whitman-Walker
23 empowers all persons to live healthy, love openly, and achieve equality and inclusion. In 2018,
24 Whitman-Walker provided health care services to more than 20,700 individuals. Whitman-Walker
25 receives various forms of federal funding from HHS and from institutions affiliated with or
26 themselves funded by HHS, including but not limited to funds under the PHSA, direct grants, Ryan
27 White funding, funds under the 340b drug subsidy program, research grants from the Centers for
28 Disease Control and Prevention and the National Institutes of Health, and Medicaid and Medicare

1 reimbursements. For 2019, Whitman-Walker's federally funded research contracts and grants total
2 more than \$2 million. Whitman-Walker therefore is subject to the Denial-of-Care Rule.

3 35. Plaintiff **Dr. Sarah Henn** is the Chief Health Officer of Whitman-Walker. Dr. Henn
4 oversees all healthcare-related services at Whitman-Walker and maintains a panel of patients for
5 whom she provides direct care. Whitman-Walker's patient population, including patients to whom
6 Dr. Henn provides direct care and whose care she oversees, includes many patients who have
7 experienced refusals of healthcare or who have been subjected to disapproval, disrespect, or
8 hostility from medical providers outside of Whitman-Walker because of their actual or perceived
9 sexual orientation, gender identity, or transgender status. Many of Dr. Henn's patients and those
10 whose care she oversees are, therefore, apprehensive or fearful of encountering stigma and
11 discrimination in healthcare settings because of their past experiences. Such experiences will
12 increase as a result of the Denial-of-Care Rule. In addition to overseeing medical care of patients
13 and working with her own patients, Dr. Henn oversees Whitman-Walker's Research Department,
14 and is personally involved in a number of clinical research projects, including as the Leader of
15 Whitman-Walker's Clinical Research Site for the AIDS Clinical Trials Group funded by the
16 National Institutes of Health.

17 36. Plaintiff **Dr. Randy Pumphrey** is Senior Director of Behavioral Health at
18 Whitman-Walker. As Senior Director of Behavioral Health, Dr. Pumphrey oversees Whitman-
19 Walker's portfolio of mental-health services and substance-use-disorder-treatment services and
20 maintains a panel of patients for whom he provides direct behavioral healthcare. In 2018, Whitman-
21 Walker provided mental-health or substance-use-disorder-treatment services to over 2,300 patients,
22 many of whom identify as LGBT or are living with HIV. Many, if not most, of the patients to whom
23 Dr. Pumphrey provides direct care and whose behavioral healthcare he oversees face considerable
24 stigma and discrimination as people living with HIV, as sexual or gender minorities, or as people
25 of color and have experienced difficulty finding therapists or other mental-health or substance-use-
26 disorder professionals who are understanding and welcoming of their sexual orientation, gender
27 identity, or transgender status. Such experiences of discrimination will increase as a result of the
28 Denial-of-Care Rule.

1 37. Plaintiff **Center on Halsted** is a 501(c)(3) nonprofit organization based in Chicago
2 and incorporated in Illinois. Center on Halsted is a comprehensive community center dedicated to
3 securing the health and well-being of the LGBT people of the Chicago area. Center on Halsted
4 provides programs and services for the LGBT community, including HIV/HCV testing; behavioral
5 health services; case management, job development, social programming, meals, and housing for
6 seniors; housing, meals, counseling, and leadership for youth; and anti-violence services. Center
7 on Halsted also administers social programming for families and advises patrons on concerns
8 related to family planning. On average, more than 1400 community members visit Center on
9 Halsted each day. Center on Halsted receives various forms of pass-through federal funding from
10 HHS, including Ryan White funding and funding from the National Institutes of Health and the
11 Centers for Disease Control and Prevention. Center on Halsted also benefits from programs
12 governed by the Centers for Medicare through Medicare reimbursements.

13 38. Plaintiff **Hartford Gyn Center**, located in Hartford, Connecticut, is the only
14 independent, state-licensed family-planning clinic in Connecticut. Hartford Gyn Center provides
15 reproductive-health services, including contraception and abortion services through 21 weeks.
16 Hartford Gyn Center's mission is to provide women with compassionate reproductive-health
17 services and abortion care, to respect the autonomy of each patient, to support and strengthen
18 reproductive rights, and to effect corresponding social change. Hartford Gyn Center sees patients
19 from all walks of life, including low-income patients who cannot easily access care elsewhere, if at
20 all. Hartford Gyn is one of the only facilities in the region that trains physicians in abortion care,
21 especially in the second trimester. The clinic also operates a medical-residency and training
22 program. Hartford Gyn Center is a subrecipient of federal Medicaid funding through the State of
23 Connecticut and therefore is subject to the Denial-of-Care Rule.

24 39. Plaintiff **Bradbury-Sullivan LGBT Community Center** is a 501(c)(3) nonprofit
25 organization based in Allentown, Pennsylvania, and incorporated in Pennsylvania. It is dedicated
26 to securing the health and well-being of LGBTQ people of the Greater Lehigh Valley. It provides
27 a variety of programs and services for the LGBTQ community, including HIV/STI testing,
28 healthcare-enrollment events, family-planning services, support groups, and a free legal clinic.

Bradbury-Sullivan Center also provides referrals to LGBT-welcoming healthcare providers, including providers engaged in family planning services. Patrons of Bradbury-Sullivan Center often seek healthcare services from other healthcare organizations, including religiously affiliated organizations. Bradbury-Sullivan Center works with patrons who have experienced discriminatory treatment when seeking healthcare services from such organizations and it advocates on behalf of those patrons by providing referrals to LGBT-welcoming agencies and providers, training agencies to provide LGBT-welcoming services, and, when necessary, communicating with agencies to inform them of their legal obligations to serve LGBT people. Bradbury-Sullivan Center also conducts research documenting health disparities in the LGBT community and performs related community-education efforts to improve public health within the LGBT community. Bradbury-Sullivan Center receives pass-through funding from HHS through the Maternal and Child Health Services Block Grant, and in the past also has received Ryan White funding. Bradbury-Sullivan Center therefore is subject to the Denial-of-Care Rule.

40. Plaintiff **Mazzoni Center**, located in Philadelphia, Pennsylvania, is a multi-service, community-based healthcare and social-service provider that primarily serves LGBTQ individuals and individuals living with HIV. Its mission is to provide quality comprehensive health and wellness services in an LGBTQ-focused environment, while preserving the dignity and improving the quality of life of the individuals whom it serves. Mazzoni Center receives various forms of federal funding, including Title X Family Planning, Centers for Disease Control, Department of Justice, and Ryan White funding. Mazzoni Center therefore is subject to the Denial-of-Care Rule.

41. Plaintiff **American Association Of Physicians For Human Rights d/b/a GLMA: Health Professionals Advancing LGBT Equality** (formerly known as the Gay & Lesbian Medical Association) is a 501(c)(3) nonprofit membership organization based in Washington, D.C., and incorporated in California. GLMA is a national organization committed to ensuring health equity for lesbian, gay, bisexual, transgender, queer, and all sexual and gender minority individuals, and equality for health professionals in such communities in their work and learning environments. To achieve this mission, GLMA utilizes the scientific expertise of its diverse multidisciplinary membership to inform and drive advocacy, education, and research. GLMA represents the interests

1 of tens of thousands of LGBTQ health professionals and millions of LGBTQ patients and families
2 across the United States. GLMA's membership includes approximately 1,000 member physicians,
3 nurses, advanced-practice nurses, physician assistants, researchers and academics, behavioral-
4 health specialists, health-profession students, and other health professionals throughout the country.
5 Their practices represent the major healthcare disciplines and a wide range of health specialties,
6 including internal medicine, family practice, psychiatry, pediatrics, obstetrics/gynecology,
7 emergency medicine, neurology, and infectious diseases.

8 42. Plaintiff **Medical Students for Choice** is a 501(c)(3) nonprofit organization based
9 in Philadelphia, Pennsylvania. MSFC provides training in the provision of abortion services to
10 medical students and residents throughout the country, works to destigmatize abortion provision,
11 and advocates for medical schools and residency programs to include abortion as part of the
12 reproductive-health-services curriculum. MSFC's members include 163 chapters of medical
13 students and residents at medical schools in 45 States. MSFC has thousands of medical-student
14 members and thousands of alumni who are practicing physicians.

15 43. Medical students receive their clinical training disproportionately at academic
16 medical centers and teaching hospitals that receive significant federal funding. Likewise, residents
17 are almost entirely subsidized through federal funding from HHS, including through Medicare
18 grants. Residents receive salaries that are directly funded by Medicare, and hospitals bill Medicare
19 for services provided to patients by residents. MSFC guides student and resident members in how
20 to obtain abortion training and runs a reproductive-health externship program that places members
21 in abortion clinics for training. MSFC also runs its own educational programs, including a
22 competitive 400-student training institute taught by alumni. Because of resource constraints, the
23 institute is already limited to accepting fewer than half the students who apply for the program.

24 44. Many of MSFC's members receive various forms of federal funding directly or
25 indirectly via federal programs. MSFC's members are, thus, subject to the restrictions of the Denial-
26 of-Care Rule. Without federal funding, MSFC members may not have the resources to provide
27 proper treatment to their patients and have a reasonable fear that they could be sanctioned and lose
28 federal funding for providing and training others to provide abortion.

45. Through its student and resident members across the country and its alumni who are practicing physicians at hospitals and clinics, MSFC is aware that many hospitals, healthcare facilities, and educational programs no longer provide abortion care or training. Because the Denial-of-Care Rule creates strong incentives for even more healthcare institutions to cease providing abortion training (including by putting at risk federal funding for those institutions that provide such training), the Rule will further strain MSFC's resources and threaten its mission of ensuring that doctors receive training in abortions and abortion-related care.

46. Plaintiff **AGLP: The Association of LGBTQ Psychiatrists** is a 501(c)(3) nonprofit organization based in Philadelphia, Pennsylvania. AGLP, the oldest association of LGBTQ+ professionals in the country, is a national organization of psychiatrists that educates and advocates on LGBTQ mental-health issues. AGLP represents the interests of 450 LGBTQ+ psychiatrists throughout the country who are members of the Association, and works to influence policies relevant to the LGBTQ+ community, as well as to support its members and advocate for its members' patients. AGLP also assists medical students and residents in their professional development; encourages and facilitates the presentation of programs and publications relevant to LGBTQ concerns at professional meetings; and serves as liaison with other minority and advocacy groups within the psychiatric community. Many of AGLP's members receive various forms of federal funding directly or indirectly via federal programs. AGLP's members therefore are subject to the restrictions of the Denial-of-Care Rule. Without federal funding, AGLP members may not have the resources to provide proper treatment to their patients or proceed with their medical-research programs. AGLP's members, therefore, have a reasonable fear that they could be sanctioned and lose federal funding for the work that they do in enforcing nondiscrimination policies and ensuring patient care in accordance with medical standards of care and ethical requirements, which are vital to providing proper care to patients.

B. Defendants

47. Defendant **HHS** is a cabinet department of the federal government, headquartered in the District of Columbia. It has responsibility for, among other things, enhancing and protecting Americans' health and well-being via the provision of health and human services.

48. Defendant **Alex M. Azar, II** is the Secretary of HHS and is sued in his official capacity. Secretary Azar is responsible for all aspects of the operation and management of HHS, including the adoption, administration, and enforcement of the Denial-of-Care Rule.

STATEMENT OF FACTS

A. Statutory Background

49. A network of federal statutes mandates nondiscriminatory treatment of patients and healthcare workers. Some statutes mandate that patients receive nondiscriminatory access to healthcare, information about treatment options, and emergency services. Other statutes allow individuals or entities to object to participating in certain medical procedures on religious or moral grounds and prohibit discrimination against them. These statutes, together with the patients' constitutional rights and healthcare providers' duties of care and ethical obligations, require healthcare providers to accommodate religious objections in a manner that does not interfere with the delivery of services or information to patients.

1. Laws Protecting Patients' Access to Care and Information

50. Congress has repeatedly recognized the paramount importance of providing patients with prompt and nondiscriminatory access to medical care and to information about all treatment options.

51. For example, Section 1554 of the Patient Protection and Affordable Care Act (ACA) provides that “[n]otwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that—

- (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
- (2) impedes timely access to healthcare services;
- (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
- (4) restricts the ability of healthcare providers to provide full disclosure of all relevant information to patients making healthcare decisions;
- (5) violates the principles of informed consent and the ethical standards of healthcare professionals; or

(6) limits the availability of healthcare treatment for the full duration of a patient’s medical needs.”

42 U.S.C. § 18114.

52. Section 1557 of the ACA, 42 U.S.C. § 18116, similarly protects against discrimination in the provision of healthcare services. It provides: “[A]n individual shall not, on [a] ground prohibited under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or section 504 of the Rehabilitation Act of 1973, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance.” This provision therefore prohibits discrimination based on sex, including discrimination based on a patient’s failure to conform to sex stereotypes, gender identity, or transgender status, all of which are forms of sex discrimination.

53. The Emergency Medical Treatment and Labor Act, 42 U.S.C. § 1395dd(b)(1) (“EMTALA”) governs when and how a patient must be examined and offered treatment (including medically necessary abortion services) while in an unstable medical condition. It requires a hospital that “determines that [an] individual has an emergency medical condition” to “provide either—(A) within the staff and facilities available at the hospital, for such further medical examination and such treatment as may be required to stabilize the medical condition, or (B) for transfer of the individual to another medical facility” *Id.*

54. The ACA, which respects certain religious objections to healthcare procedures, makes clear that nothing in it may “be construed to relieve any healthcare provider from providing emergency services as required by State or Federal law,” including EMTALA. 42 U.S.C. § 18023(d).

55. Title X of the Public Health Service Act, 42 U.S.C. §§ 300-300a-6, provides federal funding for family-planning services. Congress requires Title X grantees to operate “voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services.” 42 U.S.C. § 300(a). Title X appropriations bills, *e.g.*, 2019 Continuing Appropriations Act, Pub. L. No. 115-245, Div. B., Tit. II, 132 Stat. 2981, 3070-71 (2018), require

1 that “all pregnancy counseling shall be nondirective”; in other words, funded projects are to offer
 2 pregnant women neutral, nonjudgmental information and counseling regarding their options,
 3 including prenatal care and delivery; infant care, foster care, or adoption; and pregnancy
 4 termination.

5 **2. Laws Protecting Religious Objectors**

6 56. Certain statutes applicable to recipients of federal funds allow individuals to opt out
 7 of participating in certain medical procedures, training, or research based on their religious beliefs
 8 or moral convictions, and prohibit discrimination against individuals or entities for asserting such
 9 objections. These laws include, among others, the Weldon Amendment, *e.g.*, Department of
 10 Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and
 11 Continuing Appropriations Act, 2019, Pub. L. 115-245, § 507(d)(2), 132 Stat. 2981, 3118 (2018);
 12 the Coats-Snowe Amendment, 42 U.S.C. § 238n; and the Church Amendments, 42 U.S.C. § 300a-
 13 7.

14 57. The Weldon Amendment is a rider that has been attached to the Labor, Health, and
 15 Human Services, and Education, and Related Agencies Appropriations Act every year since 2004.
 16 162 Cong. Rec. H4844, H4852 (July 13, 2016) (Rep. Weldon). It provides that none of the funds
 17 appropriated under that Act “may be made available to a Federal agency or program, or to a State
 18 or local government, if such agency, program, or government subjects any institutional or
 19 individual healthcare entity to discrimination on the basis that the healthcare entity does not
 20 provide, pay for, provide coverage of, or refer for abortions.” Pub. L. 115-245, § 507(d)(2), 132
 21 Stat. 2981, 3118 (2018).

22 58. The Coats-Snowe Amendment prohibits abortion-related governmental
 23 discrimination in the area of medical training. It provides that “[t]he federal government, and any
 24 state or local government that receives Federal financial assistance,” may not discriminate against
 25 a healthcare entity because “the entity refuses to undergo training in the performance of induced
 26 abortions, to require or provide such training, to perform such abortions, or to provide referrals for
 27 such training or such abortions,” 42 U.S.C. § 238n(a)(1); “refuses to make arrangements” for those
 28

activities, *id.* § 238n(a)(2); or attends or attended a program that does not perform abortions or provide training in abortion care, *id.* § 238n(a)(3).

59. The Church Amendments, which were adopted in the 1970s, provide certain protections for religious and moral objections arising in medical research and training. One subsection provides that the receipt of certain federal funds by a healthcare provider does not authorize “any court or any public official or other public authority” to require an individual to perform or assist in the performance of an abortion or sterilization procedure, or to require an entity to make its facilities or personnel available for those procedures. 42 U.S.C. § 300a-7(b). Another subsection provides that an entity receiving federal funding for biomedical or behavioral research may not discriminate against personnel on the basis that they refused on religious or moral grounds to participate in a research or healthcare activity. 42 U.S.C. § 300a-7(c). A third subsection provides that an entity receiving certain federal funds may not discriminate against a physician or health care personnel in employment, promotion, termination, or the extension of staff or other privileges because he performed or refused to perform or assist in the performance of an abortion or sterilization procedure on the grounds that it would be contrary to his religious beliefs or moral convictions. 42 U.S.C. § 300a-7(c)(1). A fourth subsection prohibits discrimination by certain funding recipients against applicants for training or study based on their “reluctance, or willingness, to counsel, suggest, recommend, assist, or in any way participate in abortions or sterilizations” because of “the applicant’s religious beliefs or moral convictions.” 42 U.S.C. § 300a-7(e).

60. Subsection (d) of the Church Amendments provides that “[n]o individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions.” 42 U.S.C. § 300a-7(d).

61. The ACA prohibits discrimination by any recipient of federal funds against persons or entities because of their refusal to cause or assist in suicide or euthanasia, 42 U.S.C. § 18113; provides that the ACA does not require a health-insurance plan to provide coverage for abortions, 42 U.S.C. § 18023(b)(1)(A); prohibits any “qualified health plan offered through an [Insurance]

Exchange” from “discriminat[ing] against any individual healthcare provider or facility because” it does not “provide, pay for, provide coverage of, or refer for abortions,” 42 U.S.C. § 18023(b)(4); and states that the ACA should not be construed to affect other federal laws regarding “conscience protection” or willingness or refusal to provide abortions, 42 U.S.C. § 18023(c)(2)(A)(i)-(iii).

62. Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e *et seq.*, prohibits discrimination against employees based on their religious beliefs and requires accommodation of religious practices. Importantly, employers’ ability to ensure reliable care for their patients is recognized as a “business necessity,” 42 U.S.C. § 2000e-2(k)(1)(A)(i), and religious accommodation is required only if, and only to the extent that, it does not create “undue hardship,” 42 U.S.C. § 2000e(j).

3. The Implementation and Enforcement of Religious-Objection Laws

63. The religious-objection laws described above are self-executing and do not require regulations to go into effect. Accordingly, healthcare providers covered by the laws, including both the County and the private-healthcare-provider Plaintiffs, have adopted policies that accommodate conscience interests without compromising patients’ access to care and information.

64. Nevertheless, HHS previously promulgated regulations purporting to clarify and implement the religious-objection laws. On December 19, 2008, more than nine years before it proposed the Denial-of-Care Rule, HHS promulgated a final rule that purported to implement the Church Amendments, the Weldon Amendment, and the Coates-Snowe Amendment. *See Ensuring That Dep’t of Health & Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law*, 73 Fed. Reg. 78,072 (Dec. 19, 2008). On January 20, 2009, the final rule went into effect.

65. On March 10, 2009, HHS proposed to rescind the January 2009 rule in its entirety. It noted that no statutory provision required promulgation of regulations and that commenters had raised numerous questions and concerns about the regulations. *See Rescission of the Regulation Entitled “Ensuring That Dep’t of Health & Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law”*; Proposal, 74 Fed. Reg. 10,207 (Mar. 10, 2009).

66. On February 23, 2011, HHS largely rescinded the regulations but retained provisions delegating to HHS's Office for Civil Rights ("OCR") the authority to receive complaints of violations of religious-objection laws. *See* Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968 (Feb. 3, 2011).

67. The Rule challenged in this action is a centerpiece of the Trump Administration's concerted, aggressive effort to expand enforcement of religious-objection laws at the expense of patients. On January 18, 2018, the Acting Secretary of HHS established a new Conscience and Religious Freedom Division within OCR and delegated to this new Division the responsibility to enforce religious-objection laws. OCR then increased the budget of the Conscience and Religious Freedom division by \$1.546 million. OCR also modified its mission statement to emphasize a commitment to enforce "federal laws that guarantee the protection of conscience and free exercise of religion and prohibit coercion and religious discrimination in HHS-conducted or funded programs." When it promulgated the final Denial-of-Care Rule, HHS emphasized OCR's "singular and critical responsibility . . . to vigorously enforce" federal conscience laws. *See* Protecting Statutory Conscience Rights in Health Care, 84 Fed. Reg. 23,170, 23,178 (May 21, 2019) (to be codified at 45 C.F.R. Pt. 88).

C. The Proposed Denial-of-Care Rule

68. On January 26, 2018, the Acting Secretary proposed the Denial-of-Care Rule. *See* Protecting Statutory Conscience Rights in Health Care; Delegation of Authority, 83 Fed. Reg. 3880 (Jan. 28, 2018). The proposed Rule, like the final Rule, adopted an expansive construction of the religious-objection laws; ignored healthcare providers' obligations to ensure their patients' uninterrupted access to care and information and to advance the providers' own missions as healthcare institutions; imposed costly certification and recordkeeping requirements; would undermine Plaintiffs' ability to fulfill their missions; would require healthcare providers to rewrite and re-conceptualize their existing religious-objection policies; and threatened draconian penalties for violations without providing sufficient guidance on how to comply with the Rule.

69. During the 60-day notice-and-comment period, more than 72,000 comments were filed by interested parties, including medical associations, medical providers, civil-rights

1 organizations, states, and local governments. *See* 84 Fed. Reg. 23,170, 23,180 & n.41 (May 21,
 2 2019). The comments explained that the proposed Rule's expansive new right-of-refusal provisions
 3 were unworkable; that the Rule would upset well-developed practices by healthcare providers and
 4 medical schools that respect religious objections without compromising patient care; that it
 5 conflicted with federal and state laws and medical ethics; that it would violate patients' and
 6 providers' constitutionally protected rights; that it would severely threaten access to reproductive
 7 healthcare and LGBT healthcare; and that it threatened to deprive the nation's most vulnerable
 8 citizens of healthcare by stripping States and hospitals of Medicare and Medicaid funds.¹

9 70. Commenters identified the following problems, among others, with the proposed
 10 Rule:

11 (a) The Rule would conflict with long-standing practices by healthcare
 12 providers and medical schools that protect both the interests of healthcare workers and entities with
 13 religious objections and the rights of the patients whom they serve. Indeed, commenters explained,
 14 the Rule's prohibitions are framed so broadly that they invite healthcare workers to deny
 15 information and treatment to people without even alerting the medical facility or the patient that
 16 they have done so, thereby preventing the facility or the patient from protecting the patient's
 17 interests.²

18 (b) Because the Rule would interfere with the effective management of religious
 19 objections, it would increase barriers to care and deprive some patients of care altogether—
 20 including in emergency situations. Commenters demonstrated that when healthcare providers give
 21
 22

23 _____
 24 ¹ Medicare is the federal insurance program principally for elderly and disabled individuals.
 25 Medicaid provides health coverage to millions of Americans, including eligible low-income adults,
 26 children, pregnant women, elderly adults, and people with disabilities. Medicaid is administered by
 the States, according to federal requirements, and is funded jointly by States and the federal
 government.

27 ² *See, e.g.*, Comments of Lambda Legal HHS-OCR-2018-0002-72186; Comments of Office of the
 28 County Counsel, County of Santa Clara HHS-OCR-2018-0002-54930; Comments of GLMA HHS-
 OCR-2018-0002-71703; Comments of National Family Planning & Reproductive Health
 Association HHS-OCR-2018-0002-70260.

1 religious concerns priority over patient well-being, patients are denied care and information about
2 treatment options.³

3 (c) The Rule would encourage discrimination by health professionals based on
4 sex, sexual orientation, gender identity, transgender status, and HIV status.

5 (d) Because it allows the imposition of catastrophic sanctions while failing to
6 articulate practicable methods of compliance, the Rule would cause many healthcare providers to
7 scale back their services drastically or close certain of their clinics completely, for fear of losing
8 hundreds of millions of dollars of funding for the rest of the medical services that they provide.⁴

9 (e) The Rule would impose significant administrative burdens on healthcare
10 providers, including burdens resulting from the rule's recordkeeping and other compliance
11 requirements.⁵

12 (f) The Rule would prevent medical schools from adequately training doctors
13 to meet their professional obligations and would impair the ability to run teaching hospitals and
14 research facilities.⁶

15 71. The American Medical Association (AMA), among others, urged HHS to withdraw
16 the Denial-of-Care Rule.⁷ The AMA stated that the Rule would "undermine patients' access to
17 medical care and information, impose barriers to physicians' and health care institutions' ability to
18 provide treatment, impede advances in biomedical research, and create confusion and uncertainty

19 ³ See, e.g., Comments of Office of the County Counsel, County of Santa Clara HHS-OCR-2018-
20 0002-54930; Comments of Center for Reproductive Rights HHS-OCR-2018-0002-71830;
21 Comments of Lambda Legal HHS-OCR-2018-0002-72186; Comments of Americans United for
22 Separation of Church and State HHS-OCR-2018-0002-71232; Comments of GLMA HHS-OCR-
23 2018-0002-71703.

24 ⁴ Comments of National Family Planning & Reproductive Health Association HHS-OCR-2018-
25 0002-70260; Comments of Wisconsin Hospital Association, Inc. HHS-OCR-2018-0002-66144.

26 ⁵ Comments of Wisconsin Hospital Association, Inc. HHS-OCR-2018-0002-66144.

27 ⁶ Comments of Association of American Medical Colleges HHS-OCR-2018-0002-67592 ("AAMC
28 Comment").

⁷ Comments American Medical Association HHS-OCR-2018-0002-70564, at 1. The AMA is the
largest association of doctors and medical students in the United States. The AMA's mission is "to
promote the art and science of medicine and the betterment of public health." The AMA maintains
the AMA Code of Medical Ethics, a guide to the ethical practice of medicine created by the AMA
in 1847.

among physicians, other health care professionals, and health care institutions about their legal and ethical obligations to treat patients.” Similarly, the Association of American Medical Colleges warned that adoption of the Rule would “result in harm to patients, undermine standards of medical professionalism, and raise serious concerns regarding individuals’ rights that are protected by other federal and state laws.”⁸

D. The Final Denial-of-Care Rule

72. Despite the significant concerns raised during the comment period, HHS published the final Rule in the Federal Register on May 21, 2019. *See* Protecting Statutory Conscience Rights in Health Care, 84 Fed. Reg. 23,170 (May 21, 2019). It is attached as Exhibit 1 and incorporated by reference.

73. In adopting the final Rule, HHS failed adequately to address many of the serious issues raised by commenters, including the practical difficulties associated with the Rule, its conflict with obligations relating to emergency care and informed consent, and its detrimental effects on patients. HHS also lacked data to support its decisions and conclusions, refused without justification to credit the data that commenters submitted to it, and failed to consider alternatives to the Rule that would impose fewer costs and burdens on patients and providers. Furthermore, HHS repeatedly declined to clarify key issues or to provide guidance to regulated entities necessary for them to implement the Rule, stating instead that it would consider numerous questions on a case-by-case basis.

74. For example, HHS acknowledged that it “received comments expressing concern about the impact of the rule on access to care in rural communities, underprivileged communities, or other communities that are primarily served by religious healthcare providers or facilities.” 84 Fed. Reg. at 23,180. The agency responded by stating that finalizing the rule is appropriate even if the rule “impact[s] overall or individual access to a particular service,” such as abortion or treatment

⁸ AAMC Comment at 1. The AAMC is not-for-profit association of 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. The AAMC serves more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

1 for gender dysphoria. *Id.* at 23,182. Although it acknowledged that it lacked data to support this
2 assumption, HHS asserted that the rule would be “reasonably likely to increase, not decrease, access
3 to care” in underserved communities by attracting providers who otherwise would not practice
4 medicine because of their religious objections. *Id.* at 23,180. In support, HHS cited a small,
5 outdated, and unreliable political poll, *id.* at 23,181, in which responders stated that they would not
6 practice medicine if doing so involved violation of their religious or moral convictions but said
7 nothing about *where* they would practice medicine. HHS cited no data showing that the Rule was
8 needed to keep providers from quitting or that it would attract any new providers to underserved
9 communities. HHS also failed to address how an increase in providers that refuse to provide care
10 would address the concern that patients will struggle to get the care that they need. Moreover,
11 HHS’s evaluation prefers certain types of care over others: The agency assumes that access to care
12 will increase, and cites this as a benefit of the Rule, but does not contradict comments asserting that
13 certain types of care, including reproductive healthcare and LGBT care, will be reduced, especially
14 in rural areas.

15 75. HHS rejected comments observing that the Rule conflicted with EMTALA. *See* 84
16 Fed. Reg. at 23,182-23,183. But it failed to address whether emergency exceptions are permissible,
17 and it cited cases where nurses with religious objections were required to assist patients in
18 emergencies as examples of discrimination that it was trying to remedy. *Id.* at 23,176. HHS also
19 stated that driving a patient to the hospital in an ambulance for an emergency procedure may qualify
20 as assisting in the performance of a procedure, *id.* at 23,188, without acknowledging that the
21 procedure (removal of an ectopic pregnancy) could be necessary to save the patient’s life. In so
22 doing, HHS failed to provide any clear rule for determining whether or when ambulance drivers
23 and paramedics might object under the Rule to caring for or transporting a patient, instead stating
24 that this determination depends on the facts and circumstances of each case. *Id.* HHS also failed to
25 acknowledge or address the risk to patients’ lives if paramedics or other individuals who provide
26 emergency care refuse to administer needed treatments or refuse to transport patients when no
27 alternate staff member is immediately available to perform the service.

76. HHS acknowledged that the Rule has the potential to harm patients. *See* 84 Fed. Reg. at 23,251 (“First, the patient’s health might be harmed if an alternative is not readily found, depending on the condition. Second, there may be search costs for finding an alternative. Third, the patient may experience distress associated with not receiving a procedure he or she seeks.”). Yet it made no efforts to craft provisions that would reduce the risk of harm to patients. Instead, without evidence, HHS downplayed the risks that patients would be harmed by assuming that various types of objections would not be raised. *See, e.g., id.* at 23,188 (stating that HHS is unaware of any medical professionals who would object to treating or transporting patients experiencing complications after an abortion); *id.* at 23,244 (stating that HHS “is unaware of any religious or ethical belief systems that prohibit treatment of a person on the basis of their HIV status”). It also suggested, without citing statutory language, that the enactment of religious-objection laws justified any harm to patients resulting from their enforcement. *See, e.g.,* 84 Fed. Reg. at 23,251 (recognizing that “some patients do experience emotional distress as a consequence of providers’ exercise of religious beliefs or moral convictions” but stating that Congress “did not establish balancing tests that weigh such emotional distress against the right to abide by one’s conscience”).

77. HHS asserted that any harm to patients was attributable not to the Denial-of-Care Rule but to the religious-objection statutes themselves. For that reason, HHS deemed it unnecessary to quantify the harm to patients. It concluded that “it is appropriate to finalize this rule . . . even though the Department and commenters do not have data capable of quantifying all of its effects on the availability of care.” 84 Fed. Reg. at 23,182. Again invoking purported congressional policy, the agency deemed religious refusals “worth protecting even if they impact overall or individual access to a particular service, such as abortion.” *Id.*; *see id.* at 23,251 (asserting that “objections based on potential (often temporary) lack of access to particular procedures as a result of enforcement of the law are really objections to policy decisions made by the people’s representatives in Congress”).

1. The Rule’s Overly Broad and Distorted Definitions

78. Although HHS repeatedly attributes the Rule’s harmful consequences to the underlying statutes, the Rule sharply departs from the will of Congress. The Rule contains

1 numerous prohibitions, applicable to specified funding recipients, that purport to implement the
 2 religious-objection laws. *See* 84 Fed. Reg. at 23,264, § 88.3. But the Rule defines or redefines key
 3 statutory terms, expanding their reach far beyond their ordinary meaning and congressional intent.
 4 *See* 84 Fed. Reg. at 23,263-23,264, § 88.2.

5 79. Through these overly broad definitions, the Rule will encourage individuals or
 6 institutional healthcare providers, or even someone with only a tangential connection to a procedure
 7 (such as a receptionist, lab technician, bookkeeper, janitor, or volunteer), to claim an absolute right
 8 to refuse to provide or have any connection whatsoever to providing healthcare and information
 9 based on a religious or moral objection—regardless of the impact on patients and on other
 10 healthcare providers. The Rule also invites these individuals to refuse to provide a referral to
 11 another provider or even general information about services to which the refuser objects, thereby
 12 denying patients critical information about their treatment options. Taken together, these definitions
 13 will embolden almost any person or entity whose work has even a vague tie to healthcare delivery
 14 to decline to provide and even to block needed medical care, services, administrative support,
 15 advice, and information.

16 80. The Rule redefines key terms with extraordinary and unwarranted breadth,
 17 distorting the underlying statutes’ meaning. These terms are either undefined or more narrowly
 18 defined in the underlying statutes. When read together, the definitions of “assist in the performance,”
 19 “refer,” “health care entity,” and “discriminate” greatly expand the Rule’s prohibitions beyond the
 20 authority granted in any of the statutes. The Rule therefore interconnects various, separately enacted
 21 provisions of the Coates, Weldon, and Church Amendments to create an unlawful regulation that
 22 expands religious refusals to an unworkable, dangerous degree. For example, as discussed more
 23 fully below, the definition of “assist in the performance” includes the term “refer,” which in turn is
 24 defined with unprecedented breadth.

25 81. The Rule prohibits all federal funding recipients, including subrecipients, from
 26 “requir[ing]” any “individual to perform or **assist in the performance** of any part of a **health**
 27 **service program or research activity** . . . if the individual’s performance or assistance in the
 28 performance of such part of such program or activity would be contrary to his religious beliefs or

1 moral convictions.” 84 Fed. Reg. at 23,265, § 88.3(a)(2)(vi) (emphasis added). The Rule defines
 2 the key terms with extraordinary and unwarranted breadth, thus distorting the underlying statutes’
 3 meaning.

4 82. First, the Rule defines “**assist in the performance**” extremely broadly to include
 5 activities only tangentially related to any healthcare procedure. Only the Church Amendments refer
 6 to “assist[ing] in the performance” of an activity, and nothing in that statutory scheme envisions
 7 the broad definition in the Rule. 42 U.S.C. § 300a-7. Under the Rule, however, to “assist in the
 8 performance” means to “take an action that has a specific, reasonable, and articulable connection
 9 to furthering a procedure or a part of a health service program or research activity undertaken by
 10 or with another person or entity,” including “counseling, referral, training, or otherwise making
 11 arrangements for the procedure or a part of a health service program or research activity, depending
 12 on whether aid is provided by such actions.” 84 Fed. Reg. at 23,263, § 88.2.

13 83. HHS rejected arguments that the definition was too broad, explaining instead that
 14 the agency intends the Rule to be defined expansively. 84 Fed. Reg. at 23,186-23,187. The agency
 15 likewise defended its inclusion of counseling and referral within the definition of “assist in the
 16 performance,” asserting without authority that these are “common and well understood forms of
 17 assistance that help people reach desired medical ends.” *Id.* at 23,188. But Congress made specific
 18 references to “counsel[ing]” in one of the Church Amendments’ provisions, “training” in the Coats-
 19 Snowe Amendment, and “refer for” in the Weldon Amendment. The separation of these terms in
 20 the statutes is evidence of Congress’s intent to distinguish them. Yet the Rule includes each
 21 category of actions, which themselves are defined with incredible breadth, within the definition of
 22 “assist in the performance.” The inclusion of a panoply of additional activities within the definition
 23 of “assist in the performance” is contrary to the statutes.

24 84. Second, the Rule defines “**referral or refer**”—terms that are part of the definition
 25 of “assist in the performance”—with extreme breadth. Expanding those terms beyond any
 26 commonsense understanding or traditional meaning in the medical context, the Rule defines them
 27 to include the “provision of information in oral, written, or electronic form (including names,
 28 addresses, phone numbers, email or web addresses, directions, instructions, descriptions, or other

information resources), where the purpose or reasonably foreseeable outcome of provision of the information is to assist a person in receiving funding or financing for, training in, obtaining, or performing a particular health care service, program, activity, or procedure.” 84 Fed. Reg. at 23,264, § 88.2. This definition goes far afield from what is traditionally considered referral or counseling, instead expanding it to invite an individual worker—one who may lack the medical expertise or information about a patient’s medical history to understand the implications of this decision—to refuse to notify either the patient or the worker’s employer of the decision to deny information or care. When read in conjunction with the definition of “assist in the performance,” this definition empowers an unprecedented universe of individuals to deny care and information without providing these essential and ethically required notifications. The limited provisions of the Rule that permit healthcare providers to require certain, limited advance notice of refusals, discussed more fully below, are not sufficient to cure the unreasonable breadth and unworkability of this definition.

85. By defining participation in a procedure as any activity with “a specific, reasonable, and articulable connection” to a procedure; by explicitly including referrals, counseling, training, and arrangements for a procedure; and by defining “referral” to include the provision of any information that may foreseeably lead a person to obtain training, funding, or services, the Rule vastly expands the class of people who will be empowered to assert objections and the activities that may be the subject of objections.

86. The Rule defines “**workforce**” broadly to mean “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.” 84 Fed. Reg. at 23,264, § 88.3. The proposed Rule defined the word “individual”—a word used in several of the Rule’s prohibitions—to include any member of an entity’s workforce. 83 Fed. Reg. at 3924, § 88.2. That definition of “individual” was deleted from the Rule, but the definition of “workforce” was retained. And the preamble’s discussion of that decision makes clear that HHS’s Office for Civil Rights still asserts that it may interpret that term

1 to include members of the “workforce” as defined in the Rule, stating that “sometimes [the term
2 individual] refers to members of the workforce of an entity or health care entity. . . .”). 84 Fed. Reg.
3 at 23,199.

4 87. The preamble to the Rule makes clear that these definitions allow objections to be
5 raised by a receptionist who schedules an appointment, a janitor who prepares an operating room,
6 an orderly who provides patients with assistance in the recovery room, or an ambulance driver who
7 transports a patient to the hospital. *See* 84 Fed. Reg. at 23,186-23,187.

8 88. Indeed, the Rule could be read to cover virtually any healthcare-related task,
9 including providing information about treatment options and coverage information to allow for
10 informed consent; providing, collecting, or filing forms related to patients’ health history, insurance
11 information, or informed consent; escorting patients to treatment areas; cleaning or restocking
12 treatment rooms, operating rooms, ambulances, or other facilities to allow for treatment of patients;
13 billing, collecting fees for, and administering insurance reimbursements for treatment; and even
14 minor administrative, clerical, or supporting tasks such as scheduling appointments. Invoking the
15 definitions of “assist in the performance” and “refer,” a worker could feel empowered to object to
16 providing even basic information to a patient—such as information about insurance coverage, the
17 phone number of a medical office, or directions to a bus stop—on the theory that the worker would
18 thereby be “assisting in the performance” of a procedure to which the worker has a moral objection.

19 89. These terms reach even further when read in conjunction with the Rule’s definition
20 of “**discriminate.**” As noted above, several statutes prohibit discrimination based on the assertion
21 of religious objections in specified circumstances. The Rule includes prohibitions employing
22 language from these statutes (*e.g.*, 84 Fed. Reg. at 23,265, § 88.3(a)(2)(iv), citing 42 U.S.C. 300a-
23 7(c)(1)), but defines the word “discriminate” in an unreasonable and arbitrary manner, dramatically
24 expanding what the supposed authorizing statutes actually require or provide. That definition has
25 no basis in law and undermines policies designed to reconcile religious objections and the needs of
26 patients.

27 90. Under the Rule, “discriminate” means “(1) [t]o withhold, reduce, exclude from,
28 terminate, restrict, or make unavailable or deny any grant, contract, subcontract, cooperative

1 agreement, loan, license, certification, accreditation, employment, title, or other similar instrument,
2 position, or status; (2) [t]o withhold, reduce, exclude from, terminate, restrict, or make unavailable
3 or deny any benefit or privilege or impose any penalty; or (3) [t]o utilize any criterion, method of
4 administration, or site selection, including the enactment, application, or enforcement of laws,
5 regulations, policies, or procedures directly or through contractual or other arrangements, that
6 subjects individuals or entities protected under this part to any adverse treatment with respect to
7 individuals, entities, or conduct protected under this part on grounds prohibited under an applicable
8 statute encompassed by this part.” 84 Fed. Reg. at 23,263, § 88.2.

9 91. This definition appears to classify as prohibited discrimination any action having
10 the slightest negative effect, even if there is a compelling reason for that action. Although Title VII
11 of the Civil Rights Act of 1964 provides that employers need not provide accommodations for an
12 employee’s religious beliefs when the accommodation would cause undue hardship to the
13 employer, the Rule incorporates no such consideration and does not recognize any exception for
14 business necessity or acknowledge that employers may have legitimate, nondiscriminatory reasons
15 for an allegedly adverse employment action. As a result, it appears that a healthcare entity could be
16 deemed to have engaged in unlawful discrimination when it takes measures that are reasonably
17 necessary to ensure patient care notwithstanding the religious views of individual workers—such
18 as taking religious objections into account when making scheduling decisions, enforcing policies
19 requiring advance notice of religious objections, requiring employees to tell someone when they
20 have refused to provide care to a patient, or considering whether a job candidate is willing to
21 perform the essential duties of the position or deliver healthcare services critical to the providers’
22 mission when making hiring decisions.

23 92. HHS incorporated into the definition of “discrimination” exceptions that
24 purportedly allow certain methods, such as advance-notice requirements and use of alternate staff,
25 that providers use to reconcile objections with the needs of patients. But these provisions are
26 unreasonably narrow, vague, and unworkable.

27 93. First, the definition states that “an entity subject to any prohibition in this part shall
28 not be regarded as having engaged in discrimination against a protected entity where the entity

1 offers and the protected entity [*i.e.*, an employee or volunteer] voluntarily accepts an effective
2 accommodation for the exercise of such protected entity's protected conduct, religious beliefs, or
3 moral convictions." 84 Fed. Reg. at 23,263, § 88.2. The requirement that an accommodation be
4 "voluntarily accept[ed]" does not say what providers should do when an employee rejects an
5 offered accommodation and demands an accommodation that would put patients at risk or
6 otherwise compromise patient care.

7 94. The definition also states that "an entity subject to any prohibition in this part may
8 require a protected entity to inform it of objections to performing, referring for, participating in, or
9 assisting in the performance of specific procedures, programs, research, counseling, or treatments,
10 but only to the extent that there is a reasonable likelihood that the protected entity may be asked in
11 good faith to perform, refer for, participate in, or assist in the performance of, any act or conduct
12 just described. Such inquiry may only occur after the hiring of, contracting with, or awarding of a
13 grant or benefit to a protected entity, and once per calendar year thereafter, unless supported by a
14 persuasive justification." 84 Fed. Reg. at 23,263, § 88.2.

15 95. This provision sharply constrains providers' ability to require that workers provide
16 notice of their objections to procedures. Healthcare institutions may ask about "specific"
17 procedures, research, and treatment only; they may ask for advance notice of objections only if
18 there is "a reasonable likelihood" that the particular worker will be asked to participate in the
19 particular procedures; they may ask only *after* the worker is hired and then only once per year
20 thereafter. The Rule does not indicate how providers may handle unanticipated objections or
21 situations. Nor does it authorize providers to adopt policies requiring workers to alert them when
22 the workers decline to provide needed medical care or information to a patient, or (if the workers
23 have given such notice) when they decide to object to additional categories of patients or
24 procedures. And the Rule prohibits any questioning about religious objections before hiring,
25 notwithstanding the immense burden that would fall on a healthcare provider if it learned after
26 hiring a worker that the worker is unwilling to perform the critical and even primary aspects of the
27 job for which the worker was hired.
28

96. Finally, the Rule limits the ability of healthcare providers to ensure that patients are not denied care because of a religious objection. The Rule states that “[t]he taking of steps by an entity subject to prohibitions in this part to use alternate staff or methods to provide or further any objected-to conduct . . . would not, by itself, constitute discrimination or a prohibited referral, if such entity does not require any additional action by, or does not take any adverse action against, the objecting protected entity (including individuals or health care entities), and if such methods do not exclude protected entities from fields of practice on the basis of their protected objections. Entities subject to prohibitions in this part may also inform the public of the availability of alternate staff or methods to provide or further the objected-to conduct, but such entity may not do so in a manner that constitutes adverse or retaliatory action against an objecting entity.” 84 Fed. Reg. at 23,263, § 88.2. By appearing to foreclose requiring any “additional action” by objectors, the Rule suggests that providers may not even require objectors to assist in transferring patients to alternative providers or to tell patients that an alternative provider is available. Instead, the Rule envisions that providers will post public notices to inform patients about the availability of alternatives. That will create anxiety by alerting patients that some of a healthcare facility’s staff may refuse to treat them. The patients may have no idea that they may need a treatment to which a healthcare worker might object. This inappropriately shifts to patients the burden of anticipating possible objections by employees and finding a way to ensure that they still can receive needed care and information.

97. The Rule also expansively redefines “**health care entity**”—a phrase that is used in both the Coats-Snowe Amendment and the Weldon Amendment and is specifically defined in each. The Rule’s new definition expands “health care entity” to include new entities not covered by either statute. In so doing, the Rule goes far beyond those statutes’ scope.

98. Under the Coats-Snowe Amendment, “health care entity” “includes an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions.” 42 U.S.C. § 238n(c)(2). Under the Rule, “health care entity” for purposes of the Coats-Snowe Amendment includes “an individual physician or other health care professional, including a pharmacist; health care personnel; a participant in a program of training in the health professions; an applicant for training or study in the health professions; a post-graduate

1 physician training program; a hospital; a medical laboratory; an entity engaging in biomedical or
 2 behavioral research; a pharmacy; or any other health care provider or health care facility.” 84 Fed.
 3 Reg. at 23,264, § 88.2.

4 99. Under the Weldon Amendment, “‘health care entity’ includes an individual
 5 physician or other health care professional, a hospital, a provider-sponsored organization, a health
 6 maintenance organization, a health insurance plan, or any other kind of health care facility,
 7 organization, or plan.” *E.g.*, Pub. L. 115-245, § 507(d)(2), 132 Stat. 2981, 3118 (2018). But in the
 8 Rule, “health care entity” for purposes of the Weldon Amendment is defined to include “an
 9 individual physician or other health care professional, including a pharmacist; health care
 10 personnel; a participant in a program of training in the health professions; an applicant for training
 11 or study in the health professions; a post-graduate physician training program; a hospital; a medical
 12 laboratory; an entity engaging in biomedical or behavioral research; a pharmacy; a provider-
 13 sponsored organization; a health maintenance organization; a health insurance issuer; a health
 14 insurance plan (including group or individual plans); a plan sponsor or third-party administrator;
 15 or any other kind of health care organization, facility, or plan.” 84 Fed. Reg. at 23,264, § 88.2.

16 100. Through these sweeping definitions, the Rule broadens the universe of potential
 17 objectors to include individuals and entities not included in either of the statutory definitions of
 18 “health care entity,” including applicants for training and study and pharmacists. And the Rule
 19 expands the definition of “health care entity” for purposes of the Coats-Snowe Amendment to
 20 include any healthcare professional, healthcare provider, or healthcare facility, notwithstanding that
 21 such general terms do not appear in the statutory definition.

22 101. The Rule uses the term “**sterilization**” to describe medically necessary, gender-
 23 affirming healthcare procedures sought by transgender patients. It does so to justify denials of care
 24 to transgender and gender-nonconforming patients. But that understanding of the term sterilization
 25 is inaccurate—it is contrary to current medical, traditional, and commonsense understandings of
 26 the term. The Rule cites *Minton v. Dignity Health*, No. 17-558259 (Calif. Super. Ct. Apr. 19, 2017),
 27 as justification for the Rule’s enactment. *See* 84 Fed. Reg. at 23,276, n.27. *Minton* concerned
 28 whether a Catholic hospital was justified in blocking a surgeon’s performance of a hysterectomy

on a transgender patient as part of the patient’s prescribed course of treatment for gender dysphoria based on the hospital’s religious objection to “sterilization.” But equating treatment for gender dysphoria with sterilization is medically inaccurate. Procedures undertaken for the purpose of sterilization are distinct from medical procedures undertaken for other purposes that incidentally affect reproductive function. The Rule also expressly and improperly declines to rule out whether treatment for cancer, such as chemotherapy or surgical removal of testes or ovaries to treat cancerous tumors, could constitute “sterilization” simply because such treatment also could affect reproductive function. The Rule’s targeting of transgender patients by adopting a particular religious definition of “sterilization” violates statutory nondiscrimination requirements and medical and ethical standards of care, improperly endorses a particular religious belief, and threatens the provision of medically necessary healthcare to transgender patients, thereby threatening public health.

2. The Rule’s Inadequate Explanation of Emergency Exceptions, Compliance Certification, and Notice Requirements

102. The Rule contains no exception for emergencies. In the Rule’s preamble, HHS specifically contemplates that individuals will deny patients access to necessary care even in emergency situations in which no alternative provider is available. Further, HHS cites cases involving people being required to provide emergency care as evidence of the need for the Rule. *See, e.g.*, 84 Fed. Reg. at 23,176 (citing *Cenzon-Decarlo v. Mount Sinai Hosp.*, No. 09 CV 3120(RJD), 2010 WL 169485, at *1 (E.D.N.Y. Jan. 15, 2010), *aff’d*, 626 F.3d 695 (2d Cir. 2010) (only on-call nurse did not want to provide emergency care for patient suffering from severe preeclampsia)); *id.* at 23,176 n. 27 (citing *Means v. U.S. Conference of Catholic Bishops*, No. 1:15-CV-353, 2015 WL 3970046 (W.D. Mich. 2015) (hospital turned away patient, refusing to complete miscarriage following premature rupture of membranes, risking grave threats to patient’s health)). HHS also cites as evidence of the need for the rule a medical-ethics opinion requiring emergency care notwithstanding religious objections. *See* 83 Fed. Reg. at 3888 (citing, as evidence of the denial of conscience rights in medicine, an American Congress of Obstetricians and Gynecologists ethics opinion advising that providers have an obligation to provide emergency care in certain

1 circumstances). These examples illustrate HHS's intent to authorize the denial of care to patients
2 even in emergencies and in derogation of patients' constitutionally protected rights. HHS's only
3 response is that it will decide on a case-by-case basis how emergency needs and conscience
4 objections should be reconciled. 84 Fed. Reg. at 23,176.

5 103. The Rule requires funding recipients to certify their compliance with the Rule and
6 imposes recordkeeping requirements. 84 Fed. Reg. at 23,269-23,271, § 88.4-88.6. But the Rule
7 provides no practical guidance on compliance; it does not specify what form that the records should
8 take or how they should be maintained.

9 104. The Rule includes a notice requirement that will encourage individuals to
10 unilaterally refuse to provide care and information to patients. 84 Fed. Reg. at 23,270, § 88.5. The
11 notice purports to be "voluntary," but the Rule pressures recipients to post certain recommended
12 text. The Rule states that OCR "will consider an entity's voluntary posting of a notice of
13 nondiscrimination as non-dispositive evidence of compliance" with the Rule, as long as "such
14 notices are provided according to the provisions of this section." *Id.* The Department will take into
15 account where the notice is published—e.g., whether it is "[i]n a prominent and conspicuous
16 physical location" where it can be readily observed by the recipient's workforce and the public; in
17 personnel manuals; and in employment applications. *Id.* § 88.5(b). The Rule recommends that the
18 notice read: "You may have the right under Federal law to decline to perform, assist in the
19 performance of, refer for, undergo, or pay for certain health care-related treatments, research, or
20 services (such as abortion or assisted suicide, among others) that violate your conscience, religious
21 beliefs, or moral convictions." 84 Fed. Reg. at 23,272, App. A to Pt. 88. This recommended notice
22 does not suggest that the objector must comply with advance-notice requirements, that the objector
23 must cooperate in handing off the patient to another workforce member, or that the objector must
24 assist in an emergency. The posting of a notice in the recommended form therefore would
25 undermine policies designed to reconcile religious objections with the needs of patient care. Yet
26 the Rule does not state what the consequences will be for failing to post a notice in this form.

3. The Rule's Vague and Coercive Enforcement Provisions

105. The Denial-of-Care Rule threatens entities that violate the Rule with punitive sanctions, up to and including the total withdrawal and even clawback of Medicare and Medicaid reimbursements and all other federal funds. *See* 84 Fed. Reg. at 23,180 (emphasizing that remedies may include “termination of relevant funding, in whole or in part” and “funding claw backs to the extent permitted by law”); 84 Fed. Reg. at 23,271, § 88.7(i) (remedies for noncompliance with the Rule include withholding, denying, or terminating existing federal funding; denying or withholding new federal funding; and suspending award activities).

106. These penalties could be applied for even a single violation by a covered entity or a violation by a subrecipient or contractor. Direct recipients bear “primary responsibility to ensure that” their subrecipients are “in compliance with Federal conscience and anti-discrimination laws and this part, and shall take steps to eliminate any violations of the Federal conscience and anti-discrimination laws and this part.” 84 Fed. Reg. at 23,270, § 88.6(a). The Rule makes clear that if “a sub-recipient is found to have violated the Federal conscience and anti-discrimination laws, the recipient from whom the sub-recipient received funds may be subject to the imposition of funding restrictions or any appropriate remedies available under this part, depending on the facts and circumstances.” *Id.* The preamble further states that the conduct of contractors is attributable to States and local governments. 84 Fed. Reg. at 23,207 (“The conduct and activities of contractors engaged by the Department, a Departmental program, or a State or local government is attributable to such Department, program, or government for purposes of enforcement or liability under the Weldon amendment.”).

107. Moreover, although the Rule asserts that matters will be resolved informally “whenever possible,” it makes clear that loss of all funds can still be immediate: “Attempts to resolve matters informally shall not preclude OCR from simultaneously pursuing any action described in § 88.7.” 84 Fed. Reg. at 23,271-23,272, § 88.7(h)(2).

108. The preamble to the proposed Rule asserted that the Department may regulate an unspecified “broader range of funds or broader categories of covered entities” for “noncompliant entities.” 83 Fed. Reg. at 3898. In other words, HHS asserted the power to withhold not only federal

1 funds that are used for programs in which violations are occurring, but also federal funds used for
2 programs unrelated to any alleged offense. And the Rule provides that OCR may temporarily
3 withhold “Federal financial assistance or other Federal funds, in whole or in part, pending
4 correction of the deficiency,” without limiting that authority to funds from HHS, a limitation that
5 is present in other provisions of the same section. 84 Fed. Reg. at 23,272, § 88.7(i)(3)(i).

6 109. These draconian enforcement mechanisms will have the effect of intimidating and
7 coercing healthcare providers—leading them to adopt overly limiting constructions of ambiguous
8 provisions or to stop providing certain services altogether. Likewise, direct recipients that face
9 liability for violations by subrecipients will have little option but to regulate aggressively or to pull
10 funding from subrecipients, particularly those that provide abortion, contraception, or LGBT
11 healthcare, as well as those that will not alter their nondiscrimination or emergency policies.

12 110. The Rule provides no mechanisms for notice, a hearing, or an appeal before HHS
13 terminates or withholds funds for asserted violations of the Rule.

14 111. The Rule provides no guidelines as to which enforcement mechanisms HHS will
15 use in particular circumstances, instead leaving it entirely to the discretion of enforcement officials.
16 As a result, HHS officials could employ the most draconian punishments for even the most trivial
17 technical violations, and the healthcare provider would have no outlined avenue for appeal.

18 112. Moreover, the Rule threatens recipients and subrecipients with onerous compliance
19 and investigation requirements that infringe on patient privacy. *See* 84 Fed. Reg. at 23,270,
20 § 88.6(c) (each recipient and subrecipient “shall cooperate with any compliance review,
21 investigation, interview, or other part of OCR’s enforcement process, which may include the
22 production of documents, participation in interviews, response to data requests, and making
23 available of premises for inspection where relevant”). Investigations are mandatory whenever there
24 is a violation or “threatened” or “potential” violation, which can be demonstrated through “any
25 information.” *Id.* at 23,271, § 88.7(d) (“OCR shall make a prompt investigation, whenever a
26 compliance review, report, complaint, or any other information found by OCR indicates a
27 threatened, potential, or actual failure to comply with Federal health care conscience and associated
28 anti-discrimination laws or this part.”).

113. Each recipient or subrecipient is required to “permit access by OCR during normal business hours to such of its books, records, accounts, and other sources of information, as well as its facilities, as may be pertinent to ascertain compliance with this part.” The Rule expressly overrides patients’ privacy rights, stating that “[a]sserted considerations of privacy or confidentiality may not operate to bar OCR from evaluating or seeking to enforce compliance with this part. Information of a confidential nature obtained in connection with compliance reviews, investigations, or other enforcement activities shall not be disclosed except as required in formal enforcement proceedings or as otherwise required by law.” 84 Fed. Reg. at 23,271, § 88.5(c).

114. Given the expansiveness and vagueness of the Rule, and the severity of its penalty provisions, any individual or entity receiving federal funding—including direct recipients and subrecipients, hospitals, independent providers, contractors, and affiliates—faces a substantial risk of crippling sanctions. To avoid severe penalties, providers must either risk violating the laws (and ethical and professional obligations) that require them to provide timely and adequate access to information and care to patients, or cease offering services to which some employee or volunteer might potentially object, including reproductive-health services, care for LGBT patients, and end-of-life care.

115. The Rule thus creates especially strong disincentives for healthcare entities to provide reproductive-health services and services to LGBT patients, for fear that their funding (including their ability to obtain Medicare and Medicaid reimbursements) will be terminated and their ability to provide medical care to underserved populations will be severely reduced or curtailed.

116. The threat of punitive sanctions under the Rule also will deter healthcare facilities from taking remedial action against discrimination by an employee against patients or other employees, even when that discrimination is *not* tied to any religious belief.

E. The Rule’s Immediate and Irreparable Harms

1. Overview

117. The Denial-of-Care Rule will harm local governments, hospitals, small clinics, local providers, community centers, healthcare and professional associations and their members, and

1 their patients. These harms will occur nationwide. They will directly and irreparably injure
2 Plaintiffs, their members, their employees, and their patients.

