Nos. 19-4254(L), 20-31, 20-32, 20-41

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

STATE OF NEW YORK; CITY OF NEW YORK; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF OREGON; COMMONWEALTH OF PENNSYLVANIA; STATE OF RHODE ISLAND; STATE OF VERMONT; COMMONWEALTH OF VIRGINIA; STATE OF WISCONSIN; CITY OF CHICAGO; AND COOK COUNTY, ILLINOIS,
Plaintiffs-Appellees,

(Caption continued on inside cover)

On Appeal from the United States District Court
for the Southern District of New York

JOINT APPENDIX VOLUME VI OF X

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PLANNED PARENTHOOD FEDERATION OF AMERICA, INC.; PLANNED PARENTHOOD OF NORTHERN NEW ENGLAND, INC.; NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION; AND PUBLIC HEALTH SOLUTIONS, INC.

Consolidated-Plaintiffs-Appellees,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR, II, in his official capacity as Secretary of the United States Department of Health and Human Service; AND UNITED STATES OF AMERICA,

Defendants-Appellants,

DR. REGINA FROST AND CHRISTIAN MEDICAL AND DENTAL ASSOCIATIONS,

Intervenors-Defendants-Appellants,

ROGER T. SEVERINO, in his official capacity as Director, Office for Civil Rights, United States Department of Health and Human Services; AND OFFICE FOR CIVIL RIGHTS, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Consolidated-Defendants-Appellants.

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, *et al.* Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	No. 1:19-cv-04676-PAE (rel. 1:19-cv-05433-PAE; 1:19-cv-05435-PAE) **DEFENDANTS' CONSOLIDATED MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, MOTION FOR SUMMARY JUDGMENT, AND IN OPPOSITION TO PLAINTIFFS' MOTIONS FOR PRELIMINARY INJUNCTION**
PLANNED PARENTHOOD FEDERATION OF AMERICA, INC.; and PLANNED PARENTHOOD OF NORTHERN NEW ENGLAND, INC., Plaintiffs, v. ALEX M. AZAR II, in his official capacity as Secretary, United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROGER SEVERINO, in his official capacity as Director, Office for Civil Rights, United States Department of Health and Human Services; and OFFICE FOR CIVIL RIGHTS, United States Department of Health and Human Services, Defendants.	No. 1:19-cv-05433-PAE (rel. 1:19-cv-0476-PAE; 1:19-cv-05435-PAE)

NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION; and PUBLIC HEALTH SOLUTIONS, Plaintiffs, v. ALEX M. AZAR II, in his official capacity as Secretary of the U.S. Department of Health and Human Services; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROGER SEVERINO, in his official capacity as Director of the Office for Civil Rights of the U.S. Department of Health and Human Services; OFFICE FOR CIVIL RIGHTS of the U.S. Department of Health and Human Services, Defendants.	No. 1:19-cv-05435-PAE (rel. 1:19-cv-0476-PAE; 1:19-cv-05433-PAE)

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INTRODUCTION

Since the beginning of this nation, the United States has recognized the importance of and provided accommodations to protect conscientious objectors and to prevent the moral harm that results when a person is coerced to take an action that the person believes is wrong. This case concerns several conscience accommodations that Congress enacted in the health care arena. Collectively, these Federal Conscience Statutes protect individuals and entities with religious, moral, or other objections to providing (or, in some cases, providing coverage for) certain services in government provided or government-funded health care programs. To name one such provision, the Church Amendments bar the recipients of specific federal funds from, for example, firing a nurse because he or she declines to participate in an abortion for religious or moral reasons. 42 U.S.C. § 300a-7. Other Federal Conscience Statutes relate to different health care services, such as assisted suicide, and cover additional health care entities, such as insurers.

The Federal Conscience Statutes work by placing conditions on federal funding—those who accept the funds voluntarily accept the anti-discrimination provisions. Plaintiffs in this case are government and private entities that have accepted and plan to continue accepting federal funds subject to the Federal Conscience Statutes.[1] But Plaintiffs apparently now object to the accompanying federal conditions. Of course, it is completely routine and unobjectionable for the federal government to encourage favored conduct through conditions on federal funding—indeed, it is so routine and unobjectionable that Plaintiffs here do not challenge a single one of the Federal Conscience Statutes. Instead, Plaintiffs bring a collateral challenge to a recent regulation issued by

[1] In the case of the Planned Parenthood Federation of America, Inc., its member-affiliates have accepted federal funds subject to the Federal Conscience Statutes. *Planned Parenthood Federation of America, Inc. v. Azar*, Compl. ¶ 22., ECF No. 1, Case No. 19-cv-5433.

the Department of Health and Human Services (HHS), in which the agency describes its process for enforcing the Federal Conscience Statutes as to federal funds that HHS administers. Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 84 Fed. Reg. 23,170 (May 21, 2019) (the Rule). The Rule provides clarifying definitions and explains how HHS will take enforcement action, but the Rule is not the source of HHS's enforcement power—the Federal Conscience Statutes themselves obligate and compel HHS to meet the Statutes' conditions in disbursing HHS funding. Plaintiffs' challenge to the Rule is therefore misplaced. It is Congress—not HHS—that has made the policy determination to protect health care entities against government or government-funded discrimination.

Even if that were not the case, Plaintiffs' challenge fails on the merits.

First, Plaintiffs' cataclysmic predictions about the potential loss of all of their federal health care funding are not ripe. Before Plaintiffs' fears could possibly to come to pass, multiple events would have to occur. Plaintiffs would need to discriminate against a health care entity in violation of a Federal Conscience Statute as implemented by the Rule; HHS would need to take enforcement action against Plaintiffs pursuant to the mechanisms laid out in the Rule; Plaintiffs' attempts to resolve the dispute through formal or informal means, including any procedures provided for by HHS's grants and contracts regulations, must fail; HHS would then need to withhold at least some funding from Plaintiffs; and Plaintiffs would then have to exhaust their administrative appeals. This highly speculative chain of events has not occurred. The Court thus lacks a concrete setting and important factual information to resolve Plaintiffs' claims, such as the amount of federal funding that Plaintiffs stand to lose and the interaction between any applicable state statutes, the Rule, and the Federal Conscience Statutes.

Second, the Rule is entirely consistent with the Administrative Procedure Act (APA). The Rule does not change any of the substantive requirements of the Federal Conscience Statutes but simply clarifies HHS's enforcement process. HHS is acting squarely within its statutory authority to implement the conditions that Congress placed on federal funding. The definitions provided in the Rule, moreover, are consistent with the Federal Conscience Statutes. And the Rule is neither arbitrary nor capricious, because HHS thoroughly considered all of the concerns presented in comments.

Third, the Rule comports with the Constitution. Plaintiffs' constitutional claims are facial, and therefore to succeed Plaintiffs must show that the Rule is invalid in all its applications—a difficult task given that Plaintiffs' claims rely on a series of outlandish hypotheticals about the results of specific violations of the Federal Conscience Statutes, as well as uninitiated and speculative enforcement actions by HHS. The Federal Conscience Statutes, which Plaintiffs notably do not challenge, offer recipients a clear and simple deal: federal funding in exchange for non-discrimination. This offer is well within the bounds of the Spending Clause. If the Statutes themselves do not violate the Spending Clause, then a rule faithfully implementing them also does not. Furthermore, it is well established that when the government acts to preserve neutrality in the face of religious differences, it does not "establish" or prefer religion. Here, the Federal Conscience Statutes, and the Rule that implements them, simply ensure that the targeted federal funds are not used to disadvantage individuals or entities on the basis of objections to certain health care activities, some of which may be rooted in religion. The Rule is also far from unconstitutionally vague; its requirements are clear, and—in practice—any funding recipient can seek additional information from HHS if there is any uncertainty. Nor does the Rule interfere with patients' ability to access abortion services in any way.

Plaintiffs are welcome to structure their own health care systems in the lawful manner of their choice—the Federal Conscience Statutes and the Rule are not universal requirements binding on the world. But the Statutes and Rule do require that, if Plaintiffs accept federal funds, they must extend the accompanying tolerance and accommodation to objecting individuals and health care entities. These conditions are longstanding. If Plaintiffs are unwilling to afford such tolerance to protected parties, or have become unwilling, then they have the straightforward remedy of no longer accepting the conditioned federal funds. What Plaintiffs may *not* do is accept the benefit of their bargain, and then balk at fulfilling their anti-discrimination obligations.

The Court should dismiss this case or, in the alternative, grant summary judgment to Defendants and deny Plaintiffs' motions for a preliminary injunction.

LEGAL AND FACTUAL BACKGROUND

I. Statutory History of Relevant Conscience Protections

Congress has long acted to protect the rights of individuals and entities to maintain the free exercise of their religious, moral, and ethical beliefs in providing government-funded health care. The Rule gives effect to various conscience protection provisions put in place by Congress—known collectively as the Federal Conscience Statutes. The four key laws addressed by the Rule, 84 Fed. Reg. 23,170, and discussed below, are (1) the Church Amendments (42 U.S.C. § 300a-7); (2) the Coats-Snowe Amendment (42 U.S.C. § 238n(a)); (3) the Weldon Amendment (*see, e.g.*, Departments of Defense and Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019, Div. B., sec. 507(d), Pub. L. No. 115-245, 132 Stat. 2981, 3118 (Sept. 28, 2018)); and (4) conscience protection provisions in the Patient Protection and Affordable Care Act (*i.e.*, 42 U.S.C. § 18113; 42 U.S.C. § 14406(1); 26 U.S.C. § 5000A; 42 U.S.C.

§ 18081; 42 U.S.C. § 18023(b)(1)(A) and (b)(4)).[2]

A. The Church Amendments

Beginning in the 1970s, Congress enacted express conscience protections related to abortion, sterilization, and other health services. Today, the Church Amendments consist of five provisions, codified at 42 U.S.C. § 300a-7. The Church Amendments protect those who hold religious beliefs or moral convictions regarding sterilization procedures, abortions, or health service or research activities from discrimination by entities that receive certain federal funds, and in health service programs and research activities funded by HHS. The Church Amendments contain provisions explicitly protecting the rights of both individuals and entities. 42 U.S.C. § 300a-7.

The Church Amendments collectively protect individuals' rights to be free from discrimination and the threat of losing their livelihood, or in the case of entities, their funding. *See generally id.* They also prohibit entities receiving federal funding from discriminating in

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[2] Other statutes implemented by the Rule include: 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 Health and Human Services (Secretary) (22 U.S.C. § 7631(d)); conscience protections attached to federal funding regarding abortion and involuntarily sterilization, to the extent such funding is administered by the Secretary, (22 U.S.C. § 2151b(f), *see, e.g.*, the Consolidated Appropriations Act, 2019, Pub. L. No. 116-6, Div. F, sec. 7018, 133 Stat. 13, 307 (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)).

employment decisions based on an individual's performance (or assistance in the performance) of a lawful abortion or sterilization procedure, or health service or research activity, his or her refusal to perform (or assist in the performance of) such procedures or activities, or based on an individual's religious beliefs or moral convictions about such procedures more generally. *Id*. Although the statute codifying the Church Amendments does not define its terms, parts of it apply explicitly to both the "performance" of such procedures or activities and "assist[ing] in the performance of" such procedures or activities. 42 U.S.C. § 300a-7(b)(1), (b)(2), (c)(1)(B), (c)(2)(B), (d), (e).