3 118. The Rule privileges particular religious views over all other medical, legal, and
4 operational concerns, and it will force Plaintiff healthcare providers to rewrite their existing policies
5 to the extent that they are inconsistent with the Rule. Providers will have to choose between two
6 unacceptable courses of action: compromising their missions, operations, and medical ethics and
7 placing patients at risk by attempting to comply with the Rule, or jeopardizing the federal funding
8 supporting many of their most important functions and services. And even if providers attempt to
9 comply, the uncertainty created by the Rule will pose staffing, budgeting, and operational
10 dilemmas. The Rule fails to give providers necessary guidance on how the Rule will be applied. As
11 a result, it leaves providers unsure of what is required of them during emergencies, preventing them
12 from making critical judgments about the degree of redundant staffing and other measures that they
13 must implement to minimize the risk of harm to patients that may result from the Rule. The Rule
14 will further harm Plaintiffs' operations by undermining patient trust, constraining already limited
15 resources, and flooding Plaintiffs' facilities with patients denied care by other providers.

16 119. Patients will suffer the gravest harms. Some patients will be denied care (including
17 lifesaving care) or denied information needed for informed consent. Other patients will be exposed
18 to physical, mental, and dignitary harms, in violation of their constitutional rights. And many of the
19 most vulnerable patients will be afraid to give their providers information that is critical to
20 establishing the clinical relationship and guiding appropriate care—an unconstitutional chilling of
21 speech that harms patients and providers alike. If Plaintiffs are forced out of business or forced to
22 stop offering certain healthcare services, patients will be delayed in obtaining care and may be
23 entirely unable to obtain care.

24 120. The Rule threatens patients' ability to obtain needed and even emergency care in
25 accordance with their medical needs, and in some instances their own religious and moral beliefs,
26 particularly with respect to contraception, abortion, end-of-life care, and gender-affirming
27 healthcare. It encourages and in some instances may require the imposition of the beliefs of a single
28 employee on healthcare institutions and patients, thereby overriding or preventing patients' access

1 to healthcare. It also invites discrimination on the basis of sex, gender identity, transgender status,
 2 and disabilities such as addiction and positive HIV status. It deprives patients in need of
 3 reproductive healthcare and transgender and gender-nonconforming patients of their right to equal
 4 dignity and stigmatizes them as second-class citizens. And it impermissibly burdens and chills
 5 constitutionally protected speech by threatening to penalize certain individuals based on their
 6 gender identity, gender expression, or medical history.

7 121. The harms imposed on Plaintiffs, their members, and their patients reflect the harms
 8 that will be imposed on all similarly situated providers across the country. The Rule will be
 9 unworkable for any hospital or facility committed to providing objective, compassionate, and
 10 responsible abortion, contraception, or transition-related healthcare, because most, if not all,
 11 hospitals rely on HHS for a large percentage of their funding. Smaller medical providers may be
 12 forced to close or sacrifice elements of the care that they provide, compromising their core missions.
 13 And if Plaintiffs are either forced out of business or forced to stop offering certain healthcare
 14 services, patients will likewise be delayed in accessing care and in some instances will be entirely
 15 unable to access care.

16 122. Hospitals, clinics, community health centers, and other facilities that are unprepared
 17 to risk the loss of federal funding may entirely forgo providing abortion, contraception, or LGBT
 18 services (including referrals to such services). Indeed, the Rule will chill the provision of care in
 19 any medical facility that is unwilling or unable to take on the risks imposed by the Rule.

20 123. At facilities that do continue to provide services to which some staff members may
 21 object, the delivery of that care will suffer. Patients will be more likely to experience discriminatory
 22 treatment or be denied care altogether because a member of the workforce disapproves of them or
 23 the treatment they seek.

24 **2. Harms to the County of Santa Clara**

25 124. The County, through its departments and agencies, is committed to delivering high-
 26 quality care, including to underserved and vulnerable populations, in settings that protect and
 27 respect patients, their families, and providers alike. County departments already have in place
 28 nondiscrimination and conscience-objection policies that respect and comply with existing legal

1 requirements and medical ethics. If the Denial-of-Care Rule goes into effect, the County will
2 immediately need to rewrite and re-evaluate all of its conscience-objection policies, and it will need
3 to inquire as to the conscience objections of thousands of employees newly covered under the Rule.

4 125. For example, Valley Medical Center has a policy allowing its current and
5 prospective medical staff and employees to request in writing not to participate in certain patient
6 care that conflicts with staff members' cultural values, ethics, or religious beliefs. Once an
7 exemption is requested, the appropriate manager or director determines whether the request can be
8 granted in light of staffing levels and other relevant circumstances. If the request is granted, the
9 staff member's tasks, activities, and duties may be redistributed to ensure appropriate patient care.
10 The policy makes clear that requests for exemptions will not result in disciplinary or recriminatory
11 action. A manager or director may decline to accept an employee or medical-staff member for
12 permanent assignment, however, if the staff member has requested not to participate in an aspect
13 of care that is commonly performed in that assignment. The policy makes clear that patient care
14 must not be adversely affected by the granting of an exemption and that medical emergencies take
15 precedence over personal beliefs.

16 126. Valley Medical Center designed this policy to appropriately address the healthcare
17 needs of patients, including patients' rights to be treated in a nondiscriminatory manner, and Valley
18 Medical Center's need to plan in advance to ensure appropriate staffing, as well as to respect the
19 cultural values and ethical and religious beliefs of employees. Without prior notice and the ability
20 to plan assignments around conscience objections, the County would be unable to staff many of its
21 operations appropriately. Further, it is critical to patient care and to hospital functionality that
22 Valley Medical Center be able to rely on all medical staff to assist a patient in the event of an
23 emergency.

24 127. O'Connor and St. Louise Hospitals have similar policies regarding religious and
25 moral objections to providing certain patient care, with comparable requirements for advance notice
26 and attending to emergencies. In the near future, those facilities will transition to the Valley Medical
27 Center policy, as part of their ongoing integration into the County's health system.
28

1 128. The County is extremely concerned about the lack of an emergency exception on
2 the face of the Rule. An objector's refusal to assist in patient care during an emergency could lead
3 to delays in care and worse medical outcomes, including fatalities. If it cannot rely on all staff to
4 provide care in an emergency, the County will have to consider whether backup or double staffing
5 is necessary to protect patient welfare. Moreover, the Rule's lack of clarity about whether and when
6 an emergency exception exists creates unacceptable operational uncertainty, leaving the County in
7 the dark about what policies it would need to put in place around emergencies to be able to certify
8 compliance with the Rule.

9 129. Further, under a regime that permits only occasional inquiry into employees'
10 objections and only voluntarily accepted accommodations, the County will be unable to ensure
11 proper patient care. For example, at some County-run pharmacies, there is only one pharmacist on
12 site at any given time. Patients will be prevented from obtaining their prescribed medications if a
13 pharmacist unilaterally decides not to provide certain types of medication, or not to serve certain
14 people, without first discussing the issue with a manager and agreeing to some accommodation.

15 130. The requirement that accommodation be "voluntarily accept[ed]," 84 Fed. Reg. at
16 23,263, § 88.2—meaning that staff must consent to any reassignment or shifting of hours made to
17 account for religious objections—will similarly pose staffing challenges for the County's many
18 critical health-related programs. The County must ensure that there are sufficient non-objecting
19 staff members to cover each shift and ensure continuous patient care. If an employee's religious
20 objection is incompatible with that person's role, the person may need to be reassigned to another
21 role. And for some positions, no accommodation will be possible. For example, if a receptionist
22 objected to informing people that County hospitals provide contraceptive and abortion care and
23 also objected to connecting patients with someone who could discuss those options, there would be
24 no accommodation the County could offer that would avoid compromising access to care.

25 131. The Rule allows for an employer to ask for notice of an employee's religious or
26 moral objections once a year. But it does not address what should happen if an employee develops
27 an objection after having already told the employer that he or she has no objections. The County
28 must be able to obtain or require notice of all religious or moral objections; otherwise, it could face

1 a situation where a staff member unexpectedly objects to care, leading to staffing issues and lack
2 of continuous patient care. Under the Rule, the County could be wholly unaware that an objector
3 had ceased performing his or her assigned duties on the basis of a religious or moral objection,
4 which would gravely compromise patient care and the functioning of the County's health systems.
5 The Rule's failure to address these concrete logistical issues poses significant operational
6 challenges to the County and unacceptable health risks to patients.

7 132. The Rule will have grave effects on the County's Gender Health Center. The
8 Clinic's mission is to provide the care necessary for people of all ages to understand and explore
9 their gender identity. The Rule will imperil that mission because it will require the County to allow
10 employees who object on religious or moral grounds to the Clinic's mission to work in that setting.

11 133. The Rule's notice provision will adversely affect the County. The Rule's model
12 notice tells employees that they "have the right to decline to participate in, refer for, undergo, or
13 pay for certain health care-related treatments, research, or services . . . which violate your
14 conscience, religious beliefs, or moral convictions under Federal law." That might encourage or
15 suggest that it is permissible for employees to, for example, refuse to treat a transgender patient
16 who comes to the emergency room seeking care for a broken arm, based on the provider's "moral
17 convictions," even though refusal of service would violate federal nondiscrimination law and
18 EMTALA, 42 U.S.C. § 1395dd. And if the patient sees the notice, the patient would be discouraged
19 from communicating openly with the provider, for fear that services will be denied. Under the Rule,
20 the County must choose between displaying the model notice, or something like it, and risking loss
21 of federal funding for its decision not to display the model notice.

22 134. In the County's view, complying with the Denial-of-Care Rule is operationally
23 unworkable, endangers patient health, and creates insurmountable staffing challenges. Further, the
24 Rule will require the County to risk malpractice actions or other suits by patients whose healthcare
25 was negatively affected by a County employee's refusal to provide care. Were the County to fail to
26 provide care in an emergency situation because of an employee's religious or moral objection, the
27 County might run afoul of state and federal laws requiring hospital emergency departments to
28 provide evaluation and emergency aid and requiring its Behavioral Health Services Department to

1 provide timely access to an adequate network of mental-health care. *See* EMTALA, 42 U.S.C.
 2 § 1395dd; Cal. Health & Safety Code §§ 1317-1317.10 (2008); 42 C.F.R. §§ 438.206-438.208.

3 135. The County faces withdrawal or even clawback of hundreds of millions of dollars
 4 in federal funding annually if the Rule is enforced against it. 84 Fed. Reg. at 23,271, § 88.7(i).
 5 Without federal funding, the County's ability to provide a broad range of quality health services to
 6 many thousands of patients—including to infants and children, those with chronic diseases, the
 7 indigent, and the elderly—would be greatly diminished or potentially eliminated. These vulnerable
 8 patients would face increased healthcare costs and would likely have little choice but to forgo care
 9 or to seek it in already crowded emergency rooms of other hospitals. And those patients may face
 10 additional barriers to treatment at those hospitals if those hospitals are covered by the Rule.

11 136. Because Valley Medical Center and other County healthcare facilities are safety-net
 12 providers that primarily serve low-income individuals, vulnerable communities will be severely
 13 harmed by a loss of federal funding. For example, the Public Health Department's direct services
 14 primarily benefit low-income persons, children, people of color, and people living with chronic
 15 diseases such as HIV/AIDS. Because all 15 cities within the County are dependent on the County's
 16 public health department, many, if not most, of these individuals simply would not get the care and
 17 resources that they need without federally funded services from the Public Health Department.

18 137. Further, the Rule creates untenable budgetary uncertainty for the County as a whole,
 19 because the County is unsure what the Rule requires and whether the County is able to comply with
 20 the Rule. This makes it infeasible for the County entirely to mitigate the risk that noncompliance
 21 with the Rule could cause the County to lose more than a billion dollars in necessary federal
 22 funding.

23 2. Harms to Private Healthcare Providers

24 138. Plaintiffs include clinics and healthcare providers that operate independently from
 25 other healthcare systems, each with missions that include providing comprehensive and
 26 compassionate care. For example, Trust Women Seattle's mission is to treat patients with dignity,
 27 empathy, and respect, to give them complete and accurate medical information and to empower
 28 them to make decisions free from judgment or disruptions in their care. Likewise, the mission of

1 the LA LGBT Center—the Nation’s largest provider of LGBT medical and mental-health
2 services—is to provide a safe and affirming environment for LGBT people seeking healthcare
3 services. To fulfill that mission, the LA LGBT Center must be able to treat its patients with dignity,
4 empathy, and respect; to give them complete and accurate medical information; and to empower
5 them to make decisions free from judgment or disruptions in their care. At Hartford Gyn, clinic
6 procedures and practices are designed to ensure that patients receive the highest quality,
7 nonjudgmental care. Hartford Gyn and Trust Women have taken a public stance defending
8 reproductive rights. Abortion clinics and their patients are routinely targeted and harassed,
9 including by protestors outside clinics and by groups and individuals who pose grave security
10 threats to physicians, staff, and volunteers. Hartford Gyn and Trust Women have been targeted by
11 the anti-choice movement for harassment and threatened violence, and they are symbols of the
12 determined provision of constitutionally protected care. Ensuring the safety of everyone in the
13 clinic, including patients, is of paramount concern for both providers.

14 139. Whitman-Walker, Bradbury-Sullivan Center, Center on Halsted, and the Mazzoni
15 Center also are mission-driven healthcare providers and entities.

16 140. In the reproductive-healthcare and LGBT-healthcare settings, the Rule invites
17 individuals to deny patients care and information, which will threaten both the health of patients
18 and the sustainability of the providers’ operations. The Rule will frustrate these mission-driven
19 providers’ ability to hire personnel who will work to support their missions. By expanding the
20 definition of what it means to “assist in the performance” of a procedure to include people not
21 directly engaged in providing care, and by inviting religious or moral objections without notice to
22 patients or providers, the Rule threatens grave harms to the healthcare-provider Plaintiffs’
23 operations, provision of care to their patients, their core missions, and their reputations.

24 141. The Plaintiff healthcare providers seek to empower patients to make their own
25 decisions. But the Rule’s broad definitions invite an employee to substitute his or her own opinion
26 about a patient’s care for sound medical judgment and the patient’s consent. As with Santa Clara,
27 these providers could face situations in which a staff member unexpectedly objects to care, leading
28 to staffing issues and inadequate responses in an emergency. Even worse, Plaintiffs could be wholly

1 unaware that an objector has ceased performing his or her assigned duties on the basis of a religious
2 or moral objection, or has turned a patient away altogether, which would gravely compromise
3 patient care and Plaintiffs' missions. The Rule's failure to address these concrete logistical issues
4 poses unacceptable operational challenges and health risks to patients.

5 142. Small providers face a significant concern that staff members who assert
6 unanticipated objections will be able to unilaterally veto key aspects of patient care. This concern
7 affects even clinics devoted to providing reproductive or LGBT care. For example, someone willing
8 to process billing for pregnancy services may have objections to contraception or abortion, or
9 someone comfortable with scheduling an appointment for gay patients may have objections to
10 transgender patients. Because the Rule is designed to protect objectors from any consequences,
11 providers may be forced to reorganize their staffing structures, consume precious resources with
12 unnecessary workarounds, duplicate staffing in cost-prohibitive ways, unfairly burden
13 nonobjecting employees, reduce services, and even close programs in an attempt to reduce the risk
14 that a single employee will deny care or information to a patient.

15 143. Trust Women Seattle, for example, is a small business. It cross-trains clinical and
16 some nonclinical staff to serve multiple roles, many of which touch on providing information about
17 or scheduling, or directly providing abortion, contraception, or transgender healthcare. Likewise,
18 Hartford Gyn must operate efficiently because of its already limited income. In order to do so, all
19 staff must perform functions that touch on providing abortion and contraception. No alternative
20 human-resources structure could sustain the clinic.

21 144. At Trust Women Seattle, some employees monitor the provision of abortion care
22 and contraceptive care at the clinic. Others perform medication management, sanitize instruments,
23 and clean operating rooms and laboratories that may be used for general gynecological exams one
24 day and the provision of contraception or hormone therapy the next. Under the Rule, these sanitary
25 and custodial activities could fall within the definition of "assist in the performance," though they
26 do not involve the direct provision of care.

27 145. Further, Trust Women has an emergency policy requiring all office personnel to be
28 familiar with the facilities' agreements to transfer patients to other facilities in the case of an

1 emergency. This policy requires that any staff member assist in an emergency transfer, even if only
2 by calling ahead to the hospital. Hartford Gyn likewise has emergency practices requiring all staff
3 to be willing to help in an emergency. Trust Women also has a “no turn-away” policy for patients
4 and a nondiscrimination policy. To the extent that the Rule would prevent Trust Women and
5 Hartford Gyn from continuing to enforce these policies, it would be unworkable. To the extent that
6 they would be prevented from requiring that front-facing employees like receptionists (who do not
7 assist in procedures according to Trust Women’s current understanding) are compassionate and
8 supportive of the independent decision-making of patients, it would both undermine Trust
9 Women’s business and inhibit its patients’ access to healthcare.

10 146. The Rule will strain already limited resources. Because patients will fear refusal of
11 care at traditional healthcare facilities, providers such as the LA LGBT Center and Whitman-
12 Walker that specialize in reproductive and LGBT healthcare likely will see an increase in demand
13 resulting from patients’ hope that those clinics, which are designed to meet their specific needs,
14 will remain safe spaces. The same is true for plaintiffs who provide abortion and contraception
15 care. Such an increase will strain the limited resources of these providers. At the same time, the
16 providers will need to invest resources in educating the community about the Rule and in battling
17 the erosion of community members’ confidence in the healthcare system that will result from the
18 Rule’s application. These consequences will increase the LA LGBT Center’s and Whitman-
19 Walker’s operating costs and will take a toll on the health and well-being of the LGBT community.

20 147. In anticipation of the release of the Rule, Center on Halsted’s staff already has been
21 forced to devote resources to addressing the Rule. It has conducted additional “Know Your Rights”
22 programming regarding discrimination against LGBT people; sent and prepared staff to attend
23 meetings and events with other LGBT stakeholders in the city; and held internal training for staff
24 to manage the added strains on the mental health of Center on Halsted’s patients. This diversion
25 and additional expenditure of resources frustrates Center on Halsted’s efforts to counsel those
26 whom it serves and to advocate for them to receive necessary healthcare services from outside
27 organizations.
28

148. As a result of the Rule, Bradbury-Sullivan Center will be required to redirect its staff and resources from providing its own services to assisting patrons in determining who among the healthcare providers in the region will serve LGBT patients in a nondiscriminatory manner. Indeed, Bradbury-Sullivan Center already has had to divert staff and resources from other program activities to advocacy, policy analysis, and development of additional resources to address the ill effects of the Rule.

149. Loss of funding threatens dire results for these Plaintiffs. For example, Trust Women Seattle and Hartford Gyn are dependent on Medicaid funding to continue providing the full range of services they offer patients and keep their doors open.

3. Harms to Patients

150. If implemented, the Rule will harm Plaintiffs' patients. The Rule attacks access to reproductive and LGBT healthcare at hospitals, clinics, and other facilities throughout the country and invites an unprecedented number of individuals to delay or deny care to patients, directly affecting the patients' access to healthcare. As detailed in the comments to the proposed Rule, discrimination against these patients already is widespread and well-known, as are the harms that result from delayed and denied care.

a. Harms to patients generally

151. Healthcare refusals often result in significant costs for and harms to patients. Under the Rule, an individual employee, because of that employee's morally or religiously motivated refusal to provide care, may force a patient to choose between forgoing care or taking on the burden of locating and traveling to a willing provider. When patients are turned away from a doctor's office or a hospital without a referral or even basic information about their condition or treatment options, they must find willing providers to provide the healthcare that they need. They incur additional expenditures of time and money researching and trying other providers, including additional time off work for new appointments. In areas with a limited number of affordable healthcare providers, patients may need to travel long distances to find care, requiring additional travel expenses, sometimes including overnight stays and childcare. The harms from the additional time and expense

1 fall most heavily on low-income individuals and those without the job flexibility to take paid sick
2 time. Some patients will lack the resources to continue to pursue the treatment they need.

3 152. Patients seeking treatment from healthcare entities of last resort, such as the County
4 and other Plaintiffs, may be entirely denied the care that they seek and desperately need.

5 153. The Rule may result in denials of time-sensitive or emergency care, putting patients'
6 health and even their very lives at substantial risk.

7 154. Because the Rule does not always require objecting providers to alert either their
8 employers or the patients about religious or moral objections (and permits healthcare employers to
9 require such notice only in limited circumstances), the Rule may mean not only that some patients
10 will be denied necessary care, but also that those patients will not know that they are being denied
11 that care on the basis of an employee's religious objection. That will be true even if the patient
12 chooses to go to a particular healthcare facility because the facility normally provides that care.
13 Either way, the patient is harmed. If patients know that they are being denied care because of who
14 they are or what services they seek, that is a stigmatizing and potentially traumatizing experience.
15 If patients do not know that they are being denied the care that they seek, they will not know to
16 seek it elsewhere and their healthcare needs will remain unmet.

17 **b. Special burdens on reproductive rights**

18 155. The Rule threatens to impede or eliminate access to abortion and contraception.

19 156. Patients who are denied contraception are less able to safeguard their own health
20 and welfare.

21 157. The ability to prevent or space pregnancy, facilitated by easy and affordable access
22 to contraception, has significant health benefits.

23 158. Abortion is a fundamental part of healthcare. It is a common medical procedure: one
24 in three women in the United States has undergone an abortion and an estimated one in four women
25 will need an abortion in the future. And it is extremely safe: it is 14 times safer than childbirth and
26 even safer than a shot of penicillin. But abortion care already is a marginalized healthcare service,
27 often provided at clinics that operate independently from other healthcare systems. Because of
28 increasing regulation and targeting of abortion clinics and their staff for violence and harassment,

1 there is a national shortage of abortion providers in the United States, and their numbers are
2 shrinking. As a result, a woman who is denied abortion care at a healthcare facility may find it
3 difficult to find an available provider in a reasonable timeframe. Eighty-nine percent of counties in
4 the United States do not have a single abortion clinic, and some counties that have a clinic provide
5 abortion services only on certain days. Several States have only one clinic that provides abortion
6 care anywhere within the State.

7 159. Reproductive choice is a reality for patients only when there are enough family
8 planning providers available to meet patients' needs and those providers are available in an
9 equitable distribution. Currently, the supply of those providers is not meeting the needs of U.S.
10 patients, in large part because facilities providing abortion are increasingly concentrated in cities,
11 and very few primary-care providers are skilled in family-planning services.

12 160. Four of the ten largest healthcare systems in the United States by hospital count are
13 now religiously sponsored, often because of hospital consolidations between Catholic or other
14 religious healthcare systems and secular institutions. As a result of hospital mergers and other
15 factors, significant parts of the Southern and Midwestern United States have deserts of abortion
16 training and care.

17 161. Hospitals across the United States are large businesses that demand significant
18 administrative resources. Many hospitals already decline to provide contraception and abortion
19 because of the effort required to accommodate refusals and the additional expense that they entail.
20 If the Rule goes into effect, the United States will see an even more dramatic reduction in the
21 number of large medical education institutions that provide abortions and teach students and
22 residents about it. Access to these services in the United States already is very limited, and the Rule
23 will immeasurably exacerbate the problem.

24 162. Because of the shortage of providers, patients already must travel long distances
25 (and incur the associated costs) to obtain abortion care. In addition, in some areas the shortage of
26 providers results in significantly increased wait times or leads to some patients' being turned away
27 altogether.
28

1 163. Delays in obtaining an abortion compound the logistical and financial burdens that
2 patients face and substantially increase the health risks to patients. On average, patients must wait
3 at least a week between initially attempting to make an appointment and receiving an abortion.
4 Delays also increase the cost of an abortion, because abortions during the second trimester are
5 substantially more expensive than during the first trimester: The median price of a surgical abortion
6 at ten weeks is \$508; the cost at 20 weeks rises to \$1,195. Other costs also increase with delays.
7 For example, one recent study found that Utah's mandatory waiting period caused 47 percent of
8 women having an abortion to miss an extra day of work. More than 60 percent of the women in the
9 study were negatively affected in other ways, including having to pay increased transportation
10 costs, lost wages, or having to disclose the abortion to someone whom they otherwise would not
11 have told. Delays in obtaining an abortion also mean that patients obtain that care in later stages of
12 pregnancy. Although abortion is a safe procedure, risks increase with later gestational ages. Patients
13 approaching legal limits in their State for obtaining a medical abortion may be forced to seek care
14 in another State. Because the Rule will create incentives for more healthcare providers to stop
15 offering abortion services, it will increase delays and add to the costs of obtaining an abortion.

16 164. The Rule also further stigmatizes abortion and contraception. Stigma has
17 tremendous impact on patients, fostering fear and psychological stress. When patients perceive the
18 community's disapproval of their choice, they feel the need to maintain secrecy around their
19 decisions and will be deterred from seeking care out of fear of judgment and discrimination.

20 165. Patients seeking treatment from healthcare entities of last resort, such as the County
21 and other Plaintiffs, may be entirely denied the care that they seek and desperately need, even in
22 emergency situations. This will put patients' health and even their lives at substantial risk. If
23 patients are denied care entirely, they will encounter a whole host of additional harms. Denying
24 someone an abortion and forcing them to carry to term increases the risk of serious health harms,
25 including eclampsia and death. In addition, denying someone an abortion may lead to increased
26 risk of life-threatening bleeding, cardiovascular complications, diabetes associated with pregnancy,
27 as well as all other risks of pregnancy. A pregnant person is 14 times more likely to die from giving
28 birth than from having an abortion.

1 166. Whether because patients encounter an objector, providers are forced to close their
2 doors, or patients are deterred from seeking care because of stigma and fear of discrimination,
3 individuals seeking abortion and contraception will be either delayed or totally denied such care
4 because of the Rule.

5 167. Objections to other types of procedures will also increase healthcare costs. For
6 example, a patient who has a cesarean section and wants to have a postpartum tubal ligation
7 immediately following delivery might be denied that option by an employee of a healthcare facility
8 who objects to the latter procedure—even though having the procedure at that time is medically
9 recommended, presents fewer risks to the patient, and is more cost-effective than delaying the
10 procedure. If the patient cannot have that procedure immediately following delivery, the patient
11 must first recover from the cesarean surgery and then schedule the tubal ligation at least six weeks
12 later, when the patient is busy caring for a newborn; the patient will be required to go to another
13 doctor and possibly a different hospital; will have to arrange for the transfer of medical records;
14 and will incur duplicative costs and duplicative risks, pain, and recovery time for the second round
15 of anesthesia and invasive surgery.

16 **c. Special burdens on LGBT patients**

17 168. The Rule imposes particular burdens on transgender and gender-nonconforming
18 people as well. Transgender people are defined as transgender because their gender identity does
19 not align with the sex that they were assigned at birth. Gender identity refers to an individual's
20 sense of being a particular gender, and constitutes an essential element of human identity. Everyone
21 possesses a gender identity, which is innate, has biological underpinnings, and is fixed at an early
22 age. An individual's sex is generally assigned at birth solely on the basis of visual observation of
23 external genitalia. Other sex-related characteristics such as chromosomes, hormone levels, internal
24 reproductive organs, secondary sex characteristics, and gender identity typically are not assessed
25 or considered during the assignment of sex at birth. Most people have a gender identity that matches
26 their sex assigned at birth and other sexual characteristics.

27 169. Where an individual's gender identity does not match that individual's sex assigned
28 at birth, gender identity is the critical determinant of sex. External genitalia are but one of several

1 sex-related characteristics and are not always indicative of a person's sex. A scientific consensus
2 recognizes that attempts to change an individual's gender to bring it into alignment with the sex
3 assigned at birth are ineffective and harmful.

4 170. The dissonance between individuals' gender identity and the sex that they were
5 assigned at birth can be associated with clinically significant distress, which is known as gender
6 dysphoria. Gender dysphoria is a medical condition recognized in the American Psychiatric
7 Association's Diagnostic and Statistical Manual of Mental Disorders and by leading medical and
8 mental-health professional groups, including the AMA and the American Psychological
9 Association (APA).

10 171. Gender dysphoria can be treated in accordance with internationally recognized
11 Standards of Care formulated by the World Professional Association for Transgender Health and
12 recognized as authoritative by national medical and behavioral health organizations such as the
13 AMA and APA.

14 172. The ability to live in a manner consistent with one's gender identity is critical to a
15 person's health and well-being and is a key aspect in the treatment of gender dysphoria. The process
16 by which transgender people come to live in a manner consistent with their gender identity, rather
17 than the sex they were assigned at birth, is known as transition. The steps that each transgender
18 person takes to transition are not identical, but usually include social, legal, and medical transition.
19 Medical transition includes treatments that bring transgender people's bodies into alignment with
20 their gender identity, such as hormone-replacement therapy or surgical care such as hysterectomy
21 or orchiectomy. Whether any particular treatment is medically necessary or even appropriate
22 depends on the medical needs of the individual.

23 173. All Plaintiffs, regardless of whether they provide particular transition-related
24 treatments and services, are committed to providing inclusive and individually tailored gender-
25 affirming care and services that respect each patient's gender identity and status without
26 discrimination, in accordance with medical and ethical standards of care.

27 174. LGBT individuals, and especially transgender and gender-nonconforming people,
28 already face particularly acute barriers to care and health disparities that will be compounded by

1 the Rule. A majority of LGBT patients fear going to a healthcare provider because of past
2 experiences of anti-LGBT bias in a healthcare setting. Many LGBT patients report negative
3 experiences, including hostility, discrimination, and denials of care, when they disclose to
4 healthcare providers their sexual orientation, history of sexual conduct, gender identity, transgender
5 status, or history of gender-affirming medical treatment, and related medical histories.

6 175. For example, multiple LGBT patients at Whitman-Walker have previously been
7 refused medical care, including routine care unrelated to gender dysphoria, by providers outside of
8 Whitman-Walker simply because they are transgender or gay. In one instance, a radiological
9 technician refused to perform an ultrasound for testicular cancer on a transgender patient. In
10 another, a healthcare worker at a dialysis clinic confronted a Whitman-Walker patient with end-
11 stage renal disease and objected to being involved in the patient's care because of hostility to his
12 sexual orientation. In another, after a Whitman-Walker patient—a transgender teenager—was
13 hospitalized in a local hospital following a suicide attempt, the staff would only address or refer to
14 the young person with pronouns inconsistent with their gender identity, exacerbating the teenager's
15 acutely fragile state of mind. Local hospitals and surgeons have refused to perform transition-
16 related surgeries on Whitman-Walker transgender patients, even when they routinely perform the
17 very same procedures on non-transgender patients, including in situations when the patient's
18 insurance would have covered the procedure or when the patient was able to pay for the procedure.
19 Many local primary-care physicians unaffiliated with Whitman-Walker have refused to prescribe
20 hormone therapy for transgender patients. And multiple Whitman-Walker patients have been
21 denied prescriptions by pharmacists. Behavioral-health providers at Whitman-Walker report that
22 the vast majority of transgender patients—as many as four out of five—report instances of
23 mistreatment or discrimination by healthcare providers, hospitals, clinics, doctors' offices, or other
24 facilities outside of Whitman-Walker.

25 176. Patients of the LA LGBT Center report similar experiences of discrimination by
26 other providers. One transgender patient, who developed profuse bleeding after surgery, was denied
27 treatment at an emergency room and arrived at the LA LGBT Center in distress three days later,
28 having lost a significant amount of blood. Another patient required extensive surgery to repair

1 damage caused by a prior silicone breast-augmentation procedure. But she was turned down by an
2 academic plastic-surgery center in Los Angeles because her surgeon there said that her health
3 problems were caused by her own poor decision-making and she therefore would not be considered
4 for treatment. By the time she was able to identify a surgeon who was willing to treat her, with the
5 assistance of a physician at the LA LGBT Center, years had passed and her condition had become
6 life-threatening. For patients at the LA LGBT Center, the ability to receive gender-affirming
7 medical care can mean the difference between life and death.

8 177. In many geographic regions, a majority of LGBT people lack a provider whom they
9 consider to be their personal doctor. As a result, when they seek healthcare services, they are likely
10 to encounter a healthcare provider with whom they do not have a relationship. This makes them
11 especially vulnerable to discriminatory treatment from providers who are not LGBT-affirming. For
12 some medical specialties, there are only a handful of healthcare providers in the region who have
13 the expertise necessary to treat a patient for a particular condition, so a denial of care from even
14 one provider could make it practically impossible for an LGBT patient to receive any care at all.

15 178. In a recent study, nearly one in five LGBT people, including 31 percent of
16 transgender people, said that if they were turned away from a hospital, it would be very difficult or
17 impossible to get the healthcare that they need elsewhere. The rate was substantially higher for
18 LGBT people living in non-metropolitan areas, with 41 percent reporting that it would be very
19 difficult or impossible to find an alternative provider. Even when they are able to get access to care,
20 many individuals report that healthcare professionals have used harsh language toward them,
21 refused to touch them, used excessive precaution, or blamed the individuals for their health status.

22 179. Consequently, LGBT patients are disproportionately likely to delay preventative
23 screenings and necessary medical treatment and therefore to end up with more acute health
24 problems and outcomes. Research has identified pervasive health disparities for LGBT people with
25 respect to cancer, HIV, obesity, mental health, tobacco use, and more. In other words, LGBT
26 people, who are disproportionately likely to need a wide range of routine medical care, already
27 have reason to fear, and often do fear, negative consequences of “coming out” to healthcare
28

1 providers about their sexual orientation, history of sexual conduct, gender identity, transgender
2 status, history of gender-affirming medical treatment, and related medical histories.

3 180. The Rule encourages these patients to remain closeted to the extent possible when
4 seeking medical care. But remaining closeted to a health care provider may result in significant
5 adverse health consequences. For instance, a patient who conceals or fails to disclose a same-sex
6 sexual history may not be screened for HIV or other relevant infections or cancers, or may not be
7 prescribed preventative medications such as Pre-Exposure Prophylaxis or PrEP, which is extremely
8 effective at preventing HIV transmission. Patients who fail fully to disclose their gender identity
9 and sex assigned at birth may not undergo medically indicated tests or screenings (such as tests for
10 cervical or breast cancer for some transgender men, or testicular or prostate cancer for some
11 transgender women). The barriers to care are particularly high for transgender individuals. Nearly
12 one-quarter of transgender individuals report delaying or avoiding medical care when sick or
13 injured, at least partially because of fear of discrimination by and disrespect from healthcare
14 providers.

15 181. In the past, OCR has investigated numerous complaints from transgender patients
16 about being denied certain health services, ranging from routine to life-saving care, because of the
17 patients' gender identities. The Rule will make it more likely that these patients will be denied care
18 or will avoid seeking care altogether.

19 **d. Harms to vulnerable populations**

20 182. The effects of refusals will fall particularly heavily on rural patients in need of
21 reproductive healthcare. These patients are four times more likely than urban dwellers to reside in
22 medically underserved communities. Reproductive-health services are especially difficult for rural
23 patients to obtain because obstetric and gynecologic services and other medical specialties are not
24 common in rural settings. Further, for healthcare providers such as the County of Santa Clara that
25 operate clinics and hospitals in rural communities, experience has shown that reproductive health
26 care and gender-affirming health care are frequently in demand, contrary to the Department's
27 assertion that patients in rural communities may be more likely to share providers' religious
28 objections and therefore are not likely to seek such care. *See* 84 Fed. Reg. 23,181. The inappropriate

1 expansion of refusals under the Denial-of-Care Rule will undoubtedly exacerbate the harms to these
2 individuals.

3 183. Patients and recipients of non-medical services coming to Trust Women Seattle,
4 Hartford GYN Center, Whitman-Walker, the LA LGBT Center, Bradbury-Sullivan Center, Center
5 on Halsted, and the Mazzoni Center have been disrespected and demeaned by other healthcare
6 providers for their reproductive and LGBT healthcare decisions and will have no other options if
7 they cannot obtain care from these providers. These Plaintiffs serve communities with already
8 limited options for healthcare services.

9 184. For example, in the region where Bradbury-Sullivan Center is located, there often
10 is only one or very few healthcare providers who have the specialty necessary to treat an LGBT
11 patient for a specific service, so a denial of care from that provider could make it practically
12 impossible for a patient to receive any care at all. And some of the region's healthcare providers
13 are religiously affiliated organizations that could claim religious objections to providing care to
14 LGBT people, exempting them under the Rule from adhering to existing nondiscrimination laws
15 and standards.

16 185. The Rule will chill the expressive rights of Plaintiffs' patients by causing them to
17 hide their identities and same-sex relationships when seeking healthcare services from other
18 organizations with religious objections to serving LGBT people.

19 186. Further, the additional demand for services and advocacy caused by discrimination
20 resulting from the Rule will drain the resources of these Plaintiffs.

21 **4. Harms to Medical-Association Plaintiffs**

22 **a. AGLP**

23 187. The Denial-of-Care Rule will harm AGLP, its members, and the patients whom they
24 treat because the Rule threatens AGLP's federal funding. AGLP's members depend on that funding
25 to provide vital services and to conduct critical medical research. In addition, the Rule will frustrate
26 AGLP's mission of achieving and enforcing safe workspaces for LGBT psychiatrists and
27 nondiscriminatory healthcare services for AGLP members' patients. The Rule also will frustrate
28 AGLP's mission of advocating for nondiscriminatory standards of care for patients, culturally

competent standards of care for treatment of LGBTQ patients, and nondiscriminatory work environments for members that protect against discrimination on the basis of sexual orientation and gender identity.

188. The Rule invites additional burdens, harassment, and even discriminatory treatment of AGLP members in the workplace by fellow employees who will claim that that the Rule gives them a right to accommodations for discriminatory behavior. AGLP members and their LGBTQ patients are stigmatized and demeaned by the message communicated by the Rule—that their government privileges beliefs that disparage transgender people and their medical needs, and invites denials of care at the cost of the dignity and physical and mental health of patients based solely on transgender status.

b. MSFC

189. The Rule will also cause severe harms to MSFC and its members.

190. First, medical students receive their clinical training disproportionately at academic medical centers and teaching hospitals that receive significant federal funding. Likewise, residents depend on federal funding for their continuing medical education. If HHS determines that the institutions at which these individuals work are violating the Rule, their funding to continue working at that institution may be reduced or eliminated. Those institutions also may stop providing certain services or training in order to avoid risk of catastrophic sanctions under the Rule.

191. Second, MSFC is committed to creating the next generation of abortion providers. There is already a shortage in training opportunities. For example, members of MSFC have reported instances in which facilities across the nation have ceased providing these services based on the religious or moral objection of select staff or funders or because of the stigma and controversy surrounding these services. Even in progressive States, religious refusals by hospital leadership have already pushed abortion training out of certain facilities. Further, mergers of secular teaching hospitals with religiously affiliated facilities have reduced the number of facilities that provide abortion training, and clinic closures across the country further threaten access to training and services.

192. The Rule is so broad as to be unworkable for some hospitals and other facilities providing abortion and contraception, creating incentives for institutions to stop providing and training for abortion services. As a consequence, MSFC members will be able to acquire training at a shrinking number of facilities. As training programs grow more limited, fewer new physicians will be able to achieve competency in family planning sufficient to join existing practices or clinics right out of medical school or residency. The result will be a shrinking pool of providers that will be unable to replenish itself through normal training programs, significantly longer wait times even for patients who are able to travel and can afford to obtain care from trained providers, and decreased access to care for patients around the country.

c. GLMA

193. If not enjoined, the Denial-of-Care Rule will harm both GLMA members and the LGBT patients whose interests GLMA represents. The Rule creates a safe haven for discrimination and prevents GLMA from achieving its goals with professional accreditation bodies by preventing such bodies from holding healthcare providers accountable for discrimination against LGBT people and denial of care whenever the discriminatory conduct is ostensibly grounded in religious beliefs.

194. GLMA collaborates with professional accreditation bodies, such as The Joint Commission, on the development, implementation, and enforcement of sexual-orientation and gender-identity nondiscrimination policies as well as cultural-competency standards of care for treatment of LGBT patients. GLMA has worked with The Joint Commission, and continues to work with similar professional bodies and health-professional associations, on standards, guidelines, and policies that address LGBT health and protect individual patient health and public health in general.

195. In order for a healthcare organization to participate in and receive federal payment from Medicare or Medicaid programs, the organization must meet certain requirements, including a certification of compliance with health and safety requirements. That certification is achieved based on a survey conducted either by a state agency on behalf of the federal government, or by a federally recognized national accrediting organization. Accreditation surveys include requirements that healthcare organizations not discriminate on the basis of sex, sexual orientation, or gender identity in providing services or in employment. A healthcare organization that discriminates in

1 those ways or that otherwise deviates from medical, professional, and ethical standards of care can
2 lose its accreditation.

3 196. As explained above, all of the leading health-professional associations, including
4 the AMA, have adopted policies stating that healthcare providers should not discriminate in
5 providing care for patients and clients because of sexual orientation or gender identity.

6 197. The Rule presents a direct conflict with nondiscrimination standards adopted by the
7 Joint Commission and all the major health-professional associations, which have recognized the
8 need to ensure that LGBT patients are treated with respect and without bias or discrimination in
9 hospitals, clinics, and other healthcare settings.

10 198. The Rule would prevent state agencies and other recipients of federal funds from
11 recognizing, to the extent allowed by law, the loss of accreditation of a healthcare organization
12 because of specified anti-LGBT beliefs and denials of care. The Rule therefore will frustrate
13 GLMA's mission of achieving and enforcing accreditation standards relating to nondiscrimination
14 on the basis of sexual orientation and gender identity and cultural competency standards of care for
15 treatment of LGBT patients.

16 199. Some members of GLMA are employed by religiously affiliated healthcare
17 organizations (such as hospitals, hospices, or ambulatory-care centers) that receive federal funding.
18 These healthcare providers treat LGBT patients. Members of GLMA employed by religiously
19 affiliated providers will experience additional burdens for adhering to their medical and ethical
20 obligations to treat all patients in a nondiscriminatory manner, including providing all medically
21 necessary care that is in the patient's best interests.

22 200. The Rule invites harassment and discriminatory treatment of GLMA members in
23 the workforce by fellow employees who will claim that the Rule gives them a right to
24 accommodation for discriminatory behavior. GLMA members and their LGBT patients are
25 stigmatized and demeaned by the Rule's message that their government privileges beliefs that result
26 in the disapproval and disparagement of LGBT people in the healthcare context.

27 201. As an organization of health professionals who often serve and care for patients
28 from the LGBT community, GLMA knows that discrimination against LGBT individuals in

healthcare access and coverage remains a pervasive problem and that too often this discrimination is based on religious objections. GLMA members have reported numerous instances of discrimination in care based on religious grounds. Since HHS issued the proposed Rule, GLMA members shared with GLMA many ways that religious objections have been used to the detriment of the healthcare of LGBT patients.

CAUSES OF ACTION

FIRST COUNT

Administrative Procedure Act, 5 U.S.C. § 706(2)(A) Arbitrary And Capricious

202. Plaintiffs incorporate the preceding paragraphs as if fully set forth here.

203. Defendants are subject to the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq.* See 5 U.S.C. § 703.

204. The Denial-of-Care Rule violates the APA, 5 U.S.C. § 706(2)(A), because it is arbitrary, capricious, an abuse of discretion, and not in accordance with law, in that HHS failed adequately to consider important aspects of the issue, including harm to patients, costs to healthcare facilities, impracticability of the Rule for the efficient administration of healthcare facilities and programs and for delivery of health services, and possible alternatives to the Rule.

205. Commenters showed that the Denial-of-Care Rule will cause substantial harms to patients. The Rule nonetheless fails adequately to quantify and inappropriately disregards these costs and harms, particularly in its cost-benefit analysis. HHS also has ignored that the Rule is unnecessary and that current law provides sufficient protection for religious objectors while also considering patients' rights to care and information. Notwithstanding the concerns raised by commenters that the Rule would harm patients, HHS omitted from the Rule any provisions to lessen the Rule's adverse effects on the delivery of healthcare and on patients' health and well-being, instead opting to expand objection rights without regard to the practical effects of the rule on the healthcare system. Further, by failing to address the many issues arising from its requirements, or stating that they will be resolved on a case-by-case basis, the Rule leaves employers in the dark about what they may or may not do without running afoul of the Rule's prohibitions.

206. In addition, HHS adopted an unprecedented, confusing, and unreasonable definition of what it means to “discriminate” against an individual or entity based on a religious or moral objection. HHS’s definition would consider virtually any action to manage objections to be “discriminatory” unless the action falls within narrowly drawn and unworkable exceptions. These provisions contain no undue-hardship exception or legitimate-nondiscriminatory-reason defense, and they unreasonably limit the measures providers can take to accommodate religious and moral objections without compromising patient care.

207. Although Commenters detailed the substantial and potentially unmanageable costs of compliance with the Rule and other administrative burdens on healthcare facilities and providers that the Rule would impose, the Rule fails to take account of these costs and burdens.

208. In adopting the final Rule, HHS failed to consider pertinent data and failed to articulate a reasoned or legally sufficient basis for the Rule.

209. In adopting the Rule, HHS failed to consider alternative ways of achieving the objectives of the underlying statutes.

210. Additionally, HHS failed to respond adequately to significant comments critical of the proposed Rule that were submitted during the notice-and-comment period.

SECOND COUNT

Administrative Procedure Act, 5 U.S.C. § 706(2)(C)

Exceeds Statutory Authority

211. Plaintiffs incorporate the preceding paragraphs as if fully set forth here.

212. The Denial-of-Care Rule violates the APA, 5 U.S.C. § 706(2)(C), because it is greatly in excess of statutory jurisdiction, authority, or limitation.

213. When read together, HHS’s definitions of critical statutory terms—including “assist in the performance,” “referral or refer,” “health care entity,” and “discrimination”—are inconsistent with the statutory provisions that HHS purports to be construing, as well as the plain, accepted meanings of those terms. As a result, HHS’s construction of the statutory provisions that it purports to be implementing is inconsistent with the plain scope and meaning of those provisions, rendering the Rule in excess of statutory jurisdiction and authority.

THIRD COUNT

**Administrative Procedure Act, 5 U.S.C. § 706(2)(A)
Not in Accordance with Other Federal Laws**

214. Plaintiffs incorporate the preceding paragraphs as if fully set forth here.

215. The Denial-of-Care Rule violates the APA, 5 U.S.C. § 706(2), because it is arbitrary, capricious, an abuse of discretion, and not in accordance with law in that it conflicts with numerous federal laws. These laws include:

(a) 42 U.S.C. § 18114 (because the Rule will impede individuals’ timely access to medical care and information about treatment options);

(b) EMTALA, 42 U.S.C. § 1395dd(b)(1) and its implementing regulations (because the Rule will provide blanket license to emergency-room personnel to decline to provide or assist in the provision of emergency services, to decline to facilitate patients’ transfer to other facilities, or to decline to make referrals);

(c) ACA, 42 U.S.C. § 18023(d) (because the Rule contravenes the ACA’s prohibition against construing right-of-conscience exemptions to relieve any healthcare provider of the legal obligation to provide emergency services as required by State or Federal law, including the EMTALA);

(d) ACA, 42 U.S.C. § 18116 (because the Rule contravenes the statutory provisions stating that “[a]n individual shall not, on [a] ground prohibited under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or section 504 of the Rehabilitation Act of 1973, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance”);

(e) Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e *et seq.* (because in creating such expansive religious-accommodation requirements and inviting employees to veto the types of accommodations that may be offered, the Rule may require employing healthcare entities to take actions that are contrary to the rights of other employees to be free from the forms of discrimination prohibited by Title VII); and

(f) Title X of the Public Health Service Act, 42 U.S.C. §§ 300-300a-6 (because the Rule contravenes Congress' requirement that Title X grantees operate "voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services," 42 U.S.C. § 300(a), and because Title X appropriations bills, *e.g.*, 2019 Continuing Appropriations Act, Pub. L. No. 115-245, Div. B., Tit. II, 132 Stat. 2981, 3070-71 (2018), require that "all pregnancy counseling shall be nondirective," meaning that funded projects are to offer pregnant women neutral, non-judgmental information and counseling regarding their options, including "prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination").

FOURTH COUNT
U.S. Constitution, First Amendment; Administrative Procedure Act,
5 U.S.C. § 706(2)(B)
Establishment Clause

216. Plaintiffs incorporate the preceding paragraphs as if fully set forth here.

217. The Denial-of-Care Rule is contrary to constitutional rights, powers, privileges, or immunities and therefore must be set aside under 5 U.S.C. § 706(2)(B).

218. The Establishment Clause of the First Amendment prohibits the government from favoring one religion over another or favoring religion over nonreligion.

219. The Establishment Clause permits government to afford religious accommodations or exemptions from generally applicable laws only if, among other requirements, the accommodation (1) lifts a substantial, government-imposed burden on the exercise of religion and (2) does not impose on innocent third parties the costs or burdens of accommodating another's religious exercise.

220. The Rule fails both of these requirements and therefore violates the Establishment Clause.

221. The Rule violates the Establishment Clause because it creates expansive religious exemptions for healthcare employees at the expense of third parties, namely, Plaintiffs, other providers, and, crucially, patients.

222. HHS's asserted statutory authority for the Rule cannot be read to authorize the Rule, because if so read, those statutes would exceed Congress's legislative authority and constitute unconstitutional religious preferences, both by granting religious exemptions for purported burdens on religious exercise that are not of the federal government's own making, and by imposing costs and burdens on third parties to accommodate the religious beliefs or exercise of objecting employees.⁹

223. The effect of the Rule will be that patients who seek care at odds with the religious beliefs of a provider's employee—or whose very identity is at odds with that employee's religious beliefs—may be delayed in receiving care (including emergency care) or denied care altogether. Patients will suffer the stigma of government-sanctioned discrimination. The Rule also will burden Plaintiffs and other providers because by leaving them unable to treat patients in accord with their own ethical and legal obligations and precluding them from carrying out their organizational missions, based solely on the religious views of a single employee.

224. The Rule impermissibly advances religious beliefs in violation of the Establishment Clause because it imposes on Plaintiffs an unqualified obligation to give preferential protection to religious objections of their employees, regardless of the costs and harms to Plaintiffs, their patients, and the greater public health.

225. The Denial-of-Care Rule further violates the Establishment Clause of the First Amendment because, among other reasons, it:

(a) has the primary purpose of favoring, preferring, and endorsing certain religious beliefs and certain religious denominations over others and over nonreligion;

(b) has the primary effect of favoring, preferring, and endorsing certain religious beliefs and certain religious denominations over others and over nonreligion;

⁹ Attempts by HHS to mandate federal exemptions from burdens on religious exercise imposed by state or local governments are permissible, only if (among other requirements) there is a clear constitutional commitment of congressional power and express legislative authorization for the federal action. Otherwise, HHS impermissibly intrudes on the States' traditional prerogatives and general authority to regulate for the health and welfare of their citizens, exceeding the federal government's statutory authority in violation of the APA. *See* Second Count, *supra*.

(c) has the primary purpose and primary effect of preferring the religious beliefs of some people and institutions over the lives, health, and other rights and interests of third parties;

(d) impermissibly entangles government with religion;

(e) makes Plaintiffs, their patients, and other third parties bear the costs and harms of objecting employees' religious beliefs or religious exercise; and

(f) imposes on Plaintiffs a requirement to accommodate employees' religious objections without taking constitutionally required account of the actual burdens (if any) on the objectors or the effects on or harms to Plaintiffs, their patients, or the greater public health.

FIFTH COUNT

(Brought by Plaintiffs other than County of Santa Clara)
U.S. Constitution, Fifth Amendment; Administrative Procedure Act,
5 U.S.C. § 706(2)(B)
Substantive Due Process/Right To Privacy And Personal Autonomy

226. Plaintiffs incorporate the preceding paragraphs as if fully set forth here.

227. The Denial-of-Care Rule is contrary to constitutional rights, powers, privileges, or immunities and therefore must be set aside under 5 U.S.C. § 706(2)(B).

228. The Fifth Amendment's Due Process Clause protects individuals' substantive rights to be free to make certain decisions central to privacy, bodily autonomy, integrity, self-definition, intimacy, and personhood without unjustified governmental intrusion. Those decisions include the right to abortion and other reproductive decision-making, as well as the right to live openly and express oneself consistent with one's gender identity.

229. By imposing conditions on funding that require healthcare providers to interfere with and unduly burden patients' access to medically necessary health care, including reproductive healthcare and healthcare necessary to preserve health or life, the Rule violates the rights of Plaintiffs' patients to privacy, liberty, dignity and autonomy guaranteed by the Fifth Amendment.

230. In particular, a person's gender identity and ability to live and express oneself consistent with one's gender identity without unwarranted governmental interference constitutes a core aspect of each person's autonomy, dignity, self-definition and personhood. By imposing conditions on funding that interfere with patients' access to gender-affirming medical care, including surgical procedures, hormone therapy, and other medically necessary care, and by

interfering with the ability of transgender and gender-nonconforming patients to live and express themselves in accordance with their gender identities, the Rule infringes on patients' interests in privacy, liberty, dignity, and autonomy protected by the Fifth Amendment.

231. There is no legitimate interest supporting the Rule's infringement on patients' fundamental rights, let alone an interest that can survive the elevated scrutiny required to justify infringement of these fundamental rights.

SIXTH COUNT
(Brought by Plaintiffs Other Than County of Santa Clara)
U.S. Constitution, First Amendment; Administrative Procedure Act,
5 U.S.C. § 706(2)(B)
Free Speech

232. Plaintiffs incorporate the preceding paragraphs as if fully set forth here.

233. The Denial-of-Care Rule is contrary to constitutional rights, powers, privileges, or immunities and therefore must be set aside under 5 U.S.C. § 706(2)(B).

234. A person's disclosure of transgender or gender-nonconforming status, speech, or expression that discloses gender identity, and the person's gendered speech and expressive conduct, all receive constitutional protection under the First Amendment.

235. The Rule has the purpose and effect of chilling constitutionally protected First Amendment activity. As a result of the Rule, an increased number of LGBT people will remain closeted in healthcare settings and to doctors, nurses, and other healthcare providers, and will decline to disclose their sexual orientation, transgender or gender-nonconforming status, or gender identities. Further, an increased number of LGBT people will decline to engage in gendered speech and expression, including by declining to disclose related medical histories—even when that self-censorship impedes the ability of their healthcare providers to provide appropriate treatment and results in negative health consequences to the patients and to public health.

236. The Rule imposes conditions on funding that invite denials of care to Plaintiffs' patients based on religious or moral objections to these patients' identity or past or present healthcare decisions and needs.

237. The Rule impermissibly chills patients who are seeking medical care from being open about their reproductive-health histories and needs, including abortion and contraception.

238. The Rule will chill a patient of ordinary firmness from making such disclosures.

239. The Rule violates the Free Speech Clause of the First Amendment because it impermissibly burdens the exercise of patients' constitutionally protected speech, expression and expressive conduct based on the content and viewpoint of patients' speech.

240. Additionally, the Rule is overbroad because it will chill protected First Amendment activity.

SEVENTH COUNT
(Brought by Plaintiffs Other Than County of Santa Clara)
U.S.. Constitution, Fifth Amendment; Administrative Procedure Act,
5 U.S.C. § 706(2)(B)
Equal Protection

241. Plaintiffs incorporate the preceding paragraphs as if fully set forth here.

242. The Denial-of-Care Rule is contrary to constitutional rights, powers, privileges, or immunities and therefore must be set aside under 5 U.S.C. § 706(2)(B).

243. The Fifth Amendment's Due Process Clause provides that no person shall be deprived of life, liberty, or property without due process of law.

244. That Clause includes within it a prohibition against the denial of equal protection of the laws by the federal government, its agencies, or its officials or employees.

245. The purpose and effect of the Rule are to discriminate against Plaintiffs' patients based on their sex, gender identity, transgender status, gender nonconformity, and exercise of fundamental rights, including the rights to bodily integrity and autonomous medical decision-making, the rights of access to abortion and contraceptives, and the rights to live and express oneself consistent with one's gender identity.

246. Additionally, the purpose of the Rule is to facilitate, authorize, and encourage private discrimination against Plaintiffs' patients on the basis of sex, gender identity, transgender status, gender nonconformity, and exercise of fundamental rights, including the rights to abortion and contraceptives and to live and express oneself consistent with one's gender identity.

247. Further, the Rule is intended to have, and will have, a disproportionate impact on women and transgender people, people who exercise their rights to abortion and contraception, and

people who wish to live and express themselves consistent with their gender identity. The Rule places an impermissible special burden on these individuals.

248. Discrimination based on sex is presumptively unconstitutional and subject to heightened scrutiny.

249. Discrimination based on gender identity or transgender status also is presumptively unconstitutional and subject to heightened scrutiny. Transgender people have suffered a long history of discrimination and continue to suffer that discrimination; they are a discrete and insular group and lack the power to protect their rights through the political process; a person's gender identity or transgender status bears no relation to that person's ability to contribute to society; gender identity is a core, defining trait that is so fundamental to a person's sense of self and personhood that a person cannot be required to abandon it as a condition of equal treatment; and efforts to change a person's gender identity through intervention have been widely condemned.

250. Discrimination based on the exercise of a fundamental right is presumptively unconstitutional and is subject to strict scrutiny.

251. The Denial-of-Care Rule lacks even a rational or legitimate justification, let alone the important or compelling one that is constitutionally required. The Rule also lacks adequate tailoring under any standard of review.

252. Defendants' requirement of disparate treatment of patients and encouragement of private discrimination deprives patients of their right to equal dignity and stigmatizes them as second-class citizens in violation of equal protection.

EIGHTH COUNT
(Brought only by County of Santa Clara)
Spending Clause

253. Plaintiffs incorporate the preceding paragraphs as if fully set forth here.

254. The Denial-of-Care Rule violates the Spending Clause for at least four reasons.

(a) First, the Denial-of-Care Rule is vague and ambiguous, and it fails to provide adequate notice of what conduct by a recipient would result in HSS withholding federal funds.

(b) Second, the Rule attaches new, after-the-fact conditions to Santa Clara's receipt of federal funds, in violation of the Spending Clause.

(c) Third, the Rule is not rationally related to the federal interest in the particular programs that receive federal funds. *See South Dakota v. Dole*, 483 U.S. 203 (1987); *Massachusetts v. United States*, 435 U.S. 444, 461 (1978) (plurality op.) (conditioning federal grants illegitimate if conditions are unrelated “to the federal interest in particular national projects or programs”). The Rule places various federal grants at risk, but there is no rational relationship between the federal religious-objection laws that Defendants seek to enforce and the federal interest in those programs.