B. The Coats-Snowe Amendment

In 1996, a bi-partisan Congress enacted section 245 of the Public Health Service Act, known as the Coats-Snowe Amendment, which applies nondiscrimination requirements to the federal government and to certain State and local governments. 42 U.S.C. § 238n. The eponymous sponsor of the statute, Senator Olympia Snowe, described her goal to "protect those institutions and those individuals who do not want to get involved in the performance or training of abortion when it is contrary to their beliefs" while still maintaining adequate medical training standards for women's gynecological care. Balance Budget Downpayment Act, II, 142 Cong. Rec. S2268. (Statement of Sen. Snowe) (Mar. 19, 1996).

Specifically, the Coats-Snowe Amendment prohibits the federal government and any State or local government that receives federal financial assistance from discriminating against a health care entity that, among other things, refuses to perform induced abortions; to provide, receive, or require training on performing induced abortions; or to provide referrals or make arrangements for such activities. 42 U.S.C. § 238 n(c)(1). The Coats-Snowe Amendment defines the term "health care entity" as *including* (and, therefore, not being 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). The Coats-Snowe Amendment also applies to accreditation of postgraduate physician training programs. It provides that federal, State, and local governments 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 the accrediting agency provides exceptions or exemptions. *Id.* § 238n(b)(1).

C. The Weldon Amendment

Since 2004, Congress has also included nondiscrimination protections, referred to as the Weldon Amendment, in every appropriation bill for the Departments of Labor, Health and Human Services, and Education. *See, e.g.*, Consolidated Appropriations Act, 2005, Pub. L. No. 108-447, Title V, § 508(d)(1)–(2), 118 Stat. 2809, 3163 (2004); Pub. L. No. 115-245, Div. B., sec. 507(d), 132 Stat. at 3118. The Weldon Amendment provides, in pertinent part, that "[n]one of the funds made available in this Act may be made available to a federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions." *Id*. The Weldon Amendment's scope and definitions are broad, defining the term "health care entity" as "includ[ing] 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*. The Weldon Amendment is a restriction on HHS's use of funds, and thus, HHS must abide by the Weldon Amendment in its use and distribution of funds, through grant programs or otherwise.

D. Conscience Protections in the Patient Protection and Affordable Care Act

Congress separately included conscience protections in the Patient Protection and Affordable Care Act (ACA), including in sections 1553, 1303, and 1411.

Section 1553 of the ACA provides that the federal government, and any State or local government or health care provider that receives federal financial assistance under the ACA, or any health plan created under the ACA

> may not subject an individual or institutional health care entity to discrimination on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.

42 U.S.C. § 18113. In Section 1553, Congress again defined the term "health care entity" broadly to "include [] an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan." *Id.* Section 1553 also specifically designates HHS's Office for Civil Rights (OCR) to receive complaints of discrimination based on an entity's refusal to cause, or assist in the causing of, the death of an individual. *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)(i). 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. *See id.* § 18023(b)(4). The ACA also clarified that nothing in the act is to 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." *Id.*

§ 18023(c)(2)(A)(i)–(iii).

Section 1411 designates HHS as the agency responsible for issuing certifications to individuals who are entitled to an exemption from the individual responsibility requirement imposed under section 5000A of the Internal Revenue Code, including when such individuals are exempt based on a hardship (such as the inability to secure affordable coverage without abortion), are members of an exempt religious organization or division, or participate in a "health care sharing ministry[.]" 42 U.S.C. § 18081(b)(5)(A); *see also* 26 U.S.C. § 5000A(d)(2).

II. Unchallenged Rules that Require Compliance with the Federal Conscience Statutes

HHS has issued several rules, in addition to the challenged Rule, that require recipients of federal funds to comply with federal law, including the Federal Conscience Statutes. For example, HHS promulgated the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (UAR), which impose consistent and enforceable requirements for governed recipients. *See* 79 Fed. Reg. 75,889 (Dec. 19, 2014). These requirements are broad-ranging, and include records retention and management, property, and procurement standards, fiscal and program management standards, and importantly for this litigation, statutory and national policy requirements and remedies for noncompliance. The UAR states, "The Federal awarding agency must manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented *in full accordance with U.S. statutory and public policy requirements*: Including, but not limited to . . . prohibiting discrimination." 45 C.F.R. § 75.300 (emphasis added). It also lists remedies for noncompliance:

> If a non–Federal entity fails to comply with *Federal statutes, regulations, or the terms and conditions of a Federal award*, the HHS awarding agency or pass-through entity may impose additional conditions, as described in § 75.207. If the HHS awarding agency or pass-through entity determines that noncompliance cannot be remedied by imposing additional conditions, the HHS awarding agency or pass-through entity may take one or more of the following actions, as appropriate in the circumstances:

> (a) Temporarily withhold cash payments pending correction of the deficiency by the non–Federal entity or more severe enforcement action by the HHS awarding agency or pass-through entity.
>
> (b) Disallow (that is, deny both use of funds and any applicable matching credit for) all or part of the cost of the activity or action not in compliance.
>
> (c) Wholly or partly suspend (suspension of award activities) or terminate the Federal award.
>
> (d) Initiate suspension or debarment proceedings as authorized under 2 CFR part 180 and HHS awarding agency regulations at 2 CFR. part 376 (or in the case of a pass-through entity, recommend such a proceeding be initiated by a HHS awarding agency).
>
> (e) Withhold further Federal awards for the project or program.
>
> (f) Take other remedies that may be legally available.

45 C.F.R. § 75.371 (emphasis added). The UAR also describes how HHS may terminate a federal award. *See* 45 C.F.R. §§ 75.372–75.375. And last, the UAR sets forth standards for auditing nonfederal entities expending federal awards. *See* 45 C.F.R. §§ 75.501–75.520.

The Federal Acquisition Regulations (FARs) allow the government to enforce contractor compliance with federal law. The FARs apply to all acquisitions, which are defined, in part, as the acquiring by contract with appropriated funds of supplies or services (including construction) by and for the use of the federal government through purchase or lease. 48 C.F.R. § 2.101. The FARs provide for the inclusion of a contract clause, specifically for the purchase of commercial items, which provides that a "Contractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations applicable to its performance under this contract." 48 C.F.R. Pt. 52.212-4(q). The FARs also require inclusion of a clause in contracts that requires contractors to have a Contractor Code of Ethics and Conduct to promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law. 48 C.F.R. Pt. 52.203-13.

There are other examples wherein the FARs require compliance with federal law. Pursuant to Executive Order 11246, the FARs require in contracts of certain size, the insertion of a clause prohibiting discrimination against any employee or applicant for employment because of race, color, religion, sex, sexual orientation, gender identity, or national origin. 48 C.F.R. Pt. 52.222-36. The FARs provide a variety of mechanisms that may be used to enforce such contract provisions. 48 C.F.R. Pt. 49.

HHS has also issued its own acquisition regulation, the HHS Acquisition Regulations (HHSAR), 48 C.F.R. Ch. 3, pursuant to 48 C.F.R. § 1.103. The HHSAR sets forth specific clauses that require contractors to comply with aspects of federal law. The HHSAR additionally includes a nondiscrimination clause for conscience relating to receiving assistance under section 104A of the Foreign Assistance Act of 1961, the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, or any amendment to the foregoing Acts for HIV/AIDS prevention, treatment, or care, 48 C.F.R. Chapter 3, clause 352.270-9.

III. HHS Conscience Protection Regulations

A. 2008 and 2011 HHS Conscience Protection Regulations

In 2008, HHS issued regulations clarifying the applicability of the Church, Coats-Snowe, and Weldon Amendments and designating OCR to receive complaints and coordinate with the applicable HHS funding component to enforce the Federal Conscience Statutes. *See* 45 C.F.R. § 88 *et seq.* (2008 Rule); Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 78,072 (Dec. 19, 2008). The 2008 Rule recognized (1) the inconsistent awareness of these statutory protections among federally funded recipients and protected persons and entities, and (2)

the need for greater enforcement mechanisms to ensure that HHS funds do not support morally coercive or discriminatory policies or practices in violation of the Federal Conscience Statutes. 73 Fed. Reg. at 78,078–81.

In 2009, however, HHS proposed to rescind the 2008 Rule. *See* Rescission of the Regulation Entitled "Ensuing That Department of Health and 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). HHS explained that certain comments submitted during the 2008 rulemaking raised a number of questions warranting further review to ensure that the Rule was consistent with the new administration's priorities. *Id.* at 10,209. HHS solicited comments to reevaluate the necessity for regulations implementing the Church, Weldon, and Coates-Snowe Amendments. *Id.*

On February 23, 2011, HHS rescinded the 2008 Rule in part and issued a new rule with a more limited scope and enforcement mechanism. Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968 (2011 Rule). The preamble to the 2011 Rule expressed HHS's support for conscience protections for health care providers and indicated the need for enforcement of the Federal Conscience Statutes. *See, e.g.*, *id.* at 9968–69. Nevertheless, the 2011 Rule created ambiguity regarding OCR's enforcement tools and processes and removed the definitions of key statutory terms. *Id.* HHS ultimately concluded that the 2011 measures created confusion over the requirements and application of the Federal Conscience Statutes. Notice of Proposed Rulemaking (NPRM), Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3888 (Jan. 26, 2018).

B. Notice of Proposed Rulemaking

On January 26, 2018, HHS published a NPRM in the Federal Register to consolidate, expand, and revise earlier regulations, in order to implement properly the Federal Conscience

Statutes in programs funded by HHS. *See* 83 Fed. Reg. 3880. HHS's stated goals were to (1) "effectively and comprehensively enforce Federal health care conscience and associated anti-discrimination laws[,]" (2) grant OCR overall enforcement responsibility to ensure compliance with these federal laws; and (3) clear up confusion caused by certain OCR sub-regulatory guidance. *Id.* at 3881, 3890. Following a sixty-day comment period, HHS analyzed and carefully considered all comments on the NPRM, and made appropriate modifications before finalizing the rule. *See* 84 Fed. Reg. at 23,180.