(d) Fourth, the Rule unconstitutionally attempts to coerce state and local government recipients, such as the County of Santa Clara, to adopt the federal government’s policy by threatening to withhold, terminate, and claw back unprecedented levels of federal funding, whether or not those funds are related to the provision of health care or to the specific violation alleged. Such conditions on federal funding go beyond “relatively mild encouragement” to put a “gun to the head” of public entities, coercing them to adopt federal policy in contravention of the Spending Clause. *See National Federation of Independent Business v. Sebelius*, 567 U.S. 519, 581 (2012).

NINTH COUNT
(Brought only by County of Santa Clara)
Separation of Powers

255. The Constitution vests the Spending Power in Congress, not in the Executive Branch. U.S. Const. art. I, § 8, cl. 1.

256. Congress may delegate some discretion to the Executive Branch to decide how to spend appropriated funds, but that discretion is cabined by the scope of the delegation. *City of Arlington, Texas v. FCC*, 569 U.S. 290, 297 (2013).

257. The Executive Branch cannot amend or cancel appropriations that Congress has duly enacted. *Clinton v. City of New York*, 524 U.S. 417, 439 (1998); *Train v. City of New York*, 420 U.S. 35, 38, 44 (1975).

258. The Rule imposes requirements not authorized by the underlying federal statutes and would allow defendants to withhold, deny, suspend, or terminate federal financial assistance for noncompliance with those requirements.

259. The Rule’s conditions improperly usurp Congress’s spending power and amount to an unconstitutional refusal to spend money appropriated by Congress, in violation of constitutional separation-of-powers principles.

260. Defendants' violation causes ongoing harm to the County of Santa Clara and its residents.

TENTH COUNT

Equitable Relief To Preserve Remedy

261. Plaintiffs incorporate by reference the foregoing paragraphs as if fully set forth.

262. The Denial-of-Care Rule will become effective on July 22, 2019, unless it is enjoined. Plaintiffs are entitled to a full, fair, and meaningful process to adjudicate the lawfulness of the Rule before being required to implement its far-reaching and harmful requirements.

263. Plaintiffs will suffer irreparable injury by implementation of the Rule, which would erode hard-won trust between vulnerable populations and their healthcare providers, stigmatize and traumatize patients, interfere with core governmental and medical operations, and result in delays and denials of care leading to physical harm and even death. Preliminary and permanent injunctive relief is therefore needed to ensure that Plaintiffs' injuries are fully remedied.

264. Injunctive relief is also needed to prevent the immediate harm resulting from the uncertainty created by the Rule about the policies and procedures guiding critical medical operations and the conditions being placed on huge swaths of federal funding. On the first day that this Rule takes effect, Plaintiff providers must know how to handle medical emergencies as they happen; they cannot wait to see how HHS chooses to interpret concededly confusing provisions in after-the-fact enforcement actions. The hospitals and clinics that Plaintiffs operate need to know how to staff their facilities, how staff must handle objections when they arise, and whether the providers can rely on continued receipt of federal funding that supports life-saving services. Patients need assurance that they will receive complete, accurate information and timely and responsive medical care in an environment that protects their constitutional rights and does not expose them to stigma and harm. This Court should step in to protect Plaintiffs' institutions, their

patients, and the foremost principle guiding medical providers in responding to those in need of assistance and care—first, do no harm.

265. Accordingly, to ensure that Plaintiffs receive meaningful relief should they prevail in this action, the Court should preliminarily and permanently enjoin Defendants from implementing the Denial-of-Care Rule.

REQUEST FOR RELIEF

Plaintiffs request that the Court grant the following relief:

(a) A declaratory judgment under 28 U.S.C. § 2201(a) and 5 U.S.C. § 706(a) that the Denial-of-Care Rule is unlawful and unconstitutional;

(b) Preliminary and permanent injunctions enjoining Defendants from implementing and enforcing the Denial-of-Care Rule;

(c) Attorneys' fees, costs, and expenses and other disbursements for this action; and

(d) Any further and additional relief that this Court deems just and proper.

Dated: May 28, 2019

Respectfully submitted,

By: /s/ Richard B. Katskee

By: /s/ Mary E. Hanna-Weir

RICHARD B. KATSKEE*
katskee@au.org
KENNETH D. UPTON, JR.**
upton@au.org
AMERICANS UNITED FOR SEPARATION
OF CHURCH AND STATE
1310 L Street NW, Suite 200
Washington, DC 20005
Tel: (202) 466-3234; Fax: (202) 466-3234

*Counsel for Plaintiffs Other Than County of
Santa Clara*

JAMES R. WILLIAMS (SBN 271253)
GRETA S. HANSEN (SBN 251471)
LAURA S. TRICE (SBN 284837)
MARY E. HANNA-WEIR (SBN 320011)
SUSAN P. GREENBERG (SBN 318055)
H. LUKE EDWARDS (SBN 313756)
mary.hanna-weir@cco.sccgov.org
OFFICE OF THE COUNTY COUNSEL,
COUNTY OF SANTA CLARA
70 West Hedding Street, East Wing, 9th Floor
San José, CA 95110-1770
Tel: (408) 299-5900; Fax: (408) 292-7270

Counsel for Plaintiff County of Santa Clara

By: /s/ Genevieve Scott

GENEVIEVE SCOTT*
gscott@reprorights.org
RABIA MUQADDAM*
rmuqaddam@reprorights.org
CHRISTINE PARKER*
cparker@reprorights.org
CENTER FOR REPRODUCTIVE RIGHTS
199 Water Street, 22nd Floor
New York, NY 10038
Tel: (917) 637-3605 Fax: (917) 637-3666

Counsel for Plaintiffs Other Than County of Santa Clara

By: /s/ Jamie A. Gliksberg

JAMIE A. GLIKSBERG*
jgliksberg@lambdalegal.org
CAMILLA B. TAYLOR*
ctaylor@lambdalegal.org
LAMBDA LEGAL DEFENSE AND
EDUCATION FUND, INC.
105 West Adams, 26th Floor
Chicago, IL 60603-6208
Tel: (312) 663-4413; Fax: (312) 663-4307

OMAR GONZALEZ-PAGAN*
ogonzalez-pagan@lambdalegal.org
LAMBDA LEGAL DEFENSE AND
EDUCATION FUND, INC.
120 Wall Street, 19th Floor
New York, NY 10005-3919
Tel: (212) 809-8585

Counsel for Plaintiffs Other Than County of Santa Clara

By: /s/ Lee H. Rubin

LEE H. RUBIN (SBN 141331)
lrubin@mayerbrown.com
MAYER BROWN LLP
Two Palo Alto Square, Suite 300
3000 El Camino Real
Palo Alto, CA 94306-2112
Tel: (650) 331-2000; Fax: (650) 331-2060

MIRIAM R. NEMETZ*
mnemetz@mayerbrown.com
NICOLE A. SAHARSKY*
nsaharsky@mayerbrown.com
MAYER BROWN LLP
1999 K Street, Northwest
Washington, DC 20006-1101
Tel: (202) 263-3000; Fax: (202) 263-3300

Counsel for Plaintiffs County of Santa Clara, Trust Women Seattle, LA LGBT Center, Whitman-Walker, Bradbury-Sullivan Center, Center on Halsted, Hartford Gyn Center, Mazzoni Center, Medical Students for Choice, AGLP, GLMA, Ward Carpenter, Sarah Henn, and Randy Pumphrey

* To be admitted pro hac vice

** Licensed in Oklahoma and Texas only.
Supervised by Richard B. Katskee, a member of the D.C. Bar. To be admitted pro hac vice

EXHIBIT 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 88

RIN 0945-AA10

Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

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

ACTION: Final rule.

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

DATES: This rule is effective July 22, 2019.

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

SUPPLEMENTARY INFORMATION:

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I. Background

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

A. Statutory History

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

- Conscience protections related to abortion, sterilization, and certain other health services applicable to the Department of Health and Human Services and recipients of certain Federal funds encompassed by 42 U.S.C. 300a–7 (the “Church Amendments”);
- Conscience protections for health care entities related to abortion provision or training, referral for such abortion or training, or accreditation standards related to abortion (the “Coats-Snowe Amendment,” 42 U.S.C. 238n);
- Protections from discrimination for health care entities that do not provide, pay for, provide coverage of, or refer for abortions under programs funded by the Department’s appropriations acts (e.g., Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019, Div. B., sec. 507(d), Public Law 115–245, 132 Stat. 2981 (Sept. 28, 2018) (the “Weldon Amendment”); *id.*, sec. 209);
- Protections from discrimination under the Patient Protection and Affordable Care Act (“ACA”) for health care entities that do not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing, applicable to the Federal Government and any State or local government that receives Federal financial assistance (42 U.S.C. 18113);

and conscience protections for providers, organizations, or their employees regarding counseling regarding the same (42 U.S.C. 14406(1));

- Conscience protections regarding exemptions applicable to the ACA’s individual mandate (26 U.S.C. 5000A; 42 U.S.C. 18081);
 - Conscience protections under the ACA for qualified health plans related to coverage of abortion, and for individual health care providers and health care facilities that do not provide, pay for, provide coverage of, or refer for abortions (42 U.S.C. 18023(b)(1)(A) and (b)(4));
 - Conscience protections for Medicare Advantage organizations and Medicaid managed care organizations with moral or religious objections to counseling or referral for certain services (42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B));
 - Conscience protections related to the performance of advanced directives (42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406(2));
 - Conscience and nondiscrimination protections for organizations related to Global Health Programs, to the extent such funds are administered by the Secretary of HHS (the “Secretary”) (22 U.S.C. 7631(d));
 - Conscience protections attached to Federal funding, to the extent such funding is administered by the Secretary, regarding abortion and involuntarily sterilization (22 U.S.C. 2151b(f), *see, e.g.*, the Consolidated Appropriations Act, 2019, Pub. L. 116–6, Div. F, sec. 7018 (the “Helms, Biden, 1978, and 1985 Amendments”));
 - Conscience protections from compulsory health care or services generally (42 U.S.C. 1396f and 5106i(a)), and under specific programs for hearing screening (42 U.S.C. 280g–1(d)), occupational illness testing (29 U.S.C. 669(a)(5)); vaccination (42 U.S.C. 1396s(c)(2)(B)(ii)), and mental health treatment (42 U.S.C. 290bb–36(f)); and
 - Protections for religious nonmedical health care providers and their patients from certain requirements under Medicare and Medicaid that may burden their exercise of their religious beliefs regarding medical treatment (e.g., 42 U.S.C. 1320a–1(h), 1320c–11, 1395i–5, 1395x(e), 1395x(y)(1), 1396a(a), and 1397j–1(b)).
- For purposes of this final rule, these laws will be collectively referred to as “Federal conscience and anti-discrimination laws.”
- Congress has recognized that modern health care practices may give rise to conflicts with the religious beliefs and moral convictions of payers, providers, and patients alike. The existence of

¹ 83 FR 3880 (Jan. 26, 2018).

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

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

First, paragraph (b) of the Church Amendments provides, with regard to individuals, that no court, public official, or other public authority can use an individual's receipt of certain Federal funding as grounds to require the individual to perform, or assist in, sterilization procedures or abortions, if doing so would be contrary to his or her religious beliefs or moral convictions. 42 U.S.C. 300a–7(b)(1). Paragraph (b) further prohibits those public authorities from requiring an entity, based on the entity's receipt of Federal

funds under certain HHS programs, (1) to permit sterilizations or abortions in the entity's facilities if the performance of such procedures there violates the entity's religious beliefs or moral convictions, or (2) to make its personnel available for such procedures if contrary to the personnel's religious beliefs or moral convictions. 42 U.S.C. 300a–7(b)(2). The individuals and entities protected by this provision are recipients of grants, contracts, loans, or loan guarantees under the Public Health Service Act (42 U.S.C. 201 *et seq.*), and those entities' personnel.³

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

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

services or activities more generally. 42 U.S.C. 300a–7(c)(2).

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

Fifth, paragraph (e) of the Church Amendments applies to health care training or study programs, including internships and residencies. Paragraph (e) prohibits any entity receiving certain funds from denying admission to, or otherwise discriminating against, applicants for training or study based on the applicant's reluctance or willingness to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations contrary to, or consistent with, the applicant's religious beliefs or moral convictions. 42 U.S.C. 300a–7(e). Any recipient of a grant, contract, loan, loan guarantee, or interest subsidy under the Public Health Service Act or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15001 *et seq.*) must comply with paragraph (e).

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

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

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

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

The Weldon Amendment. The Weldon Amendment (or "Weldon") was originally adopted in 2004 and has been readopted (or incorporated by reference) in each subsequent appropriations act for the Departments of Labor, Health and Human Services, and Education. *See, e.g.,* Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, and Continuing Appropriations Act, 2019, Public Law 115–245, Div. B., sec. 507(d). Weldon provides that none of the funds made available in the applicable Labor, HHS, and Education appropriations act be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions. *E.g.,* Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, and Continuing Appropriations Act, 2019, Public Law 115–245, Div. B., sec. 507(d). Weldon states that the term "health care entity" includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan. *Id.*

Conditions on Federally Appropriated Funds Requiring Compliance with Federal Conscience and Anti-Discrimination Laws. In addition to

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

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

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

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

applies the plain text of section 1303 of the ACA. 42 U.S.C. 18023.

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

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

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

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

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

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

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

Federal Conscience and Anti-Discrimination Protections Applying to Global Health Programs. The Department administers certain programs under the President's Emergency Plan for AIDS Relief (PEPFAR), to which additional conscience protections apply. Specifically, recipients of foreign assistance funds for HIV/AIDS prevention, treatment, or care authorized by section 104A of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2), 22 U.S.C. 7601–7682,

or under any amendment made by the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (Pub. L. 110–293), cannot be required, as a condition of receiving such funds, (1) to “endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS,” or (2) to “endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection.” 22 U.S.C. 7631(d)(1)(B). The government also cannot discriminate against such recipients in the solicitation or issuance of grants, contracts, or cooperative agreements for the recipients’ refusal to do any such actions. 22 U.S.C. 7631(d)(2).

Exemptions from Compulsory Medical Screening, Examination, Diagnosis, or Treatment. This rule incorporates four statutory provisions that protect parents who, on the basis of conscience, object to their children being forced to receive certain treatments or health interventions. First, under the Public Health Service Act, certain suicide prevention programs are not to be construed to require “suicide assessment, early intervention, or treatment services for youth” if their parents or legal guardians have religious or moral objections to such services. 42 U.S.C. 290bb–36(f); section 3(c) of the Garrett Lee Smith Memorial Act (Pub. L. 108–355, 118 Stat. 1404, reauthorized by Pub. L. 114–255 at sec. 9008). Second, authority to issue certain grants through the Health Resources and Services Administration (HRSA), Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH) may not be construed to preempt or prohibit State laws which do not require hearing loss screening for newborn, infants or young children whose parents object to such screening based on religious beliefs. 42 U.S.C. 280g–1(d). Third, certain State and local child abuse prevention and treatment programs funded by HHS are not to be construed as creating a Federal requirement that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of that parent or legal guardian. 42 U.S.C. 5106i(a). Fourth, in providing pediatric vaccines funded by Federal medical assistance programs, providers must comply with any State laws relating to any religious or other exemptions. 42 U.S.C. 1396s(c)(2)(B)(ii).

Conscience Clauses Related to Religious Nonmedical Health Care. Since 1965, Congress has provided accommodations in Medicare and

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

Congress has acknowledged RNHCIs through several statutes. For example, although such institutions would not otherwise meet the medical criteria for Medicare providers, *see* 42 U.S.C. 1395x(e) (definition of “hospital”), 1395x(y)(1) (definition of “skilled nursing facility”), 1395x(k), and 1320c–11 (exemptions from other medical criteria and standards), Congress expressly included them within the definition of designated Medicare providers. Congress prohibited States from excluding RNHCIs from licensure through implementation of State definitions of “nursing home” and “nursing home administrator,” 42 U.S.C. 1396g(e), and Congress exempted RNHCIs from certain Medicaid requirements for medical criteria and standards. 42 U.S.C. 1396a(a) (exempting RNHCIs from 42 U.S.C. 1396a(a)(9)(A), 1396a(a)(31), 1396a(a)(33), and 1396b(i)(4)). Finally, Congress permitted patients at RNHCIs to file an election with HHS stating that they are “conscientiously opposed to acceptance of” medical treatment, that is neither received involuntarily nor required under Federal or State law or the law of a political subdivision of a State, on the basis of “sincere religious beliefs,” yet remain eligible for the nonmedical care and services ordinarily covered under Medicare, Medicaid, and CHIP. *See, e.g.,* 42 U.S.C. 1395x(e), 1395x(y), and 1395i–5 (Medicare provisions). Federal courts have upheld the constitutionality of such religious accommodations. *See, e.g., Kong v. Scully*, 341 F.3d 1132 (9th Cir. 2003); *Children’s Healthcare v. Min De Parle*, 212 F.3d 1084 (8th Cir. 2000).

⁸ <https://www.medicare.gov/coverage/rnhci-items-and-services.html>.

⁹ <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/RNHCIs.html>.

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

Congress has also provided particular accommodations for persons and institutions that object to medical services and items. Section 6703(a) of the Elder Justice Act of 2009 (Pub. L. 111–148, 124 Stat. 119) provides that Elder Justice and Social Services Block Grant programs may not interfere with or abridge an elder person’s “right to practice his or her religion through reliance on prayer alone for healing,” when the preference for such reliance is contemporaneously expressed, previously set forth in a living will or similar document, or unambiguously deduced from such person’s life history. 42 U.S.C. 1397j–1(b). Additionally, the Child Abuse Prevention and Treatment Act (CAPTA) specifies that it does not require (though it also does not prevent) a State finding of child abuse or neglect in cases in which a parent or legal guardian relies solely or partially upon spiritual means rather than medical treatment, in accordance with religious beliefs. 42 U.S.C. 5106i(a)(2).

B. Regulatory History

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

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

The Department received a “large volume” of comments on the August 2008 Proposed Rule. *See* 73 FR at 78074. Comments came from a wide

variety of individuals and organizations, including private citizens, individual and institutional health care providers, religious organizations, patient advocacy groups, professional organizations, universities and research institutions, consumer organizations, and State and Federal agencies and representatives. Comments dealt with a range of issues surrounding the proposed rule, including whether the rule was needed, what individuals would be protected by the proposed rule, what services would be covered by the proposed rule, whether health care workers would use the regulation to discriminate against patients, what significant implementation issues could be associated with the rule, what legal arguments could be made for and against the rule, and what cost impacts of the proposed rule could be anticipated. Many comments confirmed the need to promulgate a regulation to raise awareness of Federal conscience and anti-discrimination protections and provide for their enforcement.

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

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

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

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

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

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

Section 88.6 of the 2008 Rule designated HHS OCR to receive complaints based on the three specified Federal conscience and anti-discrimination laws, and directed OCR

to coordinate handling those complaints with the Departmental components from which the covered entity receives funding.

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

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

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

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

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

II. Overview of the Final Rule

A. Overview of Reasons for the Final Rule

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

¹¹ Since 2011, conscience and coercion in health care have been the subjects of significant litigation at the State and local level. Recently, the Supreme Court held that the State of California likely violated the Free Speech rights of prolife pregnancy resource centers that do not provide information about where to obtain abortions by adopting a statute that required them, among other things, to

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

Comments received during the rulemaking that led to the 2011 Rule were consistent with this survey.

post notices to which they objected. See *Nat’l Inst. of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361 (Jun. 26, 2018).

¹² 73 FR at 78073.

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

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

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

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

¹⁶ Comment Nos. HHS-OPHS-2009-0001-0739, -52648, -52677.

¹⁷ Comment No. HHS-OPHS-2009-0001-0868.

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

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

Continued

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

Commenters also identified a culture of hostility to conscience concerns in health care.²² Some expressed concern that the rescission of the 2008 Rule would contribute to these problems by inappropriately politicizing, and interfering in, the practice of medicine and individual providers' judgment.²³ Thousands of comments from medical personnel stated their disagreement with the rescission, often stating that they had requested exemptions in the past and were concerned rescission would make it harder to request

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

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

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

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

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

exemptions in the future.²⁴ Hundreds of commenters expressed concern over the exclusion and marginalization of health care entities and employees holding religious beliefs or moral convictions, and fears that the moral agency of the medical profession was eroding.²⁵

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

In 2016, the American Congress of Obstetricians and Gynecologists (ACOG) reaffirmed a prior ethics opinion that recommended, "Physicians and other health care professionals have the duty to refer patients in a timely manner to

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

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

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

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

other providers if they do not feel that they can in conscience provide the standard reproductive services that their patients request," and "In resource-poor areas . . . [p]roviders with moral or religious objections should either practice in proximity to individuals who do not share their views or ensure that referral processes are in place so that patients have access to the service that the physician does not wish to provide."²⁸

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

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

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

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

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

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

Some of the plaintiffs in these lawsuits also filed complaints with OCR alleging that the State laws violate the Weldon, Coats-Snowe, and/or Church Amendments. Complaints filed with OCR against the State of California, alleging California's Reproductive Freedom, Accountability, Comprehensive Care, and Transparency Act (FACT Act) (Cal. Health & Safety Code Ann. sections 123470, *et seq.*)

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

violated Federal conscience and anti-discrimination laws, were recently resolved with a finding by OCR that the State of California violated the Weldon and Coats-Snowe Amendments.³⁰ OCR determined that "California's enactment of the FACT Act violate[d] the Weldon and Coats-Snowe Amendments by discriminating against health care entities that object to referring for, or making arrangements for, abortion."³¹

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

Some States have also sought to require health insurance plans to cover abortions, triggering additional conscience-related lawsuits. California,

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

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

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

³¹ *Id.* at 9.

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

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

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

³⁵ <https://www.dmh.ca.gov/Portals/0/082214letters/abc082214.pdf>.

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

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

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

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

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

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

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

The case of a New York nurse who alleged that a private hospital forced her to assist in an abortion over her religious objections illustrates the point. The nurse filed a lawsuit in Federal

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

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

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

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

the State of California filed in 2014.³⁷ On June 21, 2016, OCR declared it found no violation stemming from California's policy requiring that health insurance plans include coverage for abortion based on the facts alleged in the three complaints it had received.³⁸ OCR's closure letter concluded that the Weldon Amendment's protection of health insurance plans included issuers of health insurance plans but not institutions or individuals who purchase or are insured by those plans. Even though California's policy resulted in complainants losing abortion-free insurance that was consistent with their beliefs and that insurers were willing to provide, the letter concluded that none qualified as an entity or person protected under the Weldon Amendment because none was an insurance issuer. Relying on an interpretation of legislative history, instead of the Weldon Amendment's text, OCR also declared that health care entities are not protected under Weldon unless they possess a "religious or moral objection to abortion," and concluded that the insurance issuers at issue did not merit protection because they had not raised any religious or moral objections. Finally, OCR called into question its ability to enforce the Weldon Amendment against a State *at all* because, according to the letter, to do so could "potentially" require the revocation of Federal funds to California in such a magnitude as to violate State sovereignty and constitute a violation of the Constitution.³⁹

The Department does not opine upon, and has not yet made a judgment on, the compatibility of California's policy with the Weldon Amendment. But clarification is in order with respect to the general interpretations of the Weldon Amendment offered in OCR's closure of complaints against California's abortion coverage requirement. The Department has engaged in further consideration of this general matter and has also further reviewed Federal conscience and anti-discrimination laws, their legislative history, and the record of rulemaking and public comments. Based on this review, the Department indicated, in the preamble to the proposed rule, that the above-mentioned sub-regulatory

guidance issued by OCR with respect to interpretation of the Weldon Amendment no longer reflects the Department's position on, and interpretation of, the Weldon Amendment. The Department continues to hold the views it expressed on that issue in the preamble to the proposed rule, *see* 83 FR at 3890–91, and has reflected those views in its analysis contained in the Notice of Violation to the State of California for OCR Complaint Nos. 16–224756 and 18–292848, discussed *supra*, in which OCR discussed the rationale behind its determination that "California's enactment of the FACT Act violate[d] the Weldon . . . Amendment[] by discriminating against health care entities that object to referring for, or making arrangements for, abortion." ⁴⁰

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

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

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

from coercion and discrimination including that stemming from moral convictions or religious beliefs.

B. Structure of the Final Rule

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

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

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

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

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

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

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

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

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

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

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

A. General Comments

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

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

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

fully exercising their consciences as protected by law.⁴⁴

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

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

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

⁴⁴ *Id.*

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

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

⁴² 73 FR at 78080–81 (Dec. 19, 2008).

⁴³ 73 FR at 78081.

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

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

Second, and relatedly, the rule might result in an increase in the number of providers overall, or in certain specialties within the health care field. Individuals and entities may have chosen not to enter the health care field

because they anticipated they would be pressured to violate their consciences. In some cases, that decision may be the result of discrimination occurring during medical training, such as medical students' experiences of discrimination on the basis of their religious beliefs or moral convictions,⁴⁷ or by pressures faced by institutions because of their religious identity or moral convictions. Reducing that discrimination and pressure may lead to more individual and institutional health care providers overall, which could help increase, rather than decrease, services for underserved communities. Another way this effect may manifest itself is if the average facility has access to more highly qualified candidates because there is a larger pool of medical professionals from which to choose. Having more providers overall, so that the field as a whole provides a wide and diverse range of services, is preferable to having fewer providers, particularly with respect to underserved areas.

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

The rule might allow an increase in the provision of health care by religious

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

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

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

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

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

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

⁴⁹ Pew Research Center, "What Unites and Divides Urban, Suburban, and Rural Communities" (May 22, 2018), available at <https://www.pewsocialtrends.org/2018/05/22/what-unites-and-divides-urban-suburban-and-rural-communities/>.

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

The Department also disagrees with the assumption that the rule's enforcement of Federal conscience and anti-discrimination laws will result in harm, or in more harm than the benefits that derive from implementing Federal laws. As explained in the Regulatory Impact Analysis, *infra* at part IV.C.3.vii, the Department expects the rule to

enhance, not impede, access to care in areas with fewer providers, such as rural communities. The Department is not aware of data establishing the views of commenters who say the rule will reduce services in underserved communities, or of data establishing quantitatively how much the rule will increase and enhance access to health care services in underserved communities. The Department concludes, instead, that it is reasonable to agree with commenters who believe the rule will not decrease access to care, and may increase it.

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

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

Response: The Department disagrees. First, this final rule provides for the enforcement of protections established by the people's representatives in Congress; the Department has no authority to override Congress's balancing of the protections. Second, protecting health care providers' rights of conscience ensures that health care providers with deeply held religious beliefs or moral convictions are not driven out of the health care industry—and, therefore, made unavailable to serve any patients and provide any health care services—because of their refusal to participate in certain objected-to activities, such as abortion, sterilization, or assisted suicide. Third, the Department believes the provider-

patient relationship is best served by open communication of conscience issues surrounding the provision of health care services, including any conscientious objections providers or patients may have to providing, assisting, participating in, or receiving certain services or procedures. By protecting a diversity of beliefs among health care providers, these protections ensure that options are available to patients who desire, and would feel most comfortable with, a provider whose religious beliefs or moral convictions match their own. Even where a patient and provider do not share the same religious beliefs or moral convictions, it is not necessarily the case that patients would want providers to be forced to violate their religious beliefs or moral convictions.

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

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

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

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

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

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

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

Response: This final rule provides the Department with the means to enforce Federal conscience and anti-discrimination laws in accordance with their terms and to the extent permitted under the laws of the United States and the Constitution. This final rule, like the 2008 Rule and the 2011 Rule, does not go into detail as to how its provisions may or may not interact with other statutes or in all scenarios, but OCR intends to read every law passed by Congress in harmony to the fullest extent possible so that there is maximum compliance with the terms of each law. With respect to EMTALA, the Department generally agrees with its explanation in the preamble to the 2008 Rule⁵¹ that the requirement under EMTALA that certain hospitals treat and stabilize patients who present in an emergency does not conflict with Federal conscience and anti-discrimination laws. The Department intends to give all laws their fullest possible effect.

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

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

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

Response: The Department disagrees, and believes that the rule would make a meaningful difference in terms of

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

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

Response: Nothing in the rule prohibits an entity from providing a lawful service it wants to provide, even as it respects the rights of personnel who may be protected by Federal laws from being required to provide, or assist in, the service. As discussed later in this preamble, the rule provides incentives for (but does not mandate) notices that parallel notice provisions under other anti-discrimination regulations. The Department believes that the provider-patient relationship is best served by open communication of conscience issues surrounding the provision of health care services, so that the consciences of patients, providers, and employees are respected whenever possible or required. Nothing in the rule precludes such communication or systems that encourage such communication. For example, providers may include notices in patient intake materials notifying patients that a provider's service provision is governed by certain ethical or religious principles. Providers may also encourage communication of moral or religious views by patients with respect to treatment in order to respect patients' wishes to the extent it is mutually acceptable or required. The Department declines to mandate any particular timeline or form in which a provider or patient must raise these sensitive issues. The Department encourages providers, if they are working with, or employing, health care professionals who may have religious or moral objections, especially with regard to certain procedures or treatments, to openly discuss these issues and have processes in place to

identify and respect a diversity of views, further the provision of health care, and comply with the law. The final rule's modifications to the definition of "discrimination" permit employers of such personnel to accommodate the professionals' religious or moral objections, without interfering in the employer's delivery of health services.

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

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

Compliance by the Department. Inherent in Congress's adoption of the statutes that require compliance by the Department, by departmental programs, and by recipients of Federal funds from the Department is the authority of the Department to take measures to ensure its own compliance. As explained more fully below, compliance reviews, complaint investigation, and record-keeping are standard measures for ensuring compliance with conditions Congress has imposed upon the Department and on recipients of Federal funds, including statutory nondiscrimination requirements. Moreover, 5 U.S.C. 301 empowers the head of an Executive department to prescribe regulations "for the government of his department, the conduct of his employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property."

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

⁵¹ 73 FR at 78087–88.

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

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

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

In sum, the Department's enforcement of the Federal conscience and anti-discrimination laws for grantees will be conducted through the normal grant compliance mechanisms applicable to

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

Contracts. With respect to Federal contracts and contractors, the Federal Property and Administrative Services Act of 1949 ("FPASA") authorizes the promulgation of the Federal Acquisition Regulation ("FAR"). 40 U.S.C. 121(c). The FAR, in turn, authorizes agency heads to "issue or authorize the issuance of agency acquisition regulations that implement or supplement the FAR and incorporate, together with the FAR, agency policies, procedures, contract clauses, solicitation provisions, and forms that govern the contracting process or otherwise control the relationship between the agency, including any of its suborganizations, and contractors or prospective contractors." 48 CFR 1.301–(a)(1). In addition, Federal agencies are required to prepare their solicitations and resulting contracts utilizing a uniform contract format, which permits agencies to include a clear statement of any "special contract requirements" that are not included in its standard government contract clauses or in other sections of the uniform contract format. 48 CFR 15.204–2–(h). Finally, pursuant to the FAR and other legal authorities, the Department has established the Department of Health and Human Services Acquisition Regulation ("HHSAR") [48 CFR parts 300 through 370], which establishes uniform departmental acquisition policies and procedures that implement and supplement the FAR. The HHSAR contains departmental policies that govern the acquisition process or otherwise control acquisition relationships between the Department's contracting activities and contractors. The HHSAR contains (1) requirements of law; (2) HHS-wide policies; (3) deviations from FAR requirements; and (4) policies that have a significant effect beyond the internal procedures of the Department or a significant cost or

administrative impact on contractors or offerors. *See* 48 CFR 301.101(b); *see also* 48 CFR 301.103(b) ("The Assistant Secretary for Financial Resources (ASFR) prescribes the HHSAR under the authority of 5 U.S.C. 301 and section 205(c) of the Federal Property and Administrative Services Act of 1949, as amended (40 U.S.C. 121(c)(2)), as delegated by the Secretary[.]"). As a result, the Department has ample authority to include terms and conditions in its contracts consistent with the Federal conscience and anti-discrimination laws. Furthermore, the Federal Acquisition Regulation provides a variety of mechanisms that may be used to enforce such contract provisions (e.g., 48 CFR part 49 "Termination of Contracts"). Thus, the Department intends to implement and enforce contract terms on the Federal conscience and anti-discrimination laws through the FAR and HHSAR and other Federal laws and regulations that govern the administration and performance of Federal contracts.

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

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

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

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

Qualified Health Plans offering individual market coverage on State exchanges.

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

rulemaking would be enforced through a compliance action under section 1902(a)(4) of the Social Security Act. For Medicare Advantage or Part C contracts, there are intermediate sanctions, civil money penalties, and potential contract termination for violations of contract requirements. In the case of Medicare providers and suppliers, enforcement could involve loss of a provider agreement or certification.

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

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

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

1. Skilled nursing facilities (SNFs)—section 1819(d)(4)(B) of the Act [42 U.S.C. 1395i–3(d)(4)(B)].
2. Medicaid nursing facilities (NFs)—section 1919(d)(4)(B) of the Act [42 U.S.C. 1396r(d)(4)(B)].
3. Hospitals—section 1861(e)(9) of the Act [42 U.S.C. 1395x(e)(9)].
4. Psychiatric hospitals—section 1861(f)(2) of the Act [42 U.S.C. 1395x(f)(2)], cross referencing 1861(e)(9).
5. Long term care hospitals—section 1861(ccc)(3) of the Act [42 U.S.C. 1395x(ccc)(3)], cross referencing section 1861(e).
6. Home health agencies (HHAs)—section 1861(o)(6) of the Act [42 U.S.C. 1395x(o)(6)].

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

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

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

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

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

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

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

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

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

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

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

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

B. Section-by-Section Analysis⁵³

Purpose (§ 88.1)

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

Summary of Regulatory Changes: The Department believes, as discussed above, that there are various reasons why this rule is needed and appropriate to provide for the implementation and enforcement of Federal conscience and anti-discrimination laws. In addition, the Department believes it is appropriate to interpret the rules broadly, within the scope of the text set forth in each statute, to effectuate their protective purposes. Generally, it is appropriate to broadly interpret laws enacted to protect civil rights and prevent discrimination. For the reasons described in the proposed rule⁵⁴ and above, and considering the comments received, the Department finalizes this section as proposed, but with technical edits to replace the word "persons" with "individuals," add the term

"certain" in regard to health care services, remove the term "for example" and "comprehensively" in relation to the degree of the protections, for clarity, and to refer to the statutes part 88 addresses as "Federal conscience and anti-discrimination laws, which are listed in § 88.3 of this part."

Definitions (§ 88.2)

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

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

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

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

Assist in the Performance. The Department proposed that "assist in the performance" means "to participate in any program or activity with an articulable connection to a procedure, health service, health program, or research activity, so long as the individual involved is a part of the workforce of a Department-funded entity." The definition specified that "[t]his includes but is not limited to counseling, referral, training, and other

arrangements for the procedure, health service, health program, or research activity." The Department received comments on this definition, including comments generally supportive of the proposed definition and generally opposed to it. Because comments evidenced significant confusion over the proposed definition, the Department amends the definition, as described further below.

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

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

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

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

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

⁵⁴ 83 FR 3880, 3892.

reasonable to consider performing these actions as constituting “assistance.”

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

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

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

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

Response: The Department agrees in part, to the extent that the reasonableness standard should be included in the definition. As stated above, in response to similar concerns about potential overbreadth, the Department has modified the sentence containing the phrase, “to participate in any program or activity with an articulable connection to a procedure,” to add the word “reasonable,” and other language to limit its scope and add greater specificity. Specifically, the final

rule describes “to take an action that has a specific, reasonable, and articulable connection to furthering a procedure or health service program or research activity undertaken by or with another person or entity.” This standard would preclude irrational assertions that an action constitutes assisting in the performance of a procedure, because it requires the action to have a specific, reasonable, and articulable connection to furthering the procedure. If the connection between an action and a procedure is irrational, there is no actual connection by which the action specifically furthers the procedure. The Department does not interpret the language to permit irrational applications.

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

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

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

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

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

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

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

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

To the extent commenters are referring to emergency transportation of persons experiencing unforeseen complications after, for example, an abortion procedure, the Department does not believe such a scenario would implicate the definition of “assist in the performance of” an abortion, because the complications in need of treatment would be an unforeseen and unintended

byproduct of a completed procedure. Further, the Department is not aware of any entities or medical professionals that would object to treating someone, or transporting someone to treatment, under these circumstances.

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

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

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

Response: Congress did not define the phrases “assist in the performance,” “counsel,” or “recommend” in the Church Amendments; “refer” or

“referral” in Weldon or Coats-Snowe; or “make arrangements for” in Coats-Snowe. Some commenters contend that the meaning of these terms are completely distinct and should never be interpreted as overlapping. The Department disagrees. When Congress enacted paragraphs (b) and (c)(1) of the Church Amendments in 1973, and paragraphs (c)(2) and (d) in 1974, it used the phrase “assist in the performance” regarding certain medical procedures. Congress then enacted paragraph (e) in 1979 to protect applicants for medical training or study from discrimination based on their reluctance or willingness “to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations.”

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

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

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

⁵⁶ 42 U.S.C. 1395dd(a).

⁵⁷ 42 CFR 489.24(b)(3) and (4).

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

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

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

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

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

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

Comment: The Department received comments expressing concern that the definition of “assist in the performance” will result in conscientious objectors refusing to provide information to

patients about objected-to treatment options, potentially in violation of principles of informed consent.

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

Summary of Regulatory Changes: For the reasons described in the proposed rule⁶⁰ and above, and considering the comments received, the Department adopts the definition of “assist in the performance” with changes to read that it means “to take an action that has a specific, reasonable, and articulable connection to furthering a procedure or health service program or research activity undertaken by or with another person or entity.” The definition specifies that “[t]his may include counseling, referral, training, or otherwise making arrangements for the procedure or health service program or research activity, depending on whether aid is provided by such actions.” This new definition removes “so long as the individual involved is a part of the workforce of a Department-funded entity” for accuracy and clarity and makes other minor language changes, for example, changing “includes but is not limited to” to “may include.”

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

Summary of Regulatory Changes: For the reasons described in the proposed rule⁶¹ and above, the Department adopts the definition of “Department” as proposed.

Discriminate or Discrimination. The Department proposed “discriminate or discrimination,” to mean one of four categories of adverse actions or treatment, for which each paragraph or type of action within each paragraph would apply as permitted by the applicable statute. Paragraph (1) of the definition addressed prohibited adverse actions or treatment, as permitted by the

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

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

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

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

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

⁶¹ 83 FR 3880, 3892.

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

Paragraph (c)(1) of the Church Amendments provides that a covered entity cannot discriminate against any physician or other health care personnel (1) because he or she performed or assisted in the performance of a sterilization or abortion procedure, (2) because he or she refused to so perform or assist “on the grounds that” doing so “would be contrary to his [or her] religious beliefs or moral convictions,” or (3) “because of his religious beliefs or moral convictions respecting sterilization procedures or abortions.” The last provision covers circumstances where a covered entity’s motive is arguably driven by anti-religious animus. But the second prohibition of discrimination does not rely on animus on the part of the entity committing the discrimination; it rests solely on whether the person refused to perform or assisted in the performance of a sterilization or abortion procedure on the grounds of the person’s religious beliefs or moral convictions with respect to such procedures. Therefore, under paragraph (c)(1), a covered entity cannot discriminate against a doctor, for example, because of his or her refusal to perform abortions on the grounds of religious beliefs or moral convictions regardless of whether the covered

entity’s discrimination is accompanied by anti-religious animus, or whether the entity would also penalize doctors who refuse to perform abortions for non-protected reasons. Nothing in the legislative history of the Church Amendments suggests that Congress intended to permit entities receiving applicable funds to coerce religiously or morally motivated doctors to perform abortions, so long as those entities also require doctors who do not have qualms about abortions to perform them.

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

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

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

anti-discrimination law to which this part applies.

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

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

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

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

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

With respect to Title VII, the Department agrees with some commenters that the definition of "discriminate or discrimination" as proposed does not function in the same way as the approach set forth in Title VII, specifically regarding parts of the

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

Comment: The Department received comments expressing concern that the proposed definition of "discriminate or

discrimination" would prohibit employers from accommodating religious objections by placing the conscientious objector in a different position, potentially requiring the double-staffing of certain positions.

Response: The Department agrees with this concern in part. As discussed above, the Department is adding language in response to public comments to acknowledge the reasonable accommodations that entities make for persons protected by Federal conscience and anti-discrimination laws. In this way, the Department recognizes that staffing arrangements can be acceptable accommodations in certain circumstances. The Department has addressed this through the addition of a new paragraph (4) in the definition of "discriminate or discrimination" that recognizes the effective and timely accommodation of an employee (which may include non-retaliatory staff rotations) as not constituting discrimination. Additionally, to address concerns raised by these commenters, the Department is adding new paragraphs (5) and (6) to clarify that, within limits, employers may require a protected employee to inform them of objections to referring for, participating, or assisting in the performance of specific procedures, programs, research, counseling, or treatments to the extent there is a reasonable likelihood⁶⁵ that the protected entity or individual may be asked in good faith to refer for, participate in, or assist in the performance of such conduct, and that the employer may use alternate staff or methods to provide or further any objected-to conduct, subject to certain limitations designed to protect the objecting person.

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

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

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

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

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

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

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

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

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

passed by Congress that are the subject of this rule.

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

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

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

Response: The Department agrees in part and disagrees in part. Because there is uncertainty about which laws, or parts of laws, implemented by this rule may or may not support a disparate impact claim, the Department is choosing to finalize the rule without explicitly including terms traditionally associated with disparate impact theories. It is specifically replacing the phrase "adverse effects" with "adverse treatment" and is deleting "otherwise," "tends to," and "defeats or substantially impairs accomplishment of a health program or activity" as elements of the definition of "discrimination." However, because the definition of

"discrimination" as adopted in this final rule is non-exclusive, as discussed above, OCR is not prejudging any complaints of violations of part 88 that are based on a claim of disparate impact, and will consider the circumstances of each complaint and apply each statute according to its text and any applicable court precedents.

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule⁶⁶ and above, and considering the comments received, the Department finalizes the definition of "discriminate or discrimination" (with additional minor changes for accuracy and clarity); changing "means" to "includes;" limiting the definition "to the extent" permitted by the statute; changing "exclude" to "exclude from;" deleting "otherwise" from paragraphs (1) and (2); adding "or impose any penalty" to the end of paragraph (2); in paragraph (3), deleting "defeating or substantially impairing accomplishment of a health program or activity," changing "tends to subject" to "subjects," and adding "on grounds prohibited under an applicable statute encompassed by this part;" deleting the proposed paragraph (4) and

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

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

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

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

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

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

Response: The Department agrees that the term “entity” should address foreign governments, foreign nongovernmental organizations, intergovernmental organizations (such as the United Nations), and related bodies, but the Department disagrees that they should be explicitly excluded. Some of the Federal conscience statutes to be enforced by the Department may implicate foreign entities,⁶⁷ but Congress did not exempt certain kinds of foreign entities that would otherwise be covered. Accordingly, the definition of “entity” is modified to clarify that “entity” may include a foreign government, foreign nongovernmental organization, or intergovernmental organization (including the United Nations and its affiliated agencies). The

Federal statutes at issue apply their protections to the funds at issue, regardless of whether those funds are awarded to domestic or foreign entities. If foreign entities wish not to be bound by these conscience protections, they may choose not to accept the relevant funds.

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule⁶⁸ and above, and considering the comments received, the Department finalizes the definition of “entity” by including “or, as applicable, a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).” The Department also adds the term “the Department” to the definition of “entity,” for clarity.

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

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

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

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

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

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

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

rule⁶⁹ and above, and considering the comments received, the Department finalizes the definition of “Federal financial assistance” as proposed, with a modification in paragraph (5) to remove references to a “Federal” agreement and “arrangement” so that the text now refers to “any agreement or other contract between the Federal government and a recipient,” and to clarify the terminology by referring to “provision of a subsidy to the recipient” to avoid a circular definition related to the provision of “assistance.”

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

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

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

Comment: The Department received comments questioning how entities that

are not natural persons can hold moral or religious beliefs.

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

Finally, religious faith and moral convictions are often the organizing principle for entities covered in this rule, and natural persons form these organizations for the purpose of asserting their faith or convictions more

forcefully and effectively in the public realm. As the Supreme Court has recognized, there is nothing about organizing in a group that diminishes the rights they would enjoy as individuals.⁷¹ Therefore, the Department considers it appropriate to finalize the definition of health care entities to include non-natural persons.

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

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

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

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

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

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

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

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

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

The Department concludes it is appropriate to include “a plan sponsor” in the definition “health care entity” for purposes of the Weldon Amendment and ACA section 1553. The Weldon Amendment explicitly protects entities that do not pay for or provide coverage of abortions, and includes “health insurance plans, or any other kind of health care facility, organization, or plan” within its own illustrative list of protected health care entities. ACA section 1553 applies to government entities receiving Federal financial assistance under the ACA, and any health plan created under the ACA. It

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

In further consideration of public comments, however, the Department has concluded that the definition of “health care entity” should be different for the Coats-Snowe Amendment than for the Weldon Amendment and ACA section 1553, including with respect to whether to include a plan sponsor. The Coats-Snowe Amendment, while providing a non-exclusive list of entities and individuals included in the term “health care entity,” contains a different list of entities and individuals than that set forth in the Weldon Amendment and ACA section 1553. Moreover, the nature and scope of protections set forth in the Coats-Snowe Amendment—which can assist in understanding the intended range of protected health care entities—also differ. The Coats-Snowe Amendment focuses generally on the performance of, training for, and referral for abortions, whereas the Weldon Amendment focuses more broadly on

not just providing and referring for, but also providing coverage of, and payment for, abortions. Similar to the Weldon Amendment, and unlike the Coats-Snowe Amendment, ACA section 1553 focuses on the context of health plans and coverage in addition to the provision of items and services. Consequently, the Department concludes that it is appropriate to finalize a definition of health care entity for the Coats-Snowe Amendment that is somewhat different from the definition applicable to the Weldon Amendment and ACA section 1553, and to not include in the definition for purposes of the Coats-Snowe Amendment entities pertaining specifically to the health insurance and coverage context, namely, a provider-sponsored organization, a health maintenance organization, a health insurance plan (including group or individual plans), a plan sponsor, an issuer, or a third-party administrator. Likewise, the Department deems it appropriate not to list in the definition applicable to the Coats-Snowe Amendment the catch-all phrase that is in the statutory text of the Weldon Amendment and ACA section 1553: “or third-party administrator; or any other kind of health care organization, facility, or plan.”

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

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

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

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

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

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

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

and entities set forth in these definitions.

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

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

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

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

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

Response: The Department disagrees. The list of individuals, persons and entities included as a “health care entity” in the Weldon Amendment and ACA section 1553 includes “an individual physician,” and also the catch-all phrases “or other health care professional.” The Coats-Snowe Amendment says the term includes “individual physician” and “a participant in a program of training in the health professions.” Because the term “health care entity” includes individuals, and the definitions are non-exclusive, the Department deems it appropriate to include other individuals who are health care personnel. Including “health care personnel” and/

or “health care professional” in the definition of “health care entity” is, therefore, consistent with Congress’s explicit inclusion of individual persons in the health care field. Doing so effectuates the remedial purposes of the Coats-Snowe Amendment, the Weldon Amendment, and ACA section 1553, and is consistent with their texts.

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule⁷³ and above, and considering the comments received, the Department finalizes the definition of “health care entity” with changes to bifurcate the definition into two: One applicable for purposes of the Coats-Snowe Amendment, and the other applicable for purposes of the Weldon Amendment and ACA section 1553. Both definitions add pharmacies and pharmacists. Both add the word “medical” before the term “laboratory” to more clearly describe its health care scope, and both note that “as applicable, components of State or local governments may be health care entities.” The definition applicable to the Coats-Snowe Amendment omits the terms “a provider-sponsored organization; a health maintenance organization; a health insurance plan (including group or individual plans); a plan sponsor, issuer, or third-party administrator; or any other kind of

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

health care organization, facility, or plan.”

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

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

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

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

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

Response: Because of the broad scope of what could constitute a “health program or activity” (now “health service program”), the Department declines to attempt a comprehensive listing of examples of such programs or activities and instead relies on the general standard proposed. The

Department believes vaccination programs would reasonably be considered a health program or activity (or a health service program) and notes that one of the statutes that is the subject of this rule concerns vaccination explicitly (42 U.S.C. 1396s(c)(2)(B)(ii)).

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

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

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule,⁷⁵ above and below, and considering the comments received, the

Department adopts the definition of “health program or activity” as proposed as the definition of “health service program,” except makes a technical edit for clarity by replacing commas with semicolons after “directly,” the phrase “through payments, grants, contracts, or other instruments,” and after “through insurance.” Additionally, it deletes the reference to “health service program” from the proposed definition as circular.

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

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

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

⁷⁴ 83 FR 3880, 3894.

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

circumstances, paragraph (d) would not apply.

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

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

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

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

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

Summary of Regulatory Changes: The Department asked for comment on whether “health program or activity” and “health service program” should or could be defined interchangeably for purposes of this regulation⁷⁶ but received no specific comments on the question. Upon further consideration the Department has concluded that there are insufficient grounds for defining such similar terms differently under the rule.

The Department’s definition for “health service program” in the proposed rule mirrored the definition of the term in the 2008 Rule.⁷⁷ The 2008 Rule, in turn, incorporated the phrase “health benefits” into the definition of “health service program” by borrowing from Section 1128B(f)(1) of the Social Security Act’s (42 U.S.C. 1320a–7b(f)(1)) definition of “Federal health care program”—the rationale being that “Federal health care program” was similar enough to “health service program,” to warrant the borrowing. With respect to the inclusion of “health benefits,” in the definition of “health service program,” this was appropriate because the Federal health service programs implemented under the Social Security Act are programs administered by the Secretary—and, thus, consistent with the language of the Church Amendment. However, the Social Security Act is not (and was not) the exclusive basis for defining the scope of

“health service program.” The Department believes that it is also appropriate to consider the Public Health Service Act (PHSA) as a source for defining the term “health service program” because, (1) the Church Amendments themselves cite the PHSA to help establish what programs are covered and (2) the PHSA uses the phrase “health service program” and “health services” numerous times. For example, the PHSA provides grant authority to assist States and other public entities “in meeting the costs of establishing and maintaining preventive health service programs” (42 U.S.C. 247b), and grants the Secretary permission to enter into contracts to “furnish health services to eligible Indians” (42 U.S.C. 238m).

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

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

⁷⁶ 83 FR 3880, 3894.

⁷⁷ *Id.*

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

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

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

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule⁷⁸ and above, the Department

adopts the definition of “instrument” as proposed.

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

Summary of Regulatory Changes: For the reasons described in the proposed rule⁷⁹ and above, the Department adopts the definition of “OCR” as proposed.

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

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

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

As discussed concerning the definition of the term “entity,” the Department is finalizing the terms “entity,” “recipient,” and “sub-recipient” with parallel language to

clarify that they all may encompass “a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).”

Summary of Regulatory Changes: For the reasons described in the proposed rule⁸⁰ and above, and considering the comments received, the Department finalizes the definition of “recipient” with a change to the last sentence, so that rather than referring only to “foreign or international organizations,” it reads “The term may include a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).”

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

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

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

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

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

⁷⁸ 83 FR 3880, 3894.

⁷⁹ 83 FR 3880, 3894.

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

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

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

Nevertheless, the Department has made significant modifications to the definition of “discrimination” that

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

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

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

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

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

Response: The Department disagrees. The rules do not prohibit any doctor or health care entity from providing information to their patients—or referring for a medical service or treatment—if they feel they have a medical, legal, ethical, or other duty to do so. The rules simply enforce existing laws that prevent doctors or other protected entities from being forced to refer for abortions against their will or judgment. The rule’s definition of “referral or refer for” ensures that doctors can use their own professional, medical, and ethical judgment without being coerced by entities receiving Federal funds to violate their moral or

religious convictions. To the extent a State subject to this rule (under, for example, the Coats-Snowe Amendment or the Weldon Amendment) legally mandates that protected individuals and entities refer for abortion, Congress has indicated such mandates are inconsistent with Federal law.

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

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

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

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

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

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

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

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

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

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

Comment: The Department received comments stating that the proposed definition of “referral or refer for” could result in a health care professional

refusing to refer a woman for treatment of ovarian cancer because sterilization would be a “possible outcome of the referral.”

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

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

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

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

rather than including the plans’ employees, exempting administrative tasks performed by a health plan’s employees, or limiting the definition of “referral or refer for” to not include health plans or their employees.

Response: The Department replaced paragraph (4) to the definition of “discriminate or discrimination” to make clear that employers can use, and are encouraged to pursue, accommodation procedures with protected employees. Additionally, the Department added paragraphs (5) and (6) to the definition of discrimination to clarify that, within limits, employers may require protected employees to inform them of objections to referring for, participating in, or assisting in the performance of specific procedures, programs, research, counseling, or treatments to the extent there is a reasonable likelihood⁸³ that the protected entity or member may be asked in good faith to refer for, participate in, or assist in the performance of such conduct.

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

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

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

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

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

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

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

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

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

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

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

Response: The Department disagrees. The DeConcini Amendment's reference to "a broad range of family planning methods and services" does not include abortion. Rather, the amendment itself contrasts abortion with that broad range of family planning methods and services and excludes abortion as a method of family planning. Another proviso bars the use of "funds made available under this Act . . . to pay for the performance of abortion as a method of family planning or to motivate or coerce any person to practice abortions" and "[t]hat nothing in this paragraph shall be construed to alter any existing statutory prohibitions against abortion under section 104 of the Foreign Assistance Act of 1961." The Department believes the best reading of that amendment is that the broad range of family planning methods and services is viewed as an alternative to abortion, not that the amendment mandates referrals for abortion as if they are part of family planning. In the context of foreign assistance, since the 1980s, four different presidential administrations

have implemented policies to prohibit foreign assistance for family planning to go to entities that perform or actively promote abortion as a method of family planning, and Congress has been aware of those policies.⁸⁵ Furthermore, the DeConcini Amendment's discussion of a broad range of family planning methods and services is nearly identical to the scope of the Title X statute, 42 U.S.C. 300. In that context, Congress made clear that it does not consider abortion to be a method of family planning and, in fact, prohibits the use of Federal funds in programs where abortion is a method of family planning. *See* 42 U.S.C. 300–6.

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule⁸⁶ and above, and considering the comments received, the Department finalizes the definition of "referral or refer for" with changes as described above. The comments lead the Department to believe the text as originally proposed was unduly long, confusing, and repetitive and therefore finalizes the definition with numerous stylistic changes and deletions and nonsubstantive reordering of text to substantially improve readability. The Department also finalizes the rule to clarify that assistance related to a "program" is also encompassed by the definition in order to track the use of that phrase in statutes, including the Weldon and Coats-Snowe Amendments,

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

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

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule⁸⁷ and above, the Department adopts the definition of “State” with one change, omitting “follows” and replacing it with “shall be defined in accordance with.”

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

Comment: The Department received a comment stating that the proposed definition of “sub-recipient” is overly broad and could be read to include every contracting party with a recipient

of Federal financial assistance. The commenter proposes that “sub-recipient” should be limited “to those for whom there is a direct pass-through of Federal financial assistance and who are identified as sub-recipients of such dollars in contracts with the direct recipient.”

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule⁸⁸ and above, and considering the comments received, the Department finalizes the definition of “sub-recipient” changing “and” to “or,” replacing the phrase “to whom Federal financial assistance is extended through a recipient or another sub-recipient, or who otherwise receives Federal funds from the Department or a component of the Department indirectly through a recipient or another sub-recipient” with “to whom there is a pass-through of Federal financial assistance or Federal funds from the Department through a recipient or another sub-recipient,” and to change the last sentence previously referring to “foreign or international organizations” to read, “The term may include a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).”

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

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

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

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

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule⁸⁹ and above, and considering the comments received, the Department

⁸⁷ 83 FR 3880, 3895.

⁸⁹ 83 FR 3880, 3895.

adopts the definition of “workforce” as proposed.

Applicable Requirements and Prohibitions (§ 88.3)

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

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

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

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

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

or to the Department’s enforcement of them.

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

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

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

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

⁹⁰ *See, e.g.*, *Vt. Alliance for Ethical Healthcare, Inc. v. Hoser*, 274 F. Supp. 3d 227, 232 (D. Vt. 2017) (“Section 300a–7(d) is one of several so-called

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

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

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

Church Amendments. It excuses individuals engaged in health care or research from any obligation to perform abortions or other procedures which may violate religious beliefs or moral convictions.” (emphasis added)); *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660, 683 (Dec. 31, 2016) (“The Church Amendment forbids requiring any individual ‘to perform or assist in the performance of any part of a health service program . . . if his performance or assistance in the performance of such part of such program . . . would be contrary to his religious beliefs or moral convictions.’” (alterations)).

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

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

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

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

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

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

Comment: The Department received comments contending that the paragraphs of the rule concerning the

Church Amendments were too broad or did not faithfully apply the statutory text.

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

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

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule⁹³ and above, and considering the comments received, the Department makes certain changes in this paragraph in this final rule. The Department finalizes § 88.3(a)(1)(vi) by changing “Any entity that carries out” to “Any entity that receives funds for any health service program or research activity under any program administered by the

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

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

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

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

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

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

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

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

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

Response: The Department disagrees. As the text of the Church Amendments makes clear, when Congress wants to limit a protection to situations in which

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

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

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

The Department finalizes § 88.3 with other changes from the proposed rule to include language from the statute as follows. Specifically, the proposed rule did not reflect, as set forth in paragraph (b)(1) of the statute, that “the government involved,” meaning Federal, State, or local, “shall formulate such regulations or other mechanisms, or enter into such agreements with accrediting agencies, as are necessary to comply with this subsection.” In

response to comments, the Department has included language at the end of § 88.3(b)(2)(ii) reflecting this relevant statutory text.

Summary of Regulatory Changes: For the reasons described in the proposed rule⁹⁴ and above, and considering the comments received, the Department finalizes § 88.3(b) with the following changes.

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

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

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

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

Department rather than the entire Federal Government.

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

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

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

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

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

Response: The Department agrees that, as proposed, § 88.3 was worded to extend the Weldon Amendment to non-governmental entities in ways not encompassed by the text of the

Amendment as written. This was due to the inclusion of paragraph (c)(1)(iii) in that section, which required compliance with the Weldon Amendment by "any entity" that receives funds to which the Weldon Amendment applies. This paragraph would render superfluous paragraphs (c)(1)(i) and (ii), which require compliance with the Weldon Amendment by the Department and its programs and by any State or local government that receives funds to which the Weldon Amendment applies. The Department is therefore finalizing § 88.3(c)(1) by removing paragraph (c)(1)(iii).

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

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

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

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

"Nothing in this Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions."

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

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

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

Comment: The Department received comments asking for clarification that

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

the Weldon Amendment only applies with respect to abortions.

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

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule⁹⁷ and above, and considering the comments received, the Department finalizes § 88.3(c) as proposed, except for changes to the citation to the most current Public Law where the Weldon Amendment may be found, and the removal of proposed paragraph (c)(1)(iii). Additionally, the Department is adding the phrase "and its programs" after "the Department" to track the statutory language more closely.

88.3(d). Medicare Advantage, Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Public Law 115–245, Div. B, sec.

209. The Department did not receive comments on this paragraph. The Department has updated the title of this paragraph for the most recent appropriations rider for the current fiscal year. For clarity and accuracy, in paragraph (d)(1), the Department changed "under the Medicare Advantage program" to read "with respect to the Medicare Advantage program," and updated the citation therein.

Summary of Regulatory Changes: For the reasons described in the proposed rule⁹⁸ and above, the Department finalizes § 88.3(d) primarily as proposed, but updates the header and citations in paragraph (d)(1) to reflect the citation for this appropriations rider for FY 2019, and replaced "under," and adds "informs the Secretary that it" for clarity in paragraph (d)(2).

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

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

Response: The Department disagrees with this comment. Congress specified in section 1553 that a health care entity is protected in its decision not to provide "any health care item or service furnished for the purposes of causing, or for the purpose of assisting in causing" assisted suicide, euthanasia, or mercy killing. The Department is unaware of any Federal requirement that an individual or health care entity provide information about a service that it does not provide. Medical ethics have long protected rights of conscience alongside the principles of informed consent. The Department does not believe that enforcement of conscience protections, many of which date to the era of *Roe v. Wade* and *Doe v. Bolton*, violates or undermines the principles of informed consent. In fact, in *Roe* the Supreme Court favorably cited an American Medical Association resolution on abortion affirming "[t]hat no physician or other professional personnel shall be compelled to perform any act which violates his good medical judgment. Neither physician, hospital, nor hospital personnel shall be required to perform

any act violative of personally-held moral principles."⁹⁹ Similarly, in *Doe* the Court spoke favorably about Georgia's statutory language giving a hospital the freedom not to admit a patient for an abortion, and protecting a physician or other hospital employee "for moral or religious reasons" from participating in an abortion procedure.¹⁰⁰ The Department interprets section 1553 as specifically encompassing the decision by a health care entity not to provide information about, or referrals for, assisted suicide.¹⁰¹

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

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

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

⁹⁹ 410 U.S. at 143–44.

¹⁰⁰ 410 U.S. at 197–98.

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

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

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

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

⁹⁸ 83 FR 3880, 3895.

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

Summary of Regulatory Changes: For the reasons described in the proposed rule¹⁰³ and above, and considering the comments received, the Department finalizes § 88.3(e) as proposed with minor technical changes for clarity and adherence to the text of section 1553 of the ACA, for example changing “any amendment” to “an amendment” and clarifying that “the Act” refers to the “Patient Protection and Affordable Care Act.” Paragraph (e)(1)(iv) clarifies that the amendment would have been “made by the Patient Protection and Affordable Care Act,” and paragraph (e)(2) deletes “provided, that.”

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

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

Response: The Department disagrees. Section 1303 contains several distinct provisions relating to conscience and conscience protections, in section 1303. While section 1303(c)(2) references and preserves the applicability of Federal laws regarding conscience protection,¹⁰⁴

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

Summary of Regulatory Changes: For the reasons described in the proposed rule¹⁰⁵ and above, and considering the comments received, the Department finalizes § 88.3(f) as proposed, with a technical correction to reflect that 42 U.S.C. 18023(b)(1)(A) is a rule of construction regarding Title I of the Patient Protection and Affordable Care Act, rather than a substantive prohibition. In paragraph (f)(2)(i), the Department clarifies that the entities shall not “construe anything in Title I of the Patient Protection and Affordable Care Act (or any amendment made by Title I of the Patient Protection and Affordable Care Act) to.”

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

The Department intended § 88.3 to faithfully apply the text of applicable statutes, including section 1411 of the Affordable Care Act, while at the same time, providing clarity to regulated persons and entities. To this end, the final rule clarifies in § 88.3(g)(2) that the Department is required not only to provide a certification documenting a religious exemption from the individual responsibility requirement and penalty under the Affordable Care Act, which appeared in the proposed rule, but also

to coordinate with State Health Benefit Exchanges (State Exchanges) in the implementing of the certification requirements of 42 U.S.C. 18031(d)(4)(H)(ii) where applicable. The Department works closely with State Exchanges to implement the Affordable Care Act, and for clarity, the final rule reflects that coordination. For similar reasons, the Department modified § 88.3(g)(2)(i) to reflect changes Congress made to 26 U.S.C. 5000A through section 4003 of the SUPPORT for Patients and Communities Act, which became law October 24, 2018.¹⁰⁶ Those changes retained a reference in 26 U.S.C. 5000A to 26 U.S.C. 1402(g)(1), which sets out various conditions for eligibility for the conscience exemption from the individual responsibility requirement. Among those conditions is a requirement that the religious sect or division thereof to which the applicant for the exemption belongs must have been in existence at all times since December 31, 1950. The Department has omitted this particular requirement from § 88.3(g)(2)(i) out of concern that it may conflict with the Establishment Clause.

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

Summary of Regulatory Changes: For the reasons described in the proposed rule¹⁰⁸ and above, the Department finalizes § 88.3(g) as proposed, with technical corrections to reflect that the individuals to whom the Department grants certifications under 42 U.S.C. 18081 are individuals who have applied for such certifications and to ensure the language follows that of the statute, a typographical correction to change the reference to “5000A(2)(B)(ii)” to “5000A(d)(2)(B)(i),” modifications to comport with Congress’s revisions to 42 U.S.C. 5000A(d) through the October 24, 2018, enactment of the SUPPORT for Patients and Communities Act, which broadens the application of the exemption and discusses exclusions regarding what constitutes medical

¹⁰³ 83 FR 3880, 3895.

¹⁰⁴ 42 U.S.C. 18023(c)(2) (“[n]othing in this Act shall be construed to have any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii)

discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion”).

¹⁰⁵ 83 FR 3880, 3895.

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

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

¹⁰⁸ 83 FR 3880, 3895.

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

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

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule¹⁰⁹ and above, and considering the comments received, the Department finalizes § 88.3(h)(2)(i) by referring to regulations that also implement the statutes containing the requirements and prohibitions, for example by adding “construe 42 U.S.C. 1395w–22(j)(3)(A) or 42 CFR 422.206(a) to,”; by deleting “offer a plan that provides, reimburses for, or provides” and replace it with “provide, reimburse for, or provide,”; inserting “offering the plan” to the end of paragraph (h)(2)(i); and adding paragraph (h)(2)(i)(B) regarding making information available to prospective enrollees and enrollees. The Department also made changes to paragraph (h)(2)(ii) by changing the phrase “shall not require a Medicaid managed care organization to provide” to “shall not construe 42 U.S.C. 1396u–2(b)(3)(A) or 42 CFR 438.102(a)(1) to require,”; deleting “objects to the provision of such service on moral or religious grounds,”; and adding paragraphs (h)(2)(ii)(A) and (B), (A) stating the organization objects on moral or religious grounds and (B) regarding the policies to prospective enrollees and enrollees.

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

Comment: The Department received a comment stating that 42 U.S.C. 1395cc(f) requires that certain entities maintain written policies and

procedures to inform patients of their “individual rights under State law to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advanced directives,” but the proposed rule “attempt[s] to rewrite this provision by prohibiting this statute from being construed to require covered entities to provide full information to patients about services to which they may object.”

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

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

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

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

rule¹¹⁰ and above, and considering the comments received, the Department finalizes § 88.3(i) with a change to correct a typographical error in § 88.3(i)(2)(i), where “1395a(w)” should instead read “1396a(w)(3).”

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

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

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

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

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

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

¹¹⁰ 83 FR 3880, 3895.

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

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

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

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

Response: Upon reviewing the text of this paragraph, the Department has revised the language to make it clearer as to which laws and amendments are implicated by this paragraph, and to more closely track the statutory language enacted by Congress. For clarity, the heading of the paragraph has been revised to refer to each of the four separate statutory provisions implemented by the paragraph, rather

than only to the Helms Amendment. For consistency with the statute, the paragraph includes a new paragraph in the “Applicability” paragraph identifying as a distinct class of covered entities those entities that are authorized to obligate or expend the Federal financial assistance in question, separate from entities that merely receive such Federal financial assistance. The paragraph also now specifies that the Federal financial assistance in question for this paragraph is that which is appropriated for the purposes of carrying out part I of the Foreign Assistance Act of 1961.

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

Summary of Regulatory Changes: For the reasons described in the proposed rule ¹¹³ and above, and considering the comments received, the Department finalizes § 88.3(k) with technical changes clarifying the citations and language as to which statutes and amendments are referenced, and to more closely follow the language of such statutes and amendments as

enacted by Congress, and adding clarity through citations to paragraphs within this part.

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

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

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

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

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

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

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

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

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

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

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

¹¹³ 83 FR 3880, 3895.

¹¹⁴ 83 FR 3880, 3895.

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

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

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

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

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

Response: Although Congress granted HHS authority to conduct research, experiments, and demonstrations related to occupational illnesses in the Occupational Safety and Health Act of 1970, such authority did not include the power to require “medical examination, immunization, or treatment for those who object thereto on religious grounds, except where such is necessary for the protection of the health or safety of others.” 29 U.S.C. 669(a)(5). The Department is required to abide by this limitation, and considers it appropriate to issue a final rule ensuring compliance.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

¹¹⁵ 83 FR 3880, 3895.

¹¹⁶ 83 FR 3880, 3895.

patients of such facilities not seeking other treatment options.

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

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

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

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

Response: Requiring religious nonmedical health care facilities to adhere to the same standards as other skilled nursing facilities and providers would contradict Congress's determination to exempt religious nonmedical health care facilities, as

provided for in 42 U.S.C. 1396a(a) and as upheld in *Children's Healthcare Is a Legal Duty, Inc. v. Min De Parle*, 212 F.3d 1084 (8th Cir. 2000) (“[S]tate plans may not establish State agency oversight of the quality of care provided in RNCHIs [sic].”). The Department, therefore, rejects this proposal.

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

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule¹¹⁹ and above, and considering the comments received, the Department made significant changes to the structure of § 88.3(q) to clarify applicable statutes and paragraphs, correct typographical errors, and more closely track the statutory language. The Department more clearly articulates which paragraphs are applicable to different entities by, for example, changing “(q)(2)(i) through (iii)” so that it now clearly states “(q)(2)(i), (ii), (iii),

and (iv).” The Department added “(h)” to the reference to 42 U.S.C. 1320a–1 to clarify the particular paragraph containing relevant information. The Department clarified in paragraph (q)(1)(ii) that some State agencies are required to comply, in paragraph (q)(1)(iii) that entities receiving Federal financial assistance from Medicare have compliance obligations, and in paragraph (q)(1)(iv) that entities including States that receive Federal financial assistance from Medicaid have compliance obligations, and in paragraph (q)(1)(v) clarified the authority related to an elder's right to practice his or her religion through reliance on prayer alone is subtitle B of Title XX of the Social Security Act (42 U.S.C. 1397j–1397m–5) and eliminated what was the last paragraph regarding the Elder Justice Block Grants. The paragraph incorporates multiple references to 42 U.S.C. 1395x(ss)(1), which defines a religious nonmedical health care institution, to add clarity to the regulation. The paragraph clarifies the application of various provisions to entities that make an agreement with the Secretary of the Department pursuant to 42 U.S.C. 1320a–1(b), or receive Federal financial assistance from Medicare, Medicaid, or Subtitle B of Title XX of the Social Security Act (42 U.S.C. 1397j–1397m–5). Last, the Department removed the references requiring compliance with § 88.5, as compliance with that section is now voluntary.

Assurance and Certification of Compliance Requirements (§ 88.4)

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

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

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

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

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

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

The Department proposed that its components be given discretion to phase in the written assurance and certification requirement by no later than the beginning of the next fiscal year following the effective date of the regulation. The Department stated its

intent to work with recipients of Federal financial assistance or other Federal funds from the Department to ensure compliance with the requirements or prohibitions promulgated in this regulation. If the applicant or recipient would fail or refuse to furnish a required assurance or certification, the Department proposed that OCR, in coordination with the relevant Department component, would be authorized to effect compliance by any of the remedies provided in § 88.7. *See Grove City College*, 465 U.S. 555 (affirming partial termination of institution's Federal funds for refusing to sign a Title IX assurance of compliance form).

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

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

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

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

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

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

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

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

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

¹²¹ *Id.*

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

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

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

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

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

Response: The Department does not agree. This collection of assurances and certifications would facilitate the Department’s obligation to ensure that the Federal financial assistance or other Federal funds that the Department awards are used in a manner that complies with Federal conscience and anti-discrimination laws and this rule. The Department is accountable to the

American public for protecting the integrity of Federal financial assistance and other Federal funds that the Department awards. The Department’s administration of a requirement for a person or entity at the time of application or reapplication to assure and certify compliance with Federal conscience and anti-discrimination laws and the final rule demonstrates that the person or entity was aware of its obligations under those laws and the rule.

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

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

Comment: The Department received a comment stating that the requirement

that covered entities provide assurances and certifications of compliance could lead to third-party *qui tam* lawsuits parallel to the Department’s enforcement actions.

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

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

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

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

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

¹²² U.S. Dep’t of Health & Human Serv., HHS Grants Policy Statement, I-31 (Jan. 2007), <https://www.hhs.gov/sites/default/files/grants/policies-regulations/hhsgrps107.pdf>.

¹²³ 45 CFR 75.300(a).

¹²⁴ *Id.*

¹²⁵ *Id.* sec. 75.208.

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

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

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

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

Response: In contrast to doctors and other health care practitioners who participate in Medicare Part B and are considered recipients under this rule because these providers receive direct payments from the Centers for Medicare & Medicaid Services, Medicare Part C (Medicare Advantage) providers are not recipients, as defined by this rule, but

instead are sub-recipients. Under the Medicare Part C program, HHS makes payments to the private plan, which is the recipient for the purpose of Medicare Part C, and the plan pays the provider, which under this rule would be considered a sub-recipient.¹²⁹ Therefore, § 88.4(c) does not need to exempt Medicare Part C providers because, as a threshold manner, the assurances and certifications requirement of § 88.4 do not apply to providers participating in Medicare Part C. The same is true of participants in Medicare Part D.¹³⁰

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule¹³¹ and above, and considering the comments received, the Department finalizes § 88.4 with the following changes: A change to paragraph (b)(1), deleting "applicants or recipients" and replacing with "entities" for accuracy; a

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

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

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

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

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

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

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

¹²⁷ 73 FR at 78101.

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

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

¹³⁰ See *id.*

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

would be required to appear: On the Department's and recipient's website(s), and in a physical location of each Department and recipient establishment where notices to the public and notices to their workforce are customarily posted. With regard to the physical posting, paragraph (b)(2) would impose readability requirements without identifying prescriptive font-size or other display requirements.

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

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

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

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

compliance with other Federal civil rights protections.

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

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

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

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

Response: The Department agrees that recipients should be permitted to draft their own notices so as to avoid misrepresentations and to tailor their notice to their particular circumstances and is modifying § 88.5 to acknowledge

and accept self-drafted notices to provide greater flexibility.

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

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

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

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

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

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

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

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

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

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

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

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

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

conscience and anti-discrimination laws.

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

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

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

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

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

Response: To the extent the commenters took this position because they did not believe that the protections of the Federal conscience and anti-discrimination laws would apply to

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

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

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

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

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

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

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule¹³² and above, and considering the comments received, the Department finalizes § 88.5 with changes so that notices are not required, but will be a voluntary best practice that may demonstrate compliance in any OCR investigation. The rule specifies that OCR may, in investigating complaints and conducting compliance reviews, consider the extent to which covered entities post notices according to the rule's notice provisions as non-dispositive evidence of compliance with substantive provisions of the rule applicable to covered entities. The section also now permits recipients to draft their own version of the notice, or to combine the notice with other non-discrimination notices, to allow greater accuracy, flexibility, and tailoring to their particular circumstances. The Department also changes the section to reflect that, while guidance regarding particular placement of notices remains a factor for compliance consideration purposes, all notice placement provisions may not be applicable or appropriate to all covered entities. The Department also changes the section to remove the requirement that the notice be posted within 90 days of the publishing of the rule, or, with respect to new recipients, within 90 days of becoming a recipient, to reflect that posting of the notice is voluntary and that there is no mandated time frame within which a notice must be posted. The Department also changes the section to include, in paragraphs (b)(3) and (4), "the Department" in addition to recipients, for additional clarity. Finally, the Department makes a technical change to relocate the proposed rule's provision regarding the readability of the notice text from

paragraph (b)(2) in the proposed rule to paragraph (b)(6) in the final rule.

Compliance Requirements (§ 88.6)

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

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

Response: The Department agrees that such reporting requirements are unnecessary in situations in which an investigation has found no violation. The Department also agrees that the provision of such reports to funding components of the Department for already awarded Federal financial assistance or Departmental funding is unnecessary because the Office for Civil Rights can notify such funding components at the time such a

determination of violation is made. The Department disagrees that such records of violations are unnecessary as to future awards of Federal financial assistance or Departmental funding, because the Department does not maintain records of all such findings in a manner that is generally accessible to funding components across the Department.

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

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

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

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

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

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

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

Response: The Department agrees that greater specificity as to the records that should be maintained, how long such records should be maintained, and in what format such records should be kept is appropriate. Therefore the Department will finalize the rule with modifications specifying that records (1) shall be maintained for a period of three years from the date the record was created, was last in force, or was obtained, by the recipient or sub-recipient; (2) shall contain any information maintained by the recipient or sub-recipient that pertains to discrimination on the basis of religious belief or moral conviction, including any complaints; statements, policies, or notices concerning discrimination on the basis of religious belief or moral conviction; procedures for accommodating employees' or other protected individuals' religious beliefs or moral convictions; and records of requests for such religious or moral accommodation and the recipient or sub-recipient's response to such requests; and (3) may be maintained in any form and manner that affords OCR with reasonable access to them in a timely manner. These modifications are consistent with recordkeeping requirements employed in other civil rights regulations. For example, the Department of Justice imposed three-year record maintenance for self-evaluations¹³³ required under

regulations implementing section 504 of the Rehabilitation Act, and the Department or the Department of Justice imposed similar requirements in regulations under Title II of the Americans with Disabilities Act, the Age Discrimination Act of 1975, and Title IX of the Education Amendments of 1972.¹³⁴ And HHS regulations under Title VI, Age Discrimination Act of 1975, and Titles VI and XVI of the Public Health Service Act generally require that a recipient maintain records necessary to determine whether the recipient has complied with the law.¹³⁵

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

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

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

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

requirements of this part and, to the extent modification of any such services, policies, and practices is required, the public entity shall proceed to make the necessary modifications." 28 CFR 35.105(a).

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule¹³⁶ and above, and considering the comments received, the Department finalizes § 88.6 with substantial changes as described above, by making a technical correction to provide OCR with greater enforcement discretion concerning the responsibility of recipients for violations of the rule by sub-recipients, by changing "shall" to "may" in paragraph (a); by providing greater specificity as to the records covered entities are required to maintain and for how long in paragraphs (b)(1) through (3); by making a technical correction to provide greater clarity on how a covered entity's failure to cooperate may result in an OCR referral to the Department of Justice by inserting "in coordination with the Department's Office of General Counsel" in paragraph (c); by making a technical correction, in keeping with the Department's intent for § 88.6 to mirror Title VI enforcement regulations where applicable, to add a provision regarding the time and manner of OCR's access to records, and the applicability of confidentiality and privacy concerns to OCR's access in paragraph (c); by shortening from five years to three years in paragraph (d) the period for disclosing in any application for new or renewed Federal financial assistance or Departmental funding any determination by OCR of noncompliance to reduce the burden on covered entities; by revising reporting requirements in paragraph (d) to reduce the burden on covered entities by eliminating reporting requirements in situations in which such reports are unnecessary or redundant with actions taken by the Department, such as disclosing the existence of complaints, compliance reviews, or investigations in any application for new or renewed Federal financial assistance or Departmental funding; and by making a technical correction at the end of paragraph (d) to clarify that recipients disclose any OCR determinations made against their sub-recipients.

Enforcement Authority (§ 88.7)

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

¹³³ See, e.g., "A public entity shall, within one year of the effective date of this part, evaluate its current services, policies, and practices, and the effects thereof, that do not or may not meet the

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

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

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

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

In this section of the proposed rule, the Department proposed to adopt the enforcement procedures for other civil rights laws, such as Title VI and section 504 of the Rehabilitation Act, for the Federal conscience and anti-discrimination laws. The Department solicited comments on what administrative procedures or opportunities for due process the Department should, as a matter of policy, or must, as a matter of law, provide (1) with respect to the remedial and enforcement measures that the Department may consider imposing or utilizing in response to a failure or threatened failure to comply with Federal conscience and anti-discrimination laws or this part, (2) before the Department may terminate Federal financial assistance or other Federal funds from the Department, or (3) before the Department may implement any or all of the remedial measures identified in § 88.7(i)(3) of the proposed rule. For example, comment was requested on whether the proposed

rule should establish notice, hearing, and appeal procedures similar to those established in the Department's regulations implementing Title VI of the Civil Rights Act of 1964, at 45 CFR 80.8–80.10. The Department also requested comment on whether and in what circumstances it would be appropriate to require remedies against a recipient for the violations of a sub-recipient, or against entities' subsidiaries that are found to be in violation of any Federal conscience and anti-discrimination law or the proposed regulation.

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

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

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

As for their reasonableness, compliance reviews are a standard tool for ensuring compliance with Federal nondiscrimination statutes, despite the fact that most Federal

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

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

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

Response: The Department agrees with this comment in part. Potential penalties vary among the Federal conscience and anti-discrimination laws as set by Congress. In addition, to the extent penalties may be imposed involuntarily, regulations such as those that apply to HHS grants, contracts, and CMS programs discussed above provide a well-established process for enforcing compliance with the terms and conditions of grants and contracts and programmatic regulations that require compliance with certain non-discrimination provisions.

Consequently, in order to increase the clarity and uniformity of involuntary remedial processes applied through this rule, the Department has concluded that penalties imposed involuntarily under this rule will be imposed through those applicable regulations, such as 45 CFR part 75, or the FAR and HHSAR. This is preferable both to an independent framework mirroring those of Title VI

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

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

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

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

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

Comment: The Department received a comment stating that the proposed

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

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

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

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

Response: The Department of Justice acts as the Department's representative in court, and the Department routinely refers matters that require litigation on its behalf, or on behalf of the United States, to the Department of Justice including laws enforced by OCR. Furthermore, entities that make assurances or certifications of compliance under § 88.4, or that make other statements or productions to the Department under this part, do so under penalty of 18 U.S.C. 1001 (prohibiting materially false statements regarding an agency matter), violations of which may warrant referral to the Department of

Justice. Additionally, the Department of Justice would be the appropriate party to receive referrals of potential violations of 42 U.S.C. 300a–8 which imposes criminal penalties on any officer or employee of the United States, or of any entity that administers federally funded programs (including States), and on any person receiving Federal financial assistance, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance. As a result, the Department finalizes the rule by amending § 88.7(i) (renumbered as § 88.7(h)) to clarify that possible appropriate referrals to the Department of Justice include potential violations of 42 U.S.C. 300a–8 and 18 U.S.C. 1001.

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

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

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

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

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

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

¹³⁷ 45 CFR 160.308.

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule¹³⁹ and above, and considering the comments received, the Department finalizes § 88.7 by making the changes discussed above, which include clarifying that OCR will serve a coordinating role with other Department

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

Relationship to Other Laws § 88.8

This section would clarify the relationship between this part and other Federal, State, and local laws that protect religious freedom and moral convictions. In the proposed rule, the preamble for this section acknowledged that many State laws provide additional conscience protections for providers

who have objections to abortion, fertility treatments, sterilization, assisted suicide, and euthanasia, among others. The Department proposed to uphold the maximum protection for the rights of conscience and the broadest prohibition on discrimination provided by Federal, State, or local law, as consistent with the Constitution. Where a State or local law provides as much or greater protection than Federal law for religious freedom and moral convictions, the Department proposed not to construe Federal law to preempt or impair the application of that law, unless expressly provided.

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

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

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

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

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

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

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

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

Third, “it is a commonplace of statutory construction that the specific governs the general,” *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992). Each Federal conscience and anti-discrimination law enforced by this rule is more specific to each set of circumstances than is section 1554, so that, to the extent there could be a potential conflict between the statutes, the more specific Federal conscience and anti-discrimination laws require that section 1554 not be interpreted to supersede them. For example, to the extent this rule enforces specific provisions of the ACA, such as ACA sections 1303(b)(1)(A) and (b)(4) and 1553, the rule enforces those laws according to their own text. The Department disagrees with the commenter’s implication that, in ACA

section 1554, 42 U.S.C. 18114, Congress intended to prohibit the enforcement of ACA sections 1303(b)(1)(A) and (b)(4) and 1553 as written. Generally, one part of a statute should not be interpreted to negate many other parts of the same statute, because that would render those parts of the statute meaningless.

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

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

or interferes with doctor-patient communications. The underlying statutes enforced by this rule apply, or do not apply, to communications between a patient and provider of their own force, and this final rule does not “interfere” in those communications merely by protecting conscience rights established by Congress.

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

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

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

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

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

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

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

Response: The Department disagrees. First, as noted above, the Department believes that this rule will result in greater access to health care or greater options from a wider and more diverse pool of medical professionals. Additionally, the finalized definition of “discriminate or discrimination” ensures that a facility that must respect conscience can use alternative staff to

accommodate an objector without violating this rule.

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

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

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

Response: The Department disagrees. Nothing in this rule permits the Federal government to discriminate against a person on the basis of such person’s membership in a suspect class. Neither the equal protection doctrine nor any other constitutional doctrine negates any of the Federal conscience and anti-discrimination laws pertaining to abortion that this rule enforces. On the contrary, the Supreme Court has upheld laws limiting Federal funding of abortions, even of those deemed to be medically necessary, against equal protection challenges. *See Harris v. McRae*, 448 U.S. 917 (1980) (upholding the Hyde Amendment against a challenge under the Equal Protection Clause because the Hyde Amendment is rationally related to the legitimate governmental interest in preserving the life of the unborn); *Maier v. Roe*, 432 U.S. 464 (1977) (holding that government may legitimately favor childbirth over abortion through public funding); *Rust v. Sullivan*, 500 U.S. 173 (1991) (same). *Roe v. Wade* and *Doe v. Bolton* both explicitly affirmed the appropriateness of conscience

protections,¹⁴⁴ and, therefore, the scope of rights defined by either case cannot be read to conflict with conscience protections relating to abortion. This rule, additionally, furthers the legitimate governmental interest in ensuring a large and diverse pool of health care providers by removing obstacles to persons who are interested in serving as health care providers but might be unwilling to do so for fear of being coerced to violate their religious beliefs or moral convictions.

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

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

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

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

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

¹⁴² *Id.*

¹⁴³ International Covenant on Economic, Cultural and Social Rights art. 12, adopted Dec. 16, 1966, 993 U.N.T.S. 3. (The ICESCR states that the “steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; (b) The improvement of all aspects of environmental and industrial hygiene; (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.” *Id.*)

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

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

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule¹⁴⁵ and above, and considering the comments received, the Department finalizes § 88.8 without change, beyond global edits to the rule as a whole.

Rule of Construction § 88.9

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

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

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

Summary of Regulatory Changes: For the reasons described in the proposed rule¹⁴⁶ and above, and considering the

comments received, the Department finalizes § 88.9 by rephrasing it to add clarity so that it now says, “This part shall be construed in favor of a broad protection of the free exercise of religious beliefs and of moral convictions, to the maximum extent permitted by the Constitution and the terms of the Federal conscience protection and associated anti-discrimination statutes.”

Severability § 88.10

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

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

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

invalidate parts of the rule that remain statutorily supported.

Summary of Regulatory Changes: For the reasons described in the proposed rule¹⁴⁷ and above, and considering the comments received, the Department finalizes § 88.10 without change.

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

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

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

IV. Regulatory Impact Analysis

A. Introduction and Summary

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

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

¹⁴⁵ 83 FR 3880, 3899.

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

¹⁴⁷ 83 FR 3880, 3899.

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

(1) Expands the regulation's scope to encompass the full panoply of Federal health-related conscience protection

and associated anti-discrimination laws that exist across the Department and that the Secretary has delegated to OCR to handle,

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

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

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

	Present value over 5 years by discount rate (millions of 2016 dollars)		Annualized value over 5 years by discount rate (millions of 2016 dollars)	
	3 Percent	7 Percent	3 Percent	7 Percent
Benefits:				
Quantified Benefits				
<i>Non-quantified Benefits:</i> Compliance with the law; protection of conscience rights, the free exercise of religion and moral convictions; more diverse and inclusive providers and health care professionals; improved provider-patient relationships that facilitate improved quality of care; equity, fairness, nondiscrimination; increased access to care.				
Costs:				
Quantified Costs	900.7	731.5	214.9	218.5
<i>Non-quantified Costs:</i> Compliance procedures (recordkeeping and compliance reporting) and seeking of alternative providers of certain objected-to medical services or procedures.				

Analysis of Economic Impacts: Executive Orders 12866 and 13563

HHS has examined the economic implications of this final rule as required by Executive Orders 12866 and 13563. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The Department estimates that the benefits of this rule, although not always quantifiable or monetized, justify the burdens of the regulatory action.

B. Executive Order 12866

Section 6(3)(C) of Executive Order 12866 requires agencies to prepare a regulatory impact analysis (RIA) for major rules that are significant. Section 3(f) of Executive Order 12866 defines a regulatory action as significant if it is likely to result in a rule that meets one of four conditions: (1) Is economically significant, (2) creates a serious inconsistency or otherwise interferes with an action taken or planned by another agency, (3) materially alters the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of the recipients of these grants and programs, or (4) raises novel

legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866. A rule is likely to be economically significant where the agency estimates that it will (a) have an annual effect on the economy of \$100 million or more in any one year, or (b) adversely and materially affect the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The Department has determined that this rule will have an annual effect on the economy of \$100 million or more in one year and, thus, is economically significant. The rule also furthers a presidential priority of protecting conscience and religious freedom. Executive Order 13798, 82 FR 21675 (May 4, 2017).

C. Executive Order 13563

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

- “propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs,”
- “tailor its regulations to impose the least burden on society,”
- “select . . . regulatory approaches that maximize net benefits,”
- “[as] feasible, specify performance objectives, rather than specifying the

behavior or manner of compliance that regulated entities must adopt,” and

- “identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior . . . or providing information upon which the public can make choices.”

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

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

1. Need for the Rule

(i) Problems That This Rule Seeks To Address

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

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

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

- An inadequate, minimalistic regulatory scheme set forth in the Department’s 2011 Rule that rescinded the comprehensive 2008 Rule, which addressed three of the 25 statutory provisions that are the subject of this rule. *See supra* at part I (describing existing and prior versions of the rule and identifying confusion about the scope and applicability of Federal conscience and anti-discrimination laws);
- An unduly narrow Departmental interpretation of the Weldon Amendment adopted by OCR in

connection with the 2011 Rule that limited the scope of prohibited discrimination, contrary to the language that Congress passed, *see supra* at part I.B (addressing confusion caused by OCR sub-regulatory guidance); and

- A lack of strategic coordination across the Department to promote awareness of Federal protections for conscience and religious freedom in health care, and to address the enforcement of Federal conscience and anti-discrimination laws set forth in authorizing statutes of programs conducted or administered by Departmental components. *See supra* at part I.A (identifying additional Federal conscience and anti-discrimination laws).

The second category of problems—lack of awareness and, where there is awareness, confusion concerning Federal conscience protection obligations and associated anti-discrimination rights, of covered entities and individuals and entities, respectively—stems from inadequate information and understanding about such Federal law, leading to possible violations of law. Relevant situations where persons, entities, and health care entities with religious beliefs or moral convictions may be coerced or suffer discrimination include:

- Being required to perform, participate in, pay for, provide coverage for, counsel or refer for abortion, sterilization, euthanasia, or other health services;¹⁴⁸
- participating in health professional training that pressures students, residents, fellows, etc., to perform, assist in the performance of, refer for, or counsel for, abortion or sterilization;
- being steered away from a career in obstetrics, family medicine, or geriatric medicine, when one has a religious or moral objection, as applicable, to abortion, sterilization, physician-assisted suicide or euthanasia;
- being asked to perform or assist in certain services within the scope of one’s employment but contrary to one’s religious beliefs or moral convictions.

Comments received in support of the proposed rule demonstrated that

¹⁴⁸ California, for example, sent a letter to seven insurance companies requiring insurers to include abortion coverage in plans used by persons who objected to such coverage. *See Letter from California Department of Managed Health Care, Re: Limitations or Exclusions of Abortion Services* (Aug. 22, 2014). The State of California estimates that at least 28,000 individuals subsequently lost their abortion-free health plans, and multiple churches have challenged California’s policy in court. *See Foothill Church v. Rouillard*, 2:15-cv-02165-KJM-EFB, 2016 WL 3688422 (E.D. Calif. July 11, 2016); *Skyline Wesleyan Church v. California Department of Managed Health Care*, No. 3:16-cv-00501-H-DHB (S.D. Calif. 2016).

persons who are unlawfully coerced to violate their consciences, or otherwise discriminated against because they have acted in accord with their moral convictions or religious beliefs, may experience real harms that are significant and sometimes devastating psychologically, emotionally, and/or financially.¹⁴⁹ This can include loss of jobs, loss of promotion possibilities, “blackballing” in the medical community, denial of acceptance into or graduation from a medical school, denial of board certification, stigmatization, shunning by peers, and trauma and stress from forced violations of the Hippocratic Oath. Commenters shared anecdotes of the occurrence and nature of coercion, discriminatory conduct, or other actions potentially in violation of Federal conscience and anti-discrimination laws. Commenters also shared their assessment of the knowledge, or lack thereof, among the general public, health care field, health care insurance industry, and employment law field of the rights and obligations that this rule implements and enforces. Examples follow.

- Numerous commenters shared anecdotes of bias and animus in the health care sector against individuals with religious beliefs or moral convictions with respect to abortion.
- Employees shared that they experienced discrimination based on their objections to prescribing abortifacients or participating in abortion or assisted suicide.
- Commenters stated that many health care professionals’ careers are jeopardized because entities are completely unaware or willfully dismissive of applicable Federal law that protects conscience, prohibits coercion, or requires nondiscrimination.
- Students, fellows, and residents shared being forced out of residency programs or fields of medicine because of their beliefs about abortion or contraception.
- Commenters shared that they considered avoiding obstetrics and gynecology programs for fear of discrimination and shared polling data, which the RIA’s benefits section describes *infra* at part IV.C.4, documenting discrimination experienced by medical students on the basis of their religious beliefs or moral convictions.
- Commenters expressed concern that States are coercing persons and entities

¹⁴⁹ *See, e.g., Compl. Cenzone-DeCarlo v. Mount Sinai Hosp.*, No. 09-3120 (E.D.N.Y. Jul. 21, 2009) at 15 (“Being forced to assist in this abortion has caused Mrs. DeCarlo extreme emotional, psychological, and spiritual suffering.”) (dismissed on other grounds).

to violate their religious beliefs or moral convictions through laws mandating health coverage for abortion.

- One commenter noted that academic medical institutions are not self-policing compliance with, or educating students on, applicable Federal conscience and anti-discrimination laws.

- Commenters shared barriers to obtaining coverage by Medicare Advantage plans for care provided by RNHCIs.¹⁵⁰ Commenters shared that plans justified the denials of coverage and preauthorization requests because medical professionals did not provide the care (even though by definition, an RNHCI provides nonmedical care).

Some commenters have suggested that the thirty-four complaints that OCR received between November 2016 and January 2018 that allege coercion, violation of conscience, or discrimination do not necessitate this final rule.¹⁵¹ These commenters misconstrue the reasons for this rule; the increase in complaints received by OCR is one of the many metrics used to demonstrate the importance of this rule. During FY 2018, the most recently completed fiscal year for which data are available, OCR received 343 complaints alleging conscience violations.¹⁵² Some complaints raise issues that affect more than one aggrieved person, entity or health care entity; therefore, although one person may have filed the complaint, the complaint may represent the concerns and objections of all nurses at a hospital, multiple pregnancy care facilities or providers in a State, or entire populations (or subpopulations) of States or communities.

(ii) How the Rule Seeks To Address the Problems

This rule corrects those problems. First, the Department revises 45 CFR part 88 from a minimal regulatory scheme to one comparable to the regulatory schemes implementing other civil rights laws. Such schemes typically include a dozen provisions, addressing a range of conduct. These provisions typically restate the substantive requirements and

obligations of the laws and often set forth procedural requirements (e.g., assurances of compliance, recordkeeping of compliance, etc.) to advance compliance with substantive rights and obligations. In addition, the regulatory schemes outline the enforcement procedures to provide regulated entities notice of the enforcement tools available to HHS and the type of remedies HHS may seek. Part 88 in effect as a result of the 2011 Rule, by contrast, was only three sentences long and provided considerably less notice and clarity about the conduct prohibited under Federal law and the enforcement mechanisms available to HHS.

This rule confirms HHS will have the authority to initiate compliance reviews where it believes compliance issues have arisen, conduct investigations, resolve complaints, and supervise and coordinate appropriate action(s) with the relevant Department component(s) to assure compliance. Under this rule, certain persons and entities must maintain records regarding compliance with part 88; cooperate with OCR investigations, compliance reviews, interviews, or other parts of OCR's investigative process; and submit written assurances and certifications of compliance to the Department. These procedural and administrative requirements are similar to those in other civil rights regulations that promote compliance with, and enforcement of, the Federal civil rights laws that the regulations implement. Finally, by expanding the scope of part 88 to cover the 25 statutory conscience and anti-discrimination laws applicable to HHS that are the subject of this rule, the rule supports the Department's strategic coordination with respect to compliance with, and enforcement of, these laws across the Department, as well as providing one location that identifies all of the health care related conscience protections and associated anti-discrimination laws enforced by the Department so that regulated entities have clear knowledge of the applicable conscience requirements.

The investigative and enforcement processes set forth by the rule are vital because other avenues of relief are inadequate or unavailable. The Department solicited comment on whether alternate remedies, such as pursuing litigation, have been sufficient to address discrimination, coercion, or other treatment that the laws that are the subject of this rule prohibit. Many commenters stated that litigation was an inadequate option because several courts have declined to recognize a private right of action, such as under the

Coats-Snowe and Church Amendments, and have concluded that persons must rely on OCR's administrative complaint process to secure relief.¹⁵³ Some commenters also viewed litigation as unviable given the high economic costs of litigation, which may be against well-funded States or medical providers.

Second, this rule promotes voluntary compliance with laws governing the ability of health care entities to act in accord with their legally protected religious beliefs or moral convictions by ensuring that health care entities are aware of, and understand, Federal conscience and anti-discrimination laws. The rule incentivizes entities to provide notice of rights and obligations under the rule by identifying the provision of notice as non-dispositive evidence of compliance that OCR will consider if an entity is subject to an OCR investigation or compliance review. Entities will be more likely to accommodate conscience and associated anti-discrimination rights if entities understand that they are legally obligated to do so. Entities will also be in a better position to accommodate these rights if they understand these rights are akin to other civil rights protecting people from discrimination on the basis of race, national origin, disability, etc.—rights for which entities already provide notice and are familiar with respecting.

In addition, as described *infra* at part IV.C.3.i, the Department anticipates that a subset of recipients that assure and certify compliance in accordance with § 88.4 will take organization-wide action, such as to update policies and procedures, implement staffing or scheduling practices that respect the exercise of conscience rights under Federal law, or take steps to disseminate the recipient's policies and procedures concerning these laws. Greater transparency of practices through open communication of recipient and sub-recipient policies “should strengthen relationships between . . . entities and their . . . [workforce members].”¹⁵⁴

Protection of religious beliefs and moral convictions serves not only individual rights, but also society as a whole. Protections for conscience help ensure a society free from discrimination and more respectful of personal freedom and fundamental

¹⁵⁰ RNHCIs can participate in Medicare and Medicaid as long as they meet the requisite conditions of coverage and participation. See *supra* at part I.A (summarizing the history of statutory provisions regarding RNHCIs, among other provisions, which this rule implements and enforces). See also <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/RNHCIs.html>.

¹⁵¹ See 83 FR 3880, 3886 (proposed Jan. 26, 2018) (to be codified at 45 CFR pt. 88) (summarizing the history of OCR enforcement of conscience laws).

¹⁵² Complaint data based on OCR's system of records as of December 20, 2018.

¹⁵³ See, e.g., *Vermont All. for Ethical Healthcare, Inc. v. Hoser*, 274 F. Supp. 3d 227, 240 (D. Vt. 2017); *Hellwege v. Tampa Family Health Centers*, 103 F. Supp. 3d 1303, 1311–12 (M.D. Fla. 2015); Order at 4, *National Institute of Family and Life Advocates, et al. v. Rauner*, No. 3:16–cv–50310 (N. D. Ill. July 19, 2017), ECF No. 65. See also *supra* at part II.A (describing the lack of private remedies).

¹⁵⁴ 73 FR 78074, 78074 (2008 Rule).

rights enshrined in the First Amendment and Federal law. The Department shares the anticipation of many commenters who reasoned that the rule will promote a culture of respect for rights of conscience and religious freedom in health care that is currently lacking. The boundaries of protection for conscience may be tested when protections for religious beliefs and moral convictions appear to impose a cost or compete with other public purposes.¹⁵⁵ However, as with other civil rights laws, it is in those cases where fidelity to the law becomes of paramount importance.

2. Affected Persons and Entities

The final rule affects (1) persons and entities already obligated to comply with the Weldon Amendment, Coats-Snowe Amendment, or Church Amendments (or a combination thereof) under the 2008 and 2011 Rules; and (2) persons and entities obligated to comply with at least one of the other Federal statutory provisions that this rule implements.

(i) Scope of Persons and Entities Covered by 45 CFR Part 88 in 2011 Rule

Depending on the operation and applicability of the underlying statutes, the 2011 Rule, *i.e.*, 45 CFR part 88 as currently in effect, extended, and continues to extend, broadly. As explained below, the diversity of entities estimated as covered is due to the applicability of the Church Amendments, which applies to non-governmental (as well as governmental) entities that operate “any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary”;¹⁵⁶ or receive a grant, contract, loan, or loan guarantee under the Public Health Service (PHS) Act,¹⁵⁷ which contains thirty titles and authorizes dozens of programs, or under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act), or receive an interest subsidy under the DD Act.¹⁵⁸

¹⁵⁵ See Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals*, 49 Ariz. St. L.J. 549, 550–51 (2017) (“[T]he growing acceptance of this ‘public utility’ model of medicine means in practice that extant Federal and State laws protecting conscience—most of which cover only a limited range of procedures and medical practitioners, lack meaningful enforcement mechanisms, and . . . are inadequate to the task of protecting the right to conscience[] . . .” (citations omitted)).

¹⁵⁶ 42 U.S.C. 300a–7(d).

¹⁵⁷ 42 U.S.C. 300a–7(c).

¹⁵⁸ 42 U.S.C. 300a–7(e).

(A) The Department

As a result of the 2011 Rule, 45 CFR part 88 applied, and still applies, to the Department because the Weldon and Coats-Snowe Amendments, as well as specific parts of the Church Amendments, apply to the Department.

The Weldon Amendment states that “[n]one of the funds made available in [the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019] may be made available to a Federal agency or program . . . if such agency [or] program . . . subjects any institutional or individual health care entity to discrimination”¹⁵⁹ The Department is a Federal agency that receives substantial funds made available in the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, which are the funds addressed in Weldon.¹⁶⁰ The Department must comply with the Weldon Amendment.

The Coats-Snowe Amendment states that “[t]he Federal Government . . . may not subject any health care entity to discrimination on the [bases]” listed in paragraphs (a)(1)–(3) of 42 U.S.C. 238n. The Department, as part of the Federal Government, must comply with the Coats-Snowe Amendment in its operations.

Paragraphs (d) and (c)(2) of the Church Amendments apply to certain programs administered by the Secretary. Paragraph (d) applies to all health service programs or research activities funded in whole or part under programs administered by the Secretary, regardless of the source of funding. Paragraph (c)(2) applies to entities that receive grants or contracts “for biomedical or behavioral research under any program administered by the Secretary.”¹⁶¹ The requirements would, thus, apply to such programs or research activities conducted by, or funded by or through, the Department.

(B) State and Local Governments

As a result of the 2008 and 2011 Rules, 45 CFR part 88 applied, and will continue to apply, to all State and local governments that receive HHS Federal financial assistance by virtue of several statutory provisions. First, the Weldon Amendment applies to State and local governments that receive funds made

available in the annual Labor, Health and Human Services, and Education Appropriations Act.¹⁶² Second, the Coats-Snowe Amendment applies to State and local governments that receive Federal financial assistance, including Federal financial assistance from the Department (without restriction to any particular funding stream), “includ[ing] governmental payments provided as reimbursement for carrying out health-related activities.”¹⁶³ Third, several paragraphs of the Church Amendments apply to State and local governments. Paragraph (b) of the Church Amendments prohibits coercion by a “public authority,” and thereby includes States and local governments. Paragraphs (c) and (e) of the Church Amendments apply to State and local governments to the extent that such governments receive funds to implement programs authorized in the public laws cited in such paragraphs. Finally, paragraph (d) of the Church Amendments applies to a State or local government (or a component thereof) to the extent that such State or local government receives funding under any program administered by the Secretary.¹⁶⁴

State and local governments (such as counties or cities) and instrumentalities of governments (such as State health and human services agencies) receive Federal financial assistance or Federal funds from the Department from a variety of financing streams as recipients or sub-recipients. Examples of programs and activities for which State and local governments (in some cases, not exclusively) receive Federal financial assistance or Federal funds from the Department may include Medicaid and the Children’s Health Insurance Program; Title X programs, public health and prevention programs, HIV/AIDS and STD prevention and education, and substance abuse screening; biomedical and behavioral research at State institutions of higher education; services for older Americans; medical assistance to refugees; and adult protection services to combat elder abuse.

¹⁶² See, e.g., Public Law 115–245, Div. B, section 507(d), 132 Stat. 2981, 3118 (“None of the funds made available in [the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019] may be made available to a . . . State or local government[] if such . . . government . . .”).

¹⁶³ 42 U.S.C. 238n(a), (c)(1).

¹⁶⁴ *Id.* section 300a–7(d) (“No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services . . .”).

¹⁵⁹ E.g., Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Public Law 115–245, Div. B, sec. 507(d), 132 Stat. 2981, 3118 (September 28, 2018).

¹⁶⁰ *Id.*

¹⁶¹ 42 U.S.C. 300a–7(c)(2) and (d).

(C) Persons and Entities

As a result of the 2008 and 2011 Rules, 45 CFR part 88 applied, and still applies, to recipients and sub-recipients that operate “any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary”¹⁶⁵; or receive a grant, contract, loan, or loan guarantee under the Public Health Service (PHS) Act¹⁶⁶ or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act), or receive an interest subsidy under the DD Act.

Examples of recipients and sub-recipients may include:

- Health facilities, including hospitals, federally qualified health centers, community health centers, and mental health clinics;
- Health-related schools and other education entities that provide health professions training for medicine, oral health, behavioral health, geriatric care, nursing, etc.;
- Community-based organizations that provide substance abuse screening, HIV/AIDS prevention and treatment, and domestic violence screening;
- Title X-funded family planning clinics;
- Private non-profit and for-profit agencies that provide medical care to unaccompanied minors;
- Interdisciplinary university centers or public or nonprofit entities associated with universities that receive financial assistance to implement the DD Act¹⁶⁷; and
- State Councils on Developmental Disabilities¹⁶⁸ and States’ Protection and Advocacy Systems that receive funds to implement the DD Act.¹⁶⁹

Several statutory provisions support this application. First, paragraphs (c)(1) and (2) of the Church Amendments apply to entities that receive a “grant, contract, loan, or loan guarantee under the [PHS Act],” or a “grant or contract for biomedical or behavioral research.” Second, paragraph (e) of the Church Amendments applies to entities that receive a “grant, contract, loan, or loan guarantee, or interest subsidy” under the PHS Act or the DD Act.¹⁷⁰ Third,

paragraph (d) of the Church Amendments applies to “any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services.”¹⁷¹ Paragraph (d) of the Church Amendment does not tie the funding source to a particular appropriation, instrument, or authorizing statute, nor does the receipt of funds under Church (d) automatically trigger coverage of all of an entity’s operations.

(ii) Persons and Entities Obligated To Comply With Additional Federal Laws That This Rule Implements and Enforces

This rule only affects persons and entities obligated to comply with at least one of the Federal statutory provisions that this rule implements and enforces. There is substantial overlap between persons and entities currently obligated to comply with 45 CFR part 88, as based on the 2011 Rule and persons and entities subject to at least one of the additional Federal laws that this final rule enforces. This overlap occurs because such persons and entities largely were, and continue to be, subject to 45 CFR part 88 by virtue of the Church Amendments, but also the Weldon Amendment and the Coats-Snowe Amendment, as explained above. Because of this substantial overlap, the Department estimated in the proposed rule that OCR’s authority to enforce the following statutory provisions would not add any new persons and entities to the coverage of this rule:

- Provisions protecting health care entities and individuals from discrimination who object to furthering or participating in abortion under Medicare Advantage, *e.g.* Public Law

[or] loan guarantee . . . under the Public Health Service Act . . . or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 may”). In addition to the PHS Act, paragraphs (c)(1) and (e) of the Church Amendments apply to entities that receive funding under the Community Mental Health Centers Act, 42 U.S.C. 2689 *et seq.* Paragraph (c)(1) of the Church Amendments additionally applies to entities that receive funding under the Developmental Disabilities Services and Facilities Construction Act, 42 U.S.C. 6000 *et seq.* Congress repealed both of these laws. See Omnibus Reconciliation Act of 1981, Public Law 97–35, Title IX, sec. 902(e)(2)(B), 95 Stat. 560 (1981); Developmental Disabilities Assistance and Bill of Rights Act of 2000, Public Law 106–402, Title IV, sec. 401(a), 114 Stat. 1737 (2000). Thus, there are no entities receiving funds under programs authorized by these statutes to consider in this RIA.

¹⁷¹ *Id.* section 300a–7(d) (“No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services”).

115–245, Div. B, Tit. II, sec. 209, 132 Stat. 2981, 3090 (2018);

- Provisions of the Affordable Care Act related to assisted suicide (42 U.S.C. 18113), the ACA individual mandate (26 U.S.C. 5000A(d)(2)), and other matters of conscience (42 U.S.C.

18023(c)(2)(A)(i)–(iii), (b)(1)(A) & (b)(4));

- Provisions regarding conscience protections for objections to counseling and referral for certain services in Medicaid or Medicare Advantage (42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B));

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

- Provisions exempting individuals from compulsory health care or services generally (42 U.S.C. 1396f & 5106i(a)(1)) and under specific programs for hearing screening (42 U.S.C. 280g–1(d)), occupational illness testing (29 U.S.C. 669(a)(5)), vaccination (42 U.S.C. 1396s(c)(2)(B)(ii)), and mental health treatment (42 U.S.C. 290bb–36(f)); and

- Protections for religious nonmedical health care relating to health facility review (42 U.S.C. 1320a–1), peer review (42 U.S.C. 1320c–11), certain health standards (42 U.S.C. 1396a(a)(9)(A)), medical evaluation (42 U.S.C. 1396a(a)(31)), medical licensing review (42 U.S.C. 1396a(a)(33)), and utilization review plan requirements (42 U.S.C. 1396b(i)(4)), and by protecting the exercise of religious nonmedical health care in the Elder Justice Block Grant Program (42 U.S.C. 1397j–1(b)) and in the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106i(a)(2)).

In the proposed rule, the Department estimated that the OCR enforcement of the following Federal statutory provisions could add new persons and entities to the coverage of 45 CFR part 88:

- Global Health Programs for HIV/AIDS Prevention, Treatment, or Care (22 U.S.C. 7631(d)), and

- The Helms, Biden, 1978, and 1985 Amendments, 22 U.S.C. 2151b(f), *e.g.*, Consolidated Appropriations Act, 2019, Public Law 116–6, Div. F, sec. 7018.

However, the proposed rule explained that because paragraph (d) of the Church Amendments does not require that the funding for the health service program or research activity be appropriated to HHS, but only that it be “funded in whole or part under a program administered by the [HHS] Secretary,” funding appropriated to other Federal Departments, but awarded by HHS in its administration of certain global health programs would be covered by paragraph (d) of the Church Amendments. Consequently, HHS’s

¹⁶⁵ 42 U.S.C. 300a–7(d).

¹⁶⁶ The PHS Act contains thirty titles and authorizes dozens of programs.

¹⁶⁷ *E.g.*, <https://www.acl.gov/node/466>.

¹⁶⁸ *E.g.*, <https://www.acl.gov/node/110>; <https://www.acl.gov/sites/default/files/about-acl/2017-12/DDC-2017.pdf>.

¹⁶⁹ *E.g.*, <https://www.acl.gov/sites/default/files/about-acl/2017-06/PADD-2017.pdf>.

¹⁷⁰ *Id.* 300a–7(c)(1)(B) (“No entity which receives a grant, contract, loan, or loan guarantee under the Public Health Service Act”); 300a–7(e) (“No entity which receives . . . any grant, contract, loan,

implementation of 22 U.S.C. 2151b(f) and 7631(d) may not expand the scope of persons and entities covered by this part.

(iii) Methodology

The Department quantitatively estimated those persons and entities covered by the final rule by relying primarily on the latest data available from the U.S. Census Bureau's Statistics of U.S. Businesses¹⁷² supplemented with other sources. The Department invited public comment on the proposed rule's methodology and solicited ideas on whether there are other methodologies that the Department could consider to refine the scope of persons and entities affected by this rule. The Department received one comment suggesting that the Department's methodology was flawed for failing to include an estimate of the number of consumers of health care affected, *i.e.*, patients, and thus did not consider consumers of health care in the list of persons and entities shown *infra* at Table 2. The purpose of Table 2 is to identify *regulated entities*, not consumers of health care. An analysis of this rule's impact on persons, entities, and health care entities is included in the rule's analysis of benefits, *infra* at part IV.C.4. The final rule's methods for quantifying the persons and entities impacted are the same methods from the proposed rule, which the Department determined was the most reasonable and reliable approach.¹⁷³

The U.S. Census Bureau's Statistics of U.S. Businesses is based on the North American Industry Classification System (NAICS).¹⁷⁴ The NAICS classifies all economic activity into 20 sectors and breaks that information down into sub-sectors and industries.¹⁷⁵ Essentially, the NAICS groups physical business establishments together based on how similar the locations' processes are for producing goods or services.¹⁷⁶ The NAICS provides information on how many singular physical locations exist for a particular business or

industry (called an "establishment"),¹⁷⁷ how many of those establishments are under common ownership or control of a business organization or entity (called a "firm"),¹⁷⁸ and the number of people who work in a particular business or industry, among other types of information. For instance, a hospital system that has common ownership and control over multiple hospital facilities is a firm, and each hospital facility is an establishment.

For the vast majority of the recipient and sub-recipient types, the Department assumed that only a portion of the industry captured in the Statistics of U.S. Businesses receives Federal funds to trigger coverage by this rule (*e.g.*, "Federal financial assistance . . . from the Department or a component of the Department, or who otherwise receives Federal funds directly from the Department or a component of the Department"). For instance, not all physician offices receive FFA or otherwise receive Federal funds as a recipient or sub-recipient. In fact, about 68.9 percent of physician offices accepted new Medicaid patients based on 2013 data from the National Electronic Health Records Survey.¹⁷⁹ Approximately 83.7 percent of physicians accepted new Medicare patients based on the same data.¹⁸⁰ Because OCR interprets the 2011 Rule to apply to physicians receiving reimbursement for Medicare Part B, which is a "health service program . . . funded in whole or in part under a program administered by the Secretary of Health and Human Services", the Department assumed that the lower of these two percentages (69 percent) represents the lower-bound of physicians nationwide subject to the 2011 Rule. In the absence of evidence with which to generate a refined upper-bound estimate, the Department assumed that the 2011 Rule covers all physicians nationwide as the upper-bound.

The Department used this same percentage range (69 to 100 percent) in estimating the coverage for other health care industry sector types, such as hospitals and various outpatient care facilities. For the social services and education industries, which generally have principal purposes other than

health and patient care, the Department adopted ranges more appropriate for those industries. For the social services industries, the Department adopted a range with 25 percent as the lower-bound and 100 percent as the upper-bound to cover 62.5 percent of the industry on average. In its notice of proposed rulemaking, the Department sought comment on this methodology, but received no comments providing a superior method of generating these estimates.

The Department assumes some portion of the social service industry will be covered by the rule, given the scope of the 2011 Rule and thereby this rule. For instance, entities that carry out social services programs and activities may do so in the context of health service programs or research activities funded in whole or in part under programs administered by the Secretary, or may receive funding through programs administered by the Secretary, as well as by grants or other mechanisms under the PHS Act¹⁸¹ or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 within the scope of the Church Amendment's application.

To estimate the number of local governments and educational institutions, the Department relied on data from other U.S. Census Bureau statistical programs or available award data available through the HHS Tracking Accountability in Government Grants System (TAGGS).¹⁸² For instance, in estimating the number of counties nationwide, the Department relied on the U.S. Census Bureau's 2010 Census Geographic Entity Tallies by State and Type to identify the total counties and equivalent areas for the U.S., Puerto Rico, the U.S. Territories, and the Island Areas.¹⁸³

As another example, the Department relied on data from TAGGS to derive a lower-bound percentage of colleges and universities that are recipients. (The upper-bound assumes all educational institutions industry-wide are recipients.) Although most colleges and universities receive Federal financial assistance from the U.S. Department of Education, not all universities are recipients of HHS funds; thus, the Department adopted a lower-bound estimate to reflect that assumption.