C. Final Rule

HHS published the Final Rule on May 21, 2019. The Rule affirms the federal nondiscrimination protections for individuals, health care providers, and health care entities with objections, including religious or moral objections, to providing, participating in, paying for, or referring for certain health care services, and the Rule provides procedures for the effective enforcement of those protections. Therefore, the Rule provides greater specificity concerning what the Federal Conscience Statutes require and ensures that governments and government-funded entities do not unlawfully discriminate against individuals, health care providers, or health care entities.

In promulgating the Rule, the "Department [] concluded that there [wa]s a significant need to amend the 2011 Rule to ensure knowledge, compliance, and enforcement of the Federal health care conscience and associated anti-discrimination laws." NPRM, 83 Fed. Reg. at 3887. For example, the 2011 Rule was inadequate because it covered only three conscience statutes rather than the full range of Federal Conscience Statutes to which the Rule gives effect. The Rule clarifies the requirements of the Federal Conscience Statutes according to their particular terms, addresses the inadequate enforcement of conscience rights under existing federal laws, and educates individuals and entities who presently lack knowledge of their statutory and civil rights or

obligations under HHS-funded or administered programs. 84 Fed. Reg. at 23,175–79.

The Rule has five principal provisions.

First, the Rule sets forth, in a single place, the various statutory conscience protections that apply to HHS-funded health programs. *See* 45 C.F.R. § 88.

Second, it defines various terms in the Federal Conscience Statutes in a way that implements the plain text and spirit of those Statutes and fully protects religious and moral conscience objections. Among the statutory terms defined in the Rule are "assist in the performance," "discriminate or discrimination," "health care entity," and "referral or refer for." *See* 45 C.F.R. § 88.2. Other than "health care entity," Congress did not define these terms in the relevant statutes. HHS thus defined these statutory terms to clarify their scope and to provide adequate enforcement notice to covered entities.

Third, the Rule requires recipients of federal funds to provide assurances and certifications of compliance with these conscience requirements. 45 C.F.R. § 88.4. Written assurances and certifications of compliance with the Federal Conscience Statutes must be submitted during the application and reapplication processes associated with receiving federal financial assistance or federal assistance. *Id.* Entities that are already receiving such assistance as of the effective date of the Rule are not required to submit an assurance or certification until they reapply for such assistance, alter the terms of existing assistance, or apply for new lines of federal assistance. *Id.* OCR may require additional assurances and certifications if OCR or HHS has reason to suspect noncompliance with the Federal Conscience Statutes. *Id.*

Fourth, the Rule establishes enforcement tools to protect conscience rights. 45 C.F.R. § 88.7. OCR will conduct outreach, provide technical assistance, initiate compliance reviews, conduct investigations, and seek voluntary resolutions, to more effectively address violations and

resolve complaints. *Id.* Where voluntary resolutions are not possible, OCR will supervise and coordinate compliance using existing and longstanding procedures to enforce conditions on grants, contracts, and other funding instruments. *Id*. (citing, *e.g.*, the FAR and 45 C.F.R. Pt. 75). To ensure that recipients of HHS funds comply with their legal obligations, as HHS does with other civil rights laws within its purview, HHS will require certain funding recipients (and sub-recipients) to maintain records and cooperate with OCR's investigations, reviews, or enforcement actions. *Id.*; NPRM, 83 Fed. Reg. 3881.

Fifth, the Rule incentivizes recipients and sub-recipients to post a notice summarizing the Federal Conscience Statutes on its website, in employee materials or student handbooks, and/or another prominent location in the workplace by favorably considering any such posting as evidence of compliance. *See* 45 C.F.R. § 88.5.

The Rule also includes a severability provision. It states that, if any part of the Rule is held to be invalid or unenforceable, it shall be severable from the remainder of the Rule, which shall remain in full force and effect to the maximum extent permitted by law. *See* 45 C.F.R. § 88.10.

IV. This Litigation

On May 21, 2019, New York, along with eighteen other states, the District of Columbia, the City of New York, the City of Chicago, and Cook County Illinois (collectively, New York) filed a complaint challenging the Rule under the APA and the Constitution. *See* Compl., ECF No. 1. The Planned Parenthood Federation of America, Inc. and Planned Parenthood of Northern New England, Inc. (together, Planned Parenthood) filed suit on June 11, 2019, asserting substantially similar claims. *See Planned Parenthood Federation of America, Inc. v. Azar*, No. 1:19-cv-05433-PAE, Compl., ECF No. 1. The National Family Planning and Reproductive Health Association and Public Health Solutions (together, NFPRHA) also filed suit on June 11, 2019, also raising substantially similar claims. *See NFPRHA v. Azar*, No. 1:19-cv-05435-PAE, Compl., ECF

No. 1. The Court consolidated the three cases on June 26, 2019. *See* Order, ECF No. 70.

On June 14, 2019, New York moved for a preliminary injunction to block implementation of the Rule. *See* New York Mot. Prelim, Inj., ECF No. 45 (NY Mem.). Planned Parenthood and NPFRHA each moved for a preliminary injunction on June 17, 2019, *see Planned Parenthood Federation of America, Inc. v. Azar*, No. 1:19-cv-05433-PAE, Mot. Prelim. Inj., ECF No. 19; *see NFPRHA v. Azar*, No. 1:19-cv-05435-PAE, Mot. Prelim. Inj., ECF No. 26 (NFPRHA Mem.), and filed a joint memorandum of law in support of their motions, *see Planned Parenthood Federation of Am., Inc. v. Azar*, No. 1:19-cv-05433-PAE, Joint Mem. Law, ECF No. 20 (PP Mem.). On July 1, 2019, the Court granted the parties' stipulated request to postpone the effective date of the Rule until November 22, 2019. ECF No. 90. Pursuant to the Court's order, ECF No. 121, Defendants now move to dismiss these cases or, in the alternative, for summary judgment and oppose Plaintiffs' motions for a preliminary injunction.

ARGUMENT

Plaintiffs'' claims fail on the merits, and thus, the Court should dismiss these cases or enter summary judgment for Defendants. Because the Court can dispose of the cases on the merits, it need not resolve Plaintiffs' motions for a preliminary injunction. But, if it does, those motions should be denied because Plaintiffs' claims lack merit and the remaining preliminary injunction factors weigh in favor of Defendants.

I. Legal Standard

Defendants move to dismiss Plaintiffs' claims in their entirety under Rule 12(b)(1) and Rule 12(b)(6) of the Federal Rules of Civil Procedure. A case may properly be dismissed for lack of subject matter jurisdiction "when the district court lacks the statutory or constitutional power to adjudicate it." *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). A plaintiff asserting subject matter jurisdiction has the burden of proving that it exists. *See id*. Under Rule 12(b)(6), a

court should grant a motion to dismiss if there are not "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Although factual allegations are viewed in the light most favorable to the plaintiff, the complaint must show "more than a sheer possibility that a defendant has acted unlawfully"; "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp.*, 550 U.S. at 570). Furthermore, Plaintiffs raise only facial challenges to the Rule, which are "the most difficult challenge[s] to mount successfully[.]" *United States v. Salerno,* 481 U.S. 739, 745 (1987). To prevail, Plaintiffs must "establish that no set of circumstances exists under which the [Rule] would be valid." *Copeland v. Vance*, 893 F.3d 101, 110 (2d Cir. 2018), *cert. denied*, --- S. Ct. ----, 2019 WL 234936 (U.S. June 17, 2019) (quoting *Salerno*, 481 U.S. at 745).

In the alternative, Defendants ask that the Court enter summary judgment in their favor. Summary judgment is appropriate if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). For claims brought under the APA, a motion for summary judgment is the appropriate vehicle for summary disposition of the case with one significant caveat: "the district judge sits as an appellate tribunal, and the entire case on review is a question of law." *R.F.M. v. Nielsen*, 365 F. Supp. 3d 350, 360 (S.D.N.Y. 2019) (quoting *Ass'n of Proprietary Colls. v. Duncan*, 107 F. Supp. 3d 332, 344 (S.D.N.Y. 2015)).

Under the APA, an agency's decision must be upheld unless arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. *See* 5 U.S.C. § 706(2)(A). Under this deferential standard, the agency's decision is presumed valid, and the Court considers only whether it "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). An agency's

decision may be deemed arbitrary and capricious only in circumstances where the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency[,]" or its decision "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The Court may not "substitute its judgment for that of the agency." *Id*.

Because cross-dispositive motions will be before the Court, there should be no need to address Plaintiffs' motion for a preliminary injunction. A preliminary injunction is "an extraordinary and drastic remedy" that should not be granted unless "the movant carries the burden of persuasion by a clear showing." *Uppal v. N.Y. State Dep't of Health*, 756 F. App'x 95, 96 (2d Cir. 2019) (citation omitted). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. NRDC*, 555 U.S. 7, 20 (2008). Plaintiffs fail to satisfy any of these requirements.

II. Plaintiffs' Spending Clause and Establishment Clause Claims Are Not Ripe

As an initial matter, Plaintiffs' Spending Clause and Establishment Clause claims are not ripe for review, because Plaintiffs have identified no specific enforcement action taken against them under the Rule—as indeed, they cannot, given that HHS has postponed the effective date of the Rule. *See Nat'l Org. for Marriage, Inc. v. Walsh*, 714 F.3d 682, 687 (2d Cir. 2013). Likewise, Plaintiffs' Establishment Clause claims rely on hypotheses about HHS's enforcement of the Rule that are not yet clearly factually defined absent enforcement of the Rule. *See, e.g.*, NY Compl. at ¶¶ 198–201, ECF No. 3 (arguing that the Rule violates the Establishment Clause because it will

compel employers "to accommodate their employees' religious beliefs to the exclusion of other interests"); PP PI Mot. at 39 (arguing that the Rule violates the Establishment Clause because it places on employers an "absolute obligation to, inter alia, accommodate any employee"). At least two courts have declined to decide similar challenges to the underlying Federal Conscience Statutes on standing and ripeness grounds. *See, e.g.*, *NFPRHA v. Gonzales*, 468 F.3d 826, 827 (D.C. Cir. 2006); *California v. United States*, No. C 05-00328 JSW, 2008 WL 744840, at *3 (N.D. Cal. Mar. 18, 2008).

"[T]he ripeness doctrine protects against 'judicial interference until a decision has been formalized and its effects felt in a concrete way by the challenging parties.'" *United States v. Quinones*, 313 F.3d 49, 58 (2d Cir. 2002) (citation omitted). "A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas*, 523 U.S. at 300 (citation omitted). That is precisely the current posture of Plaintiffs' Spending Clause and Establishment Clause claims.

For example, New York is concerned that, hypothetically, a state might discriminate against a provider who declined to participate in "the removal of life-sustaining treatment." NY Mem. at 21. This speculative scenario would require several steps to come to fruition. First, a provider would have to decline to participate in such removal of life-sustaining treatment. Next, a state would have to decide to take action against that provider in violation of the Federal Conscience Statutes. Then, the episode would have to come to the attention of HHS, HHS would have to find the state's actions to be discriminatory, and HHS would have to take enforcement action under the Rule that would endanger the state's funding. Finally, that enforcement action would have to be upheld after exhaustion of all available administrative remedies. The occurrence of any of these steps is far from certain, much less all of them. Thus, judicial resolution of

Plaintiffs' Spending Clause and Establishment Clause claims "may turn out to [be] unnecessary." *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 736 (1998).