Using the "Advanced Search" function in TAGGS, HHS identified all awards to Junior Colleges, Colleges, and

¹⁷² <https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html>. The Department relied on the data file titled "U.S. & State, NAICS, detailed employment sizes (U.S., 6-digit and States, NAICS sectors)." The latest data available is from 2015 that the Bureau made available in September of 2017, and this data relied on the 2012 NAICS codes, *id.*, which are described at https://www.census.gov/eos/www/naics/2012NAICS/2012_Definition_File.pdf.

¹⁷³ See 83 FR 3880, 3907 (describing various sources of data considered and reasons for rejecting other approaches).

¹⁷⁴ <https://www.census.gov/programs-surveys/susb/technical-documentation/methodology.html>.

¹⁷⁵ FAQ 5, <https://www.census.gov/eos/www/naics/faqs/faqs.html#q5>.

¹⁷⁶ FAQ 1, <https://www.census.gov/eos/www/naics/faqs/faqs.html#q1>.

¹⁷⁷ <https://www.census.gov/eos/www/naics/faqs/faqs.html#q2>.

¹⁷⁸ https://www.census.gov/glossary/#term_Firm.

¹⁷⁹ Esther Hing, *et al.*, Nat'l Ctr. For Health Statistics, Centers for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Acceptance of New Patients with Public and Private Insurance by Office-Based Physicians: United States, 2013, Data Brief No. 195, 1 (Mar. 2015).

¹⁸⁰ *Id.*

¹⁸¹ The PHS Act contains thirty titles and authorizes dozens of programs.

¹⁸² <http://tags.hhs.gov> (last visited Aug. 24, 2017).

¹⁸³ https://www.census.gov/geo/maps-data/data/tallies/all_tallies.html.

Universities for FY 2016 and de-duplicated the results to obtain a singular list of unique awardees from the Department, which totaled 615. Because these awardees included satellite campuses of college or university systems, the total awardee number was akin to the number of “establishments” rather than “firms” as those terms are used in the U.S. Census Bureau’s Statistics of U.S. Businesses. Similar to how an “establishment” is a location of a “firm” that has common ownership and control over at least one establishment, a satellite campus is one location of a university system with common ownership and control over multiple campus locations.

To derive an estimate of educational institutions at the “firm” level, the Department computed the ratio between firms and establishments from the U.S. Census Bureau’s Statistics of U.S.

Businesses.¹⁸⁴ This ratio is 51.32 percent (2,457 firms/4,788 establishments). The Department applied that ratio to the total number of Junior Colleges, Colleges, and Universities that received HHS funding as “establishments” (0.5132×615 awardee establishments) to get an estimate of 316 firms. Despite this method’s potential complexity, the Department found it the most reasonable method for estimating the lower-bound number of colleges and universities that are Department recipients.

(iv) Quantitative Estimate of Persons and Entities Covered by This Rule

Table 2 lists each estimated type of recipient and the estimated number of recipients that this final rule covers.

¹⁸⁴ See U.S. Census Bureau, Statistics of U.S. Businesses, 2015, NAICS code 611310 (Colleges, Universities, and Professional Schools) (identifying 2,457 firms and 4,788 establishments nationwide).

Because there is uncertainty as to the universe of actual persons and entities covered, Table 2 captures this uncertainty by reflecting estimated recipients as a range with a lower and an upper-bound. The footnotes detail the assumptions and calculations for each line of the table and assume coverage for 69–100 percent of the industry unless otherwise noted. The Department has made a technical correction to Table 2 to include the number of offices of miscellaneous health practitioners (*e.g.*, clinical pharmacists, dieticians, registered practical or licensed nurses’ offices, Christian Science practitioners’ offices) who operate private or group practices in their own centers or clinics or in the facilities of others, such as hospitals.¹⁸⁵

¹⁸⁵ See the industry description for offices of miscellaneous health practitioners, NAICS code 921399, <https://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=621399&search=2012> NAICS Search.

TABLE 2—ESTIMATED NUMBER OF PERSONS AND ENTITIES COVERED BY THIS FINAL RULE

Type	Covered by 45 CFR 88 in 2011 Rule?	Covered by final rule?	Estimate (low)	Estimate (high)
1. State and Territorial Governments ¹⁸⁶	Yes	Yes	58	58
2. Federally recognized Tribes ¹⁸⁷	Yes	Yes	573	573
3. Counties ¹⁸⁸	Yes	Yes	3,234	3,234
Hospitals				
4. General & Medical Surgical Hospitals ¹⁸⁹	Yes	Yes	1,859	2,694
5. Specialty Hospitals (e.g., psychiatric, substance abuse, rehabilitation, cancer, maternity) ¹⁹⁰	Yes	Yes	553	801
Nursing and Residential Care Facilities				
6. Skilled Nursing Facilities ¹⁹¹	Yes	Yes	6,316	9,153
7. Residential Intellectual and Developmental Disability Facilities ¹⁹²	Yes	Yes	4,310	6,246
8. Continuing Care Retirement Communities ¹⁹³	Yes	Yes	2,605	3,775
9. Other Residential Care Facilities (e.g., group homes) ¹⁹⁴	Yes	Yes	2,247	3,256
Entities Providing Ambulatory Health Care Services				
10. Entities providing Home Health Care Services ¹⁹⁵	Yes	Yes	15,062	21,829
11. Offices of Physicians (except Mental Health Specialists) ¹⁹⁶	Yes	Yes	115,673	167,642
12. Offices of Physicians (Mental Health Specialists) ¹⁹⁷	Yes	Yes	7,324	10,614
13. Offices of Mental Health Practitioners (except Physicians) ¹⁹⁸	Yes	Yes	14,340	20,782
14. Offices of Dentists ¹⁹⁹	Yes	Yes	86,874	125,904
15. Offices of Chiropractors ²⁰⁰	Yes	Yes	26,725	38,732
16. Offices of Optometrists ²⁰¹	Yes	Yes	13,775	19,964
17. Offices of Physical, Occupational and Speech Therapists, and Audiologists ²⁰²	Yes	Yes	17,623	25,540
18. Offices of Podiatrists ²⁰³	Yes	Yes	5,314	7,701
19. Offices of All Other Misc. Health Practitioners ²⁰⁴	Yes	Yes	11,502	16,670
20. Family Planning Centers ²⁰⁵	Yes	Yes	999	1,448
21. Freestanding Ambulatory Surgical and Emergency Centers ²⁰⁶	Yes	Yes	2,908	4,214
22. HMO Medical Centers ²⁰⁷	Yes	Yes	78	113
23. Kidney Dialysis Centers ²⁰⁸	Yes	Yes	305	442
24. Outpatient Mental Health and Substance Abuse Centers ²⁰⁹	Yes	Yes	3,776	5,472
25. Diagnostic Imaging Centers ²¹⁰	Yes	Yes	3,209	4,651
26. Medical Laboratories ²¹¹	Yes	Yes	2,278	3,302
27. Ambulance Services ²¹²	Yes	Yes	2,185	3,167
28. All Other Outpatient Care Centers (e.g., centers and clinics for pain therapy, community health, and sleep disorders) ²¹³	Yes	Yes	3,880	5,623
29. Entities Providing All Other Ambulatory Health Care Services (health screening, smoking cessation, hearing testing, blood banks) ²¹⁴	Yes	Yes	2,391	3,465
Insurance Carriers				
30. Direct Health and Medical Insurance Carriers ²¹⁵	Yes	Yes	607	880
Entities Providing Social Assistance Services				
31. Entities Serving the Elderly and Persons with Disabilities (provision of nonresidential social assistance services to improve quality of life) ²¹⁶	Yes	Yes	9,051	36,205
32. Entities Providing Other Individual Family Services (e.g., marriage counseling, crisis intervention centers, suicide crisis centers) ²¹⁷	Yes	Yes	5,310	21,240

¹⁸⁶ Assumes coverage of the 50 States, DC, Puerto Rico, 6 U.S. Territories, and the Island Areas.

¹⁸⁷ Assumes all federally recognized Tribes get HHS funds. Indian Health Service, FY 2019 Justification of Estimates for Appropriations Committees CJ-1 (2018), https://www.ihs.gov/budgetformulation/includes/themes/responsive2017/display_objects/documents/FY2019CongressionalJustification.pdf.

¹⁸⁸ U.S. Census Bureau, 2010 Census Geographic Entity Tallies by State and Type, https://www.census.gov/geo/maps-data/data/tallies/all_tallies.html (total counties and equivalent areas for the U.S., Puerto Rico, the U.S. Territories, and the Island Areas). The Department assumed that every county receives Federal funds as a recipient or a sub-recipient.

¹⁸⁹ U.S. Census Bureau, Statistics of U.S. Businesses, 2015 (released Sept. 2017), <https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html> (nationwide count of firms for NAICS Code 622110).

¹⁹⁰ *Id.* (sum of the nationwide count of firms for NAICS Codes 622210 and 622310).

¹⁹¹ *Id.* (relying on the nationwide count of firms for NAICS Code 623110).

¹⁹² *Id.* (nationwide count of firms for NAICS Code 623210).

¹⁹³ *Id.* (nationwide count of firms for NAICS Code 623311).

¹⁹⁴ *Id.* (nationwide count of firms for NAICS Code 623990).

¹⁹⁵ *Id.* (nationwide count of firms for NAICS Code 621610).

¹⁹⁶ *Id.* (nationwide count of firms for NAICS Code 621111).

¹⁹⁷ *Id.* (nationwide count of firms for NAICS Code 621112).

¹⁹⁸ *Id.* (nationwide count of firms for NAICS Code 621330).

¹⁹⁹ *Id.* (nationwide count of firms for NAICS Code 621210).

²⁰⁰ *Id.* (nationwide count of firms for NAICS Code 621310).

²⁰¹ *Id.* (nationwide count of firms for NAICS Code 621320).

²⁰² *Id.* (nationwide count of firms for NAICS Code 621340).

²⁰³ *Id.* (nationwide count of firms for NAICS Code 621391).

²⁰⁴ *Id.* (nationwide count of firms for NAICS Code 621399).

²⁰⁵ *Id.* (nationwide count of firms for NAICS Code 621410).

²⁰⁶ *Id.* (nationwide count of firms for NAICS Code 621493).

²⁰⁷ *Id.* (nationwide count of firms for NAICS Code 621491).

²⁰⁸ *Id.* (nationwide count of firms for NAICS Code 621492).

²⁰⁹ *Id.* (nationwide count of firms for NAICS Code 621420).

²¹⁰ *Id.* (nationwide count of firms for NAICS Code 621512).

²¹¹ *Id.* (nationwide count of firms for NAICS Code 621511).

²¹² *Id.* (nationwide count of firms for NAICS Code 621910).

²¹³ *Id.* (nationwide count of firms for NAICS Code 621498).

²¹⁴ *Id.* (nationwide count of firms for NAICS Code 62199).

TABLE 2—ESTIMATED NUMBER OF PERSONS AND ENTITIES COVERED BY THIS FINAL RULE—Continued

Type	Covered by 45 CFR 88 in 2011 Rule?	Covered by final rule?	Estimate (low)	Estimate (high)
33. Entities Providing Child and Youth Services (e.g., adoption agencies, foster care placement services) ²¹⁸ .	Yes	Yes	2,169	8,674
34. Temporary Shelters (e.g., short term emergency shelters for victims of domestic violence, sexual assault, or child abuse; runaway youth; and families caught in medical crises) ²¹⁹ .	Yes	Yes	805	3,219
35. Emergency and Other Relief Services (e.g., medical relief, resettlement, and counseling to victims of domestic or international disasters or conflicts) ²²⁰ .	Yes	Yes	169	675
Other Entities				
36. Pharmacies and Drug Stores ²²¹	Yes	Yes	13,490	19,550
37. Research and Development in Biotechnology ²²²	Yes	Yes	2,347	3,402
38. Colleges, Universities, & Professional Schools ²²³	Yes	Yes	316	2,457
Subtotal, subject to part 88 in 2011 Rule			392,236	613,367
39. HHS awarded funds appropriated to the U.S. Dept. of State & USAID ²²⁴	No	Yes	65	130
Subtotal, incremental increase in entities			65	130
TOTAL, estimated entities subject to this rule			392,301	613,497

Approximately 392,236 to 613,367 persons and entities were subject to part 88 in effect based on the 2011 Rule by virtue of the Weldon, Coats-Snowe and Church Amendments. The Department estimated that the number of entities that this final rule covers that are subject to 22 U.S.C. 7631(d) and 2151b(f), but not paragraph (d) of the Church Amendments is small and, possibly, non-existent because paragraph (d) of the Church Amendments does not tie funding to a particular appropriation or financial stream.²²⁵ Consequently, this final rule

may add 65 to 130 new persons and entities to the coverage of 45 CFR part 88.²²⁶ With this incremental increase, this final rule covers an average of 502,899 entities, which is the mid-point of the low (392,301 entities) and high-end (613,497 entities).

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

Relative to the persons and entities shown in Table 2, a smaller subset is subject to § 88.4, which requires certain recipients to submit an assurance and certification of compliance and exempts others. The Department calculated the subset of persons and entities subject to § 88.4 by (1) removing estimated sub-recipients from the total because § 88.4 applies to recipients, not sub-recipients, and (2) removing the estimated recipients exempted from § 88.4, as identified in § 88.4(c)(1) through (4). *Infra* at Table 3 shows this calculation.

Calculating Estimated Sub-Recipients

The Department sought comment on the policy for § 88.4 to apply to

(TAGGS) <http://taggs.hhs.gov> (last visited Dec. 19, 2017). HHS identified unique awardees for FY 2017 from HHS PEPFAR implementing agencies (CDC, HRSA, SAMHSA, NIH, FDA) to foreign nonprofits, foreign governments, and international organizations and used this number as a lower-bound. Because the Department also receives funds appropriated to USAID through one or more reimbursable agreements, the Department assumed that there could be twice as many recipients and sub-recipients after considering the awardees from these reimbursable agreements and thus multiplied and lower-bound by two.

²²⁵ The text of paragraph (d) states that its protection applies for health service program and research activities “funded in whole or part under a program administered by the [HHS] Secretary.”

²²⁶ But see *supra* at part IV.C.2.ii (discussing the application of paragraph (d) of the Church Amendments to such grantees).

recipients but not sub-recipients, noting that the proposed rule took this approach to reduce the burden on small entities. The Department did not receive comments addressing this question. One commenter, however, raised the question that, if the proposed rule’s policy was to exempt clinicians who are part of State Medicaid programs, then the proposed rule did not exclude such clinicians from § 88.4. However, clinicians who receive reimbursement through a State Medicaid program are *sub-recipients* of the Department (*i.e.*, recipients of the State, which is the recipient in relationship to the Department). Under a Medicaid fee-for-service model, the State pays the clinicians directly, and under the managed care model, a State pays a fee to a managed care plan, which in turn pays the clinician for the services a beneficiary may require that are within the managed care plan’s contract with the State to serve Medicaid beneficiaries.²²⁷ As sub-recipients, these clinicians that accept Medicaid are not subject to § 88.4, unless they become recipients from HHS Federal financial assistance or other Federal funds from a non-exempt HHS program (*i.e.*, a program not captured in § 88.4(c)(2) through (4)).

In the proposed rule, OCR explained that it had not found a reliable way to calculate the number of sub-recipients of this rule. The Department assumed entities in *supra* at Table 2 were all recipients except for counties, which the Department assumed were sub-recipients for the purpose of this

²²⁷ See, e.g., Provider Payment and Delivery Systems, MACPAC, <https://www.macpac.gov/medicaid-101/provider-payment-and-delivery-systems/> (last visited Jan. 29, 2019).

²¹⁵ *Id.* (nationwide count of firms for NAICS Code 524114).

²¹⁶ *Id.* (nationwide count of firms for NAICS Code 624120).

²¹⁷ *Id.* (nationwide count of firms for NAICS Code 624190).

²¹⁸ *Id.* (nationwide count of firms for NAICS Code 624110). As described *supra* at part IV.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

²¹⁹ *Id.* (nationwide count of firms for NAICS Code 624221). As described *supra* at part IV.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

²²⁰ *Id.* (nationwide count of firms for NAICS Code 624230). As described *supra* at part IV.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

²²¹ *Id.* (nationwide count of firms for NAICS Code 44610).

²²² *Id.* (nationwide count of firms for NAICS Code 541711).

²²³ *Id.* (nationwide count of firms for NAICS Code 611310). As described *supra* at part IV.C.2.iii (methodology), the Department assumes 13%–100% of institutions of higher-education are covered. See *supra* at XI.C.2.iii for a detailed explanation for how the Department supplemented Statistics of U.S. Businesses data with award data from the Department’s Tracking Accountability in Government Grants System.

²²⁴ U.S. Dep’t of Health & Human Servs., Tracking Accountability in Government Grants System

calculation. The Department received no comments regarding information, data sources, studies, or reports that could assist the Department in improving its approach.

To refine the estimates, the Department reconsidered the proposed rule's blanket assumption that all counties are sub-recipients for purposes of this calculation. Using the "Advanced Search" function in TAGGS, the Department identified the total number of county awardees and de-duplicated the results to obtain one list of unique county awardees from the Department for FY 2017. This approach identified 625 counties (19 percent) receiving funding directly from HHS as recipients. Assuming that all counties are HHS recipients or sub-recipients, the remaining of 2,609 counties (81 percent) would be sub-recipients that are not subject to § 88.4's application. This method is a more accurate proxy for estimating the number of sub-recipient counties. If some entities (other than counties) in Table 2 are sub-recipients rather than recipients, then the Department overestimated the scope of entities subject to § 88.4's application that are not exempted.

Calculating Exempted Recipients in § 88.4(c)(1) Through (4)

The Department received no comments regarding the methods used to estimate the scope of exempted recipients under § 88.4(c)(1) through (4). Therefore, the Department maintains the proposed rule's methods.

The Department assumed that all physicians' offices would meet the criteria in § 88.4(c)(1) and subtracted out 255,684 to 370,557 entities, which represents the lower and upper-bounds of all physicians' offices.²²⁸ If some physicians' offices are recipients through an instrument other than Medicare Part B reimbursement, then the Department overestimated the number of physicians' offices exempted due to § 88.4(c)(1). The Department does not have the necessary data to estimate the impact of the final rule's new exemption for pharmacies and pharmacists that receive Medicare Part B because the Department does not know whether such pharmacies or pharmacists exempted under § 88.4(c)(1) are Department recipients (as opposed to sub-recipients) of HHS Federal financial assistance or other Federal funds from a non-exempt HHS program (*i.e.*, a program not captured in § 88.4(c)(2) through (4)).

The Department subtracted out 11,220 to 44,879 persons and entities that meet the criteria in § 88.4(c)(2) and (3) regarding the exemption for recipients of grant programs administered by the Administration for Children and Families or the Administration for Community Living.²²⁹ The exemption applies if the program meets certain regulatory criteria indicating that its purpose is unrelated to health care and certain types of research, does not involve health care providers, and does not involve referral for the provision of health care. The Department reasonably

assumed that all persons and entities that provide child and youth services (such as adoption and foster care) would fall into this exemption. The Department also reasonably assumed that all entities providing services for the elderly and persons with disabilities (by providing nonresidential social assistance services to improve quality of life) would fall within this exemption. The Department did not subtract out the entities providing "Other Individual Family Services" (*e.g.*, marriage counseling, crisis intervention centers, suicide crisis centers) because there is a significant likelihood of referral for the provision of health care at crisis intervention centers and suicide crisis centers.

The Department subtracted out 230 Tribes and Tribal Organizations for the exemption in § 88.4(c)(4). This number represents the total Tribes and Tribal Organizations that operate contracts under Title I of the ISDEA Act.²³⁰ This final rule revises the requirements for federally recognized Indian tribes, tribal organizations, or urban Indian organizations who are recipients by virtue of grants or cooperative agreements under 42 U.S.C. 290bb–36, removing the requirement that such entities comply with § 88.4. The Department does not have the data necessary to estimate the number of such entities who are recipients of funds via such grants or cooperative agreements that are not already captured within the scope of the exemption in § 88.4(c)(4).

TABLE 3—ESTIMATED RANGE OF RECIPIENTS SUBJECT TO THE ASSURANCE AND CERTIFICATION REQUIREMENTS (§ 88.4)

	Low-end estimate	Upper-bound estimate
Persons or Entities Subject to This Final Rule	392,301	613,497
Sub-Recipients to which § 88.4 Does Not Apply	– 2,609	– 2,609
Range of Recipients Exempted from § 88.4	– 267,134	– 415,666
Total, Recipients Subject to § 88.4	122,558	195,222

(B) Estimated Number of Recipients Incentivized To Provide Voluntarily a Notice of Rights (§ 88.5)

The proposed rule contained a freestanding notice provision with mandatory and discretionary elements. As finalized in this rule, the notice provisions are no longer mandatory. Section 88.5 incentivizes recipients and the Department to provide notice to persons, entities, and health care entities concerning Federal conscience

and anti-discrimination laws. The rule intends to accomplish this goal by providing that OCR will consider a recipient's posting of a notice as non-dispositive evidence of compliance with this rule in any investigation or compliance review pursuant to this rule, to the extent such notices are provided according to the provisions of this section and are relevant to the particular investigation or compliance review.

The Department expects that some regulated recipients and Department components will voluntarily post the notice through one of the methods specified. Because recipients are the primary entities responsible for compliance under this rule, the Department assumes that sub-recipients will not be induced by the rule to post a notice on their own accord.

The proposed rule did not permit recipients to modify the pre-written

²²⁸ Sum of rows 11, 12, 14–16, and 18 of Table 2.

²²⁹ Sum of rows 31 and 33 of Table 2.

²³⁰ Indian Health Service, FY 2019 Justification of Estimates for Appropriations Committees CJ–243 (2018), <https://www.ihs.gov/budgetformulation/>

[includes/themes/responsive2017/display_objects/documents/FY2019CongressionalJustification.pdf](includes/themes/responsive2017/display_objects/documents/FY2019CongressionalJustification.pdf).

notice in appendix A. As discussed in the preamble for § 88.5, *supra* at part II.B, public comments asked for flexibility to modify the notice's content as applied to recipients. Paragraph (c) in § 88.5 of the final rule provides greater flexibility by stating that the recipient and the Department should *consider* using the model text provided in appendix A for the notice, but may tailor the content to address the laws that apply to the recipient or Department under the rule and the recipient's or Department's particular circumstances. Accordingly, the Department assumes that some recipients that voluntarily post notices will modify the pre-written notice in appendix A. Recipients that modify the

pre-written notice likely will do so at the firm level (*i.e.*, corporate level) rather than the establishment level (*i.e.*, at each facility). For instance, a company with common ownership and control over multiple facilities would modify the notice at its corporate ("firm") level but would post substantially the same physical notices at each facility ("establishment") where notices are customarily posted to permit ready observation for members of the workforce or for the public.

The Department estimates that eighteen recipient types, such as medical specialists, elder care providers, and entities providing primarily social services, are likely to modify the pre-written notice as applied

to them (in relation to, for example, abortion). The sum of the low-end and high-end estimates of firms associated with these eighteen recipient types is 225,751 (low-end) and 332,707 (high-end), providing an average of 279,229 firms. Given the discretionary nature of the notice provision, the Department adjusts the range of firms downward by 50 percent for the purpose of this calculation to derive the values shown in *infra* at Table 4: 112,876 firms (low-end) and 166,354 firms (high-end) for a mid-point of 139,615 firms likely to modify the pre-written notice in appendix A. To the extent that recipient types other than those listed in Table 4 modify the notice, the Department has underestimated the scope of impact.

TABLE 4—ESTIMATED NUMBER OF FIRMS ASSOCIATED WITH EACH RECIPIENT TYPE LIKELY TO MODIFY THE NOTICE OF RIGHTS IN APPENDIX A (§ 88.5)

Type	Estimate (low)	Estimate (high)
1. Skilled Nursing Facilities	3,158	4,577
2. Residential Intellectual and Developmental Disability Facilities	2,155	3,123
3. Continuing Care Retirement Communities	1,302	1,888
4. Other Residential Care Facilities (<i>e.g.</i> , group homes)	1,123	1,628
5. Entities providing Home Health Care Services	7,531	10,915
6. Offices of Physicians, Mental Health Specialists	3,662	5,307
7. Offices of Mental Health Practitioners (except Physicians)	7,170	10,391
8. Offices of Dentists	43,437	62,952
9. Offices of Chiropractors	13,363	19,366
10. Offices of Optometrists	6,888	9,982
11. Offices of Physical, Occupational and Speech Therapists, and Audiologists	8,811	12,770
12. Offices of Podiatrists	2,657	3,851
13. Offices of All Other Miscellaneous Health Practitioners	5,751	8,335
14. Kidney Dialysis Centers	152	221
15. Outpatient Mental Health and Substance Abuse Centers	1,888	2,736
16. Diagnostic Imaging Centers	1,605	2,326
17. Medical Laboratories	1,139	1,651
18. Entities Providing Child and Youth Services (<i>e.g.</i> , adoption agencies, foster care placement services)	1,084	4,337
Total, Firms Likely to Modify Pre-Written Notice Text	112,876	166,354

The Department assumes that, for all posting methods, recipients will execute the posting at the establishment level. Using the range of firms subject to this rule as a foundation, the range of establishments associated with those recipients is shown *infra* at in Table 5. Table 5 employs the methodology used for calculating the number of persons and entities shown in Table 2, but uses the U.S. Census Bureau's Statistics of U.S. Businesses data for establishments rather than firms.²³¹ The footnotes detail the assumptions and calculations

for each line and assume 69–100 percent of the industry as covered unless otherwise noted, which parallels the assumptions for Table 2.

Because there is a high degree of uncertainty as to the proportion of recipients that will voluntarily post notices through one or more of the methods specified in § 88.5 in the first year of the rule's implementation, the Department adjusts the range of establishments associated with covered recipients downward by 50 percent for the purpose of this calculation. The

values derived from this calculation appear *infra* at in Table 5: 261,735 establishments (low-end) and 408,918 establishments (high-end) for a mid-point of 335,327 establishments. The Department adjusts downward the range of establishments that would voluntarily provide notices of rights in years two through five by 25 percent, relative to year one, to reflect attrition: 196,301 establishments (low-end) and 306,689 establishments (high-end) for a mid-point of 251,495 establishments.

²³¹ <https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html>. The Department relied on the data file titled "U.S. & State, NAICS, detailed

employment sizes (U.S., 6-digit and States, NAICS sectors)." The latest data available is from 2015 that

the Bureau made available in September of 2017, and this data relied on the 2012 NAICS codes. *Id.*

TABLE 5—NUMBER OF PHYSICAL ESTABLISHMENTS OF EACH RECIPIENT TYPE ESTIMATED TO VOLUNTARILY PROVIDE NOTICE OF RIGHTS IN YEAR 1 (§ 88.5)

Type	Establishments assoc. with covered recipients		Establishments assoc. with covered recipients that would voluntarily post notices in Year 1		
	(Low)	(High)	(Low)	(High)	Mid-point
State and Territorial Governments ²³²	58	58	29	29	29
Federally recognized Tribes ²³³	573	573	287	287	287
Counties ²³⁴	625	625	313	313	313
General and Medical Surgical Hospitals ²³⁵	3,699	5,361	1,850	2,681	2,265
Specialty Hospitals (e.g., psychiatric, substance abuse, rehabilitation, cancer, maternity) ²³⁶	1,139	1,651	570	826	698
Skilled Nursing Facilities ²³⁷	11,789	17,085	5,894	8,543	7,218
Residential Intellectual & Developmental Disability Facilities ²³⁸	22,611	32,770	11,306	16,385	13,845
Continuing Care Retirement Communities ²³⁹	3,668	5,316	1,834	2,658	2,246
Other Residential Care Facilities (e.g., group homes) ²⁴⁰ ..	3,627	5,256	1,813	2,628	2,221
Entities providing Home Health Care Services ²⁴¹	21,377	30,981	10,688	15,491	13,089
Offices of Physicians (except Mental Health Specialists) ²⁴²	147,817	214,228	73,909	107,114	90,511
Offices of Physicians (Mental Health Specialists) ²⁴³	7,498	10,867	3,749	5,434	4,591
Offices of Mental Health Practitioners (except Physicians) ²⁴⁴	15,022	21,771	7,511	10,886	9,198
Offices of Dentists ²⁴⁵	92,895	134,631	46,448	67,316	56,882
Offices of Chiropractors ²⁴⁶	26,999	39,129	13,500	19,565	16,532
Offices of Optometrists ²⁴⁷	15,101	21,885	7,550	10,943	9,246
Offices of Physical, Occupational & Speech Therapists, & Audiologists ²⁴⁸	25,213	36,541	12,607	18,271	15,439
Offices of Podiatrists ²⁴⁹	5,769	8,361	2,885	4,181	3,533
Offices of All Other Misc. Health Practitioners ²⁵⁰	12,731	18,450	6,365	9,225	7,795
Family Planning Centers ²⁵¹	1,584	2,295	792	1,148	970
Freestanding Ambulatory Surgical & Emergency Ctrs. ²⁵² ..	4,609	6,679	2,304	3,340	2,822
HMO Medical Centers ²⁵³	560	812	280	406	343
Kidney Dialysis Centers ²⁵⁴	5,144	7,455	2,572	3,728	3,150
Outpatient Mental Health & Substance Abuse Ctrs. ²⁵⁵	7,227	10,474	3,614	5,237	4,425
Diagnostic Imaging Centers ²⁵⁶	4,553	6,598	2,276	3,299	2,788
Medical Laboratories ²⁵⁷	7,360	10,667	3,680	5,334	4,507

²³² Assumes coverage of the 50 States, DC, Puerto Rico, 6 U.S. Territories, and the Island Areas.

²³³ Assumes all federally recognized Tribes get HHS funds. Indian Health Service, FY 2019, Justification of Estimates for Appropriations Committees, CJ-243 (2018), https://www.ihs.gov/budgetformulation/includes/themes/responsive2017/display_objects/documents/FY2019CongressionalJustification.pdf.

²³⁴ U.S. Census Bureau, 2010 Census Geographic Entity Tallies by State and Type, https://www.census.gov/geo/maps-data/data/tallies/all_tallies.html (total counties and equivalent areas for the U.S., Puerto Rico, the U.S. Territories, and the Island Areas). The values estimate the number of recipient counties and exclude estimated sub-recipients.

²³⁵ U.S. Census Bureau, Statistics of U.S. Businesses, 2015 (released Sept. 2017), <https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html> (nationwide count of firms for NAICS Code 622110).

²³⁶ *Id.* (sum of the nationwide count of firms for NAICS Codes 622210 and 622310).

²³⁷ *Id.* (nationwide count of firms for NAICS Code 623110).

²³⁸ *Id.* (nationwide count of firms for NAICS Code 623210).

²³⁹ *Id.* (nationwide count of firms for NAICS Code 623311).

²⁴⁰ *Id.* (nationwide count of firms for NAICS Code 623990).

²⁴¹ *Id.* (nationwide count of firms for NAICS Code 621610).

²⁴² *Id.* (nationwide count of firms for NAICS Code 621111).

²⁴³ *Id.* (nationwide count of firms for NAICS Code 621112).

²⁴⁴ *Id.* (nationwide count of firms for NAICS Code 621330).

²⁴⁵ *Id.* (nationwide count of firms for NAICS Code 621210).

²⁴⁶ *Id.* (nationwide count of firms for NAICS Code 621310).

²⁴⁷ *Id.* (nationwide count of firms for NAICS Code 621320).

²⁴⁸ *Id.* (nationwide count of firms for NAICS Code 621340).

²⁴⁹ *Id.* (nationwide count of firms for NAICS Code 621391).

²⁵⁰ *Id.* (nationwide count of firms for NAICS Code 621399).

²⁵¹ *Id.* (nationwide count of firms for NAICS Code 621410).

²⁵² *Id.* (nationwide count of firms for NAICS Code 621493).

²⁵³ *Id.* (nationwide count of firms for NAICS Code 621491).

²⁵⁴ *Id.* (nationwide count of firms for NAICS Code 621492).

²⁵⁵ *Id.* (nationwide count of firms for NAICS Code 621420).

²⁵⁶ *Id.* (nationwide count of firms for NAICS Code 621512).

²⁵⁷ *Id.* (nationwide count of firms for NAICS Code 621511).

²⁵⁸ *Id.* (nationwide count of firms for NAICS Code 621910).

²⁵⁹ *Id.* (nationwide count of firms for NAICS Code 621498).

²⁶⁰ *Id.* (nationwide count of firms for NAICS Code 62199).

²⁶¹ *Id.* (nationwide count of firms for NAICS Code 524114).

²⁶² *Id.* (nationwide count of firms for NAICS Code 624120).

²⁶³ *Id.* (nationwide count of firms for NAICS Code 624190).

²⁶⁴ *Id.* (nationwide count of firms for NAICS Code 624110). As described *supra* at part IV.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

²⁶⁵ *Id.* (nationwide count of firms for NAICS Code 624221). As described *supra* at part IV.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

²⁶⁶ *Id.* (nationwide count of firms for NAICS Code 624230). As described *supra* at part IV.C.2.iii (methodology), for entities whose principal purpose is not health care, the Department assumes 25%–100% of industry is covered.

²⁶⁷ *Id.* (nationwide count of firms for NAICS Code 44611).

²⁶⁸ *Id.* (nationwide count of firms for NAICS Code 541711).

²⁶⁹ *Id.* (nationwide count of firms for NAICS Code 611310). As described *supra* at part IV.C.2.iii (methodology), the Department assumes 13%–100% of institutions of higher-education are covered.

²⁷⁰ U.S. Dep't of Health & Human Servs., Tracking Accountability in Government Grants System (TAGGS) <http://taggs.hhs.gov> (last visited Dec. 19, 2017).

TABLE 5—NUMBER OF PHYSICAL ESTABLISHMENTS OF EACH RECIPIENT TYPE ESTIMATED TO VOLUNTARILY PROVIDE NOTICE OF RIGHTS IN YEAR 1 (§ 88.5)—Continued

Type	Establishments assoc. with covered recipients		Establishments assoc. with covered recipients that would voluntarily post notices in Year 1		
	(Low)	(High)	(Low)	(High)	Mid-point
Ambulance Services ²⁵⁸	3,271	4,740	1,635	2,370	2,003
All Other Outpatient Care Centers (e.g., centers & clinics for pain therapy, community health, & sleep disorders) ²⁵⁹	8,054	11,672	4,027	5,836	4,931
Entities Providing All Other Ambulatory Health Care Services (health screening, smoking cessation, hearing testing, blood banks) ²⁶⁰	3,670	5,319	1,835	2,660	2,247
Direct Health & Medical Insurance Carriers ²⁶¹	3,712	5,379	1,856	2,690	2,273
Entities Serving the Elderly and Persons with Disabilities (provision of nonresidential social assistance services to improve quality of life) ²⁶²	10,475	41,899	5,237	20,950	13,093
Entities providing Other Individual Family Services (e.g., marriage counseling, crisis intervention centers, suicide crisis centers) ²⁶³	7,184	28,736	3,592	14,368	8,980
Entities providing Child & Youth Services (e.g., adoption agencies, foster care placement services) ²⁶⁴	2,901	11,604	1,451	5,802	3,626
Temporary Shelters (e.g., short-term emergency shelters for victims of domestic violence, sexual assault, or child abuse; runaway youth; and families caught in medical crises) ²⁶⁵	1,013	4,053	507	2,027	1,267
Emergency & Other Relief Services (e.g., medical relief, resettlement, & counseling to victims of disasters or conflicts) ²⁶⁶	309	1,236	155	618	386
Pharmacies and Drug Stores ²⁶⁷	30,450	44,130	15,225	22,065	18,645
Research and Development in Biotechnology ²⁶⁸	2,505	3,631	1,253	1,816	1,534
Colleges, Universities, & Professional Schools ²⁶⁹	615	4,788	308	2,394	1,351
HHS awarded funds appropriated to the U.S. Department of State & USAID ²⁷⁰	65	130	33	65	49
Total	523,470	817,836	261,735	408,918	335,327

3. Estimated Burdens

There are five categories of estimated monetized burdens for this final rule as summarized in Table 6, as well as burdens that cannot be fully monetized. No commenters provided alternate reliable methodologies for monetizing the rule's burden. Potential burdens associated with access to care and health outcomes are discussed *infra* at part IV.C.4.vii.

Several comments argued that the rule would impose costs on entities associated with the increased risk of litigation over incidents of providers' exercise of conscience, both between patients and providers and between individual providers and their employers.

Regarding an increase in risk for litigation between individual providers

and their employers, the Department agrees with the potential effect these commenters predict: That some entities will change their behavior to come into compliance, or improve compliance, with Federal conscience and anti-discrimination laws. Indeed, the proposed rule's RIA and this RIA estimate the burden associated with such voluntary behavior changes. However, whether entities take such action because of the risk of litigation is too speculative and uncertain for calculation in the RIA. Further, some courts have held that there is no private right of action under the Coats-Snowe and Church Amendments, excluding litigation as a viable alternative for individuals.²⁷¹

Regarding an increase in risk for litigation between patients and

providers, the Department agrees that this rule will result in more providers exercising conscientious objections to participating in services requested by patients, and that such objections may give rise to lawsuits by patients. However, the Department is unaware of any reliable basis for estimating the frequency or cost of such lawsuits.

Public comments regarding general burdens are integrated throughout the RIA. Public comments regarding the burden, if any, that may result from secondary effects of this rule, such as the monetary impact of certain health outcomes that may arise from increased conscience protection, are discussed in the rule's analysis of benefits, *infra* at IV.C.4.

²⁷¹ See, e.g., *Vermont All. for Ethical Healthcare, Inc. v. Hoser*, 274 F. Supp. 3d 227, 240 (D. Vt. 2017); *Hellwege v. Tampa Family Health Centers*, 103 F. Supp. 3d 1303, 1311–12 (M.D. Fla. 2015);

Order at 4, *National Institute of Family and Life Advocates, et al. v. Rauner*, No. 3:16-cv-50310 (N. D. Ill. July 19, 2017), ECF No. 65. See also *supra* at part II.A (describing the lack of private remedies).

²⁷² The totals in Table 6: Cost Summary of the Final Rule may not appear to add correctly, but that is due to rounding.

TABLE 6—COST SUMMARY OF THE FINAL RULE
(Discounted 3% and 7% in millions)²⁷²

	Year 1	Year 2	Year 3	Year 4	Year 5	Total (for undiscounted) annualized (for discount'd.)
Familiarization (undiscounted)	\$135	\$—	\$—	\$—	\$—	\$135
Familiarization (3%)	120					120
Familiarization (7%)	103					103
Assurance & Certification (undiscounted)	156	142	142	142	142	724
Assurance & Certification (3%)	138	123	119	116	112	608
Assurance & Certification (7%)	119	101	95	89	83	486
Voluntary Notice (undiscounted)	93	14	14	14	14	150
Voluntary Notice (3%)	83	12	12	11	11	130
Voluntary Notice (7%)	71	10	9	9	8	108
Voluntary Remedial Efforts (undisc.)	7	7	7	7	7	36
Voluntary Remedial Efforts (3%)	6	6	6	6	6	31
Voluntary Remedial Efforts (7%)	6	5	5	5	4	24
OCR Enforcement Costs (undisc.)	3	3	3	3	3	15
OCR Enforcement Costs (3%)	3	3	2	2	2	12
OCR Enforcement Costs (7%)	2	2	2	2	2	10
Total Costs (undiscounted)	394	167	167	167	167	1,061
Total Costs (3%)	350	144	140	135	131	901
Total Costs (7%)	301	119	111	104	97	731

In this impact analysis, the Department calculates labor costs using the mean hourly wage (including benefits and overhead) for a:

- Lawyer at \$134.50 per hour (\$67.25 per hour × 2),²⁷³
- Executive at \$186.88 (\$93.44 per hour × 2),²⁷⁴
- Administrative assistant at \$38.78 per hour (\$19.39 per hour × 2),²⁷⁵
- Web developer at \$69.38 per hour (\$34.69 per hour × 2),²⁷⁶ and
- Paralegal at \$51.84 per hour (\$25.92 per hour × 2).²⁷⁷

These calculations reflect the Department's standard practice of calculating a fully loaded mean hourly wage (*i.e.*, wage including benefits and overhead) by multiplying the hourly pre-tax wage by two.²⁷⁸

(i) Familiarization Burden

The Department estimates a one-time burden for regulated persons and

entities to familiarize themselves with the rule. The proposed rule estimated that on average, each person and entity would spend one hour for familiarization. The Department received comments arguing that this estimate fell short of the time needed to accomplish the goal of familiarization. In light of these comments, the Department increased the estimate from one hour to two hours. This increase reflects persons' and entities' familiarization of the rule's requirements and procedures, including the changes from the proposed rule.

The burden is a one-time opportunity cost of staff time (a lawyer) to review the rule. The labor cost is approximately \$135.3 million in the first year (\$134.50 per hour × 2 hours × 502,899 entities (the average of the low and high-end range in Table 2)) and zero dollars in years two through five. This estimated burden represents the average burden; some persons and entities may spend substantially more time than two hours on familiarization, and others may spend less time.

(ii) Burden Associated With Assurance & Certification (§ 88.4)

As a condition of the approval, renewal, or extension of any Federal financial assistance or Federal funds from the Department, § 88.4 requires every application for Federal financial assistance or Federal funds from the Department to which the rule applies to provide, contain, or be accompanied by an assurance and a certification that the applicant or recipient will comply with

applicable Federal conscience and anti-discrimination laws and this rule.

The burden to recipients not exempted from § 88.4 is the opportunity cost of recipient staff time (1) to review the assurance and certification language and the requirements of the Federal conscience and anti-discrimination laws referenced or incorporated, (2) to review recipient-wide policies and procedures or take other actions to self-assess compliance with applicable Federal conscience and anti-discrimination laws, and (3) to implement any actions necessary to come into compliance.

Infra at Table 7 summarizes these costs.

The Department estimates that each recipient not exempted from § 88.4 will spend an average of 4 hours annually reviewing the assurance and certification language and the Federal conscience protection and associated anti-discrimination laws and the rule. In the 2008 Rule, the Department estimated that it would take 30 minutes to certify compliance with three laws: The Church, Weldon, and Coats-Snowe Amendments.²⁷⁹ In this rule, there are 22 additional statutory provisions covered. Citations for each law are clearly listed in the rule, the texts of the statutes are easily found online. For many entities, it will be immediately clear when a law that this rule implements and enforces does not apply to those entities.²⁸⁰ The Department

²⁷⁹ 73 FR 78072, 78095 (2008 Rule).

²⁸⁰ For example, provisions applicable to Medicaid recipients would not apply to entities that do not receive Medicaid and, presumably, most entities readily know if they receive Medicaid reimbursements as a result of providing care to Medicaid beneficiaries.

²⁷³ Bureau of Labor Statistics, Occupational and Employment Statistics, Occupational Employment and Wages, May 2016, https://www.bls.gov/oes/current/oes_nat.htm (occupation code 23–1011).

²⁷⁴ *Id.* (occupation code 11–1011).

²⁷⁵ *Id.* (occupation code 43–6010).

²⁷⁶ *Id.* (occupation code 15–11134).

²⁷⁷ *Id.* (occupation code 23–2011).

²⁷⁸ “Guidance for Regulatory Impact Analysis,” Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, 2016, at 28; *see, e.g.*, 81 FR 31451 (2016) (“We note that one commenter suggested that we use a factor higher than 100% to adjust wages for overhead and benefits. However, the commenter’s argument is based on Federal overhead rates for contracts, and not evidence of the resource costs associated with reallocating employee time. As a result, we do not adopt the commenter’s recommendation, and we continue to use the Department’s standard of 100% for overhead and fringe benefits.”).

estimates each recipient will take 10 minutes per law on average, yielding an additional 3.5 hours on average to review the applicability of the additional laws that this rule proposes to enforce, for a total burden of 4 hours per recipient, per year, for the first five years. Some recipients may spend considerably less time; others may spend considerably more time.

The labor cost is a function of a lawyer spending 3 hours reviewing the assurance and certification and an executive spending one hour to review and sign, as § 88.4(b)(2) requires a signature by an individual authorized to bind the recipient. The weighted mean hourly wage (including benefits and overhead) is \$147.60 per hour.²⁸¹ The labor cost is \$93.8 million each year for the first five years (\$147.60 per hour × 4 hours × 158,890 recipients²⁸²).

The Department estimates that 79,445 recipients, which is half of recipients required to assure and certify compliance (158,890 recipients/2), will spend 4 hours reviewing policies and procedures or taking other actions to self-assess compliance with applicable Federal conscience and anti-discrimination laws each year for the first five years after publication of the rule. Some entities will spend more time and others will spend less time. The Department reasonably estimates such action because § 88.4(b)(4) states that the submission of an assurance and certification will not relieve a recipient of the obligation to come into compliance prior to or after submission of such assurance or certification. A first step to such actions may be to review organization-wide safeguards (or best practices), such as policies and procedures, that may be, or should be, in place. The labor cost is a function of a lawyer spending 3 hours and an executive spending one hour, which produces the a weighted mean hourly wage of \$147.60 per hour. The labor cost for self-assessing compliance is a total of \$46.9 million annually for the first five years (\$147.60 per hour × 4 hours × 79,445 entities).

The Department estimates that approximately 5 percent of entities (or 16 percent of those subject to § 88.4) will take an organization-wide action to improve compliance in the first year and 0.5 percent of entities (1.6 percent of those subject to § 88.4) will take a similar action annually in years two through five. This percentage equates to

25,145 recipients in year one and 2,514 recipients annually in years two through five. The Department estimates that these recipients would spend 4 hours annually, on average, to take remedial efforts. The Department estimates that recipients will spend an average of 4 hours to update policies and procedures, implement staffing or scheduling practices that respect an exercise of conscience rights under Federal law, or disseminate the recipient's policies and procedures. The labor cost is a function of a lawyer spending 3 hours and an executive spending one hour, which produces a weighted mean hourly wage of \$147.60 per hour. The labor cost is \$14.8 million in year one (\$147.60 per hour × 4 hours × 25,145 entities) and approximately \$1.5 million annually for years two through five (\$147.60 per hour × 4 hours × 2,514 entities).

If entities were already fully taking steps to be educated on, and comply with, all the laws that are the subject of this rule, there would likely not be any costs within the first five years of publication for remedial efforts associated with a recipient's commitment to assure and certify compliance in § 88.4. However, the fact that there would be such costs is wholly consistent with the Department's stated justifications for the rule (*i.e.*, lack of knowledge of, and compliance with, the laws).

Several commenters expressed concern with the possible burden on health care providers resulting from the requirements to assure and certify compliance with Federal conscience and anti-discrimination laws. In drafting the rule, the Department considered the possible burden on health providers and exempted certain classes of recipients from § 88.4. The impact of the exemption means that, unless such exempted persons or entities are recipients of Federal financial assistance or other Federal funds from the Department through another instrument, program, or mechanism, approximately 70 percent of recipients do not have to comply with the assurance and certification requirement.²⁸³ Given the

magnitude of the exemption, § 88.4 does not unduly burden persons and entities subject to the rule. Where the exemption does not apply, the burdens arising from assurances and certifications are fully justified, as they are with every other anti-discrimination law that requires a similar assurance or certification.

Moreover, the Department is committed to ensuring that a health care provider's assurance and certification of compliance with Federal conscience and anti-discrimination laws does not unduly burden small health care providers in their delivery of health care services to the community. As explained in the Paperwork Reduction Act analysis for § 88.4, the Department is leveraging existing grant, contract, and other Departmental forms and government-wide systems, consistent with OMB's government-wide effort to reduce recipient burden.²⁸⁴

Finally, the Department has made efforts to reduce the frequency of information collected. Paragraph (b)(6) in § 88.4 allows an applicant or recipient to incorporate the assurances and certification by reference in subsequent applications to the Department or Department component if prior assurances or certifications are initially provided in the same year. This approach is consistent with the HHS Grants Policy Statement.²⁸⁵ Because recipients file an assurance of compliance form "for the organization and . . . not . . . for each application," a recipient with a signed assurance on file assures through its signature on the award application that it has a signed Form 690 on file.²⁸⁶

Paragraph (b)(1) in § 88.4 requires submission more frequently than the time of application if the applicant or recipient fails to meet a requirement of the rule, or OCR or the relevant Department component has reason to suspect or cause to investigate the possibility of such failure. The ability to require assurances outside of the application process permits OCR and the Department to ensure that the Federal financial assistance or other Federal funds that the Department awards are used in a manner compliant with Federal conscience and anti-discrimination laws and the final rule. As this is a new requirement, OCR has

²⁸³ The average between the lower-bound (267,134) and upper-bound (415,666) of recipients exempted is 341,400 recipients, which represents 68 percent of the estimated total 500,290 recipients of the rule (which is the result of 502,899 entities minus the estimated 2,609 counties that are estimated for the purposes of this rule as sub-recipients). If fewer recipients are impacted by the exemptions in § 88.4(c)(1) through (4) than estimated, and if such recipients do not receive HHS Federal financial assistance or other Federal funds from a non-exempted HHS program, then the Department overestimated the percent of recipients that do not have to comply with the assurance and certification requirement.

²⁸¹ Sum of (\$134.50 × .75) and (\$186.88 × .25).

²⁸² This estimate is the average of the low and high-end estimates in *supra* at Table 3. As explained *supra* at part IV.C.2.iv.A, sub-recipients are not subject to this requirement.

²⁸⁴ Exec. Office of the President, Memorandum from Mick Mulvaney, Dir., Office of Management & Budget to Heads of Executive Departments and Agencies, Strategies to Reduce Grant Recipient Reporting Burden, at 2 (Sept. 5, 2018), <https://www.whitehouse.gov/wp-content/uploads/2018/09/M-18-24.pdf>.

²⁸⁵ See HHS Grants Policy Statement (Jan. 2007), <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgrps107.pdf>.

²⁸⁶ *Id.* at I-31.

not yet gained the experience to know how many recipients, if any, would be

required by OCR or a Department component to sign assurances on an as-

needed basis outside of the application process.

TABLE 7—SUMMARY OF ASSURANCE AND CERTIFICATION COSTS

Cost categories	Total costs	
	Year 1	Annually Years 2–5
Review and Sign	\$93.8	\$93.8
Review Policies & Procedures	46.9	46.9
Update or Disseminate Policies & Procedures	14.8	1.5
Total Costs	155.6	142.2

(iii) Burden Associated With Voluntary Actions To Provide Notices of Rights (§ 88.5)

As explained *supra* at in part IV.C.2.iv.B, the Department assumes that some recipients and Department components will voluntarily post and distribute a notice of rights through one of the methods specified in § 88.5. The expected cost to recipients and the Department is \$93.4 million in the first year of the rule's implementation and \$14.1 million annually in years two through five. The cost to the Department makes up a miniscule portion of the cost—about 0.04 percent in the first year and 0.10 percent annually in years two through five.

As explained *supra* at part IV.C.2.iv.B, the Department assumes that an estimated 139,615 recipients (the average of the low-end and high-end estimates shown in Table 4) will likely modify the pre-written notice in Appendix A as applied to them. Because the scope of such modifications would likely be limited, the Department estimates that modifying the notice constitutes a minimal opportunity cost of 20 minutes of a lawyer's time for drafting and 10 minutes of an executive's time to provide final approval. For some recipients, modifying the notice will take more of the lawyer's or executive's time; for other recipients, it will take less time. The weighted mean hourly wage (including benefits and overhead) of these two occupations is \$151.79 per hour.²⁸⁷ The one-time labor cost is \$10.6 million in the first year (\$151.79 per hour × 0.5 hours × 139,615 recipients).

There is uncertainty regarding how many recipients will voluntarily post notices and which method or methods in § 88.5 they will employ. For the purposes of this calculation, the Department erred on the side of overestimating the burden and assumes that recipients likely to provide notice will do so:

- At physical locations,
- On their websites, and
- In two publications, such as a personnel manual or other substantially similar document for members of the recipient's workforce; in an application for membership in the recipient's workforce or for participation in a service, benefit or other program, including for training or study; or in a student handbook or other substantially similar document for students participating in a program for training or study, including for post-graduate interns, residents, and fellows.

One commenter suggested that the final rule should permit the notice requirement to be posted electronically only, and not in paper form. Because the rule does not require recipients to provide notices of rights, recipients are free to provide notice in electronic form only and have such action considered by OCR as non-dispositive evidence of compliance with the substantive provisions of the rule, to the extent such notices are otherwise provided according to § 88.5 and relevant to the particular OCR investigation or compliance review.

For recipients that voluntarily post notices through any of the methods in § 88.5, the Department assumes that the recipients will act by the end of the first year after the rule's implementation. An entity that posts on its website and in a physical location will incur a one-time burden. A recipient that includes an insert in a publication may incur an annual burden represented by the costs of labor, materials (paper and ink for hard-copy publication), and in some cases, postage.

Burden for Voluntary Posting in Physical Locations

The Department estimates that it will take ⅓ of an hour for an administrative assistant to print notice(s) and post them in physical locations of the establishment where notices are customarily posted to permit ready observation. For some establishments, it

may take an administrative assistant longer to perform his or her respective functions; for other establishments, it may take less time. As shown in Table 5, 335,327 establishments is the average in the range of estimated establishments associated with covered recipients that would voluntarily post notices in the first year after the rule's publication. The estimated labor cost is \$4.3 million (⅓ hour × \$38.78 per hour × 335,327 establishments).

A key uncertainty is the total number of locations per establishment where recipients commonly post notices; the per-establishment total will vary based on multiple factors. These factors include the type of recipient, floor plans of the building, the square footage of the common areas, the square footage of the building, the number of floors, the size of the workforce, and the number of ultimate beneficiaries, among other variables. The Department assumes that the average establishment will print and post five notices in physical locations where notices are customarily posted; larger recipients might post more and smaller recipients might post fewer. The Department assumes that the cost of materials (paper and ink) is \$0.05 per page. Based on this assumption, the first-year cost to post 5 notices across all establishments would be \$83,832 (335,327 establishments × \$0.05 per page × 5 pages). Because the Department assumes that this cost is a one-time cost during the first year of this rule's implementation, the cost will not recur in years two through five. The total labor and materials costs for 335,327 establishments to post notices in physical locations is \$4.4 million (\$4.3 million in labor costs and \$83,832 for materials) in year one with zero recurring costs.

Burden for Web Posting

To post the notice on the web, the Department estimates that it will take 2 hours for a web developer to execute the design and technical elements for posting. A key uncertainty is whether

²⁸⁷ Sum of (\$134.50 × .67) and (\$186.88 × .33).

each recipient maintains separate websites for each facility, and if so, whether those websites are maintained at the corporate (*i.e.*, firm) level or facility (*i.e.*, establishment) level. In the proposed rule, the Department erred on the side of overestimating the burden and assumed that recipients maintained separate websites for each of their facilities at the establishment level. Thus, a web developer at each recipient's physical location would post the notice on the web. For some establishments, it may take web developers longer to perform their respective functions; for other establishments, it may take less time. This labor cost is approximately \$46.5 million (2 hours $\times$ \$69.38 per hour $\times$ 335,327 establishments).

If, however, recipients maintain one website at the corporate level for all of their facilities, a web developer at the firm-level, rather than at each establishment, would bear the burden. In contrast to recipients bearing the cost across 335,327 facilities, about 250,145 recipients at the firm-level would each bear this cost, which equals \$34.7 million (2 hours $\times$ \$69.38 per hour $\times$ 250,145 firms). Thus, if recipients voluntarily post notices on their websites, and if they do so at their corporate level for all sites including facility-specific websites, recipients would save on average about 25 percent of their labor costs to execute web posting in this manner.

Burden for Posting in Two Publications

The Department did not receive specific comments estimating the annual costs of labor or materials that may be incurred by entities that include notices in relevant publications as set forth in the proposed rule (which remain voluntary under the final rule). Given the key uncertainties in how recipients will disseminate the notices of rights, as explained in subsequent paragraphs, the Department assumes that: (1) Establishments that include notices of rights in publications will most often do so in online publications or in hard-copy publications hand-distributed, where the notice's inclusion results in an additional 100 hard copy notices per establishment per year, and (2) half of the establishments associated with covered recipients voluntarily providing hard-copy notices (*i.e.*, 167,663 establishments in year one and 125,747 establishments annually in years two through five)²⁸⁸ will

distribute the publications via U.S. mail where the weight of the notice incrementally increases the postage costs.

The Department assumes that, within the first year after the rule's publication, each recipient voluntarily posting notices in publications would identify the two publications in which to include the notice, revising the documents or their layouts to include the notice, or otherwise printing an insert to include with hard copies of the publication. A recipient that adds the notice to a publication disseminated only online that is not disseminated in hard copy will incur a one-time labor cost with zero costs for materials. In contrast, recipients that add the notice to a publication disseminated via hard copy may incur the annual cost of materials or incremental postage, or both, as well as the associated labor cost. For instance, a recipient that is unable to add the notice to the back page of an existing publication might add the notice as a separate page to the underlying publication or may print notices annually to include as inserts with the hard-copy publications. A recipient that does so and disseminates the publication via U.S. mail might incur incremental postage costs if the incremental weight of the notice places the total weight of the mailing in the next bracket of postage costs.

These assumptions may differ from recipients' implementation experiences. Some recipients may distribute fewer than 100 hard-copy notices with relevant publications while others will distribute more than 100. Some recipients that mail relevant publications with notices of rights may not experience any incremental postage costs if the total weight of the mailings with notices does not place the mailing in the next postage bracket. Notwithstanding these uncertainties, the Department sets forth the following monetization as its best estimate of the burden based on its assumptions.

The Department assumes an administrative assistant would spend an average of two hours in year one and one hour annually in years two through five to execute the activities except for mailing. The average labor cost, excluding mailing-related labor costs, is \$26.0 million in year one (\$38.78 per hour $\times$ 2 hours $\times$ 335,327 establishments) and \$9.8 million annually in years two through five (\$38.78 per hour $\times$ 1 hour $\times$ 251,495 establishments).²⁸⁹ Based on the

marginal cost of postage per ounce of \$0.15,²⁹⁰ an annual number of mailings of 100 pages per establishment, average annual labor cost for mailing of \$38.78 per hour, and an average number of labor hours per mailing of 0.25 hours, the total costs due to the voluntary mailing of notices are \$4.1 million in year one²⁹¹ and \$3.1 million annually in years two through five.²⁹² Finally, the annual cost of printed materials for notices (both mailed and hand distributed) is \$1.7 million (335,327 establishments $\times$ 100 pages $\times$ \$0.05 per page) in year one and \$1.3 million annually in years two through five (251,495 establishments $\times$ 100 pages $\times$ \$0.05 per page).