That being so, the Court should decline for now to decide these claims, for it is "[a] fundamental and longstanding principle of judicial restraint . . . that courts [must] avoid reaching constitutional questions in advance of the necessity of deciding them." *BGA, LLC v. Ulster Cty., N.Y.*, 320 F. App'x 92, 93 (2d Cir. 2009) (quoting *Lyng v. Nw. Indian Cemetery Protective Ass'n*, 485 U.S. 439, 445 (1988)); *see Poe v. Ullman*, 367 U.S. 497, 503 (1961). "Under these circumstances, where 'we have no idea whether or when'" enforcement action under the Rule will be taken, or even be threatened, and what any such enforcement action will look like if it is taken, "the issue is not fit for adjudication." *Texas*, 523 U.S. at 300 (citation omitted); *see Ass'n of Am. Med. Coll. v. United States* (AAMC), 217 F.3d 770, 779–80 (9th Cir. 2000).

In addition to the fact that Plaintiffs' imagined hypotheticals may never occur, Plaintiffs' Spending Clause and Establishment Clause claims are also unfit for review at this time because the case presents no concrete factual situation in which to evaluate Plaintiffs' claims. Courts "should not decide constitutional questions in a vacuum." *United States v. Santos*, No. S 91 CR. 724 (CSH), 1992 WL 42249, at *5 (S.D.N.Y. Feb. 24, 1992); *cf. W. E. B. DuBois Clubs of Am. v. Clark*, 389 U.S. 309, 311 (1967). Because the Rule has never been enforced, and indeed, no funding has ever been withheld under the Federal Conscience Statutes, the contours of any such enforcement action and the scope of funding that may be at risk is unknown. To exercise jurisdiction in advance of any such enforcement action runs the risk of "entangl[ing]" this Court "in an abstract disagreement" over the Rule's validity before "it [is] clear that [Plaintiff's conduct is] covered by the [Rule]," and before any decision has been made that "affect[s] [Plaintiffs] in any concrete way." *American-Arab Anti-Discrimination Comm. v. Thornburgh*, 970 F.2d 501, 511

(9th Cir. 1991). That is precisely the situation the ripeness doctrine is meant to avoid. *Id*.

These claims are also unripe because Plaintiffs would suffer no hardship if judicial review were postponed. A party suffers no hardship warranting review unless governmental action "now inflicts significant practical harm upon the interests that the [plaintiff] advances," *Ohio Forestry Ass'n*, 523 U.S. at 733. *See Nat'l Park Hosp. Ass'n v. U.S. Dep't of the Interior*, 538 U.S. 803, 810 (2003) (noting that a case is not ripe unless "the impact" of the challenged law is "'felt immediately by those subject to it in conducting their day-to-day affairs'" (citation omitted)).

Plaintiffs cannot claim hardship based on the mere existence of the Rule. In *Marchi*, the Second Circuit considered a teacher's challenge to his school's directive that he refrain from religious instruction. *Marchi v. Bd. of Coop. Educ. Servs. of Albany*, 173 F.3d 469, 478 (2d Cir. 1999). The court concluded that, in the absence of a specific enforcement action against the teacher, the teacher's challenge as to off-campus religious discussion—for which he had never been disciplined—was not ripe because "a court entertaining [the teacher's] challenge would be forced to guess at how [the school] might apply the directive and to pronounce on the validity of numerous possible applications of the directive, all highly fact-specific and, as of yet, hypothetical. Such an open-ended and indefinite challenge is not well suited to judicial decision."[3] *Marchi*, 173 F.3d at 478; *see also id.* ("Given the unique circumstances of student-teacher relationships, it is easy to imagine a variety of circumstances that would fall within the challenged hypothetical application of the directive, some of which may be regulated constitutionally and others of which may not."). Here, likewise, Plaintiffs' many hypothetical enforcement scenarios (*see* NFPRHA

[3] The court did adjudicate the teacher's challenge to the school's actual enforcement regarding a letter, and denied the teacher leave to amend his complaint to add claims concerning hypothetical on-campus expression for the same ripeness reasons. *Marchi*, 173 F.3d at 476-79.

Mem. at 1–2) illustrate the difficulty of undertaking an unnecessary quest now to resolve Plaintiffs' imagined Spending and Establishment Clause challenges in the absence of any factual context.

Nor are Plaintiffs in any immediate danger. The "Hobson's choice" of which Plaintiffs complain—between abandoning state health care policy or losing billions of dollars in federal funds—is not an "immediate" one justifying review of their premature claims. Should Plaintiffs discriminate in a fashion barred by the Federal Conscience Statutes, and should HHS take enforcement action under the Rule, and should Plaintiffs decide not to comply through informal means, Plaintiffs will then have the opportunity, if necessary, to present their constitutional challenges to the Rule or the Federal Conscience Statutes to a court. *AAMC*, 970 F.2d at 511. Because no "irremediable adverse consequences [will] flow from requiring [Plaintiffs to bring] a later challenge," *Toilet Goods*, 387 U.S. at 164, there is no need to decide Plaintiffs' Spending Clause and Establishment Clause claims at this time. *See Lee v. Waters*, 433 F.3d 672, 677 (9th Cir. 2005); *see Poe*, 367 U.S. at 503.

As noted above, these considerations have caused two courts to decline—on ripeness and standing grounds—to adjudicate similar challenges to the underlying Federal Conscience Statutes. In *NFPRHA v. Gonzalez*, 468 F.3d 826 (D.C. Cir. 2006), plaintiffs brought Spending Clause and vagueness challenges to the Weldon Amendment. The D.C. Circuit dismissed, holding that plaintiff lacked standing, given that it had not been injured by the Amendment and could not show that it was likely to be. *Id.* Similarly, in *California v. United States*, No. C 05-00328 JSW, 2008 WL 744840 (N.D. Cal. Mar. 18, 2008), California challenged the Weldon Amendment on Spending Clause and other grounds. The court dismissed the case as lacking standing and not ripe because "whether California will risk losing federal funds pursuant to the Weldon Amendment if it seeks to enforce [a particular state law provision] is contingent upon a series of future events

that may not ever occur." *Id.* at *5. This Court should likewise dismiss Plaintiffs' Spending Clause and Establishment Clause claims as unripe.

III. Plaintiffs' Claims Lack Merit

A. HHS Has Statutory Authority to Issue the Rule

Plaintiffs' statutory authority claims fail because HHS acted within its authority when promulgating the Rule. Much of the error in Plaintiffs' argument stems from their misidentification of the statutes that provide HHS with authority to issue the Rule. As HHS explained, *see* 84 Fed. Reg. at 23,183–86, the enforcement portion of the Rule, which allegedly poses the most imminent threat to Plaintiffs' funding, merely sets forth existing internal HHS processes: OCR will investigate complaints and seek voluntary resolutions, and any involuntary remedies will occur through HHS funding components in coordination with OCR, with those components using pre-existing grants and contracts regulations processes. *See* 84 Fed. Reg. at 23,271 (to be codified at 45 C.F.R. § 88.7(i)). Overall, these are housekeeping matters, enacted pursuant to 5 U.S.C. § 301, concerning how HHS is governed and how it administers federal statutes. Despite Plaintiffs' assertion to the contrary, the Rule is also supported by each of the Federal Conscience Statutes themselves. When Congress required HHS, its programs, and recipients of its Federal funds to comply, that implicitly included a grant of authority to HHS to take measures to ensure HHS administers its programs in compliance with federal law. Moreover, the procedures set forth in the Rule that Plaintiffs most take issue with—the involuntary remedies outlined at § 88.7(i)(3) if voluntary resolutions cannot be reached—state they are to be pursued under the authority of HHS's other, preexisting grants and contracts regulations—regulations whose authority Plaintiffs do not challenge. *See, e.g.*, 45 C.F.R. §§ 75.300, 75.371, 75.503, 75.507; 2 C.F.R Pt. 376; 48 C.F.R. Pt. 9.4; 48 C.F.R. § 9.406-2, 9.406-3.

The assurance and certification requirement of the Rule simply implements other

unchallenged requirements in those grants and contracts regulations that require entities receiving federal funds to comply "with U.S. statutory and public policy requirements." *See* 45 C.F.R. § 75.300(a). The substantive requirements of the Rule on covered entities, 84 Fed. Reg. at 23,264–69 (to be codified at 45 C.F.R. § 88.3), do nothing more than reiterate the text of the Federal Conscience Statutes themselves and specify, according to that text, which entities the statutes affect. And the definitions in the Rule are another housekeeping matter concerning how HHS interprets the Federal Conscience Statutes when it complies and ensures compliance with them.

Therefore, as HHS explained, the agency's authority does not derive solely from the Federal Conscience Statutes, but rather from the interaction of those statutes with HHS's authority to impose terms and conditions in its grants, contracts, and other funding instruments. *See* 84 Fed. Reg. at 23,183–85. In brief, when Congress instructs HHS to withhold federal funds from entities that do not comply with conscience laws, HHS has the authority, enshrined in 5 U.S.C. § 301, 40 U.S.C. § 121(c), their implementing regulations, and various other statutes, to ensure that Congress's instructions are carried out. Standard measures for ensuring compliance with Congress's directives, such as complaint investigation or defining relevant terms, do not conflict with that authority.

Pursuant to 5 U.S.C. § 301, which permits "[t]he head of an Executive department [to] prescribe regulations for the government of his department," HHS has issued several regulations regarding the administration of funding instruments, such as grants or contracts. Chief among these for purposes of this litigation are UAR and the HHSAR, which were promulgated pursuant to 40 U.S.C. § 121(c), in addition to § 301. The UAR requires "that Federal funding is expended 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." 45 C.F.R. § 75.300(a) (emphasis added). Similarly, the HHSAR permits HHS to include "requirements of law" and "HHS-wide policies" in its contracts. *See* 48 C.F.R. § 301.101(b)(1)(i).

Of course, some of the federal statutes with which recipients of federal funds must comply are the Federal Conscience Statutes, which prohibit the government and recipients of federal funds from discriminating against entities that decline to engage in certain activities. The Rule does not alter or amend the obligations of the respective statutes, 84 Fed. Reg. at 23,185, but rather ensures that recipients of federal funds do not violate those statutes through the ordinary grant and contract issuing process.

The authority to ensure compliance with grant conditions is consistent with the well-established power of the United States "to fix the terms and conditions upon which its money allotments to state and other government entities should be disbursed." *See United States v. Marion Cty. Sch. Dist.*, 625 F.2d 607, 609 (5th Cir. 1980) (collecting Supreme Court cases). Inherent in the authority to fix such terms and conditions is the authority to sue for specific performance of the recipient's obligations under the grants that it accepts. *See id.*; *United States v. Mattson*, 600 F.2d 1295, 1298 (9th Cir. 1979). Nowhere is this authority exercised with greater prominence than to enforce civil rights. *See Marion Cty. Sch. Dist.*, 625 F.2d at 609. In light of this inherent authority to sue for specific performance, it must be the case that HHS can rely on § 301, the UAR, and the HHSAR to take more modest steps to assure compliance, such as investigating a complaint.

In addition to HHS's authority to enforce the conditions of the grants and contracts that it awards, certain statutes explicitly authorize HHS to promulgate regulations implementing conscience protections. For instance, the ACA authorizes the Secretary to issue regulations setting standards for meeting certain of the statute's requirements, including the prohibition against

discrimination on the basis of provision of abortion, 42 U.S.C. § 18023(b)(4), and the prohibition against discrimination regarding assisted suicide, *id.* § 18113. *See id.* § 18041(a)(1). The latter statutory provision explicitly authorizes OCR to receive complaints of discrimination regarding assisted suicide. *Id.* § 18113(d). The Secretary is also authorized to promulgate regulations "as may be necessary to the efficient administration of the functions with which" he is charged under Medicare, Medicaid, and the Children's Health Insurance Program. *See* 42 U.S.C. § 1302; *see also* 42 U.S.C. § 1302 (granting rulemaking authority regarding small rural hospitals); 42 U.S.C. 263a(f)(1)(E) (granting rulemaking authority regarding certification of laboratories). And, the Secretary has authority to promulgate regulations related to certain Centers for Medicare and Medicaid Services funding instruments. *See, e.g.*, 42 U.S.C. § 1315a; *see generally* 84 Fed. Reg. at 23,185 (listing statutes).

Planned Parenthood and NFPRHA argue that the Federal Conscience Statutes do not delegate interpretative or enforcement authority to HHS. This is not entirely true, *see, e.g.*, 42 U.S.C. § 18113, but it is also beside the point; HHS's authority to issue the Rule stems from its authority to ensure that recipients of HHS funds comply with the terms and conditions associated with the receipt of those funds. HHS does not claim to have interpretive or enforcement authority beyond enforcing the condition in *HHS's* funding instruments that funding recipients comply with federal law, which includes the Federal Conscience Statutes.

Planned Parenthood and NFPRHA also contend that the Rule's noncompliance remedies, 84 Fed. Reg. at 23,272 (to be codified at 45 C.F.R. § 88.7(i)(3)), exceed those permitted under the Federal Conscience Statutes. This is incorrect for several reasons. First, the Rule's involuntary noncompliance remedies merely use preexisting regulations that apply to all grants, contracts, or funding arrangements—regulations that Plaintiffs have not challenged. *See* 45 C.F.R. § 75.371.

Plaintiffs' alleged injury is, in this sense, nonredressible by an injunction against the Rule, because, for example, grants recipients are already required to comply with U.S. statutory requirements under 45 C.F.R. § 75.300(a) and (b), and are subject to the remedies in 45 C.F.R. § 75.371. HHS's promulgation of the Rule is, therefore, truly a housekeeping measure, setting forth how the Secretary has delegated OCR to receive and investigate complaints, and then coordinate with HHS funding components to use underlying grants and contracts (and other) regulations to enforce federal law, if no voluntary resolution can be reached.

Second, all of the remedies that OCR may pursue in coordination with the relevant HHS component are consistent with the Federal Conscience Statutes' own conditions on federal funding. The Federal Conscience Statutes restrict the use of federal funding, impose requirements on the recipients of federal funds, and govern the participants in federal programs. The Rule merely provides a mechanism for implementing those statutes. For example, the Weldon Amendment prohibits funding for an "agency, program, or government [that] 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." Pub. L. No. 115-245, § 507(d)(1), 132 Stat. at 3118. Likewise, five of the seven remedies that the Rule identifies involve withholding federal funds—precisely what the Weldon Amendment and other Federal Conscience Statutes require. *See* 84 Fed. Reg. at 23,272 (to be codified at 45 C.F.R. § 88.7(i)(3)(i)–(v)). And Plaintiffs do not and cannot seriously contest the final two remedies, which permit referral to the Department of Justice (DOJ) and "any other remedies that may be legally available." *Id.* (to be codified at 45 C.F.R. § 88.7(i)(3)(vi)–(vii)). DOJ acts as HHS's representative in court, and HHS routinely refers matters that require litigation on its behalf to DOJ. And the final remedy is, by its terms, limited to what is legally available.

Last, but by no stretch least, Plaintiffs' statutory authority claims fail because their theory would leave the very people protected by the Federal Conscience Statutes without recourse against discrimination by recipients of federal funds. Courts have held that some of the Federal Conscience Statutes do not provide a private right of action. *See, e.g.*, *Cenzon-DeCarlo v. Mount Sinai Hosp.*, 626 F. 3d 695, 698–99 (2d Cir. 2010). Instead, HHS enforces these statutes through conditions it attaches to its grants and contracts requiring recipients to comply with federal law. *See* 76 Fed. Reg. at 9,968, 9,976 (Feb. 23, 2011) ("provid[ing] 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"); *see also* 45 C.F.R. §§ 75.300, 75.371–75.375 (setting forth remedies for noncompliance with federal law); 45 C.F.R. Pt. 75.500 (setting forth procedures for auditing recipients of federal funds). If the Court were to conclude that HHS cannot enforce the term in its funding instruments that requires funding recipients to comply with federal law, the corresponding lack of a private right of action would leave victims of unlawful discrimination without a remedy. It would be this resultant stripping of conscience protections, not HHS's modest exercise of its authority to impose requirements associated with the receipt of federal funds, that would truly contravene congressional intent.

B. The Challenged Definitions Are Reasonable Exercises of HHS's Authority

Plaintiffs' claim that certain definitions in the Rule exceed HHS's authority to interpret the statutes it administers also lacks merit. In their complaints and preliminary injunction motions, Plaintiffs attack five definitions: (1) *assist in the performance*, (2) *discriminate* or *discrimination*, (3) *entity*, (4) *health care entity*, and (5) *referral* or *refer for*. As Plaintiffs acknowledge, *see, e.g.*, PP & NFPRHA's Mem. 26–27, these claims are governed by *Chevron, U.S.A., Inc. v. Nat. Res.*

Def. Council, Inc., 467 U.S. 837, 842–43 (1984).[4] Under this standard, a court first asks "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If the answer is yes, the court must give effect to Congress's intent. If the answer is no—that is, the statute is ambiguous—"the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. For the reasons set forth below, Plaintiffs' challenge to each definition fails at step one or, in the alternative, at step two of *Chevron*.

"Assist in the Performance"

HHS's definition of "assist in the performance" is entirely consistent with the Church Amendments, the Federal Conscience Statute that contains the term. The Church Amendments generally prohibit recipients of certain federal funds from discriminating against individuals who hold religious or moral beliefs regarding certain health care procedures. One provision states, for example, that "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 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) (emphasis added). The Rule defines the term "assist in the performance" as follows:

> 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

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[4] Although Planned Parenthood and NFPRHA invoke § 706(2)(A) to challenge the definitions, and New York invokes § 706(2)(C), the Court should analyze all claims under *Chevron* because Plaintiffs have challenged the "agency's initial interpretation of a statutory provision." *See Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA*, 846 F.3d 492, 521 (2d Cir. 2017).

by such actions.

84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2).

1. Plaintiffs' challenge fails at *Chevron* step one because Congress has directly spoken to the precise question at issue. *See Lawrence & Mem'l Hosp. v. Burwell*, 812 F.3d 257, 264 (2d Cir. 2016). The Court need only open the dictionary, *see Mayo Found. for Med. Educ. & Research v. United States*, 562 U.S. 44, 52 (2011) (applying a dictionary definition at step one); *VIP of Berlin, LLC v. Town of Berlin*, 593 F.3d 179, 187 (2d Cir. 2010) (referring to the *Merriam-Webster* online dictionary), which contains the same commonsense definition as the Rule: *Merriam-Webster* defines *assist* as "to give usually supplementary support or aid to," https://www.merriam-webster.com/dictionary/assist (last visited Aug. 12, 2019), and *performance* as "the execution of an action," https://www.merriam-webster.com/dictionary/performance (last visited Aug. 12, 2019). The Rule's definition is as close to the dictionary definition of these terms as can be without repeating them verbatim: *assist in the performance* is limited to "specific, reasonable, and articulable" connections between the conscientious objector's action and the medical procedure. 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2). "If the connection between an action and a procedure is irrational, there is no actual connection by which the action specifically furthers the procedure." *Id.* at 23,187. Plaintiffs point to no daylight between the dictionary definitions and the Rule, instead arguing that the Rule applies "to all ancillary conduct that 'furthers a procedure.'" NY Mem. 28 (quoting 84 Fed. Reg. at 23,263). This is true but consistent with the statute. *Ancillary* means *supplementary*, https://www.merriam-webster.com/dictionary/ancillary, so to assist is either "to give usually supplementary support or aid to" *or* "to give usually ancillary support or aid to."

An intra-textual reading of the Church Amendments further supports that the Rule's definition is consistent with Congress's clear intent. Congress prohibited requiring an individual

"to *perform* or *assist in the performance* of any part of a health service program or research activity [that] would be contrary to his religious beliefs or moral convictions." 42 U.S.C. § 300a-7(d) (emphasis added). Employing the term "perform" alongside "assist in the performance" indicates that Congress intended for "assist in the performance" to be more capacious than simply "perform." Put differently, Congress did not limit the scope of the Church Amendments to those who *actually perform* the particular procedure, but rather extended it to those who *assist in the performance*, and thus have a more ancillary relationship to the procedure.

Plaintiffs' counterarguments under step one can be dismissed in turn. First, Plaintiffs' list of entities that purportedly do not assist in the performance of an abortion could in fact be dictionary examples of the term "assist in the performance." As HHS has explained, "[s]cheduling an abortion or preparing a room and the instruments for an abortion are necessary parts of the process of providing an abortion" and are within the definition of assistance. 84 Fed. Reg. at 23,186. To schedule an abortion is "to give . . . supplementary support or aid" to that abortion because it allows for the abortion to take place. Plaintiffs have offered no plausible alternative meaning of "assist in the performance" that would comport with the ordinary understanding of that term and give meaning to that phrase.