In sum, the burden to recipients related to the voluntary posting and distributions of notices that \$88.5 incentivizes is \$93.4 million in the first year and \$14.1 million annually in years two through five.

Burden to the Federal Government

Federal agencies are encouraged to identify costs and savings to government agencies where significant.²⁹³ The burden of \$88.5 to the Federal government is the cost associated with the Department's components posting the notice voluntarily. Although this burden is not significant, the RIA monetizes the burden for completeness.

The Department uses a framework for estimating its burden that is similar to the framework used to estimate the burden to recipients. For instance, the Department assumes that half of its components will post notices of rights voluntarily in the first year of the rule's publication (*i.e.*, 10 of the 20 HHS Operating and Staff Divisions will post online). Because of attrition in compliance, 75 percent of that number will continue posting annually in certain publications in years two through five. As a proxy for that assumption to enable monetization of the physical posting, the Department assumes that staff at half of 533 physical

in year one will continue to do so in out years and there will be lower attrition compared to the estimate provided in the proposed rule.

²⁹⁰ See U.S. Postal Service Postage Rates, <https://www.stamps.com/usps/current-postage-rates/>.

²⁹¹ Sum of incremental postage of \$2.5 million (\$0.15 per mailing $\times$ 100 mailings $\times$ 167,663 establishments) and incremental labor of \$1.6 million (\$38.78 per hour $\times$ 0.25 hours $\times$ 167,663 establishments).

²⁹² Sum of incremental postage of \$1.9 million (\$0.15 per mailing $\times$ 100 mailings $\times$ 125,747 establishments) and incremental labor of \$1.2 million (\$38.78 per hour $\times$ 0.25 hours $\times$ 125,747 establishments).

²⁹³ OMB Circular A-4, Regulatory Analysis 37 (2003), <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>.

²⁸⁸ Product of 335,327 establishments times 50 percent for year one. Product of 251,495 establishments times 50 percent for years two through five.

²⁸⁹ Under the final rule, because all the notice provisions are voluntary, the Department assumes that 75% of entities that voluntarily provide notices

locations owned or leased by the Department²⁹⁴ (277 physical locations) would post an average of five hard-copy notices per physical location and would post in certain publications. In years two through five, 75 percent of the 277 locations (207 locations) would post in certain publications. The Department assumes that the duration of the anticipated activities (*e.g.*, downloading, printing, and posting the notice) would take Department staff the same time as it would take recipient staff. Similarly, the Department assumes that half of the physical locations associated with HHS components voluntarily providing hard copy notices (*i.e.*, 138 locations in year one and 104 locations annually in years two through five)²⁹⁵ will distribute the publications via U.S. mail where the weight of the notice incrementally increases the postage costs.

The methods diverge in how the web posting is implemented (by each HHS Operating and Staff Division but not by each facility owned or leased) and in the average hourly wage rate used: A GS-7 step 5,²⁹⁶ which, adjusted upward for benefits and overhead, equals \$47.44 per hour (\$23.72 per hour $\times$ 2).²⁹⁷

Based on these assumptions, the total labor cost is \$5,277 in the first year: (\$47.44 per hour $\times$ $\frac{1}{3}$ hour $\times$ 277 locations) + (\$47.44 per hour $\times$ 2 hours $\times$ 10 Departmental components). Cost for materials for the notice is \$1,452 dollars²⁹⁸ in the first year after publication of the final rule and \$1,037 annually²⁹⁹ in years two through five. Finally, the cost associated with the portion of Department locations that mail notices of rights with certain publications is \$3,713 in the first

year³⁰⁰ and \$2,785³⁰¹ annually in years two through five. In sum, the burden to the Federal government associated with \$88.5 is \$36,677 in the first year and \$13,660 annually in years two through five.

(iv) Record-Keeping (§ 88.6(b))

Paragraph (b) in § 88.6 of the final rule requires recipients and sub-recipients to maintain records evidencing their compliance with this part. In the proposed rule, the Department did not identify record-keeping as a separate burden because it assumed that recipients and sub-recipients already maintain records in the course of evidencing compliance with the terms and conditions of a Federal award, which would include not only financial management requirements but all applicable Federal laws, including Federal conscience and anti-discrimination laws. The Department requested comment on that assumption. The Department received numerous comments stating that the record-keeping requirements in § 88.6(b) were too vague and requesting clarity on what kinds of records must be maintained. However, the Department received no comments contradicting its assumption that recipients and sub-recipients already follow record-keeping practices that suffice to document compliance with Federal civil rights laws. Therefore, because the Department understands that recipients and sub-recipients must document such compliance in the course of receiving a Federal award,³⁰² any potential marginal increase in the cost of maintaining records according to the clarity set forth in § 88.6(b) would be *de minimis*.

(v) Reporting a Finding of Noncompliance (§ 88.6(d))

Paragraph (d) in § 88.6 of the proposed rule would have required recipients and sub-recipients to report to the relevant Departmental funding component the existence of an OCR

compliance review, investigation, or complaint under 45 CFR part 88 over a five-year period as such incidents arise and in any application for new or renewed Federal financial assistance or Departmental funding. The Department received numerous comments that stated this requirement was too burdensome.

Accordingly, the Department has significantly revised § 88.6(d). Recipients and sub-recipients would no longer have to report a compliance review, investigation, or complaint against them as it arises. Moreover, recipients and sub-recipients would only be required to disclose the existence of a determination by OCR of noncompliance with this rule in any application for new or renewed Federal financial assistance or Departmental funding (rather than reporting compliance reviews, investigations, or complaints). Recipients would be responsible for disclosing any OCR determinations of non-compliance made against their sub-recipients. Finally, the final rule shortens the reporting period from five to three years following an OCR determination of noncompliance.

Given the revisions to § 88.6(d), the Department has revisited its methodology for estimating the costs imposed by § 88.6(d). The Department estimates that the burden is the opportunity cost for recipients and sub-recipients who have had OCR determine that they are noncompliant with this rule to retrieve information from their records systems and enter in the application basic identifying information regarding the determination. The components to monetize this burden include: (1) The time spent for a staff member to execute the reporting functions and that person's fully loaded mean hourly wage, (2) the number of times a recipient or sub-recipient applies for new or renewed funding administered by the Department annually, and (3) the number of recipients and sub-recipients that OCR finds noncompliant with this part annually.

The Department estimates it would take a records custodian at the experience level of a paralegal about 15 minutes to retrieve the relevant information (such as date of the OCR determination of noncompliance and the OCR "transaction number" (*i.e.*, case number)) from the recipient's or sub-recipient's records and an administrative assistant 15 minutes to enter the information in the application for Federal financial assistance or other Federal funds from the Department. The mean weighted hourly wage for the paralegal and administrative assistant is

²⁹⁴ Obtained from U.S. General Services Administration on October 30, 2018 (on file with HHS OCR).

²⁹⁵ Product of 277 locations times 50 percent for year one. Product of 207 locations times 50 percent for years two through five.

²⁹⁶ The hourly wage rates of staff are likely to vary from a GS-3 to a GS-11. The Department uses the mid-point GS-level and step and relies on hourly wage rates for the locality salary adjustment for the District of Columbia and surrounding geographic area.

²⁹⁷ https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DCB_h.pdf. Executive Order 13771 requires agencies to estimate costs in 2016 dollars.

²⁹⁸ Sum of costs for materials to post in physical locations (5 pages $\times$ \$0.05 per page $\times$ 277 locations) plus costs for materials to post in certain publications (100 pages $\times$ \$0.05 per page $\times$ 277 locations).

²⁹⁹ Costs for materials to post in certain publications (100 pages $\times$ \$0.05 per page $\times$ 207 locations).

³⁰⁰ Sum of incremental postage of \$2,074 (\$0.15 per mailing $\times$ 100 mailings $\times$ 138 facilities) and incremental labor of \$1,640 (\$47.44 per hour $\times$ 0.25 hours $\times$ 138 facilities).

³⁰¹ Sum of incremental postage of \$1,555 (\$0.15 per mailing $\times$ 100 mailings $\times$ 104 facilities) and incremental labor of \$1,230 (\$47.44 per hour $\times$ 0.25 hours $\times$ 104 facilities).

³⁰² See 45 CFR 75.302 (regarding the sufficiency of an HHS awardee's financial management system, including "records documenting compliance with Federal statutes, regulations, and the terms and conditions of the Federal award"). See also *id.* section 75.361 (requiring an HHS awardee to maintain records for three years from the date of the final expenditure report or from the date the awardee submits its quarterly or annual financial report).

\$45.31.³⁰³ The Department estimates that a recipient would bear this labor cost at the firm level for every award action the recipient applied, including new funding opportunities, supplemental funding, and non-competing continuations, among others.

Because OCR had no publicly available or reliable data source to estimate how many total applications for new or renewed funding in a fiscal year a recipient might make to the Department or its component, actual award data from HHS TAGGS was used as a proxy. The Department considered the number of award actions the Department and its components made to State agencies and State universities in FY 2017 to inform the estimate. Award data in HHS TAGGS for FY 2017 indicated that some State universities receive less than 100 awards per fiscal year and others receive nearly 2,000 awards. Some State agencies receive one or two awards per fiscal year and others receive 80 awards per fiscal year. Consequently, a recipient or sub-recipient found in violation of this part, on the extreme end, would expend \$45,310 per year in labor costs at the firm level (2,000 applications per year $\times$ \$45.31 per hour $\times$ 0.5 hours).

The most significant uncertainty for monetizing the burden of § 88.6(d) is the number of recipients and sub-recipients that OCR will determine as noncompliant with this rule. OCR employs a range of fact-finding methods and evaluates each complaint based on the relevant facts, circumstances, and law at issue, which is an approach that this rule codifies in § 88.7(d). OCR is gaining experience in handling the complexity and volume of complaints received alleging violations of the Weldon Amendment, Church Amendment, Coats-Snowe Amendment, and section 1553 of the Affordable Care Act. Most of the statutes that are the subject of the rule have no case law interpreting them. In addition, compared to OCR's experience handling complex cases for other civil rights and health information privacy matters, there is little institutional history of OCR enforcement of the Weldon Amendment, Church Amendments, Coats-Snowe Amendment, and section 1553 of the Affordable Care Act. Indeed, OCR was receiving only approximately 1.25 complaints per year alleging such violations during the eight years preceding the change in Administration. However, during FY 2018, the most recently completed fiscal year for which data are available, OCR received 343

complaints alleging conscience violations.³⁰⁴ Given this variable posture at this stage of the Department's renewed efforts on conscience and religious freedom, the Department cannot reliably predict the number of OCR determinations of noncompliance to monetize this burden, but estimates that, for those to whom it applies, the related reporting cost is about \$45,310 per year per entity with the highest number of applications for HHS funding.

(vi) Voluntary Remedial Efforts

The proposed rule noted that the Department anticipates that some recipients will institute a grievance or similar process to handle internal complaints raised to the recipient's or sub-recipient's attention. The rule does not require such a process, but in HHS OCR's enforcement experience, informal resolution of matters at the recipient or sub-recipient level may effectively resolve a beneficiary's or employee's concern. The Department received no comments regarding the proposed rule's methodology for estimating these costs. The Department anticipates 0.5 percent of entities, or 2,514 entities,³⁰⁵ would conduct such internal investigations should complaints come to the recipient's or sub-recipient's attention or would undertake remedial efforts to resolve complaints.

The burden is the opportunity cost of staff time to handle internal investigations and take remedial action. Uncertainty exists as to how many hours annually a recipient or sub-recipient would devote to this effort. On average, the Department anticipates entities spending 20 hours annually: 16 hours of a lawyer's time and 4 hours of an executive's time. The weighted mean hourly wage (including benefits and overhead) is \$144.98 per hour.³⁰⁶ The labor cost is \$7.3 million ($\$144.98 \text{ per hour} \times 20 \text{ hours} \times 2,514 \text{ entities}$). Some recipients may spend more than 20 hours on voluntary remedial efforts, and if this is the case, the labor cost will be greater. Other recipients may spend less than 20 hours, and if this is the case, the labor cost will be lower.

(vii) OCR Enforcement and Associated Costs

The Department anticipates a temporary increase in investigation and enforcement costs to OCR over the five years immediately following publication

of the final rule. The Department expects this increase from the synergistic impact of persons' increased awareness of rights; increased confidence in the Department's ability and willingness to address those rights through the administrative complaint process; and an increase in the number of Federal conscience and anti-discrimination laws that the rule proposes to enforce. Indeed, since during FY 2018, the most recently completed fiscal year for which data are available, OCR received 343 complaints alleging conscience violations.³⁰⁷

The impact of the rule on OCR is the opportunity cost of about 12 FTEs to perform investigative responsibilities and coordinate enforcement with HHS components, as set forth in § 88.7, which is an increase of 7.5 FTEs from the proposed rule's estimate. These responsibilities include receiving and handling complaints, initiating compliance reviews, conducting investigations, coordinating compliance within the Department, and performing other associated activities as part of its program to promote widespread voluntary compliance of Federal conscience and anti-discrimination laws. The Department anticipates that the 12 FTEs consist of a member of the Senior Executive Service, four GS-15 employees, three GS-14 employees, two GS-13 employees, and two GS-12 employees, each paid a mid-level salary for the DC area.³⁰⁸ The fully loaded labor cost (including benefits and overhead) for those twelve employees is estimated to be \$3 million annually. The difference between the proposed rule's estimate for OCR's enforcement costs and this estimate is primarily the result of the increase in the number of FTEs. This increase is informed by OCR's experience since publication of the proposed rule, which has demonstrated that OCR will need to devote greater resources to the area of conscience protections than OCR had anticipated at the time of publication of the proposed

³⁰⁷ Complaint data based on OCR's system of records as of December 20, 2018.

³⁰⁸ Using the locality salary adjustment for the District of Columbia and surrounding geographic area, the annual salaries adjusted upward for benefits and overhead are as follows: \$290,324 for GS-15 step 5 ($145,162 \times 2$); \$246,812 for GS-14 step 5 ($123,406 \times 2$); \$208,866 for GS-13 step 5 ($104,433 \times 2$); and \$175,642 for GS-12 step 5 ($87,821 \times 2$). See <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/16Tables/html/DCB.aspx>. The mid-level salary adjusted for benefits and overhead for a Senior Executive is \$308,275 ($154,138 \times 2$), which is the average of the minimum and maximum salary for agencies with a certified SES performance appraisal system. See <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/16Tables/exec/html/ES.aspx>.

³⁰³ Sum of $(0.5 \times \$38.78 \text{ per hour})$ and $(0.5 \times \$51.84 \text{ per hour})$.

³⁰⁴ Complaint data based on OCR's system of records as of December 20, 2018.

³⁰⁵ Product of $0.005 \times 502,899$ recipients.

³⁰⁶ Sum of $(\$67.25 \times .80) + (\$93.44 \times .20)$ and multiplied by two to adjust upward for overhead and benefits.

rule. This estimate also has been adjusted upwards based on the method of calculating the wages of the FTEs. The proposed rule assumed a fully loaded wage for each of the 4.5 FTEs at \$201,000, but the final rule estimates the cost of the 12 FTEs based on various GS levels and therefore relies upon the fully loaded wage using the estimated hourly salaries of employees under the GS schedule.

One commenter stated that the costs associated with OCR's enforcement efforts would double to the extent that both a provider and a patient file a complaint over the same matter. The commenter did not provide an example of a scenario where such "double filing" would occur. The Department believes that such scenarios, if they occur at all, would constitute a *de minimis* proportion of complaints received by OCR and would not involve increased or doubled costs, as resources for resolution of the two complaints would be shared through investigation of similar matters.

4. Estimated Benefits

The Department expects this final rule to produce a net increase in access to health care, improve the quality of care that patients receive, and secure societal goods that extend beyond health care. These effects will occur primarily via four mechanisms.

First, this rule is expected to remove barriers to the entry of certain health professionals, and to delay the exit of certain health professionals from the field, by reducing discrimination or coercion that health professionals anticipate or experience. Comments received by the Department demonstrate that a lack of conscience protections diminishes the availability of qualified health care providers. For example, in a survey of providers belonging to faith-based provider organizations, over nine in ten (91 percent) agreed with the statement, "I would rather stop practicing medicine altogether than be forced to violate my conscience."³⁰⁹

Second, in supporting a more diverse medical field, the rule will benefit patients by improving doctor-patient relationships and quality of care. Academic literature supports the proposition that prohibiting the exercise of conscience rights in medicine decreases the quality of care that patients receive. As one article noted, "[I]f physicians do not have loyalty and fidelity to their own core moral beliefs,

it is unrealistic to expect them to have loyalty and fidelity to their professional responsibilities."³¹⁰

Third, the rule is expected to decrease the harm that providers suffer when they are forced to violate their consciences, with attending improvements to patient health. Scholars have observed that "[a]bandoning the right to conscience of the medical practitioner not only harms the individual practitioner but also threatens harm to his patients as well—the harms, however paradoxical it might seem, are actually inseparable from one another."³¹¹

Fourth, by providing for OCR investigation and HHS enforcement of Federal conscience and anti-discrimination laws, this final rule is expected to decrease unlawful discrimination, thereby permitting greater personal freedom. The rule will promote protection of religious beliefs and moral convictions, which is a societal good based on fundamental rights. As James Madison, often hailed as the "father of the Constitution," wrote,

The Religion then of every man must be left to the conviction and conscience of every man; and it is the right of every man to exercise it as these may dictate It is the duty of every man to render to the Creator such homage, and such only, as he believes to be acceptable to him.³¹²

The Department received comments arguing that the proposed rule did not provide a sufficient articulation of the benefits that this rule would create or secure. In addition to analyses provided elsewhere in this preamble where germane, the Department's analysis of the rule's benefits responds to those comments and reflects a review of academic literature on the benefits of conscience protections in health care.

³¹⁰ D. White and B. Brody, *Would Accommodating Some Conscientious Objections by Physicians Promote Quality in Medical Care?*, 305 J. Am. Med. Assoc., May 4, 2011, at 1804–1805 (arguing that prohibiting conscience-based refusals "may negatively influence the type of persons who enter medicine[.] . . . may negatively influence how practicing physicians attend to professional obligation[.] . . . [may cause] higher levels of callousness [by physicians] toward patients[.] . . . [and] may reciprocally diminish physicians' willingness to be sympathetic to and accommodating of patients' diverse moral beliefs").

³¹¹ Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals*, 49 Ariz. St. L.J. 549, 565 (2017); see also J. McCarthy & C. Gastmans (2015). *Moral distress: A review of the argument-based nursing ethics literature*, Nursing Ethics, 22(1), 131–152 (finding a consensus in academic literature that moral distress involves suffering that is psychological, emotional, and physiologic).

³¹² James Madison, "Memorial and Remonstrance Against Religious Assessments", in 2 The Writings of James Madison 183, 184 (G. Hunt ed. 1901)

The analysis demonstrates that the rule creates and secures significant benefits.

(i) Historical Support for Conscience Protections

The people of the United States of America have valued conscience protections since the country's founding era. Madison said that "[c]onscience is the most sacred of all property; . . . the exercise of that, being a natural and unalienable right. To guard a man's house as his castle, to pay public and enforce private debts with the most exact faith, can give no title to invade a man's conscience which is more sacred than his castle."³¹³ George Washington wrote, "Government being, among other purposes, instituted to protect the Persons and Consciences of men from oppression, it certainly is the duty of Rulers, not only to abstain from it themselves, but according to their Stations, to prevent it in others, . . . [and] the Conscientious [sic] scruples of all men should be treated with great delicacy & tenderness."³¹⁴ Some scholars have argued that the right to conscience was a hallmark of our founding and in fact, "[p]rotection for individual exercise of rights of conscience was one of the essential purposes for the founding of the United States of America and one of the great motivations for the drafting of the Bill of Rights."³¹⁵

(ii) Expected Postive Impact on the Recruitment and Maintenance of Health Care Professionals

Numerous studies and comments show that the failure to protect conscience is a barrier to careers in the health care field.

A 2009 survey found that 82% of responding faith-based health care providers said it was either "very" or "somewhat" likely that they personally would limit the scope of their practice of medicine if conscience rules were not in place. This was true of 81% of medical professionals who practice in rural areas and 86% who work full-time serving poor and medically underserved populations . . . 91% agreed, "I would rather stop practicing medicine

³¹³ James Madison, "Property", in The Founders' Constitution, <http://press-pubs.uchicago.edu/founders/documents/v1ch16s23.html>.

³¹⁴ Letter from George Washington, to The Society of Quakers (October 13, 1789), <https://founders.archives.gov/documents/Washington/05-04-02-0188>.

³¹⁵ Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals*, 49 Ariz. St. L.J. 549, 561 (2017) (citing Lynn Wardle, *Protection of Health-Care Providers' Rights of Conscience in American Law: Present, Past, and Future*, 9 Ave Maria L. Rev. 1, 78 (2010)).

³⁰⁹ Christian Medical Association & Freedom2Care summary of polls conducted April, 2009 and May, 2011, available at https://docs.wixstatic.com/ugd/809e70_7ddb46110dde46cb961ef3a678d7e41c.pdf.

altogether than be forced to violate my conscience.”³¹⁶

The Department expects this rule to remove barriers to entry into the health care professions and into certain specializations within the health care profession³¹⁷ that arise from anticipated or experienced discrimination against such persons’ religious beliefs or moral convictions. The Department also expects this rule to delay the exit of certain types of health professionals who are considering leaving the field in order to avoid such coercion or discrimination.³¹⁸ Although the rule does not create substantive protections beyond those in existing law, the Department believes that greater awareness and enforcement of those laws will help promote compliance and provide these follow-on effects. The Department has a significant interest in removing unlawful barriers to careers in the health care field.

The American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), which represents 2,500 members and associates,³¹⁹ wrote in 2009, “Like pro-life physicians generally, AAPLOG members overwhelmingly would leave the medical profession—or relocate to a more conscience-friendly jurisdiction—before they would accept coercion to participate or assist in procedures that violate their consciences.”³²⁰ AAPLOG’s members and associates represent 13 percent of OB/GYNs in the United States.³²¹ Yet, as explained above, the Department has received significant anecdotal evidence of violations of the very conscience laws that Congress has enacted to protect such providers.

Because the rule is expected to remove a barrier to entry into the health care profession, the rule is expected to engender more people to be willing to enter the health care profession. Since

there is an unmet need for health care providers in the United States, the Department assumes that an increase in the number of people willing to enter the health care profession (or a certain specialization within the health care profession) will result in an increase in the number of providers. Similarly, a certain proportion of decisions by currently practicing health providers to leave the profession are motivated by coercion or discrimination based on providers’ religious beliefs or moral convictions,³²² so the Department anticipates that this rule’s protections will decrease such departures from the field. Several commenters agreed anecdotally, stating that without the rule, access to medical care will suffer, because pro-life and faith-based medical providers will leave the profession.

The Department anticipates that this effect will also occur at the macro-scale in the health industry. For example, religiously-operated hospitals or health care systems, being granted greater security to practice medicine consistent with their religious beliefs, may find it worthwhile to hire more providers to serve more people, or to serve new populations (geographic, etc.), and will have a larger pool of medical professionals to choose from. The Department is not aware, however, of data enabling it to quantify any effect the rule may have on increasing the number of health care providers or the possible result of increasing access to care. The Department instead believes it is reasonable to conclude that the rule will increase, or at least not decrease, access to health care providers and services.

Several commenters stated that permitting or honoring conscientious objections, especially objections to referring for a health service, will exacerbate current lack of access to health care caused by the existing shortage of health care providers. This argument appears to not adequately take into account how greater awareness and enforcement of conscience rights will (1) remove a barrier to entry for certain individuals and institutions into the health care field, and (2) encourage individuals and institutions with religious beliefs and moral convictions currently in the health care field that may be thinking about leaving the field to remain, thereby creating net benefits. As described in the analysis below on the effects of this final rule on access to

care, commenters who raised the claim that the rule would exacerbate current barriers to accessing health care failed to provide data that the Department believes enables a reliable quantification of the effect of the rule on access to providers and to care. For the reasons explained in this analysis, the Department disagrees with those commenters and believes it is more likely that removing the barriers to entry that may exist due to insufficient enforcement of conscience laws will result in an overall increase in access to care. Again, however, the Department is not aware of data that allows for an estimate of the effect of this rule on access to services.

(iii) Expected Positive Impact on Patient Care by Religious Health Care Professionals and Organizations

Many comments discussed the subject of the management of miscarriages in Catholic hospitals, alleging that Catholic hospitals’ adherence to the Ethical and Religious Directives (ERDs), a document that expresses the teaching of the Catholic Church on matters of health care, risks harm to women undergoing a miscarriage. Approximately forty-three public comment submissions (each of which may represent more than one comment per submission) cited the article “When There’s a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals,” which describes experiences of a handful of physicians across the nation’s Catholic health care facilities that adhered to ERDs.³²³ The article relays anecdotes and quotes from six physicians out of the thirteen interviewed by the authors. The authors do not state why the article omits quotes from the other seven providers, nor does it highlight anecdotes from positive or neutral experiences with facilities’ adherence to ERDs. The authors use the anecdotes and quotes as support for the idea that adherence to ERDs creates actual, potential, or perceived deficiencies in the facilities’ management of miscarriages by Catholic health care facilities. Anecdotal accounts of such a limited nature do not provide the Department with a robust basis for estimating the rule’s impact on the management of miscarriages.

Twenty-four public comment submissions (each of which may represent more than one comment per submission) discussed the case of Tamesha Means, who was treated for a miscarriage by a Catholic hospital in

³¹⁶ Christian Medical & Dental Association summary of Key Findings on Conscience Rights Polling conducted April, 2009, available at https://docs.wixstatic.com/ugd/809e70_2f66d15b88a0476e96d3b8e3b3374808.pdf.

³¹⁷ *Id.* (finding that 20% of responding faith-based medical students chose not to pursue a career in obstetrics/gynecology because of perceived coercion and discrimination in that field).

³¹⁸ *Id.*

³¹⁹ *About Us*, American Association of Pro-Life Obstetricians and Gynecologists, <http://aaplog.org/about-us>.

³²⁰ Letter from Lawrence J. Joseph, on behalf of the American Association of Pro-Life Obstetricians & Gynecologists, to the Office of Public Health & Science, Dep’t of Health & Human Servs. 2 (Apr. 9, 2009), <http://downloads.frc.org/EF/EF09D50.pdf>.

³²¹ Compare *id.*, with Occupational Employment Statistics: Occupational Employment and Wages, May 2017 (March 30, 2018), <https://www.bls.gov/oes/current/oes291064.htm> (calculation assumes all AAPLOG members are OB/GYNs).

³²² Christian Medical Association & Freedom2Care summary of Online Survey of Faith-Based Medical Professionals polls conducted April, 2009 and May, 2011, available at https://docs.wixstatic.com/ugd/809e70_7ddb46110dde46cb961ef3a678d7e41c.pdf.

³²³ Lori R. Freedman, *When There’s a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/>.

Michigan, as an example of the harm to patient health caused by the faith-based practices of Catholic hospitals. Ms. Means subsequently brought a lawsuit claiming that the hospital's adherence to the ERDs constituted negligence. Yet the U.S. Court of Appeals for the Sixth Circuit ruled that Ms. Means had not alleged any harm or injury that could sustain her claim. *Means v. U.S. Conf. of Catholic Bishops*, No. 15–1779 (6th Cir. 2016).

The rule does not incorporate ERDs, and it does not enforce them. Nothing in the rule requires any individual or institutional provider to abide by any religious belief or moral conviction in his or her practice of medicine, and this rule does not take a position on whether any facility should or should not adhere to ERDs. Instead, the rule provides mechanisms for the enforcement for Federal conscience laws and anti-discrimination statutes, which are very different from ERDs in their text, structure, and legal significance.

Numerous commenters also cited statistics demonstrating that women of color are disproportionately served by Catholic hospitals. These commenters argued that, because ERDs prohibit Catholic hospitals from performing elective abortions, sterilizations, and other procedures that are counter to Catholic beliefs, women of color would be disproportionately harmed by exercises of religious belief protected by the rule.

The question of the ultimate effect of Catholic hospitals' adherence to ERDs on general access to reproductive health care, or access by any particular population, is outside the scope of this rule, but appears to be less settled than many commenters portray it to be. A metastudy in 2019 found a surprising paucity of data on the issue, stating that "Although many may assume that institutional restrictions cause harm, our current understanding demonstrates that the landscape of provision [of reproductive health care services] is wide-ranging and complex in nature."³²⁴ On the subject of miscarriages in particular, another study observed that "Anecdotal reports have suggested that Catholic hospitals are putting women in danger due to the restrictions on miscarriage management. Contrary to these reports, we find some evidence that Catholic ownership is in fact associated with a *reduction in miscarriages that involve a complication*, suggesting that anecdotal

accounts may not be indicative of a widespread pattern."³²⁵

Additionally, Catholic and other religiously affiliated health care providers play a major role in the delivery of health care to residents of the United States, including to underserved or underprivileged communities in particular, and are motivated by their beliefs to serve such communities.³²⁶ As some commenters noted, that role may explain the disproportionately large share of charitable care and service given by religious providers to underserved communities. For example, Ascension, the nation's largest religiously affiliated non-profit health care system, had an annual operating revenue in 2016 that was about one-third the size of the annual operating revenue for Kaiser Permanente, the nation's largest non-profit health care system that is not religiously affiliated.³²⁷ However, both organizations provided approximately \$2 billion in care and other benefit programming to underserved communities in 2017.³²⁸

As the Department discusses above in response to comments, *supra* at part

³²⁵ Hill, et al., *Reproductive Health Care in Catholic-Owned Hospitals*, NBER Working Paper No. 23768 (2017), at 4 (emphasis added).

³²⁶ Ascension, RE: Docket HHS–OCR–2018–0002, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (Mar. 27, 2018) ("As the largest non-profit health system in the U.S. and the world's largest Catholic health system, Ascension is committed to delivering compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable. In FY2017, Ascension provided more than \$1.8 billion in care of persons living in poverty and other community benefit programs."); Catholic Health Association, REF: RIN 0945–ZA 03 Protecting Statutory Conscience Rights in Health Care; Delegations of Authority: Proposed Rule, 83 FR 3880, January 26, 2018 (Mar. 27, 2018) ("As a Catholic health ministry, our mission and our ethical standards in health care are rooted in and inseparable from the Catholic Church's teachings about the dignity of each and every human person, created in the image of God. Access to health care is essential to promote and protect the inherent and inalienable worth and dignity of every individual. These values form the basis for our steadfast commitment to the compelling moral implications of our health care ministry and have driven CHA's long history of insisting on and working for the right of everyone to affordable, accessible health care.").

³²⁷ Compare Kaiser Foundation Health Plan and Hospitals Report: 2017 Financial Results, Kaiser Permanente (Feb. 9, 2018), <https://share.kaiserpermanente.org/article/kaiser-foundation-health-plan-hospitals-report-2017-financial-results/> (last visited Dec. 3, 2018), with *Our One Ascension Journey: Year in Review*, Ascension, <https://ascension.org/about/community-and-investor-relations/year-in-review> (last visited Dec. 3, 2018).

³²⁸ Facts and Stats, Ascension, <https://ascension.org/About/Facts-and-Stats> (last visited Dec. 3, 2018); Thrive: Give Back, Kaiser Permanente, <https://thrive.kaiserpermanente.org/thrive-together/give-back> (last visited Dec. 3, 2018).

III.A., and as observed in the analysis below on the effects of this final rule on access to care, the Department concludes that the relationship between enforcement of Federal conscience and anti-discrimination laws through this rule and the impact on access to care is more complicated than suggested by commenters who claim this rule will decrease access. The Department believes the rule is just as, or more, likely to result in a net increase access to care because religious or other conscientiously objecting providers are already more likely to serve underserved communities; imposing violations on their conscience may lead to them limiting their practices rather than providing services in violation of their beliefs; and in some underserved communities patients may have a proportionate likelihood to agree with religious providers on controversial services such as abortion. The Department believes that, in passing Federal conscience and anti-discrimination laws, Congress likely intended to protect objecting providers precisely to prevent them from limiting their practices, especially to underserved communities, so as not to exacerbate shortages to those communities.

In light of the demonstrated commitment that religious health care providers have to caring for those for whom it may not always be profitable to care, it likely would harm underprivileged populations if the Department did not provide enforcement mechanisms and certain procedural and administrative status quo risks driving such entities out of underserved communities altogether. Again, however, the Department is not aware of data either in its possession, from commenters, or from the public, that would enable the Department to reliably estimate what the impact of this rule would be on increasing, or allegedly decreasing, access to providers or services. The Department, instead, concludes that enforcing Federal conscience and anti-discrimination laws is an appropriate implementation of Congressional intent, and is more likely overall to lead to net benefits, and possibly to an increase in, health care provider and services access, than to lead to its reduction.

(iv) Expected Reduction in the Moral Distress That Individual Providers Experience

The Department anticipates that this final rule will reduce the incidence of the harm that being forced to violate one's conscience inflicts on providers.

³²⁴ Thorne, et al., *Reproductive Health Care in Catholic Facilities: A Scoping Review*, *Obstet. Gynecol.* 2019;133:105–15, at 114.

Substantial academic literature documents the existence among health care providers of “moral distress,” which is “a sense of complicity in doing wrong” and “a deep anguish that comes from the nature of those circumstances [of the provider’s work environment] as systemic, persistently recurrent, and pervasively productive of crises of conscience.”³²⁹ Moral distress functions as a pressure on providers to leave the health care profession: “Prolonging these conditions can lead to exhaustion of their resistance resources and cause dissatisfaction with the workplace. Those who continue to work despite these conditions experience stress and burnout along with dissatisfaction.”³³⁰

It is difficult to quantify the impact of the psychological trauma that results from moral distress. The strength of the provider’s moral objection may vary based on the facts and circumstances of each case, including the service in question.

(v) Expected Patient Benefits From This Rule

To the extent the rule supports a more diverse medical field, the rule would create positive effects for patients. The rule could assist patients in seeking counselors and other health care providers who share their deeply held convictions. Some patients appreciate the ability to speak frankly about their own convictions concerning questions that touch upon life and death and treatment options and preferences with a doctor best suited to provide such treatment. A pro-life woman may seek a pro-life OB/GYN to advise her on

decisions relating to her fertility and reproductive choices. Open communication in the doctor-patient relationship will foster better overall care for patients.

The benefit of open and honest communication between a patient and her doctor is difficult to quantify. One study showed that even “the quality of communication [between the physician and patient] affects outcomes . . . [and] influences how often, and if at all, a patient will return to that same physician.”³³¹ But poor communication negatively affects continuity of care and undermines the patient’s health goals.³³² When conscience protections are robust, both patients and their physicians can communicate openly and honestly with one another at the outset of their relationship.

Facilitating open communication between providers and their patients also helps to eliminate barriers to care, particularly for people of faith, and especially in migrant communities where culturally competent care matters greatly. Because positions of conscience are often grounded in religious influence, “[d]enying the aspect of spirituality and religion for some . . . patients can act as a barrier. These influences can greatly affect the well-being of people. They were reported to be an essential element in the lives of certain migrant women which enabled them to face life with a sense of equality.”³³³ It is important for patients seeking care to feel assured that their religious beliefs and their moral convictions will be honored. This will ensure that they feel they are being treated fairly.³³⁴ And for some, being able to find health care providers that share the same moral convictions can be a source of personal healing.

As mentioned above, academic literature supports the proposition that prohibiting the exercise of conscience rights in medicine may decrease the quality of care that patients receive.³³⁵

Commentary on the concept of moral distress among providers also expresses concern over how a degraded moral culture in health care can jeopardize patients’ health.³³⁶ As one review of literature on moral distress in nursing found, “There is also a general consensus among the reviews that [moral distress] arises from a number of different sources, and that it (mostly) impacts negatively on nurses’ personal and professional lives and, ultimately, harms patients.”³³⁷ Similarly, allowance for the exercise of conscience rights may promote ethical behavior by providers more broadly,³³⁸ preserve a preferable model of health care practice,³³⁹ and improve the doctor-patient relationship.³⁴⁰

³³⁶ Josh Hyatt, *Recognizing Moral Disengagement and Its Impact on Patient Safety*, J. of Nursing Regulation, 7:4, 18 (“Perhaps, patients experience the most significant and dangerous consequences of moral distress and moral disengagement . . . As health care providers reduce their communications with patients, patients may feel less safe and less satisfied with their medical experiences, and their clinical progress may be hindered. Further, if health care providers avoid patients or distance themselves from patients emotionally, they minimize their ability to advocate for their patients’ welfare. Providers’ emotional transition can also manifest as frustration toward patients, which may impair the quality of care. If health care providers do not fulfill their commitments or perform at a mediocre level, patient care can become inadequate or inappropriate . . . Lower quality of care leads to several costs for the patient. Patients may have to stay longer in the hospital or may miss care. Patient autonomy may also be threatened, and patients can be more likely to be coerced into pursuing therapeutic options they would otherwise decide against. Care can then become less patient centered and more paternalistic, a structure associated with worse health outcomes.” (citations omitted)).

³³⁷ J. McCarthy & C. Gastmans (2015). *Moral distress: A review of the argument-based nursing ethics literature*, Nursing Ethics, 22(1), 150.

³³⁸ White and Brody, *supra* at note 120; Stephen J. Genuis and Chris Lipp, *Ethical Diversity and the Role of Conscience in Clinical Medicine*, 2013 Int’l. J. Fam. Med. 587541 (2013), 5 (“Compromise of personal moral integrity, of any kind or nature, will inevitably lead to an erosion of ethical behavior—a prospect not conducive to the optimal provision of healthcare.”).

³³⁹ Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals*, 49 Ariz. St. L.J. 549, 565–66 (2017) (“[T]he ‘public utility’ model of medicine is not only a ‘challenge [to] a conscientious physician’s integrity as a physician,’ it also ‘depreciates his expertise, reduces his discretionary latitude in decisionmaking, and makes him a technical instrument of another person’s wishes,’ thereby ‘subvert[ing] the healing purpose for which medicine is intended in the first place.’ The myopic view of medicine that views a medical practitioner as a mere service provider ‘can rebound to the patient’s harm by undermining the physician’s moral obligation to provide sound advice and sound practice and to avoid medically useless or futile treatments.’” (citations omitted)).

³⁴⁰ Genuis & Lipp, at 5 (arguing that “[f]reedom of conscience promotes open, transparent physician-patient relationships and engenders patient advocacy . . . It is unlikely that individual patients or society would support a situation in which

³²⁹ Christy A. Rentmeester, *Moral Damage to Health Care Professionals and Trainees: Legalism and Other Consequences for Patients and Colleagues*, Journal of Medicine and Philosophy, 33: 27–43, 2008, p. 37 (elaborating that “[M]oral distress is a sense of complicity in doing wrong. This sense of complicity does not come from uncertainty about what is right but from the experience that one’s power to resist participation in doing wrong is severely restricted by one’s work environment and from the experience that resisting participation in doing wrong exposes one to harm. Moral distress is generated in the health care work environment when a practitioner is aware that he is acting other than how he is motivated to act, but he believes that he cannot act as he is motivated to act without suffering some morally significant harm . . . A number of situations can generate moral distress. Broad systemic changes in the recent past in health care—in how health care institutions are organized, how health care is financed, and how health care resources are managed, for example—have de facto demanded that individual practitioners adjust to being treated more like laborers than autonomous professionals and less like trusted fiduciaries than like employees with suspicious conflicts of interest.”) (emphasis added).

³³⁰ Borhani et al., *The relationship between moral distress, professional stress, and intent to stay in the nursing profession*, J. Med. Ethics Hist. Med. 2014; 7: 3.

³³¹ Fallon E. Chipidza, et al., *Impact of the Doctor-Patient Relationship*, 17(5) The Primary Care Companion for CNS Disorders (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4732308/>.

³³² *Id.*

³³³ Emmanuel Scheppers, et al., *Potential Barriers to the Use of Health Services Among Ethnic Minorities: A Review*, 23 Family Practice 325, 343 (2006), <https://academic.oup.com/fampra/article/23/3/325/475515>.

³³⁴ *Id.*

³³⁵ Stephen J. Genuis and Chris Lipp, *Ethical Diversity and the Role of Conscience in Clinical Medicine*, 2013 Int’l. J. Fam. Med. 587541 (2013), 4–5 (arguing that “if successive physicians lose individual liberty of conscience and are morally compromised because of authoritarian dictates, the end result [may] be a diminishing of collective professionalism and physician morale, leading to inadequate patient care.”).

As noted above, the Department assumes that this rule will increase the overall number of providers because (1) it will reduce barriers to entry into the health care field (and reduce pressure to leave the field) for individuals and organizations with religious beliefs or moral convictions, and (2) there exists an unmet demand for more providers. If the Department is incorrect in assuming that the rule will increase the overall number of providers—*i.e.*, if health care employers and medical training programs do not increase their hiring rates and the size of their programs, respectively, despite an increase in applicants—then the rule will increase the quality of the average provider, because the increase in the pool of available professionals will result in the selection of better providers overall. An increase in the quality of providers will increase the quality of care that patients receive. The Department is not, however, aware of data that provides a basis for quantifying these effects.

(vi) Expected Societal Benefits From This Rule

The rule will also yield lasting societal benefits. The rule mitigates current misunderstanding about what conduct the Federal government is legally able to support and fund, and educates individuals about their Federal conscience rights. By requiring certifications and assurances (with some exemptions), this rule provides a mechanism by which regulated entities will learn about—and, thus, be more likely to comply with—Federal conscience and anti-discrimination laws. The rule also provides a centralized office within the Department for individuals and institutions to file complaints with the Department when such individuals and institutions believe that their rights have been infringed. The Department expects that, as a result of this rule, more individuals, having been apprised of those rights, will assert them. The combination of

these mechanisms will contribute to the general public's knowledge and appreciation of the foundational nature of these rights, as well as the protections afforded by Federal law.

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

[L]aw and conscience are deeply intertwined. . . . But the phenomenon of conscience isn't important only to legal experts. Just as conscience helps explain why people follow legal rules, it helps explain why people follow other types of rules as well, such as employers' rules for employees, parents' rules for children, and schools' and universities' rules for students. It may also help explain why people adhere to difficult-to-enforce ethical rules and to the sorts of cultural rules ("social norms") that make communal life bearable. . . . Twenty-first century Americans still enjoy a remarkably cooperative, law-abiding culture.³⁴¹

Because fostering conscience in individuals—and compliance with Federal conscience laws—contribute to a more lawful and virtuous society, governments and their subdivisions have a significant interest in encouraging expressions of, and fidelity to, conscience.

Forcing religious believers to violate their consciences involves harms that go beyond these individuals and their communities. When an individual is forced to act in ways that they view as deeply wrong, indeed as prohibited by the ultimate power responsible for everything that exists, moral habits essential for democratic citizenship are undermined.³⁴²

Governments also have an interest in ensuring the implementation and enforcement of existing laws, as part of the greater virtue of the rule of law.

It is difficult to monetize the benefits of respect for conscience to the individual and society as a whole, but they are clearly significant. As the Supreme Court has said:

Both morals and sound policy require that the state should not violate the conscience of the individual. All our history gives confirmation to the view that liberty of conscience has a moral and social value which makes it worthy of preservation at the hands of the state. So deep in its significance and vital, indeed, is it to the integrity of man's moral and spiritual nature that nothing short of the self-preservation of the state should warrant its violation; and it may well be questioned whether the state which preserves its life by a settled policy of

violation of the conscience of the individual will not in fact ultimately lose it by the process.³⁴³

To protect the rights of conscience is to protect personal and interpersonal goods that permit peaceful and fulfilling lives.³⁴⁴

(vii) Analysis of Expected Effects of This Final Rule on Access to Care

The Department solicited information on costs that may arise as secondary effects of this rule, such as those associated with changes in health outcomes arising from increased protection of conscience for health care providers, as well as information about whether the existence or expansion of rights to exercise religious beliefs or moral convictions in health care improves or worsens patient outcomes and access to health care. The Department also requested comment on the related question of whether this final rule would result in unjustified limitations on access to health care.

The questions of access to care and of health outcomes are largely interdependent; access to care matters because of its effects on health outcomes, and the discussion in the public comments on health outcomes in the context of this rule were typically framed as a consequence of changes in access to care. Many comments the Department received argued that the rule would decrease access to care and harm patient health outcomes, and most such comments focused on the potential that providers would decline to perform a particular service for a patient.

Generally, however, instead of attempting to answer the difficult question of how this rule would affect access to care and health outcomes, and how to quantify those effects, such comments argued that significant discrimination against some segments of the population in health care exists and is *per se* proof that the rule would result in harm. The comments made this argument without establishing a causal relationship between this rule and how it would affect health care access, and without providing any data the Department believes enables a reliable quantification of the effect of the rule on access to providers and to care.

³⁴³ *United States v. Seeger*, 380 U.S. 163, 169 (1965) quoting Harlan Fisk Stone, *The Conscientious Objector*, 21 Col. Univ. Q. 253, 269 (1919).

³⁴⁴ Christopher C. Lund, *Religion Is Special Enough*, 103 Va. L. Rev. 481, 504 (2017) ("Freedom of moral conscience, it turns out, serves many of the same values served by freedom of religion—among other things, it can serve to ameliorate psychological distress, reduce civil strife, and preserve individual identity.").

physicians were being coerced to hide their convictions, making decisions they felt were morally wrong or unethical, or failing to act in what they perceived to be their patients' best interests"); Christian Medical Association & Freedom2Care summary of polls conducted April, 2009 and May, 2011, available at https://docs.wixstatic.com/ugd/809e70_7ddb46110dde46cb961ef3a678d7e41c.pdf ("77% of American adults surveyed said it is either 'very' or 'somewhat' important to them that 'that healthcare professionals in the U.S. are not forced to participate in procedures or practices to which they have moral objections;' " "88% of American adults surveyed said it is either 'very' or 'somewhat' important to them that they share a similar set of morals as their doctors, nurses, and other healthcare providers"). Comments received by the Department supported the finding that patients prefer providers who share their general belief system.

³⁴¹ Lynn Stout, *Cultivating Conscience: How Good Laws Make Good People* 17 (2011).

³⁴² Kathleen A. Brady, *The Disappearance of Religion from Debates about Religious Accommodation*, 20 Lewis & Clark L. Rev. 1093, 1110 (2017).

Other comments focused on whether health disparities exist among demographics that tend to utilize health services that may be the subject of conscientious objections protected by this final rule, but again without establishing a causal link between the provisions of this rule and the predicted or speculated effects.

Many comments observed that various demographic groups—women, LGBT people, immigrants and refugees, people of color, people living with HIV/AIDS, people with language barriers, people living in poverty, people with disabilities, and people living in rural areas—already face barriers to access to care and therefore would be disproportionately harmed by any additional barriers to access to care. The Department does not dispute that people in such demographic categories face health care disparities of various forms. The Department does disagree, however, with these comments' conclusions that the rule will create any negative effect on access to care that cannot be otherwise addressed, or that is not outweighed by gains in overall public health, overall access to care due to the removal of barriers for providers, or the benefits of compliance with the law and respect for conscience and religious freedom. In fact, as the Department discusses *supra* at part IV.C.4.iii and *infra*, the Department expects the rule to specifically benefit underserved populations.

A common sentiment expressed in comments was that conscience protections for providers are only appropriate to the extent they do not interfere with, impose upon, or in any way result in others feeling harmed. This type of objection is not accepted for any other anti-discrimination law. For example, the Fair Housing Act and the Americans with Disabilities Act, under certain circumstances, require building and apartment owners to incur costs to ensure that facilities are accessible to persons with disabilities. These statutes impose costs, but Congress and several Presidents have deemed it important to remove barriers to full participation in economic and social life for persons with disabilities. Similarly, America has since the founding recognized that Free Speech results in harm and hurt feelings (sometimes extraordinarily so) for many Americans, yet it is deemed a price worth paying. Conscience protection should be not be a special exception to the principle that fundamental rights do not depend on there being zero conflicts or disagreements in their exercise.

In any event, the objections based on potential (often temporary) lack of

access to particular procedures as a result of enforcement of the law are really objections to policy decisions made by the people's representatives in Congress in enacting the Federal conscience and anti-discrimination laws in the first place, rather than to this rule's mechanisms for implementing and enforcing those laws.

An analysis of any change in access to care caused by this final rule is not the same as an analysis of the total impact of the exercise of religious belief and moral conviction on access to care. Nor is it the same as estimating the total impact of discrimination against women, LGBT individuals, or individuals in any other population demographic on access to care. Rather, the question involves isolating the impact of the exercises of religious belief or moral conviction attributable to this final rule specifically, over and above whatever impact is attributable to the pre-existing base rate of exercise of religious belief or moral conviction.

Different types of harm can result from denial of a particular procedure based on an exercise of such belief or conviction. First, the patient's health might be harmed if an alternative is not readily found, depending on the condition. Second, there may be search costs for finding an alternative. Third, the patient may experience distress associated with not receiving a procedure he or she seeks. These three potential harms, however, would also be applicable for denials of care based on, for example, inability to pay the requested amount. Fourth, there may be a harm resulting from a conscientious objection to referring for a health service, distinct from the harm of the initial objection to performing the service. Fifth, some commentators allege others in the community to which the patient belongs may be less willing to seek medical care.

On the other hand, it is important not to assume that every patient who wants a particular service is offended by a provider's unwillingness to provide that service, or wishes that the provider would do so against his or her religious beliefs or moral convictions. Some persons, out of respect for the beliefs of providers, may want a service but not take any offense, nor deem it any burden on themselves, for the provider to not provide that service to them. Some patients may even value the health care provider's willingness to obey his or her conscience, because the patient feels that provider can be trusted to act with integrity in other matters as well. The Department does not believe it is appropriate to assume that all patients who want a particular service

also want to force unwilling providers to provide it in violation of their consciences.

Lastly, numerous comments focused on the potential for a patient to feel insulted or emotionally distressed because of a perception that a provider, in declining for reasons of religious belief or moral conviction to perform an objected-to service or procedure, is expressing disapprobation of the patient, especially regarding his or her personal identity or personal conceptions of morality. Although the Department does not understand such conscientious objections to be necessarily intended to convey such disapprobation, the Department recognizes that, in some circumstances, some patients do experience emotional distress as a consequence of providers' exercise of religious beliefs or moral convictions. However, Congress, in considering the statutes enforced by this rule, did not establish balancing tests that weigh such emotional distress against the right to abide by one's conscience.

On the other side of the equation, those who suffer discrimination on the basis of their religious beliefs or moral convictions, or those coerced to violate those convictions, may themselves experience emotional distress, as well as economic harms such as job loss or rejection from admission into a training program.

There appears to be no empirical data on how previous legislative or regulatory actions to protect conscience rights have affected access to care or health outcomes. In fact, studies have specifically found that there is insufficient evidence to conclude that conscience protections have negative effects on access to care.³⁴⁵

Many commenters reasoned that, despite this lack of empirical evidence, the rule would cause an increase in denials of care. For example, one comment cited various statistics on the rates of discrimination against LGBT individuals, but those statistics were general in nature and did not assist the

³⁴⁵ See Chavkin et al., *Conscientious objection and refusal to provide reproductive healthcare: A White Paper examining prevalence, health consequences, and policy responses*, 123 Int'l J. Gynecol. & Obstet. 3 (2013), S41–S56 (“[I]t is difficult to disentangle the impact of conscientious objection when it is one of many barriers to reproductive healthcare. . . . [C]onscientious objection to reproductive health care has yet to be rigorously studied.”); K. Morrell & W. Chavkin, *Conscientious objection to abortion and reproductive healthcare: a review of recent literature and implications for adolescents*, 27 Curr. Opin. Obstet. Gynecol. 5 (2015), 333–338 (“[T]he degree to which conscientious objection has compromised sexual and reproductive healthcare for adolescents is unknown.”).

Department in estimating what degree may be attributable to the lawful exercise of religious beliefs or moral convictions. The comment also identified numerous health disparities between LGBT individuals and non-LGBT individuals, but did not explain the extent to which such disparities are the product of the lawful exercise of religious beliefs or moral convictions. The comment then concluded that “discrimination and related health disparities facing the LGBT population stand to worsen if health care providers are authorized to refuse to serve LGBT people.”

The same comment attached an amicus brief that cited two studies on how State laws affect health disparities among LGBT populations—one study on States that either did not include sexual orientation as a protected category in its hate crimes statute or did not prohibit employment discrimination on the basis of sexual orientation, and another on States that had constitutional amendments banning gay marriage on the ballot in 2004 and 2005. Neither study provides a reliable basis for inferring an answer to the questions at issue here.

Another comment cited to a 2018 report on anecdotal experiences of discrimination among LGBT individuals in eight States where laws had been passed to protect religious freedom. The report itself includes a citation to one study finding that awareness of legislation prohibiting discrimination on the basis of sexual orientation is associated with a decrease in the rate of such discrimination in interpersonal employment contexts. While analogous, such a finding is not the same as a finding that the awareness of legislation protecting conscience rights increases the rates of discriminatory conduct by people with religious beliefs or moral convictions. The report provides anecdotal accounts of discrimination from LGBT residents of those States. However, the report does not attempt to determine if the laws passed by those States played any causal role in the discrimination experienced by the respondents, *e.g.*, via comparison to LGBT individuals’ experiences in States where no such laws had been passed.

Multiple comments provided lists of various incidents in which providers declined to participate in a service or procedure to which they had a religious or moral objection. Such lists offer no suitable data for estimating the impact of this rule.

No comment attempted a detailed description of the actual impact expected from the rule on access to care,

health outcomes, and associated concerns.

The Department attempted to quantify the impact of this rule on access to care but determined that there is not enough reliable data, and that the analysis was subject to too many confounding variables, for the Department to arrive at a useful estimate. For instance, the Department is not aware of a source for data on the percentages of providers who have religious beliefs or moral convictions against each particular service or procedure that is the subject of this rule.³⁴⁶

Likewise, the Department is not aware of data on the actual rate of providers’ exercise of conscientious objections to performing such services or procedures. Some providers who have a religious or moral objection to performing a service or procedure may nonetheless perform it for one reason or another, such as fear of legal reprisal. Others may respond to pressure to violate their consciences by limiting their practices, rather than providing the service to which they object. Commenters who contend the rule will reduce access to care seem to assume all providers with conscientious objections that are not being honored are providing those services anyway, so that the rule will reduce their provision of those services. The Department does not believe that assumption is correct. The Department considered methods for estimating the increase in the rate of such exercise of conscientious objections that may occur as a result of this rule, but determined that no reliable method was available. The Department likewise considered whether providers who, for reasons of religious beliefs or moral convictions, have left the practice of medicine or limited their scope of practice may reenter the field or resume their previous scope of practice, given the rule’s expanded enforcement of protections for religious beliefs or moral convictions. If providers who limited

³⁴⁶ For instance, even in the case of abortion, for which some data on the rates of providers’ objections actually exists, those rates vary significantly based on the facts and circumstances of the scenario presented, confounding an attempt to produce a single measure of providers’ rate of objection to abortion in general. See Harris, *et al.*, *Obstetrician-Gynecologists’ Objections to and Willingness to Help Patients Obtain an Abortion* 118 OBSTETRICS & GYNECOLOGY 905 (2011) (“These data suggest that ob-gyns also consider contextual factors, including risk of physical harm to the woman by continuing pregnancy (breast cancer, cardiopulmonary disease), the circumstances of the sexual encounter that resulted in pregnancy (rape), the impact abortion may have on pregnancy outcome (selective reduction), the potential for fetal anomaly (diabetes), and the duration of pregnancy (second versus first trimester) Among ob-gyns, support for abortion varies widely depending on the context in which abortion is sought and physician characteristics.”).

their practices because of threats to their consciences expand them because of this rule, those would not be instances of a reduction in the provision of services to which they object, but of an increase in other services. However, the Department was unable to find reliable data on this question, and concluded that no useful quantitative estimate of this impact was feasible.

The impact on health outcomes from the exercise of conscientious objections to particular services and procedures also resisted a useful quantitative estimate. Without data—to inform an estimate of the quantity of such objections that would be attributable this rule, the number of those objections that led to providers offering services to which they object rather than limiting their practices, the number of persons who left or did not enter certain fields or practices altogether because conscience laws were insufficiently enforced, the market effect of providers expanding or moving into different areas because conscience laws are enforced, and the overall resulting availability of access, both to objected-to services and to other health care overall—the Department lacks the predicate for estimating the impact on health outcomes of any change in the availability of services. The analysis on this point is also generally subject to the same confounding factors discussed below regarding the impact of conscientious objections to providing referrals.

The Department expects any decreases in access to care to be outweighed by significant overall increases in access generated by this rule. If the laws that are the subject of this rule are not enforced, many of the exact same people who would face a burden from a denial of access to a particular procedure from a particular doctor or provider would face the potential of receiving no health care at all from that doctor or provider because such providers may limit, or leave, their practices if unable to comply with their religious beliefs or moral convictions. The absence or departure of those providers from the health field does not clearly lead to any increase in other providers who are willing to offer services that are the subject of Federal conscience and anti-discrimination laws, but is more likely to simply diminish the overall availability of health care services. The burden of not being able to receive any health care clearly outweighs the burden of not being able to receive a particular treatment.

For example, after the Department proposed in 2009 to rescind the 2008

rule providing conscience protections for providers, a survey found that 81 percent of faith-based health care professionals working in rural areas and 86 percent of faith-based health care professionals working full-time in service to underserved communities said that they were either “very” or “somewhat” likely to limit the scope of their practice if the 2008 rule was rescinded.³⁴⁷ For such providers who did not in fact limit their scope of practice, this rule will help to prevent future situations in which they feel forced to do so. For those who did, this rule provides protections that may induce them to resume their previous scope of practice. In this sense the Department believes the rule will both preserve and expand access to health care generally.