Second, Plaintiffs' legislative history arguments are meritless. The short of the matter is that there is limited legislative history on the meaning of "assist in the performance." Plaintiffs cite a single statement by Senator Frank Church, the sponsor of the eponymous bill, on the Senate floor. As a general matter, a legislator's "isolated remarks are entitled to little or no weight" in assessing legislative history. *See Murphy v. Empire of Am., FSA*, 746 F.2d 931, 935 (2d Cir. 1984). And although courts occasionally look to a sponsor's statements on the floor as "an expression of legislative intent," they do so only when the legislation lacks an accompanying committee report.

See In re Ionosphere Clubs, Inc., 922 F.2d 984, 990 (2d Cir. 1990). Here, however, Senator Church's statement is entitled to little or no weight because the relevant House committee issued a report on the statute, which did not endorse Senator Church's floor statement. *See* H.R. Rep. No. 93-227, at 11 (1973). In any event, whether or not the Court considers Senator Church's statement is of no consequence. Just as he did not intend, when voting for the bill, "to permit a frivolous objection from someone unconnected with the procedure," 119 Cong. Rec. 9,597 (Mar. 27, 1973), so too does the Rule exclude such unconnected persons from its definition. Rather, there must be "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." 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2).

Third, New York argues that "counseling, referral, [or] training" cannot mean "assist in the performance," 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2), because the Church Amendments already use the term "counsel," the Weldon Amendment already uses the term "referral," and the Coats-Snowe Amendment already uses the term "training." This argument should be dismissed out of hand. As a general matter, merely because "counsel," "referral," and "training" are used elsewhere in the Church Amendments or other Federal Conscience Statutes does not mean that Congress intended for them to be excluded from the meaning of "assist in the performance." When several "statutes were enacted by the same legislative body at the same time," the *in pari materia* canon of statutory construction permits courts to interpret certain words consistently across those statutes. *See Erlenbaugh v. United States*, 409 U.S. 239, 243–44 (1972). However, the sections that New York compares were enacted by different Congresses as different public laws. The Coats-Snowe and Weldon Amendments were enacted after the Church Amendments. And the provision of the Church Amendments that employs the term "counsel," 42

U.S.C. § 300a-7(e), was enacted after the subsections that contain the more general phrasing "assist in the performance." *See* An Act to Amend Title VIII of the Public Health Service Act to Extend Through Fiscal Year 1980 the Program of Assistance for Nurse Training, and for Other Purposes, Pub. L. No. 96-76, § 208, 93 Stat. 579. Therefore, New York's comparisons fail.

Furthermore, even if the statutes were comparable, counseling, referral, and training are all common forms of assistance as Congress understands the term. For example, and as HHS has explained, "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." 84 Fed. Reg. at 23,188. And "counseling of some form regarding abortion is often required before the procedure can be performed, as is the case in thirty-three States, and many hospitals and health care facilities likely require some kind of counseling as a prerequisite to abortion of their own accord." *Id.* Second, Congress may have used the term "assist in the performance" instead of "counseling" or "referral" because not all counseling or referrals constitute assisting in the performance. For example, some counseling entails the *direct* performance of a health service program, such as psychotherapy. The Rule recognizes this distinction, noting that "assist in the performance . . . *may* include counseling [or] referral." *Id.* at 23,263 (to be codified at 45 C.F.R. § 88.2) (emphasis added).

2. Even if the Court determines that the term "assist in the performance" is ambiguous, the Court should still uphold HHS's definition because it is eminently reasonable. Under *Chevron* step two, "'the question for the court is whether the agency's answer is based on a permissible construction of the statute'" and "an agency regulation warrants deference unless it is 'arbitrary, capricious, or manifestly contrary to the statute.'" *Lawrence & Mem'l Hosp.*, 812 F.3d at 264 (quoting *Chevron*, 467 U.S. at 844)). "The agency's view need not be 'the only possible

interpretation, nor even the interpretation deemed most reasonable by the courts.'" *Catskill Mountains Chapter of Trout Unlimited, Inc.*, 846 F.3d at 520.

As described above, HHS's definition is a reasonable one in light of the dictionary definitions of "assist" and "performance" and the Rule's requirement that "a specific, reasonable, and articulable connection" exist between the conscientious objector's action and the medical procedure, 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2); *id.* at 23,187 (prohibiting irrational or excessively attenuated connections). In addition, the Rule furthers the statute's purpose to protect individuals and health care entities from discrimination on the basis of their religious or moral convictions by recipients of federal funds; for example, an individual who schedules a patient's abortion is not outside the scope of the Church Amendments merely because they did not perform the abortion themselves. The Rule recognizes that such individuals too are protected because they provide necessary assistance in the performance of an abortion. *See id.* at 23,188.

"Discriminate or Discrimination"

Plaintiffs' challenge to HHS's definition of "discriminate or discrimination" is also meritless. The definition, which consists of a three-point list of examples that apply *only to the extent permitted by the Federal Conscience Statutes*, is by definition reasonable.

First, some background: Virtually all of the Federal Conscience Statutes covered by the Rule employ the term "discriminate" and do not define it. For example, the Coats-Snowe Amendment provides that government recipients of federal funds "may not subject any health care entity to discrimination" on certain bases, such as the "refus[al] to undergo training in the performance of induced abortions." 42 U.S.C. § 238n(a)(1). Consistent with the varying types of discrimination that the Federal Conscience Statutes prohibit, the Rule provides a non-exhaustive

list of actions that may constitute discrimination "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.

45 C.F.R. § 88.2. The definition then provides several safe harbors, consisting of actions that, if taken by a regulated entity, would not constitute discrimination. *Id.*

1. Plaintiffs' challenge to this definition fails at *Chevron* step one. By its terms, the definition does not extend beyond the statutes to which it applies. *See* 45 C.F.R. § 88.2 (defining the term to include actions "as applicable to, and to the extent permitted by, the applicable statute"). Therefore, the definition does not exceed Congress's intent because it explicitly *cannot* exceed Congress's intent. Moreover, the common definition of "discrimination" is "to make a difference in treatment or favor on a basis other than individual merit," *Discriminate*, Merriam-Webster, https://www.merriam-webster.com/dictionary/discriminate (last visited Aug. 12, 2019), and the Rule merely makes explicit the various manifestations of that broad definition.

2. In the event the Court determines that the term "discrimination" as used in the Federal Conscience Statutes is ambiguous, it should still uphold HHS's definition at step two. As discussed above, the definition by its terms does not extend beyond the meaning of the Statutes, but rather "must be read in the context of each underlying statute at issue, any other related provisions of the

rule, and the facts and circumstances." 84 Fed. Reg. at 23,192. To provide guidance on the meaning of discrimination without being under-inclusive, HHS used the word "includes" to establish a non-exhaustive list of examples that could, in the context of the particular underlying Federal Conscience Statute, constitute discrimination. *See id.* at 23,190. And, to ensure that the Rule was not over-inclusive, HHS included three provisions to protect entities that seek to accommodate those with religious or moral objections. *See* Final Rule, 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2).

Planned Parenthood and NFPRHA unconvincingly argue that these accommodation provisions, which stemmed from comments that HHS received, are not a logical outgrowth of the proposed rule. Under basic logical outgrowth principles, this is incorrect. The APA requires an agency to provide notice of "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). "A final rule 'need not be an exact replica of the rule proposed in the notice,' only a 'logical outgrowth.'" *Cooling Water Intake Structure Coal. v. EPA*, 905 F.3d 49, 61 (2d Cir. 2018) (quoting *Riverkeeper, Inc. v. EPA*, 475 F.3d 83, 113 (2d Cir. 2007)). The key question is "whether the agency's notice would fairly apprise interested persons of the subjects and issues of the rulemaking." *Id.* (quoting *Nat'l Black Media Coal. v. FCC*, 791 F.2d 1016, 1022 (2d Cir. 1986)). For example, the D.C. Circuit has held that a "garden-variety" exception to a general rule constitutes a logical outgrowth, even if the exception is not contained in the proposed rule. *See Timpinaro v. SEC*, 2 F.3d 453, 457 (D.C. Cir. 1993). The paragraphs to which Planned Parenthood and NFPHRA object, satisfy the logical outgrowth standard because they provide exceptions to HHS's proposed definition of "discriminate or discrimination" and were added in response to specific comments submitted in response to the proposed rule's broader definition. *See* 84 Fed. Reg. at 23,191. Although the exceptions may not

be as capacious as Planned Parenthood and NFPRHA would like, comments requesting exceptions belie any claim that Plaintiffs lacked notice that HHS may provide such exceptions.

Planned Parenthood and NFPHRA' other objections to these exceptions are plainly based on policy, not legal, differences. It is true that paragraph (4) of the definition applies when a recipient of federal funds "offers and the protected entity voluntarily accepts an *effective* accommodation." 45 C.F.R. § 88.2 (emphasis added). But Planned Parenthood and NFPHRA do not explain why that is *legally* impermissible, as opposed to simply contrary to their preferred definition of *discrimination*. Likewise, paragraph (5) permits recipients of federal funds to require a protected entity to inform it of certain objections *after* the protected entity is hired. But again, other than making clear that this is not Plaintiffs' preferred safe harbor provision, Plaintiffs do not explain why the definition is an impermissible construction of the statutes. After all, being forced to disclose an objection before a protected entity is hired may provide an opportunity for precisely the discrimination that the Federal Conscience Statutes prohibit.

"Entity"

Planned Parenthood's challenge to HHS's definition of "entity" fares no better. The term, in contrast to "health care entity," appears on its own only in the Church Amendments and that statute does not define the term. The Rule defines it as follows:

> 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).

84 Fed. Reg. at 23,263.

Planned Parenthood's challenge to this definition fails at *Chevron* step one. The term "entity" has an exceedingly capacious dictionary definition: "something that has separate and

distinct existence and objective or conceptual reality." *Definition of Entity*, Merriam-Webster, https://www.merriam-webster.com/dictionary/entity (last visited Aug. 4, 2019). Contrary to Plaintiff's suggestion, there simply is no way that Congress, in using such a broad term, did not intend to include public agencies, public organizations, and the like. For these reasons, this definition is also a permissible construction of the term "entity" at step two.

"Health Care Entity"

Plaintiffs' challenge to HHS's definition of "health care entity," which appears in the Weldon Amendment, the Coats-Snowe Amendment, and the ACA, also fails. The Rule defines "health care entity" in two parts: first for the purposes of the Coates-Snowe Amendment and the parts of the Rule that implement that law, and second for the purposes of the Weldon Amendment, Section 1553 of the ACA, and the parts of the Rule that implement those laws. 84 Fed. Reg. at 23,264 (to be codified at 45 C.F.R. § 88.2).

1. Beginning with the text, each of these statutes defines the term through a nonexhaustive list of constituent entities. The Coats-Snowe Amendment provides that the term "*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) (emphasis added). The Weldon Amendment and the ACA provide 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." 42 U.S.C. § 18113(b) (emphasis added); § 507(d)(2), 132 Stat. at 3118. The Second Circuit has held that the term "includes" indicates that what follows is nonexhaustive. *Lyons v. Legal Aid Soc'y*, 68 F.3d 1512, 1514–15 (2d Cir. 1995). Furthermore, both statutes contain catch-all phrases: "a participant in a program of training in the health professions" in the Coats-Snowe Amendment and "other health care professional" and "any other kind of health care facility, organization, or

plan" in the Weldon Amendment and ACA. 42 U.S.C. § 238n(c)(2); 42 U.S.C. § 18113(b). Given these features, the statutes plainly contemplate a broader group of health care entities than merely those explicitly listed.

Nevertheless, Plaintiffs contend that pharmacies, health plan sponsors, and third party administrators are not "health care entities." This makes no sense. A pharmacy provides pharmaceuticals and information, both of which are health care items and services. 84 Fed. Reg. at 23,196. At a minimum, a pharmacy constitutes "any other kind of health care facility." 42 U.S.C. § 18113(b); § 507(d)(2), 132 Stat. at 3118. Similarly, plan sponsors and third party administrators of plans, which are included only with respect to the Weldon Amendment and the ACA because those statutes focus on the protection of health "plans," *see* 84 Fed. Reg. at 23,195, play a crucial role in the delivery of health care by paying for or administering health coverage or health care services. And they certainly constitute "*any other kind* of health care facility, organization, or plan." 42 U.S.C. § 238n(c)(2) (emphasis added).

2. Even if the term "health care entity" in these Federal Conscience Statutes were ambiguous, the Rule's definition is reasonable for the reasons stated above: the statutes explicitly contemplate the inclusion of entities beyond those explicitly listed in the statutes, and Plaintiffs have not identified any entity in the Rule's definition that would not meet the ordinary dictionary definition of "health care entity" or the statutes' catch-all provisions. Furthermore, the Rule recognizes that the definition of "health care entity" is a flexible one that depends on "the context of the factual and legal issues applicable to the situation." 84 Fed. Reg. at 23,196. None of the Rule's definitions apply in all circumstances, which underscores their reasonableness. *See id.*

"Referral or Refer For"

Last, the Rule's definition of "referral or refer for" is consistent with the term's meaning in the Weldon and Coats-Snowe Amendments. As with many of the other definitions in the Rule,

"referral or refer for" is not defined in the Weldon and Coats-Snowe Amendments. The Coats-Snowe Amendment uses the term on several occasions. It prohibits a recipient from discriminating against an entity because it "refuses . . . to provide *referrals* for [certain] training or . . . abortions." 42 U.S.C. § 238n(a)(1) (emphasis added). It also prohibits discrimination because "the entity 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) . . . *refer for* training in the performance of induced abortions." *Id.* § 238n(a)(3) (emphasis added). The statute also requires the federal government and State and local governments that receive federal financial assistance to deem accredited any training program that would be accredited but for the accrediting agency's reliance "upon an accreditation standards that require an entity to . . . *refer for* training in the performance of induced abortions." *Id.* § 238n(b)(1) (emphasis added). And last, the statute contains an exception that it should not "prevent any health care entity from voluntarily electing . . . to make *referrals for* induced abortions." *Id.* § 238n(b)(2)(B)(i) (emphasis added). The Weldon Amendment prohibits federal funds from being disbursed to a recipient if that recipient "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." § 507(d)(1), 132 Stat. at 3118 (emphasis added).

The Rule defines "referral or refer for" through a list of items that qualify as "referral or refer for": the term "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." 45 C.F.R. § 88.2.

1. Congress has directly spoken to the question of what constitutes a referral, and the Rule's definition is consistent with Congress's intent. Although the statutes do not include a definition of "referral or refer for" and the legislative history is silent on the matter, the ordinary dictionary definition of the term indicates Congress's intent. *See Mayo Found. for Med. Educ. & Research*, 562 U.S. at 52. As HHS explained, "The rule's definition of 'referral' or 'refer for' . . . 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.'" 84 Fed. Reg. at 23,200 (quoting Refer, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/refer) (citing Refer, Dictionary.com, available at https://www.dictionary.com/browse/refer). The statutes' structure also makes Congress's intent clear. The addition of the term "for" following "refer" indicates that Congress did not intend the statutes to be limited to a referral document, but rather to include any referral *for* abortion (or other health services) in a more general sense. For example, the Coats-Snowe Amendment protects not only a health care entity that declines to refer a patient to an abortion provider, but also a health care entity that decline to refer "for" abortions generally. *See, e.g.*, 42 U.S.C. § 238n(a)(1).

2. In the alternative, the Rule's definition should be upheld at *Chevron* step two. In addition to being consistent with dictionary definitions and the statutes' structure, the Rule's definition is faithful to the statutes' remedial purposes. As HHS explained, defining the term "referral or refer for" more narrowly would exclude forms of coercion that the statutes protect against. For example, the Supreme Court recently held that a law requiring health care providers to post notices regarding the availability of state-subsidized abortion likely violated the First Amendment. *See Nat'l Inst. of*

Family & Life Advocates v. Becerra, 138 S. Ct. 2361, 2378–79 (2018). A narrower definition would not include referrals of this sort, even though they constitute unconstitutional coercion of a health care entity that has a conscientious objection to abortion. The Weldon and Coats-Snowe Amendments are not this narrow, and HHS acted reasonably when it interpreted the term accordingly.

The Rule is reasonable for another reason as well: it uses a non-exhaustive list that "guide[s] the scope of the definition," recognizing that the terms "take many forms and occur in many contexts." 84 Fed. Reg. at 23,201. This flexibility means that "the applicability of the rule would turn on the individual facts and circumstances of each case" (i.e., "the relationship between the treatment subject to a referral request and the underlying service or procedure giving rise to the request"). *Id.*

C. The Rule Is Consistent with Other Provisions of Law

Plaintiffs also argue, incorrectly, that the Rule is unlawful because it allegedly conflicts with certain provisions within the United States Code. No such conflict exists.

Section 1554 of the ACA

Plaintiffs claim that the Rule conflicts with Section 1554 of the ACA. *See* NY Mem. at 30–31; PP Mem at 37–38. That provision states that, "[n]otwithstanding any other provision of this [the Affordable Care] 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 health care services"; (3) "interferes with communications regarding a full range of treatment options between the patient and the provider"; (4) "restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions"; (5) "violates the principles of informed

consent and the ethical standards of health care professionals"; or (6) "limits the availability of health care treatment for the full duration of a patient's medical needs." 42 U.S.C. § 18114.

Plaintiffs' claim is meritless. All six subjects of Section 1554's sub-sections involve the *denial* of information or services to patients. The Rule, however, denies nothing. It merely revises the 2011 Rule to ensure knowledge of, compliance with, and enforcement of, the longstanding Federal Conscience Statutes, in order to ensure that entities covered by those laws receive proper protection. Consistent with the Federal Conscience Statutes, specific health care entities under specific circumstances may not be forced to perform certain services, but nothing in the Rule requires providers to decline to perform any service, nor does it preclude patients from receiving those services from non-objecting entities, or from receiving any other appropriate health information or treatment. At bottom, Plaintiffs' objection is not so much to the Rule as to the Federal Conscience Statutes that the Rule interprets. Under Plaintiffs' theory, any time a specific health care entities declines to provide a service to which it objects, HHS would violate Section 1554 by allowing health care entities to refuse to perform or participate in certain services to which they object. *See, e.g.*, NY Mem. at 31. Plaintiffs' argument, then, is that Congress essentially abrogated the Federal Conscience Statutes through Section 1554—because Section 1554 would be violated whenever a health care entity exercised its right under those statutes to decline to perform a service. Plaintiffs take this position even as to the Weldon Amendment, which Congress has readopted every year since the ACA's passage.

The Court should reject Plaintiffs' untenable position. First, Section 1554 expressly applies "[n]otwithstanding any other provision *of this Act*," 42 U.S.C. § 18114 (emphasis added)—that is, the ACA. The great majority of the Federal Conscience Statutes that the Rule implements, of course, are not part of the ACA. Nor are the statutes that give the Secretary authority to award

funding grants part of the ACA. Had Congress intended Section 1554 to extend beyond the ACA, it could have simply specified that it applies "notwithstanding any other provision of law[.]" 42 U.S.C. § 18032(d)(3)(D)(i). Indeed, such language is frequently used in the U.S. Code, and in the ACA specifically twenty-one times, by the government's count. *See, e.g.*, *id.* By its own terms, Section 1554 does not apply to the conscience protection provisions outside of the ACA, and therefore does not undermine the Rule's validity. Thus, even if Section 1554 somehow applied to the conscience protection provisions contained within the ACA—which is utterly implausible—it does not apply to the majority that exist outside the ACA.[5]

It is a basic principle of statutory interpretation, moreover, that Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Plaintiffs would have this Court believe that Congress effectively gutted the Federal Conscience Statutes, without any meaningful legislative history so indicating, when it passed Section 1554. That proposition is implausible on its face. And—to the contrary—Congress went out of its way in the ACA to make clear that nothing in that statute undermines the Federal Conscience Statutes on which the Rule is based. Specifically, Section 1303(c)(2) of the ACA states that

> Nothing in this Act [*i.e.*, the ACA, including Section 1554] 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.

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[5] Another reason that Section 1554 is of no moment is that the Rule does not create, impede, interfere with, restrict, or violate anything. Instead, it simply limits what the government chooses to fund—*i.e.*, providers that do not engage in discrimination.

42 U.S.C. § 18023(c)(2) (emphasis added). This clear expression of congressional intent fatally undercuts Plaintiffs' argument that Section 1554 somehow prevents HHS from giving effect to the Federal Conscience Statutes. Yet, even if that somehow were not enough, Congress also went on to add *additional* conscience protection provisions in Section 1303 itself and elsewhere in the ACA. In Section 1553, for example, Congress added protections against discrimination on the basis of whether a health care entity provides assisted suicide, euthanasia, or mercy killing. *See* 42 U.S.C. § 18113. The ACA, then, adds to and underscores the importance of the Federal Conscience Statutes. Plaintiffs' reading of Section 1554—which would effectively gut all such protections—therefore must be incorrect.

Defendants' interpretation of Section 1554 also comports with common sense. Section 1554's subsections are open-ended. Nothing in the statute specifies, for example, what constitutes an "unreasonable barrier[]," "appropriate medical care[,]" "all relevant information[,]" or "the ethical standards of health care professionals[.]" 42 U.S.C. § 18114. And there is nothing in the ACA's legislative history that sheds light on this provision. Under these circumstances, it is a substantial question whether Section 1554 claims are reviewable under the APA at all. *See Citizens to Pres. Overton Park*, 401 U.S. at 410 (explaining APA bars judicial review of agency decision where, among other circumstances, "statutes are drawn in such broad terms that in a given case there is no law to apply" (citation omitted)).[6] But even if Section 1554 claims are reviewable, it is

[6] Even within the ACA, HHS routinely issues regulations placing criteria and limits on what the government will fund, and on what will be covered in ACA programs. Under Plaintiffs' standardless interpretation of Section 1554, it is far from clear that the government could ever impose any limit on any parameter of a health program—even if the program's own statute requires it. Nor is it evident how a court could possibly evaluate challenges brought under Section 1554 if that provision sweeps as broadly as Plaintiffs claim.

inconceivable that Congress intended to subject the entire U.S. Code to these general and wholly undefined concepts—and that it did so without leaving any meaningful legislative history.