Furthermore, as one academic article observed, “[P]atients choose not merely particular services, but particular kinds of professionals.”³⁴⁸ As noted earlier in this section, a survey of patients found that 88 percent would prefer that their providers share their moral beliefs.³⁴⁹ Another survey conducted by a former Chair of Bioethics of the National Institutes of Health Clinical Center “reinforces the existence of patient preference for physicians with shared values . . . [finding] that nearly one-fifth of [cancer] patients surveyed ‘thought they would change physicians if their physician told them he or she ‘had provided euthanasia [sic] or assisted suicide’ for other patients.’”³⁵⁰ The Department, accordingly, expects this rule, through its recognition of the “fundamental necessity of conscience

protections to ensuring patient access” for “patients who want access to physicians of conscience,” to result in an increase in access to care.³⁵¹

The Effect of the Rule’s Protection of Refusals To Refer for Services

As with the analysis in the above factors, there exists some baseline rate of exercise of conscientious objection to referring for a service to which the provider morally objects. A significant percentage of providers believe that they are not obligated to refer for a service to which they morally object.³⁵² It is reasonable to assume that the rates of exercise of the right not to refer will increase under the rule, but it is difficult to determine by how much. It is likewise difficult to estimate what part of the baseline instances of conscientious objection manifest themselves in providers providing the referrals in violation of their objections, instead of limiting their practices so as to avoid the conflict.

First, it is unclear how many providers understand their existing right to decline to refer, whether grounded in ethics or the law, to be coextensive with the freedom that the rule reflects. For example, a provider who objects to performing sterilizations may feel ethically obligated to inform a patient where vasectomies are locally available—an act that the rule may allow the provider to abstain from—but may not feel obligated to provide the patient any further information about how to obtain that procedure. Research suggests that providers may often draw such a distinction.³⁵³

It is also difficult to estimate what actual impact the increase in refusals to refer would have. One confounding factor is that the practical effect of a provider’s exercise of conscientious objection to providing a referral may vary greatly depending on the particular facts and circumstances of the case. Public knowledge of the availability of certain medical services may be extensive or minimal depending on the

procedure. For instance, any pregnant woman is almost certainly aware of the existence and purpose of abortion, and the extensive efforts of pro-choice groups to facilitate women’s access to abortion make information about how to obtain an abortion relatively easy to find.³⁵⁴ So the effect of a provider’s refusal to refer for an abortion is mitigated by the patient’s own knowledge and the widespread availability of information about abortion access on the internet and elsewhere.

The Change in the Number of Patients Who Delay or Forgo Health Care for Fear of Being Denied a Health Service

As numerous public comments demonstrate, certain minority groups already experience significant health care disparities. Commenters state that negative health outcomes from some demographics are due to fear of discrimination leading to avoidance of seeking health care. However, the Department is not aware of any data establishing what, if any, part of this avoidance phenomenon is attributable to the exercise of conscientious objections protected by this rule or by implementation of the enforcement mechanisms of this rule.

Other Comments on Access to Care

Many of the comments that claimed that the rule would result in more frequent denials of service to patients also argued that the rule is unnecessary because there is no current problem with health care providers being coerced into violating their consciences. These arguments are contradictory. If, under the final rule, a provider exercises a right protected by the rule to decline to perform a service that he had been performing prior to this rule, his previous performances of the service would likely have been contrary to his conscience.

Many commenters observed that, in rural areas, if a provider were to decline on religious or moral grounds to provide a particular service or procedure, there may not be alternative providers within a feasible distance of the patient. The Department does not dispute that patients in rural areas are more likely than patients in urban areas to suffer adverse health outcomes as a result of being denied care. That is why enforcement of Federal conscience and anti-discrimination laws to prevent health care providers from being unlawfully driven out of business,

³⁴⁷ Christian Medical Association & Freedom2Care summary of polls conducted April, 2009 and May, 2011, available at https://docs.wixstatic.com/ugd/809e70_7ddb46110dde46cb961ef3a678d7e41c.pdf.

³⁴⁸ M. Bowman & C. Schandavel, *The Harmony between Professional Conscience Rights and Patients’ Right of Access*, 6 Phoenix L. Rev. 31 (2012) at 56 (“First, a patient who chooses a pro-life physician is not merely choosing a physician who does not do something. She is choosing a physician who affirmatively practices medicine according to principles that unconditionally value human life, whether in the context of the preborn, the born, the disabled, or the terminally ill Second, patients seek physicians not only for discrete services, but even more so for relationships of trust.”)

³⁴⁹ Christian Medical Association & Freedom2Care summary of polls conducted April, 2009 and May, 2011, available at https://docs.wixstatic.com/ugd/809e70_7ddb46110dde46cb961ef3a678d7e41c.pdf (“88% of American adults surveyed said it is either ‘very’ or ‘somewhat’ important to them that they share a similar set of morals as their doctors, nurses, and other healthcare providers”).

³⁵⁰ Bowman & Schandavel, citing Ezekiel J. Emanuel et al., *Euthanasia and Physician-Assisted Suicide: Attitudes and Experiences of Oncology Patients, Oncologists, and the Public*, 347 Lancet 1805, 1808 (1996).

³⁵¹ *Id.* at 36.

³⁵² Combs et al., *Conscientious refusals to refer: findings from a national physician survey*, J. Med. Ethics 2011;37:397–401, 399 (“[43%] of physicians in this present study . . . did not agree that physicians are obligated to make referrals that they believe are immoral.”).

³⁵³ Farr A. Curlin M.D., et al., Religion, Conscience, and Controversial Clinical Practices, NEW ENG. J. MED. 593–600, 593 (2007) available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2867473/> (finding that some providers will inform patients of options but not refer for such options) (“Most [providers] also believe that physicians are obligated to present all options (86%) and to refer the patient to another clinician who does not object to the requested procedure (71%)”).

³⁵⁴ See, e.g., <https://prochoice.org/think-youre-pregnant/find-a-provider/> (first result for Google search of phrase “find abortion clinic near me” performed 10/17/18).

especially in rural areas, is of paramount importance. Instead of a decrease in access to a particular procedure from a particular doctor or provider, the residents of a rural area would face the potential of receiving no health care at all from that doctor or provider because such providers may leave the practice if unable to practice medicine according to their religious beliefs or moral convictions. In addition, as discussed in response to comments *supra* at part III.A., some polls show populations in rural communities may be more likely to agree with providers in objecting to certain procedures encompassed by Federal conscience and anti-discrimination laws. This implies that the demand for such services may not exist (or be as great) in such communities, partially offsetting the impact of a higher number of conscientious objections that may be effectuated because of the rule. Persons in urban areas, in contrast, may feel less effect from an increase in conscientious objections because of the relatively greater availability of alternative providers as compared to rural areas.

One commenter noted that individuals whose health insurance does not provide financially adequate coverage for a large enough number of providers may similarly face a lack of alternative providers in the event one provider exercises a conscientious objection to a desired service. The Department regards its analysis herein regarding rural areas to be applicable to such situations as well.

Just as the consequences of denials of care may in some cases be magnified in rural areas, so too may be the consequences of forcing a rural health care provider to violate her conscience. First, the provider may limit her practice or exit the field, harming health care access in a significant way. Second, if the provider continues to practice, the stress of having to violate her conscience may detract from the quality of care the provider delivers to her patients in general, who have no alternative provider.

Additionally, if a provider is in an area where the majority of the population shares the provider's belief system, and if the provider leaves the area due to inability to exercise protected beliefs, many in the community may lose the ability to have a provider with values they share, thus negatively impacting the delivery of health care and the doctor-patient relationship.

5. Analysis of Regulatory Alternatives

The Department carefully considered alternatives to this final rule. The Department determined that no alternative could achieve appropriately robust enforcement of, and respect for, Federal conscience and anti-discrimination laws without unduly burdening covered persons and entities subject to those laws and this rule. The following alternatives represent the major approaches the Department considered, including how burden reduction was a consideration in constructing this rule.

The Department considered preserving the status quo by maintaining 45 CFR part 88 without change from the 2011 Rule. Under this approach, the Department would largely defer to the States to enforce their respective conscience laws or to enact new laws to fill gaps in the landscape of Federal and State conscience protection and associated anti-discrimination rights and their enforcement, continue with the current inadequate enforcement scheme, and provide no meaningful enforcement of the conscience and associated anti-discrimination laws that were not part of the 2011 Rule. The Department received comments advocating this approach since, in commenters' views, State law, in conjunction with Federal law, already provides adequate accommodation of religious beliefs. Furthermore, some commenters stated that the stringent protections for conscience established by the statutes implemented by this rule are in tension with State nondiscrimination laws, State pharmaceutical dispensing laws, and State immunization laws that offer employers greater leeway in handling situations in which an employee asserts a conscientious objection.³⁵⁵ As stated elsewhere in response to similar comments, the Department disagrees with these arguments. As described above and further in the rule's Federalism analysis, to eliminate or reduce any tension between this rule's application of Federal statutes and State law, the final rule narrows the scope of the definitions of "discrimination" and "referral" in § 88.2.

The Department also disagrees that maintaining the status quo is preferable to this rule. Deference to States would perpetuate the current circumstances necessitating Federal regulation, which include (1) inadequate to non-existent

Federal government frameworks to enforce Federal conscience and anti-discrimination laws and (2) inadequate information and understanding about the obligations of regulated persons and entities and the rights of persons, entities, and health care entities under the Federal conscience and anti-discrimination laws. State action cannot correct these deficiencies at the Federal level. Furthermore, the Department could not, in good faith, choose to rely on States to promote conscience protection policies, knowing that some States have adopted laws that are inconsistent with, or have otherwise expressed indifference towards, the rights protected by the laws that part 88 (as written in the 2011 Rule) implements—the Weldon, Church, and Coats-Snowe Amendments.³⁵⁶

Additionally, as noted more extensively in the preamble's summary of regulatory history, *supra* at part I, many commenters have pointed out the mutually reinforcing inadequate circumstances of the status quo contribute to the critical need for this final rule, including a conspicuously minimalistic regulatory scheme (compared to regulations implementing other civil rights laws OCR enforces); a lack of recognition by courts of a private right of action under certain Federal conscience and anti-discrimination laws;³⁵⁷ and hostility to conscience protections in some portion of the population and in certain State and local governments. Maintaining the status quo leaves a gap where HHS has a responsibility to coordinate compliance with, and enforcement of, Federal conscience protection and anti-discrimination laws but does not have the regulatory scheme to accomplish that goal. The Department consequently promulgates this final rule to eliminate that gap.

The Department considered maintaining the status quo, but dramatically increasing its outreach. Numerous commenters asserted the strong need for outreach to combat bias and animus in the health care sector against individuals with religious beliefs or moral convictions, to raise awareness of the conscience rights of individuals, entities, and health care entities, and to clarify the legal obligations of regulated persons and entities. Commenters suggested a range

³⁵⁶ See *supra* at part II.A (discussing laws and policies that some States have adopted).

³⁵⁵ These comments paralleled the concerns, described *supra* at part III.B, raised by commenters who argued that this rule conflicts with other Federal statutes like Title VII of the Civil Rights Act of 1964.

³⁵⁷ See, e.g., *Cenzon-DeCarlo v. Mount Sinai Hospital*, 626 F.3d 695 (2d Cir. 2010); *Hellwege v. Tampa Family Health Centers*, 103 F. Supp. 3d 1303 (M.D. Fla. 2015); *National Institute of Family and Life Advocates, et al. v. Rauner*, No. 3:16-cv-50310, at 4 (N.D. Ill. July 19, 2017).

of ideas, including that the Department publish educational materials for academic medical institutions to educate students about their protected conscience rights and the obligation of regulated entities to comply with Federal conscience and anti-discrimination laws; that HHS partner with State institutions regulating health professions; and that HHS create an advisory team with diverse members to develop a plan for extensive outreach to combat ignorance about Federal conscience and anti-discrimination laws.

The Department remains committed to robust outreach. Outreach has tremendous benefits to clarify legal obligations, raise awareness of OCR, and elevate awareness of the importance of conscience protections generally. The Department, however, agrees with one commenter who noted that, although outreach is important, it is insufficient without an enforceable rule to uphold the substantive protections under Federal law. As with every other civil rights law, outreach without adequate enforcement mechanisms is not enough to ensure appropriate compliance.

The Department considered a regulatory scheme that was more prescriptive than this rule by requiring all recipients and sub-recipients to establish policies and procedures for accommodating workforce members who objected to certain services based on moral convictions or religious beliefs; to address certain substantive elements in their policies and procedures; and to require the dissemination of information to workforce members about Federal conscience and anti-discrimination laws, this rule, or the recipient's and sub-recipient's policies and procedures. The burden under this option across 502,899 entities (the mid-point of the range shown in *supra* at Table 2) is the labor of a lawyer's time (3 hours) and an executive's time (1 hour). Using the mean hourly wages for these occupations adjusted upward for benefits and overhead, the annual average burden would be \$297 million.³⁵⁸

The Department rejected this alternative, but estimates *supra* at part IV.C.3.ii that five percent of entities in year one and 0.5 percent of entities annually in years two through five would voluntarily update policies and procedures or disseminate them to staff as a by-product of assuring and certifying compliance with Federal

conscience and anti-discrimination laws and this rule.

As discussed above, the Department considered requiring recipients to post notices of nondiscrimination in various physical locations and online, but has chosen to make the notice provisions voluntary, in part to reduce burden. The final rule allows recipients and sub-recipients flexibility to decide what measures will best ensure compliance with Federal conscience and anti-discrimination laws and this rule, while providing for vigorous enforcement in cases of violation. Recipients and sub-recipients are better positioned to decide whether organization-wide action is necessary, and if so, what extent, content, and manner of that action is appropriate to ensure compliance. This approach allows recipients and sub-recipients to tailor appropriate organization-wide action based on their type, the populations they serve, their size, the scope of their workforce members likely to exercise protected rights under the Federal conscience and anti-discrimination laws and this rule, and other relevant considerations. This rule, therefore, permits recipient employers to establish their own policies and procedures for how they will handle individuals' objections to certain procedures, such as abortion, sterilization, or assisted suicide, and recognizes the availability of appropriate accommodation procedures. In addition, this rule permits recipient employers who do have institution-wide objections to performing certain procedures, such as sterilization, but that do not object to referring for such procedures, to establish referral systems with nearby institutions that do not have objections to such procedures to facilitate the delivery of the services or programs.

D. Executive Order 13771

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations "to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." The Department believes that this final rule is a significant regulatory action as defined by section 3(f) of Executive Order 12866. This rule is also considered a regulatory action under Executive Order 13771. Excluding any negative externalities attributed to this rule in the form of health outcomes or other effects not compensated by positive health or other externalities from protecting conscience rights, the Department estimates that this rule will generate \$148.2 million in annualized costs at a 7 percent discount rate,

discounted relative to year 2016, over a perpetual time horizon.

One commenter argued that the final rule violates Executive Order 13771 because it imposes costs but does not identify what other burdens imposed by other regulations are being eliminated. Although each agency must identify offsetting deregulatory actions for each new regulatory burden, OMB does not interpret Executive Order 13771 to require each regulation that imposes costs to cite the particular deregulatory actions that offset that particular burden.³⁵⁹

E. Regulatory Flexibility Act

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

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

³⁵⁹ Office of Management & Budget, Guidance Implementing Executive Order 13771, Titled Reducing Regulation and Controlling Regulatory Costs, at 16 (Apr. 5, 2017), <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf> (stating in the answer to question 37 that "[w]hile each Federal Register notice should identify whether the regulation is an E.O. 13771 regulatory action, there is no need to discuss specific offsetting E.O. 13771 deregulatory actions within the same Federal Register entry.").

³⁵⁸ Product of weighted mean hourly wage of \$147.60 per hour × 4 hours × 502,899 entities.

industry.³⁶⁰ Persons and States are not included in the definition of a small entity. The Department assumes that most of the entities affected meet the threshold of a small entity.

Although this final rule will apply to and, thus, affect small entities, this rule's per-entity effects are relatively small. The Department estimates that this rule would impose an average cost of \$778 per entity in the first year of compliance³⁶¹ and about \$325.30 per year in years two through five.³⁶² Furthermore, these costs would generally be proportional to the size of an entity, so that the smallest affected entities will face lower average costs. Given the thresholds discussed in the preceding paragraphs, the average costs are below those required to have a significant impact on a substantial number of small entities, within the meaning of the RFA.

Furthermore, the rule attempts to minimize costs imposed on small entities. For example, the assurance and certification requirements in § 88.4 contain exceptions to relieve many small entities of the requirement to submit an assurance and certification. Approximately 70 percent of recipients are exempted from the assurance and certification requirement, assuming that those exempted do not receive HHS funding through a non-exempt program.³⁶³ Given the magnitude and type of entities granted the exception, § 88.4 should not be understood as unduly burdening small entities subject to the rule.

The Department has further committed to leveraging existing grant, contract, and other Departmental forms where possible to implement § 88.4, rather than create additional, separate forms for recipients to sign. Similarly, § 88.5 no longer requires recipients to provide notices of conscience rights, but incentivizes recipients to voluntarily provide such notices. In light of this determination, the Secretary certifies that this rule will not result in a

significant impact on a substantial number of small entities.

F. Unfunded Mandates Reform Act

The Department similarly concludes that the requirements of the Unfunded Mandates Reform Act of 1995 are not triggered by this final rule. Section 202(a) of that Act requires the Department to prepare a written statement, including an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$150 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. As discussed in this RIA, this rule will not result in an expenditure in any year that meets or exceeds that amount with regard to State, local, or tribal governments, but will exceed that amount with regard to the private sector. An in-depth analysis of the rule with respect to State and local governments specifically appears in the following section of this RIA regarding Executive Order 13132 (Federalism).

G. Executive Order 13132—Federalism; Executive Order 13175—Impact on Tribal Entities

Federalism

The Secretary has determined that this final rule comports with Executive Order 13132.³⁶⁴ Executive Order 13132 aims to "guarantee the division of governmental responsibilities between the national government and the States that was intended by the Framers of the Constitution . . . [and] ensure that the principles of federalism . . . guide the executive departments and agencies in the formulation and implementation of policies."³⁶⁵ Some of the Federal laws that this rule implements and enforces, such as the Weldon and Coats-Snowe Amendments, directly regulate States and local governments that receive Federal funding by conditioning the receipt of such funding on the governments' commitments to refrain from discrimination on certain bases or by imposing certain requirements on States and local governments that receive Federal funding. This impact, however, is a result of the statutory prohibitions and requirements themselves, and are not due to the mechanisms provided by this rule.

Under the Supremacy and Spending Clauses of the Constitution, States and their political subdivisions are subject to Acts of Congress,³⁶⁶ and Federal conscience and anti-discrimination laws are no exception. This rule holds States and local governments accountable for compliance with these laws by setting forth mechanisms for OCR investigation and HHS enforcement related to those requirements. The rule does not change the substantive conscience protections or anti-discrimination requirements of these statutes.

The Department received comments arguing that the enforcement of this rule through § 88.7 could infringe on State sovereignty, in violation of the limits of the Spending Clause power afforded by the U.S. Constitution to Congress. The Federal government presumes the constitutionality of statutes that Congress enacts. Congress has exercised the broad authority afforded to it under the Spending Clause to attach clear conditions on Federal funds to secure conscience protection and associated anti-discrimination rights. In cases of violation of the Federal conscience and anti-discrimination laws, the Department intends to interpret and apply the remedies that § 88.7 sets forth in a manner consistent with the particular Federal law(s) at issue and the U.S. Constitution, and, as discussed in response to earlier comments, will comply with relevant Supreme Court precedents concerning federalism.³⁶⁷

Some commenters argued that the rule implicates the requirements of Executive Order 13132 and unconstitutionally impedes the ability of States to exercise power in areas traditionally reserved to them, such as health, safety, and welfare. Commenters also raised concerns that the rule may inhibit States from implementing their own conscience protections. The Department disagrees with these concerns. The Department promulgates this rule under longstanding Federal laws that leave ample room for State activity. States are free to enact their own conscience protection and anti-discrimination laws that consider their own respective needs, populations, and prerogatives. Indeed, all fifty States have some protections in place for conscientious objectors to certain health or medical services and several provisions of this rule explicitly apply to reinforce and respect State conscience protections.³⁶⁸ States are

³⁶⁰ U.S. Small Business Administration, Table of Small Business Size Standards Marched to North American Industry Classification System Codes (Oct. 1, 2017), https://www.sba.gov/sites/default/files/files/Size_Standards_Table_2017.pdf (identifying the size standards by NAICS code for the health care and social service industries).

³⁶¹ Result of \$391.5 million in first year costs to non-HHS entities divided by 502,899 entities.

³⁶² Result of \$163.6 million annually to non-HHS entities in years two through five divided by 502,899 entities.

³⁶³ The average between the lower-bound (267,134) and upper-bound (415,666) of recipients exempted is 341,400 recipients, which represents 68 percent of the estimated total 500,290 recipients of the rule (excluding the estimated 2,609 counties that for the purpose of this rule are estimated to be sub-recipients).

³⁶⁴ E.O. 13132, 64 FR 43255 (Aug. 4, 1999).

³⁶⁵ *Id.*

³⁶⁶ *Id.* section 2(d).

³⁶⁷ See *supra* at part III.B (section-by-section analysis for § 88.7) and part I.B (this regulation's history) for further discussion of this matter.

³⁶⁸ See Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare*

free to experiment with various approaches to promote respect of, and tolerance for, the exercise of conscience rights, and this final rule respects that prerogative. States are also free to reject Federal funding if they object to conditions required by any of the laws that are the subject of this rule.

Section 88.8 of the rule makes clear that the rule is not intended to interfere with the operation of State law. For State laws equally or more protective of religious freedom and moral convictions than this rule, § 88.8 of this rule states that nothing in the rule “shall be construed to preempt” such State or local law. Section 88.8 also declares that nothing in the rule “shall be construed to narrow the meaning or application of any State . . . law protecting free exercise of religious beliefs or moral convictions.”

Some statutes that the rule implements, such as 42 U.S.C. 1396s(c)(2)(B)(ii), *require* providers to comply “with applicable State law, including any law relating to any religious or other exemption” as a condition of participation in the program that the statute authorizes (in this example, the Federal pediatric vaccine program). Other laws that this rule implements, such as 42 U.S.C. 280g–1(d), clarify that Federal assistance for newborn and infant hearing screening programs do not preempt or prohibit any State law protections for parents to assert religious objections to such screenings. Similarly, 42 U.S.C. 1396f clarifies that nothing requires a State to compel a person to undergo medical screenings, examination, diagnosis, treatment, health care or services if a person objects on religious grounds, with limited exceptions.

This rule’s requirements and prohibitions do not impose substantial direct effects on States and their political subdivisions, modify the relationship between the Federal government and the States, or alter the distribution of power and responsibilities among the various levels of government.³⁶⁹

Some commenters argued that this rule, or the statutes that the rule implements, conflict with State and local laws regarding student and health provider immunizations, mandated

provision of abortion coverage, employer protections, counseling related to assisted suicide, or employers being able to accommodate objectors with alternative arrangements. These comments paralleled the concerns already addressed above. In short, the Department finalizes the rule to recognize forms of accommodation and to eliminate or reduce such tension between applicable statutes or between this final rule and State laws. Accordingly, the final rule narrows the scope of the definitions of “discrimination” and “referral” in § 88.2.

The impact of § 88.4 is minimal in terms of the added labor costs for State and local government staff to assure and certify compliance.³⁷⁰ Additionally, the rule relies on enforcement mechanisms already available to HHS for grants and other forms of financial assistance.

In light of the above, the rule cannot be properly understood to impose substantial direct effects on States or their political subdivisions, their relationship with the Federal Government, or the distribution of power among the various levels of government.

One comment noted that it “does not threaten principles of federalism [to] requir[e] respect for constitutionally-protected conscience rights as a condition of receiving Federal funds.” The Department agrees. The Department has not identified any Federal laws or jurisprudence that indicates that merely implementing and enforcing Federal laws as written violates constitutional principles of federalism.

Impact on Tribal Entities

One comment stated that the Department would be required to engage in tribal consultation regarding the rule as required under Executive Order 13175. However, because the final rule removes the requirement in the proposed § 88.3(p)(1)(iii) that certain federally recognized Indian tribes or tribal organizations and urban Indian organizations comply with sections 88.4 and 88.6 of the rule, the Department believes that the rule does not have tribal implications as defined in Executive Order 13175, and that tribal consultation regarding the rule was, therefore, not necessary.

H. Congressional Review Act

The Congressional Review Act defines a “major rule” as “any rule that the Administrator of the Office of Information and Regulatory Affairs

(OIRA) of the Office of Management and Budget finds has resulted in or is likely to result in—(A) an annual effect on the economy of \$100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.” 5 U.S.C. 804(2). Based on the analysis of this final rule under Executive Order 12866, the Office of Management and Budget has determined that this rule is a major rule for purposes of the Congressional Review Act.

I. Assessment of Federal Regulation and Policies on Families

In the proposed rule, the Department included a discussion of section 654 of the Treasury and General Government Appropriations Act of 1999, Public Law 105–277, sec. 654, 112 Stat. 2681 (1998) as amended by Public Law 108–271, sec. 654, 118 Stat. 814 (2004), which required Federal departments and agencies to determine whether a policy or regulation could affect family well-being. These provisions are codified as a “note” to 5 U.S.C. 601. Because Congress did not renew these requirements in the most recent appropriations act applicable to the Department,³⁷¹ the Department believes it is not obligated to conduct an analysis of potential impact on family well-being before finalizing regulations. Additionally, OMB Circular A–4 does not require such an analysis. Nevertheless, out of an abundance of caution, the Department conducts such an analysis below.

Section 601 (note) of 5 U.S.C. required agencies to assess whether a regulatory action (1) impacts the stability or safety of the family, particularly in terms of marital commitment; (2) impacts the authority of parents in the education, nurture, and supervision of their children; (3) helps the family perform its functions; (4) affects disposable income or poverty of families and children; (5) if the regulatory action which financially impacts families, is justified; (6) may be carried out by State or local government or by the family; and (7) establishes a policy concerning the relationship between the behavior

Professionals, 49 Ariz. St. L.J. 549, 575–76, 587–600 (2017) (summarizing State laws).

³⁶⁹ E.O. 13132, section 1(a). Executive Order 13132 requires an agency to meet certain requirements when it promulgates a rule with “policies that have federalism implications.” *Id.* sections 2–3, 6(b)–(c) (identifying federalism principles, policymaking criteria, and consultation requirements).

³⁷⁰ See *supra* at part IV.C.2.vi of this RIA estimating the rule’s burden.

³⁷¹ Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Public Law 115–245, 132 Stat. 2981 (2018).

and personal responsibility of youth and the norms of society.

The Department received comments stating that it did not adequately assess the impact on families in the proposed rule and reached an incorrect conclusion in determining that it is unlikely that this rule will negatively impact factors (1)–(4), with respect to the stability of the family, parental authority, or the disposable income or poverty of families and children. Other comments referenced concerns about how delays or refusals in treatment or in the transmission of information could affect factor (5): The emotional and financial well-being of families. The Department did not receive comments addressing factors (6) or (7). In response to these comments, the Department notes that these concerns do not constitute an impact on the well-being of the family within the meaning of 5 U.S.C. 601 (note) and that, in any event, the objections are to the underlying statutes that are the subject of the rule, not the mechanisms provided by the rule itself. With regard to factor (5), the prospect of a person losing their job, thus affecting the emotional and financial well-being of their family, is greater if conscience laws are not enforced as people of faith and moral conviction risk being driven out of the health care field as discussed above. Further discussion on the impact of this rule on patients and individuals can be found in part IV.C.4 (Estimated Benefits).

As the Department noted in the proposed rule, the action taken in this rule cannot be carried out by State or local governments or by the family on their own (factor (6)) because the rule pertains to enforcement of certain Federal laws. Additionally, by protecting parents' ability to assert conscience rights on behalf of their children, the rule clearly enhances parental authority under factor (2). None of the rule's provisions impact factors (1), (3)–(5), or (7) to the degree contemplated by 5 U.S.C. 601 (note). Accordingly, this rule will not negatively affect family well-being within the meaning of 5 U.S.C. 601 (note) in the event such provisions apply.

J. Paperwork Reduction Act

This final rule requires new collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Congress enacted the Paperwork Reduction Act of 1995 to “maximize the practical utility and public benefit of the information created, collected, disclosed, maintained, used, shared and

disseminated by or for the Federal government” and to minimize the burden of this collection. 44 U.S.C. 3501(2). As defined in 5 CFR 1320.3(c), “collection of information” comprises reporting, record-keeping, monitoring, posting, labeling, and other similar actions. The Department sought comments regarding the burden estimates and the information collections generally. Some comments are discussed *supra* at part IV.C.3.ii–vi and others discussed in the following sections. The collections of information required by this final rule relate to §§ 88.4 (Assurance and Certification), 88.5 (Voluntary Posting of Notice of Rights), and 88.6(d) (Compliance Requirements).

1. Information Collection for § 88.4 (Assurance and Certification)

(i) Summary of the Collection of Information

This final rule requires each recipient (or applicant to become a recipient), with limited exceptions, to assure and certify compliance with Federal conscience and anti-discrimination laws. Specifically, § 88.4(a)(1) and (2) requires each recipient or applicant to include in its application for Federal funds, or accompany its application with, an assurance and a certification that it will operate applicable projects or programs in compliance with applicable Federal conscience and anti-discrimination laws and this rule.

Operationalizing the Assurance of Compliance Requirement

To operationalize the requirement in § 88.4(a)(1) for a recipient or applicant to sign an assurance of compliance, the Department is seeking clearance under the PRA to update the HHS–690 form, which is entitled “Assurance of Compliance”³⁷² and is described in the section-by-section analysis of the preamble for § 88.4. The new language that the Department is adding to the HHS–690 form identifies the major Federal conscience and anti-discrimination laws by their popular titles and their U.S. Code provisions (if codified) and directs the reader to OCR's Conscience and Religious Freedom web page for a full listing of the laws.

Operationalizing the Certification of Compliance Requirement

In response to public comments that encouraged the Department to use existing forms, the Department explored operationalizing the certification of

compliance requirement in § 88.4(a)(2) by updating the HHS form 5161–1, but this form is only used by two HHS components rather than by all or most HHS operating or staff divisions. The Department also explored updating the Assurances for Non-Construction Programs (SF–424B), which, despite its name, enables the authorized representative of the applicant to certify up to nineteen paragraphs of agency and program-specific laws and regulations, such as housing, environmental, and labor laws and regulations.³⁷³ Pursuant to an OMB directive, “[e]ffective January 1, 2019, the SF–424B will become optional and agencies shall make plans to phase out use in Funding Opportunity Announcements.”³⁷⁴ Given this directive, the Department did not further explore updating the SF–424B.

The Department is seeking PRA clearance to operationalize the certification of compliance requirement during calendar year 2019 through the existing signature block of the government-wide Application for Federal Assistance (SF–424)³⁷⁵ or, for research or related grants, through the Application for Federal Assistance for Research and Related (R&R) Series (SF–424 R&R).³⁷⁶ The signature block for both applications contains the following statement:

By signing this application, I certify (1) to the statements contained in the list of certifications ** and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances ** and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001).

** The list of certifications and assurances, or an internet site where you may obtain this list, is contained in the announcement or agency specific instructions.

In calendar year 2020 and the outyears, the Department is seeking PRA

³⁷³ Assurances for Non-Construction Programs, SF–424B, (OMB #4040–0007) <https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf> (last visited Apr. 11, 2019).

³⁷⁴ Exec. Office of the President, Memorandum from Mick Mulvaney, Dir., Office of Management & Budget to Heads of Executive Departments and Agencies, Strategies to Reduce Grant Recipient Reporting Burden, at 2 (Sept. 5, 2018), <https://www.whitehouse.gov/wp-content/uploads/2018/09/M-18-24.pdf>.

³⁷⁵ Application for Financial Assistance, SF–424, (OMB # 4040–0004), https://apply07.grants.gov/apply/forms/sample/SF424_2_1-V2.1.pdf (last visited Apr. 11, 2019).

³⁷⁶ Application for Financial Assistance, SF–424 (R&R), (OMB # 4040–0001), https://apply07.grants.gov/apply/forms/sample/RR_SF424_2_0-V2.0.pdf (last visited Apr. 11, 2019).

³⁷² U.S. Dep't of Health & Human Servs., Assurance of Compliance, HHS 690, <https://www.hhs.gov/sites/default/files/hhs-690.pdf>.

clearance to operationalize the certification of compliance requirement through the government-wide System for Award Management (SAM) ³⁷⁷ because this system, pursuant to an OMB directive, “will become the central repository for common government-wide certifications and representations required of Federal grants recipients.” ³⁷⁸ The certifications and representations through SAM replace the government-wide assurances contained in the Assurances for Non-Construction Programs (SF-424B). ³⁷⁹

In submitting the general certifications and representations through SAM, ³⁸⁰ the authorized representative certifies to several statements, two of which the Department interprets as operationalizing § 88.4(b). ³⁸¹ First, the authorized representative certifies that it “[w]ill comply with U.S. statutory and public policy requirements which prohibit discrimination, including but not limited to[]” certain Federal civil rights statutes. ³⁸² The Federal conscience and anti-discrimination laws are not listed because the general certifications and representations identified in SAM are government-wide, rather than agency or multi-agency specific. However, the Department construes the non-exhaustive list as incorporating the Federal conscience and anti-discrimination laws, as

applicable, that the final rule implements.

Another statement conveys that the authorized representative certifies that it “[w]ill comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies government financial assistance awards and any financial assistance project covered by this certification document.” ³⁸³ The Department construes this catch-all statement as incorporating the Federal conscience and anti-discrimination laws, as applicable, and the final rule.

(ii) Need for Information

Requiring certain recipients and applicants to assure and certify compliance serves two purposes. First, through the act of reading and reviewing the statutory requirements to which recipients or applicants assure and certify compliance, recipients would be apprised of their obligations under the applicable Federal conscience and anti-discrimination laws and this rule. Second, a recipient’s or applicant’s awareness of its obligations would increase the likelihood that it would comply with such laws and, consequently, afford entities and individuals protection of their conscience rights and protection from coercion or discrimination.

In the proposed rule, the Department requested comment on whether the collection of information is necessary for the proper performance of the Department’s functions to enforce Federal laws on which Federal funding is conditioned. At least one commenter encouraged the Department to add the assurance and certification requirements in § 88.4 because of the “surge in harassment and coercion of medical providers of faith.” Other commenters stated that assurance and certification was unnecessary because recipients already must certify compliance with Federal law upon the receipt of Federal funds.

This collection of information facilitates the Department’s obligation to ensure that the Federal financial assistance or other Federal funds that the Department awards are used in a manner compliant with Federal conscience and anti-discrimination laws and the final rule. The Department’s administration of a requirement for an entity at the time of application or reapplication to assure and certify compliance with Federal conscience and anti-discrimination laws and the

final rule demonstrates that the person or entity was aware of its obligations under those laws and the rule.

In addition, HHS has the authority to place terms and conditions consistent with those statutes in any instrument HHS issues or to which it is a party (e.g., grants, contracts or other HHS instruments). A Department component extending an award must communicate and incorporate statutory and public policy requirements and obligate the recipient to comply with Federal statutes and “public policy requirements, including . . . those . . . prohibiting discrimination.” ³⁸⁴ More specifically, the Department component “must communicate . . . all relevant public policy requirements, including those in general appropriations provisions, and incorporate them either directly or by reference in the terms and conditions of the Federal award.” ³⁸⁵ The Departmental component may require a recipient “to submit certifications and representations required by Federal statutes, or regulations . . .” ³⁸⁶

(iii) Use of Information

The Department and its components awarding Federal funds and OCR will use the signed assurance and certification as documentation of (1) a recipient’s or applicant’s awareness of its obligations under the Federal conscience and anti-discrimination laws and this rule, and (2) a recipient’s or applicant’s binding agreement to abide by such obligations. This use would most likely occur during an OCR investigation of the recipient’s compliance with Federal conscience and anti-discrimination laws and this rule, and as part of an entity’s record keeping obligations under this rule.

(iv) Description of the Respondents

The respondents are applicants or recipients for Federal financial assistance or Federal funds from the Department as set forth in § 88.3, which identifies the applicability of this rule for each of the underlying statutes that would be implemented and enforced. Respondents include hospitals, research institutions, health professions training programs, qualified health plan issuers, Health Insurance Marketplaces, home health agencies, community mental health centers, and skilled nursing facilities.

(v) Number of Respondents

The Department estimates the number of respondents at 158,890 persons or

³⁷⁷ U.S. Gen. Servs. Admin., System for Award Management, *Home*, <https://www.sam.gov/SAM/pages/public/index.jsf> (last visited Apr. 11, 2019).

³⁷⁸ Exec. Office of the President, Memorandum from Mick Mulvaney, Dir., Office of Management & Budget to Heads of Executive Departments and Agencies, Strategies to Reduce Grant Recipient Reporting Burden, at 2 (Sept. 5, 2018), <https://www.whitehouse.gov/wp-content/uploads/2018/09/M-18-24.pdf>.

³⁷⁹ See *id.* (“[R]egistration in SAM is required for eligibility for a Federal award and registration must be updated annually Federal agencies will use SAM information to comply with award requirements and avoid increased burden and costs of separate requests for such information, unless the recipient fails to meet a Federal award requirement, or there is a need to make updates to their SAM registration for other purposes.”).

³⁸⁰ U.S. Gen. Servs. Admin., System for Award Management, SAM Release Notes Build 2019-02-01, at 3 (Feb. 2, 2019), https://www.sam.gov/SAM/transcript/SAM_Release_Notes_2019_02_01.pdf (describing under “enhancements” that SAM has “a new government-wide Financial Assistance Representations and Certifications module within the SAM entity management registration” and “[a]ll non-federal registrants in SAM will be required to certify to the new Financial Assistance Reps & Certs as part of their registration”).

³⁸¹ The certifications and representations are not publicly available until an individual creates an account. The list of certifications and representations were obtained from staff at *Grants.gov* on March 19, 2019, and are on file with OCR.

³⁸² Financial Assistance General Certifications and Representations, at 2, para. 9 (on file with OCR).

³⁸³ Financial Assistance General Certifications and Representations, at 1, para. 7 (on file with OCR).

³⁸⁴ 45 CFR 75.300(a).

³⁸⁵ *Id.*

³⁸⁶ *Id.* at § 75.208.

entities, which is the average between the low (122,558) and high (195,222) estimates of entities required to sign an assurance or a certification. These figures appear *supra* at Table 3, part IV.C.2.iv.A. Respondents are a subset of the recipients because § 88.4(c)(1) through (4) excludes certain categories of recipients. The rule excludes physicians, as defined in 42 U.S.C. 1395x(r), physician offices, other health care practitioners or pharmacists who are recipients in the form of reimbursements for services provided to beneficiaries under Medicare Part B. *See* § 88.4(c)(1). The rule also exempts recipients of certain grant programs administered by the Administration for Children and Families or the Administration for Community Living when the program's purpose is unrelated to health care and certain types of research, does not involve health care providers, and does not involve any significant likelihood of referral for the provision of health care. *See* § 88.4(c)(2) and (3). Finally, this final rule excludes Indian Tribes and Tribal Organizations when contracting with the Indian Health Service under the Indian Self-Determination and Education Assistance Act. *See* § 88.4(c)(4).

(vi) Burden of Response

The Paperwork Reduction Act burden is the opportunity cost of recipient staff time to review the assurance and certification language as well as the requirements of the underlying Federal conscience and anti-discrimination laws referenced or incorporated. The methods that the Department uses are outlined *supra* at part IV.C.3.ii, and the mean hourly wage is adjusted downward to exclude benefits and overhead.

The labor cost is a function of a lawyer spending 3 hours reviewing the assurance and certification and an executive spending one hour to review and sign, as § 88.4(b)(2) requires a signature by an individual authorized to bind the recipient. The weighted mean hourly wage (not including benefits and overhead) of these two occupations is \$73.80 per hour.³⁸⁷ The labor cost is \$46.9 million each year (\$73.80 per hour × 4 hours × 158,890 entities).³⁸⁸

The Department asked for public comment on the information collection under § 88.4. Several specific questions that the Department posed received no comments:

- Whether the exception for Indian Tribes and tribal Organizations in proposed 45 CFR 88.4(c)(vi) avoids “tribal implications” and does not “impose substantial direct compliance costs on Indian Tribal governments” as stated in Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, sec. 5(b) (Nov. 9, 2000);
- Whether assuring compliance with the Federal conscience protection and associated anti-discrimination statutes would constitute a burden exempt from the Paperwork Reduction Act as a usual and customary business practice incurred by recipients during the ordinary course of business;
- How the quality, utility, and clarity of the information to be collected may be enhanced; and
- How the manner of compliance with the assurance and certification requirements could be improved, including through use of automated collection techniques or other forms of information technology.

The Department received public comments expressing concern with the possible burden on health care providers resulting from § 88.4, which is discussed *supra* at part IV.C.3.ii. In addition, as explained in the summary of this Paperwork Reduction Act analysis, the Department is leveraging existing grant, contract, and other Departmental forms and government-wide systems, consistent with OMB's government-wide effort to reduce recipient burden.³⁸⁹

2. Information Collection for § 88.5 (Notice)

(i) Summary of the Collection of Information

Under this rule as finalized, § 88.5 does not mandate the provision of notice, but rather incentivizes recipients and Department components to provide notice concerning Federal conscience and anti-discrimination laws. The rule intends to accomplish this goal by considering a recipient's or a Department component's posting of the notice as non-dispositive evidence of compliance with the rule when OCR investigates or initiates a compliance review of a recipient or Department component. If recipients voluntarily provide notice to implement § 88.5, recipients are encouraged to use the pre-written notice in appendix A. The

recipient is otherwise free to draft its own notices tailored to its specific circumstances and applicable laws under the rule.

(ii) Need for Information

The Department incentivizes recipients and Department components to provide notice of rights because notice serves three primary purposes. First, individuals become apprised of their rights under applicable Federal conscience and anti-discrimination laws, including the right to file a complaint with HHS OCR. Second, an individual's awareness of his or her rights increases the likelihood that the individual will exercise those rights. Third, recipients and their managers and employees will be more likely to be reminded, and be made aware, of their own obligations under these laws.

(iii) Use of Information

Individuals, entities, and health care entities will use the information to increase their awareness of their rights and file complaints with OCR if they believe their rights have been violated. Entities required to comply will have an increased likelihood of understanding their obligations to thus act accordingly to fulfill them. During OCR investigation or compliance review of a recipient, OCR will consider as non-dispositive evidence of compliance whether and how the recipient posted a notice according to § 88.5.

(iv) Description of the Respondents

The respondents are recipients as defined in this rule at § 88.2. Respondents include, but are not limited to, States, hospitals, research institutions, and skilled nursing facilities.

(v) Number of Respondents

The number of respondents is estimated at 335,327 recipients at the establishment-level in year one and 75 percent of that amount in years two through five (*i.e.*, 251,495 establishments). This estimate represents the average between the lower and upper-bound estimates of how many recipient establishments will voluntarily post notices through one of more of the methods in § 88.5 in years one and annually in years two through five. A subset of respondents, about 139,615 recipients at the firm level, will likely modify the pre-written notice in appendix A.

(vi) Burden of Response

Even though the notice provision of the final rule is entirely voluntary, the Department expects that some segment

³⁸⁷ Sum of (\$67.25 × .75) and (\$93.44 × .25).

³⁸⁸ This total differs from the burden in the RIA because a fully-loaded wage that is adjusted upwards for benefits and overhead must be used in the RIA.

³⁸⁹ Exec. Office of the President, Memorandum from Mick Mulvaney, Dir., Office of Management & Budget to Heads of Executive Departments and Agencies, Strategies to Reduce Grant Recipient Reporting Burden, at 2 (Sept. 5, 2018), <https://www.whitehouse.gov/wp-content/uploads/2018/09/M-18-24.pdf>.

of the recipients and Department components that this rule regulates will choose to post the notice through one of the methods specified. The burden is mix of labor, materials, and in some cases, postage costs. The methods and assumptions that the Department uses are outlined *supra* at part IV.C.3.iii, and the mean hourly wage is adjusted downward to exclude benefits and overhead. Unlike the burden estimated in the RIA of the rule, the PRA burden associated with § 88.5 excludes the costs of posting the notice for those entities that post it verbatim because the Department is supplying the language for the notice for the purpose of disclosure to the public, under 5 CFR 1320.3(c)(2).

Assuming that 139,615 recipients at the firm level alter the text of the notice in appendix A, these recipients will, on average, bear a minimal opportunity cost of $\frac{1}{3}$ hour of a lawyer's time for drafting and ten minutes of an executive's time to provide final sign-off. The weighted mean hourly wage (excluding benefits and overhead) of these two occupations is \$75.89 per hour. The one-time labor cost is \$5.3 million in the first year ($\$75.89 \text{ per hour} \times 0.5 \text{ hours} \times 139,615 \text{ recipients}$).

The assumptions regarding the timing of providing notices of rights and the various uncertainties inherent in the implementation of § 88.5 described in detail in the RIA *supra* at part IV.C.3.iii apply to this analysis, too, such as the number of locations where notices are customarily posted, and the length of time it may take an administrative assistant or web developer to perform their respective functions.

(vii) Burden for Voluntary Posting in Physical Locations

The Department estimates that it will take $\frac{1}{3}$ of an hour for an administrative assistant to print notice(s) and post them in physical locations of the establishment where notices are customarily posted. The 139,615 recipients at the firm level estimated to alter the notice are associated with 180,331 establishments. Assuming that about 180,331 facilities at the establishment level choose voluntarily to post notices in physical locations, the estimated labor cost is \$1.2 million ($\frac{1}{3} \text{ hour} \times \$19.39 \text{ per hour} \times 180,331 \text{ establishments}$).³⁹⁰ The cost to post 5 notices across all establishments would be \$45,083 ($180,331 \text{ establishments} \times \$0.05 \text{ per page (paper and ink)} \times 5 \text{ pages}$). The total labor and materials costs

associated with voluntary posting in physical locations by 180,331 establishments is \$1.2 million (\$1.2 million in labor costs and \$45,083 for materials) in the first year of implementation with zero recurring costs.

One commenter raised concerns with the notice requirement being overly broad because it would require a multi-State health care entity to post notices at every location where workforce notices are customarily posted to permit ready observation, even if the particular location had no connection to the funding or activity giving rise to the obligation to post the notice. The final rule's modification of the notice from mandatory to voluntary should resolve this concern. Additionally, the rule provides for posting in locations as "applicable and appropriate."

One commenter expressed concern that the Department's estimate of time that an administrative assistant would spend to post the notice did not take into account the multiple facilities owned by a corporate entity. The estimates for the Paperwork Reduction Act and in the RIA, however, do take this into account because the Department multiplied the per facility labor and materials costs by the number of facilities (*i.e.*, establishments) over which a corporate entity (*i.e.*, firm) exercises common ownership and control.

(viii) Burden for Voluntary Web Posting

To post the notice on the web, the Department estimates that it will take 2 hours for a web developer at each recipient's physical location to execute the design and technical elements for posting. This labor cost is approximately \$12.5 million ($2 \text{ hours} \times \$34.69 \text{ per hour} \times 180,337 \text{ establishments}$) in the first year of implementation with zero recurring costs.³⁹¹

(ix) Burden for Voluntary Posting in Two Publications

The Department assumes that, within the first year after the rule's publication, each recipient voluntarily posting notices in publications would identify two publications in which to include the notice, revising the document or its layout to include the notice, or otherwise printing an insert to include with hard copies of the publication.³⁹²

³⁹¹ This total differs from the estimate of the burden in the RIA because the RIA uses a fully loaded wage rate (*i.e.*, including benefits and overhead) not employed here.

³⁹² Under the final rule, because all the notice provisions are voluntary, the Department assumes that 75% of entities that voluntarily provide notices

Acknowledging the uncertainties outlined *supra* at part IV.C.3.iii, the Department estimates the annual costs of labor, material, and postage according to the following assumptions. The Department assumes that (1) establishments that include notices of rights in publications will most often do so in online publications or in hard-copy publications hand-distributed, where the notice's inclusion results in an additional 100 hard copy notices per establishment per year, and (2) half of the establishments associated with covered recipients voluntarily providing hard copy notices (*i.e.*, 90,166 establishments in year one and 67,624 establishments annually in years two through five)³⁹³ will mail the publications for which the weight of the notice incrementally increases the postage costs. These assumptions may differ from the actual experience of recipients' implementation, as described *supra* at part IV.C.3.iii.

Using the model, hourly estimates, and other assumptions described *supra* at part IV.C.3.iii, the average labor cost, excluding mailing-related labor costs, resulting from including notices in relevant publications is \$7.0 million in year one ($\$19.39 \text{ per hour} \times 2 \text{ hours} \times 180,331 \text{ establishments}$) and \$2.6 million annually in years two through five ($\$19.39 \text{ per hour} \times 1 \text{ hour} \times 135,249 \text{ establishments}$).³⁹⁴ Based on the marginal cost of postage per ounce of \$0.15,³⁹⁵ an annual number of mailings of 100 pages per establishment, average annual labor cost for mailing of \$19.39 per hour, and an average number of labor hours per mailing of 0.25 hours, the total costs due to the voluntary mailing of notices is \$1.8 million³⁹⁶ in year one and \$1.3 million³⁹⁷ annually in years two through five.³⁹⁸ Finally, the

in year one will continue to do so in out years and there will be lower attrition compared to the estimate provided in the proposed rule.

³⁹³ Product of 180,331 establishments times 50 percent for year one. Product of 135,249 establishments times 50 percent for years two through five.

³⁹⁴ These totals differ from the estimate of the burden in the RIA because the RIA uses a fully loaded wage rate (*i.e.*, including benefits and overhead) not employed here.

³⁹⁵ See U.S. Postal Service Postage Rates, <https://www.stamps.com/usps/current-postage-rates/>.

³⁹⁶ Sum of incremental postage of \$1.4 million ($\$0.15 \text{ per mailing} \times 100 \text{ mailings} \times 90,166 \text{ establishments}$) and incremental labor of \$437,078 ($\$19.39 \text{ per hour} \times 0.25 \text{ hours} \times 90,166 \text{ establishments}$).

³⁹⁷ Sum of incremental postage of \$1.0 million ($\$0.15 \text{ per mailing} \times 100 \text{ mailings} \times 67,624 \text{ establishments}$) and incremental labor of \$327,809 ($\$19.39 \text{ per hour} \times 0.25 \text{ hours} \times 67,624 \text{ establishments}$).

³⁹⁸ This total differs from the estimate of the burden in the RIA because the RIA uses a fully

³⁹⁰ This total differs from the burden in the RIA because a fully loaded wage that is adjusted upwards for benefits and overhead must be used.

annual cost of printed materials for notices (both mailed and hand distributed) is \$0.9 million (180,331 establishments $\times$ 100 pages $\times$ \$.05 per page) in year one and \$676,243 annually in years two through five (135,249 establishments $\times$ 100 pages $\times$ \$.05 per page).

In sum, the total expected cost of activities related to the voluntary posting and distributions of notices that § 88.5 incentivizes is \$28.7 million in the first year and \$4.6 million annually in years two through five.

(x) Burden to the Federal Government

Unlike the burden estimated in the RIA of the rule, the PRA burden to the Department associated with § 88.5 excludes the costs of posting the notice for those HHS components that post it verbatim because the Department is supplying the language of the notice for the purpose of disclosure to the public, under 5 CFR 1320.3(c)(2). Because the Department components will likely post the notice from Appendix A verbatim, all costs to the Department under the PRA for § 88.5 are excluded.

The remaining issue raised by commenters is whether the rule requires translation of the notice into non-English languages. Under the conscience protection and associated anti-discrimination laws and this rule, translation or posting of translated notices is not independently required. However, recipients subject to this rule may also have independent obligations to provide language assistance services and meaningful access to individuals with limited English proficiency when abiding by the prohibition of national origin discrimination in Federal civil rights laws that OCR enforces.³⁹⁹

The Department asked for public comment on the following issues and received no comments:

- Whether the proposed collection of information is necessary for the proper performance of the Department's functions to enforce Federal laws on which Federal funding is conditioned, including whether the information will have practical utility;
- Whether the public had feedback on the assumptions that formed the basis of the cost estimates for the notice provision; and
- How the manner of compliance with the notice provision could be

improved, including through the use of automated collection techniques or other forms of information technology.

3. Compliance Procedures (§ 88.6(d))

(i) Summary of the Collection of Information

Paragraph 88.6(d) requires any recipient or sub-recipient that is subject to a determination by OCR of noncompliance with this part concerning Federal conscience and anti-discrimination laws to report this fact in any application for new or renewed Federal financial assistance or Departmental funding in the three years following the determination of noncompliance. This includes a requirement that recipients disclose any OCR determinations made against their sub-recipients.

(ii) Need for Information

The information alerts applicable Departmental components of OCR's determination of noncompliance on the part of the recipient or sub-recipient, to ensure appropriate coordination within the Department during OCR's enforcement of Federal conscience and anti-discrimination laws, and to inform funding decision-making.

(iii) Use of Information

This requirement puts the Departmental component on notice of OCR's determination of noncompliance to inform a component's decision whether to approve, renew, or modify Federal funding to the recipient. This requirement also facilitates coordination between the component and OCR on the status of the recipient or sub-recipient's compliance status.

(iv) Description of the Respondents

The respondents are recipients and sub-recipients that HHS OCR has found noncompliant with this final rule.

(v) Number of Respondents

As explained, *supra* at part IV.C.3.v, the Department cannot predict the number of entities that OCR will find noncompliant with the rule.

(vi) Burden of Response

The Department estimates it would take a records custodian at the experience level of a paralegal about 15 minutes to retrieve the relevant information (such as date of the violation finding and the OCR "transaction number" (*e.g.*, case number)) from the recipient's or sub-recipient's records and an administrative assistant 15 minutes to enter the information on the application. Based on the methods and

assumptions *supra* at part IV.C.3.v, the Department assumes that a recipient, at the highest end, would submit 2,000 applications each year for new funding opportunities, supplemental funding, and non-competing continuations, among others. The mean weighted hourly wage for the paralegal and administrative assistant is \$22.66, which excludes benefits and overhead. Each recipient or sub-recipient found in violation of the rule would expend on the highest end, \$22,655 per year in labor costs at the firm level (\$22.66 per hour $\times$ 2,000 applications $\times$ 0.5 hours).⁴⁰⁰

Commenters stated that the version of this requirement in the proposed rule was redundant and duplicative. The Department agrees. The final rule and this information collection has been modified substantially to require recipients and sub-recipients to notify the Departmental components from which the recipient or sub-recipient receives Federal funds in the three years following a determination of noncompliance with Federal conscience and anti-discrimination laws and this final rule by OCR.

List of Subjects in 45 CFR Part 88

Abortion, Adult education, Advanced directives, Assisted suicide, Authority delegations, Childbirth, Civil rights, Coercion, Colleges and universities, Community facilities, Contracts, Educational facilities, Employment, Euthanasia, Family planning, Federal-State relations, Government contracts, Government employees, Grant programs-health, Grants administration, Health care, Health facilities, Health insurance, Health professions, Hospitals, Immunization, Indian Tribes, Insurance, Insurance companies, Laboratories, Manpower training programs, Maternal and child health, Medicaid, Medical and dental schools, Medical research, Medicare, Mental health programs, Mercy killing, Moral convictions, Nondiscrimination, Nursing homes, Nursing schools, Occupational safety and health, Occupational training, Physicians, Prescription drugs, Public assistance programs, Public awareness, Public health, Religious discrimination, Religious beliefs, Religious liberties, Religious nonmedical health care institutions, Reporting and recordkeeping requirements, Rights of conscience, Scholarships and fellowships, Schools, Scientists, State and local governments, Sterilization,

loaded wage rate (*i.e.*, including benefits and overhead) not employed here.

³⁹⁹ *E.g.*, 42 U.S.C. 2000d (Title VI of the Civil Rights Act of 1964); 45 CFR part 80 (HHS implementing regulations); Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 FR 47311, 47313 (Aug. 8, 2003).

⁴⁰⁰ This total differs from the burden in the RIA because a fully loaded wage that is adjusted upwards for benefits and overhead must be used.

Students, Technical assistance, Tribal Organizations.

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

PART 88—PROTECTING STATUTORY CONSCIENCE RIGHTS IN HEALTH CARE; DELEGATIONS OF AUTHORITY

Sec.

88.1 Purpose.

88.2 Definitions.

88.3 Applicable requirements and prohibitions.

88.4 Assurance and certification of compliance requirements.

88.5 Notice of rights under Federal conscience and anti-discrimination laws.

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—Model Text: Notice of Rights Under Federal Conscience and Anti-Discrimination Laws

Authority: 42 U.S.C. 300a–7 (the Church Amendments); 42 U.S.C. 238n (Coats-Snowe Amendment); the Weldon Amendment (e.g., Pub. L. 115–245, Div. B, sec. 507(d)); 42 U.S.C. 18113 (Section 1553 of the Affordable Care Act); Medicare Advantage (e.g., Pub. L. 115–245, Div. B, sec. 209); the Helms, Biden, 1978, and 1985 Amendments, 22 U.S.C. 2151b(f) (e.g., Pub. L. 116–6, Div. F, sec. 7018); 22 U.S.C. 7631(d); 29 U.S.C. 669(a)(5); 42 U.S.C. 300gg–92; 42 U.S.C. 1302(a); 42 U.S.C. 18041(a) (Section 1321 of the Affordable Care Act); 42 U.S.C. 18081 (Section 1411 of the Affordable Care Act); 42 U.S.C. 18023 (Section 1303 of the Affordable Care Act); 26 U.S.C. 5000A(d)(2); 42 U.S.C. 18031; 42 U.S.C. 280g–1(d); 42 U.S.C. 290bb–36(f); 42 U.S.C. 1315; 42 U.S.C. 1315a; 42 U.S.C. 1320a–1; 42 U.S.C. 1320c–11; 42 U.S.C. 1395cc(f); 42 U.S.C. 1395i–3; 42 U.S.C. 1395i–5; 42 U.S.C. 1395w–22(j)(3)(B); 42 U.S.C. 1395w–26; 42 U.S.C. 1395w–27; 42 U.S.C. 1395x; 42 U.S.C. 1396a; 42 U.S.C. 1396a(w)(3); 42 U.S.C. 1396f; 42 U.S.C. 1396r; 42 U.S.C. 1396s(c)(2)(B)(ii); 42 U.S.C. 1396u–2(b)(3)(B); 42 U.S.C. 1397j–1(b); 42 U.S.C. 5106i(a); 42 U.S.C. 14406; 5 U.S.C. 301; 40 U.S.C. 121(c); 42 U.S.C. 263a(f)(1)(E); 45 CFR parts 75 and 96; 48 CFR chapter 1; 48 CFR parts 300 thru 370; 2 CFR part 376.

§ 88.1 Purpose.

The purpose of this part is to provide for the implementation and enforcement of the Federal conscience and anti-discrimination laws listed in § 88.3. Such laws, for example, protect the rights of individuals, entities, and health care entities to refuse to perform, assist in the performance of, or undergo certain health care services or research activities to which they may object for religious, moral, ethical, or other reasons. Such laws also protect patients from being subjected to certain health

care or services over their conscientious objection. Consistent with their objective to protect the conscience and associated anti-discrimination rights of individuals, entities, and health care entities, the statutory provisions and the regulatory provisions contained in this part are to be interpreted and implemented broadly to effectuate their protective purposes.

§ 88.2 Definitions.

For the purposes of this part:

Assist in the performance means to take an action that has a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program or research activity undertaken by or with another person or entity. This may include counseling, referral, training, or otherwise making arrangements for the procedure or a part of a health service program or research activity, depending on whether aid is provided by such actions.

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

Discriminate or discrimination includes, as applicable to, and to the extent permitted by, the applicable statute:

(1) To withhold, reduce, exclude from, terminate, restrict, or make unavailable or deny any grant, contract, subcontract, cooperative agreement, loan, license, certification, accreditation, employment, title, or other similar instrument, position, or status;

(2) To withhold, reduce, exclude from, terminate, restrict, or make unavailable or deny any benefit or privilege or impose any penalty; or

(3) To utilize any criterion, method of administration, or site selection, including the enactment, application, or enforcement of laws, regulations, policies, or procedures directly or through contractual or other arrangements, that subjects individuals or entities protected under this part to any adverse treatment with respect to individuals, entities, or conduct protected under this part on grounds prohibited under an applicable statute encompassed by this part.

(4) Notwithstanding paragraphs (1) through (3) of this definition, an entity subject to any prohibition in this part shall not be regarded as having engaged in discrimination against a protected entity where the entity offers and the protected entity voluntarily accepts an effective accommodation for the exercise of such protected entity's protected conduct, religious beliefs, or moral convictions. In determining

whether any entity has engaged in discriminatory action with respect to any complaint or compliance review under this part, OCR will take into account the degree to which an entity had implemented policies to provide effective accommodations for the exercise of protected conduct, religious beliefs, or moral convictions under this part and whether or not the entity took any adverse action against a protected entity on the basis of protected conduct, beliefs, or convictions before the provision of any accommodation.

(5) Notwithstanding paragraphs (1) through (3) of this definition, an entity subject to any prohibition in this part may require a protected entity to inform it of objections to performing, referring for, participating in, or assisting in the performance of specific procedures, programs, research, counseling, or treatments, but only to the extent that there is a reasonable likelihood that the protected entity may be asked in good faith to perform, refer for, participate in, or assist in the performance of, any act or conduct just described. Such inquiry may only occur after the hiring of, contracting with, or awarding of a grant or benefit to a protected entity, and once per calendar year thereafter, unless supported by a persuasive justification.

(6) The taking of steps by an entity subject to prohibitions in this part to use alternate staff or methods to provide or further any objected-to conduct identified in paragraph (5) of this definition would not, by itself, constitute discrimination or a prohibited referral, if such entity does not require any additional action by, or does not take any adverse action against, the objecting protected entity (including individuals or health care entities), and if such methods do not exclude protected entities from fields of practice on the basis of their protected objections. Entities subject to prohibitions in this part may also inform the public of the availability of alternate staff or methods to provide or further the objected-to conduct, but such entity may not do so in a manner that constitutes adverse or retaliatory action against an objecting entity.

Entity means a “person,” as defined in 1 U.S.C. 1; the Department; a State, political subdivision of any State, instrumentality of any State or political subdivision thereof; any public agency, public institution, public organization, or other public entity in any State or political subdivision of any State; or, as applicable, a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).

Federal financial assistance includes:

(1) Grants and loans of Federal funds;
 (2) The grant or loan of Federal property and interests in property;
 (3) The detail of Federal personnel;
 (4) The sale or lease of, and the permission to use (on other than a casual or transient basis), Federal property or any interest in such property without consideration or at a nominal consideration, or at a consideration which is reduced for the purpose of assisting the recipient or in recognition of the public interest to be served by such sale or lease to the recipient; and

(5) Any agreement or other contract between the Federal government and a recipient that has as one of its purposes the provision of a subsidy to the recipient.

Health care entity includes:

(1) For purposes of the Coats-Snowe Amendment (42 U.S.C. 238n) and the subsections of this part implementing that law (§ 88.3(b)), an individual physician or other health care professional, including a pharmacist; health care personnel; a participant in a program of training in the health professions; an applicant for training or study in the health professions; a post-graduate physician training program; a hospital; a medical laboratory; an entity engaging in biomedical or behavioral research; a pharmacy; or any other health care provider or health care facility. As applicable, components of State or local governments may be health care entities under the Coats-Snowe Amendment; and

(2) For purposes of the Weldon Amendment (e.g., Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, and Continuing Appropriations Act, 2019, Pub. L. 115–245, Div. B., sec. 507(d), 132 Stat. 2981, 3118 (Sept. 28, 2018)), Patient Protection and Affordable Care Act section 1553 (42 U.S.C. 18113), and to sections of this part implementing those laws (§ 88.3(c) and (e)), an individual physician or other health care professional, including a pharmacist; health care personnel; a participant in a program of training in the health professions; an applicant for training or study in the health professions; a post-graduate physician training program; a hospital; a medical laboratory; an entity engaging in biomedical or behavioral research; a pharmacy; a provider-sponsored organization; a health maintenance organization; a health insurance issuer; a health insurance plan (including group or individual plans); a plan sponsor or third-party administrator; or any other kind of

health care organization, facility, or plan. As applicable, components of State or local governments may be health care entities under the Weldon Amendment and Patient Protection and Affordable Care Act section 1553.

Health service program includes the provision or administration of any health or health-related services or research activities, health benefits, health or health-related insurance coverage, health studies, or any other service related to health or wellness, whether directly; through payments, grants, contracts, or other instruments; through insurance; or otherwise.

Instrument is the means by which Federal funds are conveyed to a recipient and includes grants, cooperative agreements, contracts, grants under a contract, memoranda of understanding, loans, loan guarantees, stipends, and any other funding or employment instrument or contract.

OCR means the Office for Civil Rights of the Department of Health and Human Services.

Recipient means any State, political subdivision of any State, instrumentality of any State or political subdivision thereof, and any person or any public or private agency, institution, organization, or other entity in any State, including any successor, assign, or transferee thereof, to whom Federal financial assistance is extended directly from the Department or a component of the Department, or who otherwise receives Federal funds directly from the Department or a component of the Department, but such term does not include any ultimate beneficiary. The term may include a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).

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

State includes, in addition to the several States, the District of Columbia. For those provisions related to or relying upon the Public Health Service Act, the term “State” includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Northern Mariana Islands,

the U.S. Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands. For those provisions related to or relying upon the Social Security Act, such as Medicaid or the Children’s Health Insurance Program, the term “State” shall be defined in accordance with the definition of “State” found at 42 U.S.C. 1301.

Sub-recipient means any State, political subdivision of any State, instrumentality of any State or political subdivision thereof, or any person or any public or private agency, institution, organization, or other entity in any State, including any successor, assign, or transferee thereof, to whom there is a pass-through of Federal financial assistance or Federal funds from the Department through a recipient or another sub-recipient, but such term does not include any ultimate beneficiary. The term may include a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).

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

§ 88.3 Applicable requirements and prohibitions.

(a) *The Church Amendments, 42 U.S.C. 300a–7*—(1) *Applicability.* (i) The Department is required to comply with paragraphs (a)(2)(i) through (vii) of this section and § 88.6 of this part.

(ii) Any State or local government or subdivision thereof and any other public entity is required to comply with paragraphs (a)(2)(i) through (iii) of this section.

(iii) Any entity that receives a grant, contract, loan, or loan guarantee under the Public Health Service Act (42 U.S.C. 201 *et seq.*) after June 18, 1973, is required to comply with paragraph (a)(2)(iv) of this section and §§ 88.4 and 88.6 of this part.

(iv) Any entity that receives a grant or contract for biomedical or behavioral research under any program administered by the Secretary of Health and Human Services after July 12, 1974, is required to comply with paragraph (a)(2)(v) of this section and §§ 88.4 and 88.6 of this part.

(v) The Department and any entity that receives funds for any health

service program or research activity under any program administered by the Secretary of Health and Human Services is required to comply with paragraph (a)(2)(vi) of this section and §§ 88.4 and 88.6 of this part.

(vi) Any entity that receives, after September 29, 1979, any grant, contract, loan, loan guarantee, or interest subsidy under the Public Health Service Act or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 [42 U.S.C. 15001 *et seq.*] is required to comply with paragraph (a)(2)(vii) of this section and §§ 88.4 and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Pursuant to 42 U.S.C. 300a–7(b)(1), the receipt of a grant, contract, loan, or loan guarantee under the Public Health Service Act by any individual does not authorize entities to which this paragraph (a)(2)(i) applies to require such individual to perform or assist in the performance of any sterilization procedure or abortion if his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions.

(ii) Pursuant to 42 U.S.C. 300a–7(b)(2)(A), the receipt of a grant, contract, loan, or loan guarantee under the Public Health Service Act by any recipient does not authorize entities to which this paragraph (a)(2)(ii) applies to require such recipient to make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the recipient on the basis of religious beliefs or moral convictions.

(iii) Pursuant to 42 U.S.C. 300a–7(b)(2)(B), the receipt of a grant, contract, loan, or loan guarantee under the Public Health Service Act by any recipient does not authorize entities to which this paragraph (a)(2)(iii) applies to require such recipient to provide personnel for the performance or assistance in the performance of any sterilization procedure or abortion if the performance or assistance in the performance of such procedure or abortion by such personnel would be contrary to the religious beliefs or moral convictions of such personnel.

(iv) Pursuant to 42 U.S.C. 300a–7(c)(1), entities to which this paragraph (a)(2)(iv) applies shall not discriminate against any physician or other health care personnel in employment, promotion, termination of employment, or extension of staff or other privileges because such physician or other health care personnel performed or assisted in the performance of a lawful sterilization

procedure or abortion, because he refused to perform or assist in the performance of a lawful sterilization procedure or abortion on the grounds that his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting sterilization procedures or abortions.

(v) Pursuant to 42 U.S.C. 300a–7(c)(2), entities to which this paragraph (a)(2)(v) applies shall not discriminate against any physician or other health care personnel in employment, promotion, termination of employment, or extension of staff or other privileges because such physician or other health care personnel performed or assisted in the performance of any lawful health service or research activity, because he refused to perform or assist in the performance of any such service or activity on the grounds that his performance or assistance in the performance of such service or activity would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting any such service or activity.

(vi) Pursuant to 42 U.S.C. 300a–7(d), entities to which this paragraph (a)(2)(vi) applies shall not require any individual to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if the individual's performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions.

(vii) Pursuant to 42 U.S.C. 300a–7(e), entities to which this paragraph (a)(2)(vii) applies shall not deny admission to or otherwise discriminate against any applicant (including applicants for internships and residencies) for training or study because of the applicant's reluctance or willingness to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations contrary to, or consistent with, the applicant's religious beliefs or moral convictions.

(b) *The Coats-Snowe Amendment (Section 245 of the Public Health Service Act), 42 U.S.C. 238n—(1) Applicability.* (i) The Department is required to comply with paragraphs (b)(2)(i) through (ii) of this section and § 88.6 of this part.

(ii) Any State or local government or subdivision thereof that receives Federal

financial assistance, including Federal payments provided as reimbursement for carrying out health-related activities, is required to comply with paragraphs (b)(2)(i) through (ii) of this section and §§ 88.4 and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Pursuant to 42 U.S.C. 238n(a)(1), (2), and (3), entities to which this paragraph (b)(2)(i) applies shall not subject any health care entity to discrimination on the basis that the health care entity—

(A) Refuses to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions;

(B) Refuses to make arrangements for any of the activities specified in (b)(2)(i)(A); or

(C) Attends or attended a post-graduate physician training program or any other program of training in the health professions that does not or did not perform induced abortions or require, provide, or refer for training in the performance of induced abortions, or make arrangements for the provision of such training.

(ii) Pursuant to 42 U.S.C. 238n(b), entities to which this paragraph (b)(2)(ii) applies shall not, for the purposes of granting a legal status to a health care entity (including a license or certificate), or providing such entity with financial assistance, services, or benefits, fail to deem accredited any postgraduate physician training program that would be accredited but for the accrediting agency's reliance upon accreditation standards that require an entity to perform an induced abortion or that require an entity to require, provide, or refer for training in the performance of induced abortions or make arrangements for such training, regardless of whether such standards provide exceptions or exemptions. Entities to which this paragraph (b)(2)(ii) applies and which are involved in such matters shall formulate such regulations or other mechanisms, or enter into such agreements with accrediting agencies, as are necessary to comply with this paragraph.

(c) *Weldon Amendment (See, e.g., Pub. L. 115–245, Div. B, sec. 507(d))—*

(1) *Applicability.* (i) The Department and its programs, while operating under an appropriations act that contains the Weldon Amendment, are required to comply with paragraph (c)(2) of this section and § 88.6 of this part.

(ii) Any State or local government that receives funds under an appropriations act for the Department that contains the Weldon Amendment is required to

comply with paragraph (c)(2) of this section and §§ 88.4 and 88.6 of this part.

(2) *Prohibition.* The entities to which this paragraph (c)(2) applies shall not subject any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for, abortion.

(d) *Medicare Advantage* (See, e.g., Pub. L. 115–245, Div. B, sec. 209)—(1) *Applicability.* The Department, while operating under an appropriations act that contains a provision with respect to the Medicare Advantage program as set forth by Public Law 115–245, Div. B, sec. 209, is required to comply with paragraph (d)(2) of this section and § 88.6 of this part.

(2) *Prohibition.* The entities to which this paragraph (d)(2) applies shall not deny participation in the Medicare Advantage program to an otherwise eligible entity (including a Provider Sponsored Organization) because that entity informs the Secretary that it will not provide, pay for, provide coverage of, or provide referrals for abortions.

(e) *Section 1553 of the Affordable Care Act, 42 U.S.C. 18113*—(1) *Applicability.* (i) The Department is required to comply with paragraph (e)(2) of this section and § 88.6 of this part.

(ii) Any State or local government that receives Federal financial assistance under the Patient Protection and Affordable Care Act (or under an amendment made by the Patient Protection and Affordable Care Act) is required to comply with paragraph (e)(2) of this section and §§ 88.4 and 88.6 of this part.

(iii) Any health care provider that receives Federal financial assistance under the Patient Protection and Affordable Care Act (or under an amendment made by the Patient Protection and Affordable Care Act) is required to comply with paragraph (e)(2) of this section and §§ 88.4 and 88.6 of this part.

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

(2) *Prohibition.* The entities to which this paragraph (e)(2) applies shall not subject an individual or institutional health care entity to discrimination on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy

killing. Nothing in this paragraph shall be construed to apply to, or to affect, any limitation relating to:

(i) The withholding or withdrawing of medical treatment or medical care;

(ii) The withholding or withdrawing of nutrition or hydration;

(iii) Abortion; or

(iv) The use of an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as such item, good, benefit, or service is not also furnished for the purpose of causing, or the purpose of assisting in causing, death, for any reason.

(f) *Section 1303 of the Affordable Care Act, 42 U.S.C. 18023*—(1) *Applicability.*

(i) The Department is required to comply with paragraph (f)(2)(i) of this section and § 88.6 of this part.

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

(2) *Requirements and prohibitions.* (i) Pursuant to 42 U.S.C. 18023(b)(1)(A)(i), entities to which this paragraph (f)(2)(i) applies shall not construe anything in Title I of the Patient Protection and Affordable Care Act (or any amendment made by Title I of the Patient Protection and Affordable Care Act) to require a qualified health plan to provide coverage of abortion or abortion-related services as described in 42 U.S.C. 18023(b)(1)(B)(i) or (ii) as part of its essential health benefits for any plan year.

(ii) Pursuant to 42 U.S.C. 18023(b)(4), entities to which this paragraph (f)(2)(ii) applies shall not discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.

(g) *Section 1411 of the Affordable Care Act, 42 U.S.C. 18081*—(1)

Applicability. The Department shall comply with paragraph (g)(2) of this section and § 88.6 of this part.

(2) *Requirement.* The Department shall provide a certification documenting a religious exemption from the individual responsibility requirement and penalty under the Patient Protection and Affordable Care Act and shall coordinate with State Health Benefit Exchanges in the implementing of the certification requirements of 42 U.S.C.

18031(d)(4)(H)(ii) where applicable to:

(i) Any applicant for such a certificate for any month who provides

information demonstrating that the applicant:

(A) Is an adherent of religious tenets or teachings by reason of which he is conscientiously opposed to acceptance of the benefits of any private or public insurance which makes payments in the event of death, disability, old-age, or retirement or makes payments toward the cost of, or provides services for, medical care (including the benefits of any insurance system established by the Social Security Act), or

(B) Is an adherent of religious tenets or teachings that are not described in paragraph (g)(2)(i)(A) of this section, who relies solely on a religious method of healing, and for whom the acceptance of medical health services would be inconsistent with the religious beliefs of the individual, and the application for the certificate includes an attestation that the individual has not received medical health services during the preceding taxable year.

(1) For purposes of this paragraph (g)(2)(i)(B), “medical health services” does not include routine dental, vision and hearing services, midwifery services, vaccinations, necessary medical services provided to children, services required by law or by a third party, and such other services as the Secretary may provide in implementing section 1311(d)(4)(H) of the Patient Protection and Affordable Care Act; and

(ii) Any applicant for such a certificate for any month who provides information demonstrating that the applicant is a member of a “health care sharing ministry,” as defined in 26 U.S.C. 5000A(d)(2)(B)(ii), for the month.

(h) *Counseling and referral provisions of 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B)*—(1) *Applicability.* (i) The Department is required to comply with paragraphs (h)(2)(i) and (ii) of this section and § 88.6 of this part.

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

(2) *Requirements and prohibitions.* (i) Pursuant to 42 U.S.C. 1395w–22(j)(3)(B), entities to which this paragraph (h)(2)(i) applies shall not construe 42 U.S.C. 1395w–22(j)(3)(A) or 42 CFR 422.206(a) to require a Medicare Advantage organization to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization offering the plan:

(A) Objects to the provision of such service on moral or religious grounds, and

(B) In the manner and through the written instrumentalities such organization deems appropriate, makes

available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization adopts a change in policy regarding such a counseling or referral service.

(ii) Pursuant to 42 U.S.C. 1396u–2(b)(3)(B), entities to which this paragraph (h)(2)(ii) applies shall not construe 42 U.S.C. 1396u–2(b)(3)(A) or 42 CFR 438.102(a)(1) to require a Medicaid managed care organization to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization:

(A) Objects to the provision of such service on moral or religious grounds, and

(B) In the manner and through the written instrumentalities such organization deems appropriate, makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization adopts a change in policy regarding such a counseling or referral service.

(i) *Advance Directives*, 42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406—(1) *Applicability*. (i) The Department is required to comply with paragraph (i)(2) of this section and § 88.6 of this part with respect to the Medicare and Medicaid programs.

(ii) Any State agency that administers a Medicaid program is required to comply with paragraph (i)(2) of this section and §§ 88.4 and 88.6 of this part with respect to its Medicaid program.

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

(i) Construe 42 U.S.C. 1395cc(f) or 1396a(w)(3) to require any provider or organization, or any employee of such a provider or organization, to inform or counsel any individual regarding any right to obtain an item or service furnished for the purpose of causing, or the purpose of assisting in causing, the death of the individual, such as by assisted suicide, euthanasia, or mercy killing; or to apply to or affect any requirement with respect to a portion of an advance directive that directs the purposeful causing of, or the purposeful assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing; or

(ii) Construe 42 U.S.C. 1396a to prohibit the application of a State law which allows for an objection on the basis of conscience for any health care provider or any agent of such provider which as a matter of conscience cannot implement an advance directive.

(j) *Global Health Programs*, 22 U.S.C. 7631(d)—(1) *Applicability*. (i) The

Department is required to comply with paragraph (j)(2) of this section and § 88.6 of this part.

(ii) Any entity that is authorized by statute, regulation, or agreement to obligate Federal financial assistance under section 104A of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2), under Chapter 83 of Title 22 of the U.S. Code or under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, to the extent such Federal financial assistance is administered by the Secretary, is required to comply with paragraph (j)(2) of this section and §§ 88.4 and 88.6 of this part.

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

(i) Require an organization, including a faith-based organization, that is otherwise eligible to receive assistance under section 104A of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2), under Chapter 83 of Title 22 of the U.S. Code, or under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, to the extent such assistance is administered by the Secretary, for HIV/AIDS prevention, treatment, or care to, as a condition of such assistance:

(A) Endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or

(B) Endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection.

(ii) Discriminate against an organization, including a faith-based organization, that is otherwise eligible to receive assistance under section 104A of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2), under Chapter 83 of Title 22 of the U.S. Code, or under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, to the extent such assistance is administered by the Secretary, for HIV/AIDS prevention, treatment, or care, in the solicitation or issuance of grants, contracts, or cooperative agreements under such provisions of law for refusing to meet any requirement described in paragraph (j)(2)(i) of this section.

(k) *The Helms, Biden, 1978, and 1985 Amendments*, 22 U.S.C. 2151b(f); *see, e.g., Consolidated Appropriations Act, 2019, Public Law 116–6, Div. F, sec. 7018—(1) Applicability*. (i) The

Department is required to comply with paragraph (k)(2)(i) of this section and § 88.6 of this part.

(ii) Any entity that is authorized by statute, regulation, or agreement to obligate or expend Federal financial assistance under part I of the Foreign Assistance Act of 1961, as amended (22 U.S.C. 2151b–2), to the extent administered by the Secretary, is required to comply with paragraph (k)(2)(i) of this section and §§ 88.4 and 88.6 of this part.

(iii) Any entity that receives Federal financial assistance under part I of the Foreign Assistance Act of 1961, as amended (22 U.S.C. 2151b–2), to the extent administered by the Secretary, is required to comply with paragraph (k)(2)(ii) of this section and §§ 88.4 and 88.6 of this part.

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

(A) Permit Federal financial assistance identified in paragraph (k)(1)(ii) of this section to be used in a manner that would violate provisions in paragraphs (k)(2)(ii)(A)(1) through (5) of this section related to abortions and involuntary sterilizations.

(B) Obligate or expend Federal financial assistance under an appropriations act that contains the 1985 Amendment and identified in paragraph (k)(1)(ii) of this section for any country or organization if the President certifies that the use of these funds by any such country or organization would violate provisions in paragraphs (k)(2)(ii)(A)(1) through (5) of this section related to abortions and involuntary sterilizations.

(ii) The entities to which this paragraph (k)(2)(ii) applies shall not:

(A) Use such Federal financial assistance identified in paragraph (k)(1)(iii) of this section to:

(1) Pay for the performance of abortions as a method of family planning;

(2) Motivate or coerce any person to practice abortions;

(3) Pay for the performance of involuntary sterilizations as a method of family planning;

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

(5) Pay for any biomedical research that relates in whole or in part, to methods of, or the performance of, abortions or involuntary sterilization as a means of family planning.

(B) Obligate or expend Federal financial assistance under an appropriations act that contains the 1985 Amendment and identified in paragraph (k)(1)(iii) of this section for

any country or organization if the President certifies that the use of these funds by any such country or organization would violate provisions in paragraphs (k)(2)(ii)(A)(1) through (5) of this section related to abortions and involuntary sterilizations.

(l) *Newborn and Infant Hearing Loss Screening, 42 U.S.C. 280g-1(d)–(1) Applicability.* The Department is required to comply with paragraph (l)(2) of this section and § 88.6 of this part.

(2) *Requirement.* The Department shall not construe 42 U.S.C. 280g-1 to preempt or prohibit any State law that does not require the screening for hearing loss of children of parents who object to the screening on the grounds that it conflicts with the parents' religious beliefs.

(m) *Medical Screening, Examination, Diagnosis, Treatment, or Other Health Care or Services, 42 U.S.C. 1396f–(1) Applicability.* The Department is required to comply with paragraph (m)(2) of this section and § 88.6 of this part.

(2) *Requirements and prohibitions.* The Department shall not construe anything in 42 U.S.C. 1396 *et seq.* to require a State agency that administers a State Medicaid Plan to compel any person to undergo any medical screening, examination, diagnosis, or treatment or to accept any other health care or services provided under such plan for any purpose (other than for the purpose of discovering and preventing the spread of infection or contagious disease or for the purpose of protecting environmental health), if such person objects (or, in case such person is a child, his parent or guardian objects) thereto on religious grounds.

(n) *Occupational Illness Examinations and Tests, 29 U.S.C. 669(a)(5)–(1) Applicability.* (i) The Department is required to comply with paragraph (n)(2) of this section and § 88.6 of this part.

(ii) Any recipient of grants or contracts under 29 U.S.C. 669, to the extent administered by the Secretary, is required to comply with paragraph (n)(2) of this section and §§ 88.4 and 88.6 of this part.

(2) *Requirements.* Entities to which this paragraph (n)(2) applies shall not deem any provision of 29 U.S.C. 651 *et seq.* to authorize or require medical examination, immunization, or treatment, as provided under 29 U.S.C. 669, for those who object thereto on religious grounds, except where such is necessary for the protection of the health or safety of others.

(o) *Vaccination, 42 U.S.C. 1396s(c)(2)(B)(ii)–(1) Applicability.* (i) The Department is required to comply

with paragraph (o)(2) of this section and § 88.6 of this part.

(ii) Any State agency that administers a pediatric vaccine distribution program under 42 U.S.C. 1396s is required to comply with paragraph (o)(2) of this section and §§ 88.4 and 88.6 of this part.

(2) *Requirement.* The entities to which this paragraph (o)(2) applies shall ensure that, under any State-administered pediatric vaccine distribution program under 42 U.S.C. 1396s, the provider agreement executed by any program-registered provider, as defined under 42 U.S.C. 1396s(c)(1), includes the requirement that the program-registered provider will provide pediatric vaccines in compliance with all applicable State law relating to any religious or other exemption. Such State law may include State statutory, regulatory, or constitutional protections for conscience and religious freedom, where applicable.

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

(ii) Any State, political subdivision, public organization, private nonprofit organization, institution of higher education, or tribal organization actively involved with the State-sponsored statewide or tribal youth suicide early intervention and prevention strategy, designated by a State to develop or direct the State-sponsored Statewide youth suicide early intervention and prevention strategy under 42 U.S.C. 290bb-36 and that receives a grant or cooperative agreement thereunder, is required to comply with paragraph (p)(2)(iii) of this section and §§ 88.4 and 88.6 of this part.

(iii) Any federally recognized Indian tribe or tribal organization (as defined in the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5301 *et seq.*)) or an urban Indian organization (as defined in the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*)) that is actively involved in the development and continuation of a tribal youth suicide early intervention and prevention strategy under 42 U.S.C. 290bb-36 and that receives a grant or cooperative agreement thereunder is required to comply with paragraph (p)(2)(iii) of this section.

(iv) Any entity that receives funds under 42 U.S.C. chapter 67, subchapters I or III is required to comply with paragraphs (p)(2)(i) and (ii) of this section and §§ 88.4 and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) Entities to which this paragraph (p)(2)(i) applies shall not construe the receipt of funds under or anything in 42 U.S.C. chapter 67, subchapters I or III as establishing any Federal requirement that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of the parent or legal guardian.

(ii) Entities to which this paragraph (p)(2)(ii) applies shall not construe the receipt of funds under or anything in 42 U.S.C. chapter 67, subchapters I or III as requiring a State to find, or prohibiting a State from finding, child abuse or neglect in cases in which a parent or legal guardian relies solely or partially upon spiritual means rather than medical treatment, in accordance with the religious beliefs of the parent or legal guardian.

(iii) Entities to which this paragraph (p)(2)(iii) applies shall not construe anything in 42 U.S.C. 290bb-36 to require suicide assessment, early intervention, or treatment services for youth whose parents or legal guardians object based on the parents' or legal guardians' religious beliefs or moral objections.

(q) *Religious nonmedical health care, 42 U.S.C. 1320a-1(h), 1320c-11, 1395i-5, 1395x(e), 1395x(y)(1), 1396a(a), and 1397j-1(b)–(1) Applicability.* (i) The Department is required to comply with paragraphs (q)(2)(i) through (iv) of this section and § 88.6 of this part.

(ii) Any State agency that makes an agreement with the Secretary pursuant to 42 U.S.C. 1320a-1(b) is required to comply with paragraph (q)(2)(i) of this section and §§ 88.4 and 88.6 of this part.

(iii) Any entity receiving Federal financial assistance from participating in Medicare is required to comply with paragraphs (q)(2)(ii) of this section and §§ 88.4 and 88.6 of this part.

(iv) Any entity, including a State, receiving Federal financial assistance from participating in Medicaid, including any entity receiving Federal financial assistance through CHIP that is used to expand Medicaid, is required to comply with paragraphs (q)(2)(iii) of this section and §§ 88.4 and 88.6 of this part.

(v) Any entity, including a State or local government or subdivision thereof, receiving Federal financial assistance under subtitle B of Title XX of the Social Security Act (42 U.S.C. 1397j-1397m-5) is required to comply with paragraph (q)(2)(iv) of this section and §§ 88.4 and 88.6 of this part.

(2) *Requirements and prohibitions.* (i) The entities to which this paragraph (q)(2)(i) applies shall not apply the provisions of 42 U.S.C. 1320a-1 to a

religious nonmedical health care institution as defined in 42 U.S.C. 1395x(ss)(1).

(ii) With respect to a religious nonmedical health care institution as defined in 42 U.S.C. 1395x(ss)(1), the entities to which this paragraph (q)(2)(ii) applies shall not:

(A) Fail or refuse to make a payment under part A of subchapter XVIII of chapter 7 of Title 42 of the U.S. Code for inpatient hospital services, post-hospital extended care services, or home health services furnished to an individual by a religious nonmedical health care institution that is a hospital as defined in 42 U.S.C. 1395x(e), a skilled nursing facility as defined in 42 U.S.C. 1395x(y), or a home health agency as defined in 42 U.S.C. 1395x(aaa), respectively, if the condition under 42 U.S.C. 1395i-5(a)(2) is satisfied and an individual makes an election pursuant to 1395i-5(b) that:

(1) Such individual is conscientiously opposed to acceptance of medical care or treatment other than medical care or treatment (including medical and other health services) that is:

(i) Received involuntarily, or

(ii) Required under Federal or State law or law of a political subdivision of a State; and

(2) Acceptance of such medical treatment would be inconsistent with such individual's sincere religious beliefs, or

(B) In administering 42 U.S.C. 1395i-5 or 1395x(ss)(1):

(1) Require any patient of a religious nonmedical health care institution to undergo medical screening, examination, diagnosis, prognosis, or treatment or to accept any other medical health care service, if such patient (or legal representative of the patient) objects to such service on religious grounds, or

(2) Subject a religious nonmedical health care institution or its personnel to any medical supervision, regulation, or control, insofar as such supervision, regulation, or control would be contrary to the religious beliefs observed by the institution or such personnel, or

(C) Subject religious nonmedical health care institution to the provisions of part B of subchapter XI of Chapter 7 of Title 42 of the U.S. Code.

(iii) Pursuant to 42 U.S.C. 1396a(a), the entities to which this paragraph (q)(2)(iii) applies shall not fail or refuse to exempt a religious nonmedical health care institution from the Medicaid requirements to:

(A) Meet State standards described in 42 U.S.C. 1396a(a)(9)(A);

(B) Be evaluated under 42 U.S.C. 1396a(a)(33), on the appropriateness and quality of care and services;

(C) Undergo a regular program, under 42 U.S.C. 1396(a)(31), of independent professional review, including medical evaluation, of services in an intermediate care facility for persons with mental disabilities; and

(D) Meet the requirements of 42 U.S.C. 1396(b)(i)(4) to establish a utilization review plan consistent with, or superior to, the utilization review plan criteria under 42 U.S.C. 1395x(k) for Medicare.

(iv) Pursuant to 42 U.S.C. 1397j-1(b), the entities to which this paragraph (q)(2)(iv) applies shall not construe subtitle B of Title XX of the Social Security Act (42 U.S.C. 1397j-1397m-5) to interfere with or abridge an elder's right to practice his or her religion through reliance on prayer alone for healing when this choice:

(A) Is contemporaneously expressed, either orally or in writing, with respect to a specific illness or injury which the elder has at the time of the decision by an elder who is competent at the time of the decision;

(B) Is previously set forth in a living will, health care proxy, or other advance directive document that is validly executed and applied under State law; or

(C) May be unambiguously deduced from the elder's life history.

§ 88.4 Assurance and certification of compliance requirements.

(a) *In general*—(1) *Assurance*. Except for an application or recipient to which paragraph (c) of this section applies, every application for Federal financial assistance or Federal funds from the Department to which § 88.3 of this part applies shall, as a condition of the approval, renewal, or extension of any Federal financial assistance or Federal funds from the Department pursuant to the application, provide, contain, or be accompanied by an assurance that the applicant or recipient will comply with applicable Federal conscience and anti-discrimination laws and this part.

(2) *Certification*. Except for an application or recipient to which paragraph (c) of this section applies, every application for Federal financial assistance or Federal funds from the Department to which § 88.3 of this part applies, shall, as a condition of the approval, renewal, or extension of any Federal financial assistance or Federal funds from the Department pursuant to the application, provide, contain, or be accompanied by, a certification that the applicant or recipient will comply with

applicable Federal conscience and anti-discrimination laws and this part.

(b) *Specific requirements*—(1) *Timing*. Entities who are already recipients as of the effective date of this part or any applicants shall submit the assurance required in paragraph (a)(1) of this section and the certification required in paragraph (a)(2) of this section as a condition of any application or reapplication for funds to which this part applies, through any instrument or as a condition of an amendment or modification of the instrument that extends the term of such instrument or adds additional funds to it. Submission may be required more frequently if:

(i) The applicant or recipient fails to meet a requirement of this part, or

(ii) OCR or the relevant Department component has reason to suspect or cause to investigate the possibility of such failure.

(2) *Form and manner*. Applicants or recipients shall submit the assurance required in paragraph (a)(1) of this section and the certification required in paragraph (a)(2) of this section in the form and manner that OCR, in coordination with the relevant Department component, specifies, or shall submit them in a separate writing signed by the applicant's or recipient's officer or other person authorized to bind the applicant or recipient.

(3) *Duration of obligation*. The assurance required in paragraph (a)(1) of this section and the certification required in paragraph (a)(2) of this section will obligate the recipient for the period during which the Department extends Federal financial assistance or Federal funds from the Department to a recipient.

(4) *Compliance requirement*. Submission of an assurance or certification required under this section will not relieve a recipient of the obligation to take and complete any action necessary to come into compliance with Federal conscience and anti-discrimination laws and this part prior to, at the time of, or subsequent to, the submission of such assurance or certification.

(5) *Condition of continued receipt*. Provision of a compliant assurance and certification shall constitute a condition of continued receipt of Federal financial assistance or Federal funds from the Department and is binding upon the applicant or recipient, its successors, assigns, or transferees for the period during which such Federal financial assistance or Federal funds from the Department are provided.

(6) *Assurances and certifications in applications*. An applicant or recipient may incorporate the assurances and

certifications by reference in subsequent applications to the Department or Department component if prior assurances or certifications are initially provided in the same fiscal or calendar year, as applicable.

(7) *Enforcement of assurances and certifications.* The Department, Department components, and OCR shall have the right to seek enforcement of the assurances and certifications required in this section.

(8) *Remedies for failure to make assurances and certifications.* If an applicant or recipient fails or refuses to furnish an assurance or certification required under this section, OCR, in coordination with the relevant Department component, may effect compliance by any of the mechanisms provided in § 88.7.

(c) *Exceptions.* The following persons or entities shall not be required to comply with paragraphs (a)(1) and (2) of this section, provided that such persons or entities are not recipients of Federal financial assistance or other Federal funds from the Department through another instrument, program, or mechanism, other than those set forth in paragraphs (c)(1) through (4) of this section:

(1) A physician, as defined in 42 U.S.C. 1395x(r), physician office, pharmacist, pharmacy, or other health care practitioner participating in Part B of the Medicare program;

(2) A recipient of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration for Children and Families, the purpose of which is either solely financial assistance unrelated to health care or which is otherwise unrelated to health care provision, and which, in addition, does not involve—

(i) Medical or behavioral research;

(ii) Health care providers; or

(iii) Any significant likelihood of referral for the provision of health care;

(3) A recipient of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration on Community Living, the purpose of which is either solely financial assistance unrelated to health care or which is otherwise unrelated to health care provision, and which, in addition, does not involve—

(i) Medical or behavioral research;

(ii) Health care providers; or

(iii) Any significant likelihood of referral for the provision of health care.

(4) Indian Tribes and Tribal Organizations when contracting with the Indian Health Service under the

Indian Self-Determination and Education Assistance Act.

§ 88.5 Notice of rights under Federal conscience and anti-discrimination laws.

(a) *In general.* In investigating a complaint or conducting a compliance review, OCR will consider an entity's voluntary posting of a notice of nondiscrimination as non-dispositive evidence of compliance with the applicable substantive provisions of this part, to the extent such notices are provided according to the provisions of this section and are relevant to the particular investigation or compliance review.

(b) *Placement of the notice text.* In evaluating the Department's or a recipient's compliance with this part, OCR will take into account whether, as applicable and appropriate, the Department or recipient has provided the notice under this section:

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

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

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

(4) In applications to the Department or recipient for inclusion in the workforce or for participation in a service, benefit, or other program, including for training or study; and

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

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

(c) *Content of the notice text.* The recipient and the Department should consider using the model text provided in Appendix A for the notice, but may tailor its notice to address its particular circumstances and to more specifically address the laws that apply to it under this rule.

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

§ 88.6 Compliance requirements.

(a) *In general.* The Department and each recipient has primary responsibility to ensure that it is in compliance with Federal conscience and anti-discrimination laws and this part, and shall take steps to eliminate any violations of the Federal conscience and anti-discrimination laws and this part. If a sub-recipient is found to have violated the Federal conscience and anti-discrimination laws, the recipient from whom the sub-recipient received funds may be subject to the imposition of funding restrictions or any appropriate remedies available under this part, depending on the facts and circumstances.

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

(1) Shall be maintained for a period of three years from the date the record was created or obtained by the recipient or sub-recipient;

(2) Shall contain any information maintained by the recipient or sub-recipient that pertains to discrimination on the basis of religious belief or moral conviction, including, without limitation, any complaints; statements, policies, or notices concerning discrimination on the basis of religious belief or moral conviction; procedures for accommodating employees' or other protected individuals' religious beliefs or moral convictions; and records of requests for such religious or moral accommodation and the recipient or sub-recipient's response to such requests; and

(3) May be maintained in any form and manner that affords OCR with reasonable access to them in a timely manner.

(c) *Cooperation.* The Department, each recipient, and each sub-recipient shall cooperate with any compliance review, investigation, interview, or other part of OCR's enforcement process, which may include production of documents, participation in interviews, response to data requests, and making available of premises for inspection where relevant. Failure to cooperate may result in an OCR referral to the Department of Justice, in coordination with the Department's Office of the General Counsel, for

further enforcement in Federal court or otherwise. Each recipient or sub-recipient shall permit access by OCR during normal business hours to such of its books, records, accounts, and other sources of information, as well as its facilities, as may be pertinent to ascertain compliance with this part. Asserted considerations of privacy or confidentiality may not operate to bar OCR from evaluating or seeking to enforce compliance with this part. Information of a confidential nature obtained in connection with compliance reviews, investigations, or other enforcement activities shall not be disclosed except as required in formal enforcement proceedings or as otherwise required by law.

(d) *Reporting requirement.* If a recipient or sub-recipient is subject to a determination by OCR of noncompliance with this part, the recipient or sub-recipient must, in any application for new or renewed Federal financial assistance or Departmental funding in the three years following such determination, disclose the existence of the determination of noncompliance. This includes a requirement that recipients disclose any OCR determinations made against their sub-recipients.

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

§ 88.7 Enforcement authority.

(a) *In general.* OCR has been delegated the authority to facilitate and coordinate the Department's enforcement of the Federal conscience and anti-discrimination laws, which includes the authority to:

- (1) Receive and handle complaints;
- (2) Initiate compliance reviews;
- (3) Conduct investigations;
- (4) Coordinate compliance within the Department;
- (5) Seek voluntary resolutions of complaints;
- (6) In coordination with the relevant component or components of the Department and the Office of the General Counsel, make enforcement referrals to the Department of Justice;
- (7) In coordination with the relevant Departmental funding component, utilize existing regulations for

involuntary enforcement, such as those that apply to grants, contracts, or CMS programs; and

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

(b) *Complaints.* Any entity, whether individually, as a member of a class, on behalf of others, or on behalf of an entity, may file a complaint with OCR alleging any potential violation of Federal conscience and anti-discrimination laws or this part. OCR shall coordinate handling of complaints with the relevant Department component(s). The complaint filer is not required to be the entity whose rights under the Federal conscience and anti-discrimination laws or this part have been potentially violated.

(c) *Compliance reviews.* OCR may conduct compliance reviews or use other similar procedures as necessary to permit OCR to investigate and review the practices of the Department, Department components, recipients, and sub-recipients to determine whether they are complying with Federal conscience and anti-discrimination laws and this part. OCR may initiate a compliance review of an entity subject to this part based on information from a complaint or other source that causes OCR to suspect non-compliance by such entity with this part or the laws implemented by this part.

(d) *Investigations.* OCR shall make a prompt investigation, whenever a compliance review, report, complaint, or any other information found by OCR indicates a threatened, potential, or actual failure to comply with Federal conscience and anti-discrimination laws or this part. The investigation should include, where appropriate, a review of the pertinent practices, policies, communications, documents, compliance history, circumstances under which the possible noncompliance occurred, and other factors relevant to determining whether the Department, Department component, recipient, or sub-recipient has failed to comply. OCR shall use fact-finding methods including site visits; interviews with the complainants, Department component, recipients, sub-recipients, or third-parties; and written data or discovery requests. OCR may seek the assistance of any State agency.

(e) *Failure to respond.* Absent good cause, the failure of an entity that is subject to this part to respond to a request for information or to a data or document request within 45 days of

OCR's request shall constitute a violation of this part.

(f) *Related administrative or judicial proceeding.* Consistent with other applicable Federal laws, testimony and other evidence obtained in an investigation or compliance review conducted under this part may be used by the Department for, and offered into evidence in, any administrative or judicial proceeding related to this part.

(g) *Supervision and coordination.* If as a result of an investigation, compliance review, or other enforcement activity, OCR determines that a Department component appears to be in noncompliance with its responsibilities under Federal conscience and anti-discrimination laws or this part, OCR will undertake appropriate action with the component to assure compliance. In the event that OCR and the Department component are unable to agree on a resolution of any particular matter, the matter shall be submitted to the Secretary for resolution. OCR may from time to time request the assistance of officials of the Department in carrying out responsibilities in connection with the enforcement of Federal conscience and anti-discrimination laws and this part, including the achievement of effective coordination and maximum uniformity within the Department.

(h) *Referral to the Department of Justice.* If as a result of an investigation, compliance review, or other enforcement activity, OCR determines that a recipient or sub-recipient is not in compliance with the Federal conscience and anti-discrimination laws or this part, OCR may, in coordination with the relevant Department component and the Office of the General Counsel, make referrals to the Department of Justice, for further enforcement in Federal court or otherwise. OCR may also make referrals to the Department of Justice, in coordination with the Office of the General Counsel, concerning potential violations of 18 U.S.C. 1001 or 42 U.S.C. 300a-8 for enforcement or other appropriate action.

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

(2) If an investigation or compliance review indicates a failure to comply with Federal conscience and anti-discrimination laws or this part, OCR will so inform the relevant parties and the matter will be resolved by informal means whenever possible. Attempts to resolve matters informally shall not preclude OCR from simultaneously

pursuing any action described in paragraphs (a)(5) through (7) of this section.

(3) If OCR determines that there is a failure to comply with Federal conscience and anti-discrimination laws or this part, compliance with these laws and this part may be effected by the following actions, taken in coordination with the relevant Department component, and pursuant to statutes and regulations which govern the administration of contracts (*e.g.*, Federal Acquisition Regulation), grants (*e.g.*, 45 CFR part 75) and CMS funding arrangements (*e.g.*, the Social Security Act):

(i) Temporarily withholding Federal financial assistance or other Federal funds, in whole or in part, pending correction of the deficiency;

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

(iii) Wholly or partly suspending award activities;

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

(v) Denying or withholding, in whole or in part, new Federal financial assistance or other Federal funds from the Department administered by or through the Secretary for which an application or approval is required, including renewal or continuation of existing programs or activities or authorization of new activities;

(vi) In coordination with the Office of the General Counsel, referring the matter to the Attorney General for proceedings to enforce any rights of the United States, or obligations of the recipient or sub-recipient, under Federal law or this part; and

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

(j) *Noncompliance with § 88.4.* If a recipient of Federal financial assistance or applicant therefor fails or refuses to furnish an assurance or certification required under § 88.4 or otherwise fails or refuses to comply with a requirement imposed by or pursuant to that section, OCR, in coordination with the relevant Department component, may effect compliance by any of the remedies provided in paragraph (i) of this section. The Department shall not be required to provide assistance in such a case during the pendency of the administrative proceedings brought under such paragraph.

§ 88.8 Relationship to other laws.

Nothing in this part shall be construed to preempt any Federal, State, or local law that is equally or more protective of religious freedom and moral convictions. Nothing in this part shall be construed to narrow the meaning or application of any State or Federal law protecting free exercise of religious beliefs or moral convictions.

§ 88.9 Rule of construction.

This part shall be construed in favor of a broad protection of the free exercise of religious beliefs and moral convictions, to the maximum extent permitted by the Constitution and the terms of the Federal conscience and anti-discrimination laws.

§ 88.10 Severability.

Any provision of this part held to be invalid or unenforceable either by its terms or as applied to any entity or circumstance shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event such provision shall be severable from this part, which shall remain in full force and effect to the maximum

extent permitted by law. A severed provision shall not affect the remainder of this part or the application of the provision to other persons or entities not similarly situated or to other, dissimilar circumstances.

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

[Name of recipient, the Department, or Department component] complies with applicable Federal conscience and anti-discrimination laws prohibiting exclusion, adverse treatment, coercion, or other discrimination against individuals or entities on the basis of their religious beliefs or moral convictions. You may have the right under Federal law to decline to perform, assist in the performance of, refer for, undergo, or pay for certain health care-related treatments, research, or services (such as abortion or assisted suicide, among others) that violate your conscience, religious beliefs, or moral convictions.

If you believe that [Name of recipient, the Department, or Department component] has failed to accommodate your conscientious, religious, or moral objection, or has discriminated against you on those grounds, you can file a conscience and religious freedom complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf> or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW, Room 509F, HHH Building Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms and more information about Federal conscience and anti-discrimination laws are available at <http://www.hhs.gov/conscience>.

Dated: May 2, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019-09667 Filed 5-20-19; 8:45 am]

BILLING CODE 4153-01-P

The JS-CAND 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS
County of Santa Clara, Trust Women Seattle, Los Angeles LGBT Center, Whitman Walker Clinic, Inc. d/b/a Whitman Walker Health, et al. (See full list of plaintiffs attached.)
(b) County of Residence of First Listed Plaintiff Santa Clara County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)
See attached list of attorneys.

DEFENDANTS
U.S. Department of Health and Human Services and Alex M. Azar, II, in his official capacity as Secretary of Health and Human Services
County of Residence of First Listed Defendant n/a
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

☐ 1 U.S. Government Plaintiff ☐ 3 Federal Question (U.S. Government Not a Party)

☒ 2 U.S. Government Defendant ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

	PTF	DEF
Citizen of This State	☐ 1	☐ 1
Citizen of Another State	☐ 2	☐ 2
Citizen or Subject of a Foreign Country	☐ 3	☐ 3

	PTF	DEF
Incorporated or Principal Place of Business In This State	☐ 4	☐ 4
Incorporated and Principal Place of Business In Another State	☐ 5	☐ 5
Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment Of Veteran's Benefits 151 Medicare Act 152 Recovery of Defaulted Student Loans (Excludes Veterans) 153 Recovery of Overpayment of Veteran's Benefits 160 Stockholders' Suits 190 Other Contract 195 Contract Product Liability 196 Franchise	PERSONAL INJURY 310 Airplane 315 Airplane Product Liability 320 Assault, Libel & Slander 330 Federal Employers' Liability 340 Marine 345 Marine Product Liability 350 Motor Vehicle 355 Motor Vehicle Product Liability 360 Other Personal Injury 362 Personal Injury -Medical Malpractice CIVIL RIGHTS 440 Other Civil Rights 441 Voting 442 Employment 443 Housing/ Accommodations 445 Amer. w/Disabilities-- Employment 446 Amer. w/Disabilities--Other 448 Education	PERSONAL INJURY 365 Personal Injury -- Product Liability 367 Health Care/ Pharmaceutical Personal Injury Product Liability 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY 370 Other Fraud 371 Truth in Lending 380 Other Personal Property Damage 385 Property Damage Product Liability PRISONER PETITIONS HABEAS CORPUS 463 Alien Detainee 510 Motions to Vacate Sentence 530 General 535 Death Penalty OTHER 540 Mandamus & Other 550 Civil Rights 555 Prison Condition 560 Civil Detainee-- Conditions of Confinement	625 Drug Related Seizure of Property 21 USC § 881 690 Other LABOR 710 Fair Labor Standards Act 720 Labor/Management Relations 740 Railway Labor Act 751 Family and Medical Leave Act 790 Other Labor Litigation 791 Employee Retirement Income Security Act IMMIGRATION 462 Naturalization Application 465 Other Immigration Actions	422 Appeal 28 USC § 158 423 Withdrawal 28 USC § 157 PROPERTY RIGHTS 820 Copyrights 830 Patent 835 Patent--Abbreviated New Drug Application 840 Trademark SOCIAL SECURITY 861 HIA (1395ff) 862 Black Lung (923) 863 DIWC/DIWW (405(g)) 864 SSID Title XVI 865 RSI (405(g)) FEDERAL TAX SUITS 870 Taxes (U.S. Plaintiff or Defendant) 871 IRS--Third Party 26 USC § 7609	375 False Claims Act 376 Qui Tam (31 USC § 3729(a)) 400 State Reapportionment 410 Antitrust 430 Banks and Banking 450 Commerce 460 Deportation 470 Racketeer Influenced & Corrupt Organizations 480 Consumer Credit 490 Cable/Sat TV 850 Securities/Commodities/ Exchange 890 Other Statutory Actions 891 Agricultural Acts 893 Environmental Matters 895 Freedom of Information Act 896 Arbitration ☒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District (specify) ☐ 6 Multidistrict Litigation--Transfer ☐ 8 Multidistrict Litigation--Direct File

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
Administrative Procedure Act, 5 U.S.C. § 706(2)
Brief description of cause:
Plaintiffs seek an injunction and declaration that the regulation entitled Protecting Statutory Conscience Rights in Health Care is unlawful and unenforceable.

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, Fed. R. Civ. P. **DEMAND \$** **CHECK YES only if demanded in complaint: JURY DEMAND:** ☐ Yes ☒ No

VIII. RELATED CASE(S), IF ANY (See instructions): **JUDGE** Spero **DOCKET NUMBER** 3:19-cv-02405-JCS; 3:19-cv-02769-JCS

IX. DIVISIONAL ASSIGNMENT (Civil Local Rule 3-2)
(Place an "X" in One Box Only) ☐ SAN FRANCISCO/OAKLAND ☒ SAN JOSE ☐ EUREKA-MCKINLEYVILLE

DATE 05/28/2019 **SIGNATURE OF ATTORNEY OF RECORD** /s/ Lee Rubin

Civil Cover Sheet for *County of Santa Clara, et al, v. U.S. Department of Health and Human Services and Alex M. Azar, II*

Attachment 1

Answer to Question 1(a) - Plaintiffs

County Of Santa Clara

Trust Women Seattle

Los Angeles LGBT Center

Whitman-Walker Clinic, Inc. D/B/A Whitman-Walker Health

Bradbury-Sullivan LGBT Community Center

Center On Halsted

Hartford Gyn Center,

Mazzoni Center,

Medical Students For Choice,

AGLP: The Association Of LGBTQ+ Psychiatrists

American Association Of Physicians For Human Rights D/B/A GLMA: Health Professionals
Advancing LGBTQ Equality

Colleen McNicholas

Robert Bolan

Ward Carpenter

Sarah Henn

Randy Pumphrey

Civil Cover Sheet for *County of Santa Clara, et al, v. U.S. Department of Health and Human Services and Alex M. Azar, II*

Attachment 2

Answer to Question 1(c) - Attorneys for Plaintiffs

For Plaintiff County of Santa Clara:

James R. Williams
Office of the County Counsel,
County of Santa Clara
70 West Hedding Street, East Wing, 9th Floor
San José, CA 95110-1770
Tel: (408) 299-5900

Greta S. Hansen
Office of the County Counsel,
County of Santa Clara
70 West Hedding Street, East Wing, 9th Floor
San José, CA 95110-1770
Tel: (408) 299-5900

Laura S. Trice
Office of the County Counsel,
County of Santa Clara
70 West Hedding Street, East Wing, 9th Floor
San José, CA 95110-1770
Tel: (408) 299-5900

Mary E. Hanna-Weir
Office of the County Counsel,
County of Santa Clara
70 West Hedding Street, East Wing, 9th Floor
San José, CA 95110-1770
Tel: (408) 299-5900

Susan P. Greenberg
Office of the County Counsel,
County of Santa Clara
70 West Hedding Street, East Wing, 9th Floor
San José, CA 95110-1770
Tel: (408) 299-5900

H. Luke Edwards
Office of the County Counsel,
County of Santa Clara
70 West Hedding Street, East Wing, 9th Floor
San José, CA 95110-1770
Tel: (408) 299-5900

For Plaintiffs Other Than County of Santa Clara:

Richard Katskee
Americans United for Separation of Church and State
1310 L Street NW, Suite 200
Washington, D.C. 20005
Tel: (202) 466-3234

Kenneth D. Upton, Jr.
Americans United for Separation of Church and State
1310 L Street NW, Suite 200
Washington, D.C. 20005
Tel: (202) 466-3234

Genevieve Scott
Center for Reproductive Rights
199 Water Street, 22nd Floor
New York, NY 10038
Tel: (917) 637-3605

Rabia Muqaddam
Center for Reproductive Rights
199 Water Street, 22nd Floor
New York, NY 10038
Tel: (917) 637-3605

Christine Parker
Center for Reproductive Rights
199 Water Street, 22nd Floor
New York, NY 10038
Tel: (917) 637-3605

Jamie A. Gliksberg
Lambda Legal Defense and Education Fund, Inc.
105 West Adams, 26th Floor
Chicago, IL 60603-6208
Tel: (312) 663-4413

Camilla B. Taylor
Lambda Legal Defense and Education Fund, Inc.
105 West Adams, 26th Floor
Chicago, IL 60603-6208
Tel: (312) 663-4413

Omar Gonzalez-Pagan
Lambda Legal Defense and Education Fund, Inc.
120 Wall Street, 19th Floor
New York, NY 10005-3919
Tel: (212) 809-8585

For Plaintiffs County of Santa Clara, Trust Women Seattle, LA LGBT Center, Whitman-Walker, Bradbury-Sullivan Center, Center on Halsted, Hartford Gyn Center, Mazzoni Center, Medical Students for Choice, AGLP, GLMA, Ward Carpenter, Sarah Henn and Randy Pumphrey:

Lee H. Rubin
Mayer Brown LLP
Two Palo Alto Square, Suite 300
3000 El Camino Real
Palo Alto, CA 94306-2112
Tel: (650) 331-2000

Miriam R. Nemetz
Mayer Brown LLP
1999 K Street, N.W.
Washington, D.C. 20006-1101
Tel: (202) 263-3000

Nicole Saharsky
Mayer Brown LLP
1999 K Street, N.W.
Washington, D.C. 20006-1101
Tel: (202) 263-3000

XAVIER BECERRA
Attorney General of California
MICHAEL L. NEWMAN
Senior Assistant Attorney General
KATHLEEN BOERGERS, State Bar number 213530
Supervising Deputy Attorney General
NELI PALMA
STEPHANIE YU
KARLI EISENBERG
Deputy Attorneys General
1515 Clay Street, 20th Floor
P.O. Box 70550
Oakland, CA 94612-0550
Telephone: 510-879-0011
Fax: 510-622-2270
E-mail: Kathleen.Boergers@doj.ca.gov
*Attorneys for State of California, by and through
Attorney General Xavier Becerra*

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

**CITY AND COUNTY OF SAN
FRANCISCO,**

Plaintiff,

v.

**ALEX AZAR, in his OFFICIAL
CAPACITY as SECRETARY of the U.S.
DEPARTMENT of HEALTH & HUMAN
SERVICES; ROGER SEVERINO,
Director, Office for Civil Rights,
Department of Health and Human Services;
U.S. DEPARTMENT of HEALTH &
HUMAN SERVICES; and DOES 1-25,**

Defendants.

3:19-cv-2405-JCS

CERTIFICATE OF SERVICE

[N. D. CAL. CIVIL L.R. 3-12 & 7-11]

CERTIFICATE OF SERVICE

Case Name: State of California v Azar et al No. 3:19-cv-02769

I hereby certify that on June 3, 2019, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

CALIFORNIA'S ADMINISTRATIVE MOTION TO CONSIDER WHETHER CASES SHOULD BE RELATED

[PROPOSED] ORDER IN SUPPORT OF CALIFORNIA'S ADMINISTRATIVE MOTION TO CONSIDER WHETHER CASES SHOULD BE RELATED

DECLARATION OF KATHLEEN BOERGERS IN SUPPORT OF CALIFORNIA'S ADMINISTRATIVE MOTION TO CONSIDER WHETHER CASES SHOULD BE RELATED

I certify that **all** participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct and that this declaration was executed on June 3, 2019, at Oakland, California.

Kelinda Crenshaw
Declarant

/s/ Kelinda Crenshaw
Signature