Other principles point in the same direction. "[I]t is a commonplace of statutory construction that the specific governs the general," *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992). "The general/specific canon is perhaps most frequently applied to statutes in which a general permission or prohibition is contradicted by a specific prohibition or permission." *Id*. Under such circumstances, "[t]o eliminate the contradiction, the specific provision is construed as an exception to the general one." *Id.* Thus, even if Section 1554 applied to regulations implementing the Federal Conscience Statutes (it does not), and even if Section 1554 and those Statutes were in conflict (they are not), the Federal Conscience Statutes would prevail over Section 1554. Section 1554 is at best a general prohibition of certain types of regulations (very broadly described) and does not speak to conscience objections at all. The Federal Conscience Statutes, by contrast, contain specific protections with respect to specific activities in the context of federally funded health programs and research activities. Section 1554, therefore, must give way to the more specific Federal Conscience Statutes and the Rule interpreting them.

EMTALA

Plaintiffs also argue that the Rule conflicts with EMTALA, which requires hospitals with emergency departments to either (1) provide emergency care "within the staff and facilities available at the hospital," or (2) transfer the patient to another medical facility in circumstances permitted by the statute. 42 U.S.C. § 1395dd(b)(1)(A). *See* NY Mem. at 33–34; PP Mem. at 31–34. There is no conflict, however.

EMTALA applies only to hospitals that elect to operate an emergency room, and the obligations it imposes are limited to the capabilities of the particular hospital. 42 U.S.C. § 1395dd(b); 73 Fed. Reg. at 78,087. As HHS explained in the preamble to the Rule, 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." 84 Fed. Reg. at 23,183. With respect to EMTALA specifically, HHS indicated that it generally agrees with the explanation in the preamble to the 2008 Rule that fulfilling the requirements of EMTALA would *not* conflict with the Federal Conscience Statutes that the Rule interprets. *See id.*

In an attempt to create a conflict where none exists, Plaintiffs allege that the Rule may "reduc[e] access to emergency care," NY Mem. at 34, and speculate that the Rule may result in women with an ectopic pregnancy being denied emergency care, *id.* at 33–34; *see also* PP Mem. at 31–32. Plaintiffs' hypothetical rests on the untenable assumption that, in the event of an emergency, there will be no provider who is willing to assist a patient with an emergency medical condition or facilitate the transfer of such patient in a manner consistent with EMTALA—in other words, that *every single* available member of the hospital staff, or every member of an ambulance team, will object on religious or moral grounds to providing care and to transferring the patient to another facility, and that health care entities that must comply with the Federal Conscience Statutes could not take any steps to assure the availability of willing staff. In considering Plaintiffs' facial challenge to the Rule, the Court should not assume that such a far-fetched hypothetical conflict will come to pass. *See Reno v. Flores*, 507 U.S. 292, 309 (1993) (declining to assume facts on a facial challenge). Indeed, as HHS explained previously, it is "not aware of any instance where a facility required to provide emergency care under EMTALA was unable to do so because its entire staff objected to the service on religious or moral grounds." 73 Fed. Reg. 78,087. Regardless, HHS has stated that "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." 84 Fed. Reg. 23188.

Moreover, although Planned Parenthood and NFPRHA suggest that the Rule somehow discourages hospitals from making staffing and scheduling decisions necessary to ensure that patients facing emergencies receive treatment, *see* PP Mem. at 41, in fact, the opposite is true. The Rule explicitly carves out of the definition of discrimination efforts to "use alternate staff or methods to provide or further any objected-to conduct," precisely to address the concern that health care entities may need to double certain staff positions to ensure certain services continue to be available. *See* 42 C.F.R. § 82.2(6); 84 Fed. Reg. at 23,263. This flexibility to make appropriate staffing arrangements effectively eliminates any risk personnel will be unavailable to meet EMTALA's requirements.

Medicaid Informed Consent Requirements

New York further contends that the Rule violates a provision of the Medicaid statute, 42 U.S.C. § 1396u-2(b)(3)(B). *See* NY Mem. at 32. That provision states that the Medicaid statute "shall not be construed" to require Medicaid managed care organizations to provide (or otherwise assist in providing) a counseling or referral service if the organization objects to the provision of that service on moral or religious grounds, *id.* § 1396u-2(b)(3)(B). That provision, as HHS acknowledged in the preamble to the Rule, is itself among the Federal Conscience Statutes that the Rule implements and weighs in favor of protecting the conscience rights of health care individuals and entities.

New York, however, points to the part of § 1396u-2(b)(3)(B) that states "[n]othing in this subparagraph shall be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974." *Id.* New York reasons that (1) because § 1396u-2(b)(3)(B) should not be construed to affect State disclosure laws, and (2) because the Rule would preempt state disclosure laws if those laws required health care entities to engage in activities to which they object, then (3) the Rule is unlawful.

New York's conclusion does not follow from its premises. The Rule merely implements the construction required by § 1396u-2(b)(3)(B). It does not implicate any state disclosure requirements except to the extent they rely on that specific statute for authority, which New York does not allege. Section 1392u-2(b)(3) is simply not implicated here.

Title X

Planned Parenthood and NFPRHA also argue that the Rule somehow conflicts with Title X of the Public Health Services Act, *see* Pub. L. No. 91-572, 84 Stat. 1504 (1970), which provides federal subsidies for certain types of family planning services. *See* PP Mem. at 34–37. Although Planned Parenthood and NFPRHA insist that the Rule "directly conflicts with Title X's plain statutory text and clear Congressional mandates," they fail to identify any specific part of the Title X statute that is in conflict with the Rule. They suggest that the Rule may be inconsistent with the requirement that Title X family planning services be "voluntary." *See* PP Mem. at 34–35 (italicizing the word "voluntary"); *id.* at 35 (same). But, of course, nothing in the Rule—which merely facilitates health care entities' exercise of their federal conscience rights—makes any person accept Title X family planning services against his or her will.

Nor does the Rule "flout[] the Congressional purpose of the Title X program[.]" PP Mem. at 36. Congress passed the Federal Conscience Statutes that the Rule implements; thus, Congress clearly did not believe there was a conflict between protecting conscience rights and Title X's goals. And, indeed, nothing in the Rule can plausibly be read to be in tension with Title X. As with any other health care service, Title X providers are free to ensure that patients receive the full range of available Title X services—they simply must do so while also accounting for the protections provided under the Federal Conscience Statutes.

Planned Parenthood and NFPRHA also point to several district court decisions that addressed separate HHS regulations issued earlier this year to interpret the requirements of Title

X. *See* PP Mem. at 36–37. Those courts preliminarily held that the Title X regulations likely violate HHS appropriations language requiring that "all pregnancy counseling shall be nondirective." *See, e.g.*, *California v. Azar*, --- F. Supp. 3d ---, 2019 WL 1877392, at *5 (N.D. Cal. Apr. 26, 2019), *rev'd* 927 F.3d 1068 (9th Cir. 2019) (citation and emphasis omitted). The Ninth Circuit is currently reviewing those decisions,[7] and other courts have rejected the arguments Plaintiffs make here, *see Mayor and City Council of Baltimore*, --- F. App'x ---, 2019 WL 3072302, *1 (4th Cir. July 2, 2019) (granting stay of district court's preliminary injunction); *Family Planning Ass'n of Me. v. U.S. Dep't of Health & Human Servs.*, No. 1:19-cv-00100-LEW, 2019 WL 2866832, *15–17 (D. Me. July 3, 2019) (denying motion for preliminary injunction). Still, Planned Parenthood and NFPRHA attempt to piggyback on the decisions they agree with to argue that the Rule somehow requires Title X grant recipients to provide *directive* pregnancy counseling. *See* PP Mem. at 36–37. But Planned Parenthood and NFPRHA do not explain how that could be so. The Rule does not require funding recipients (of Title X grants or otherwise) to engage in pregnancy counseling at all—much less counseling that directs women to any particular outcome with respect to their pregnancy. The Rule simply implements the Federal Conscience Statutes. Accepting Plaintiffs' argument that the Rule unlawfully requires withholding information from Plaintiffs would require the Court to believe that—despite Congress's explicit provisions in the Federal Conscience

[7] A unanimous motions panel of the Ninth Circuit correctly rejected the district court's conclusions and stayed the preliminary injunctions entered in the cases Plaintiffs cite. Although the Ninth Circuit ordered the defendants' appeal to be reheard en banc and instructed that the motions panel's order not be cited as precedential in the Ninth Circuit, *California v. Azar*, No. 19-15974, Order (9th Cir. July 3, 2019), the motions panel's order constitutes persuasive authority. The Ninth Circuit also expressly indicated that the motions panel's order has not been vacated. *California v. Azar*, No. 19-15974, Order (9th Cir. July 11, 2019). The *en banc* Ninth Circuit denied the plaintiffs' motions for an administrative stay of the motions panel's order and is now in the process of rehearing the question of a stay of the preliminary injunction pending appeal.

Statutes—Congress, through an appropriations rider, effectively repealed those protections and compelled health care entities to counsel on all pregnancy options, including abortion, even if they have religious or moral objections to providing such counseling. That proposition is wholly implausible and should be rejected. *See, e.g.*, *Tennessee Valley Auth. v. Hill*, 437 U.S. 153, 190 (1978) (indicating that the presumption against implied repeals "applies with even *greater* force when the claimed repeal rests solely on an Appropriations Rider").

Paperwork Reduction Act

New York also argues that the assurance and certification of compliance requirements contained at 42 C.F.R. § 88.4 violate the Paperwork Reduction Act, 44 U.S.C. § 3501, *et seq.*, because, when the Rule was issued, the Office of Management and Budget (OMB) had not yet approved the paperwork that recipients must complete to satisfy § 88.4. *See* NY Mem. at 35–36. Since publishing the Rule, however, HHS has submitted updated forms for clearance from OMB, and HHS fully expects approval prior to the Rule's revised effective date. Plaintiffs' argument is meritless or, at the very least, will be moot.

D. The Rule Is Neither Arbitrary Nor Capricious

Agency action must be upheld in the face of an APA claim if the agency "examined the relevant data and articulated a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n, of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted); *Waterkeeper All., Inc. v. EPA*, 399 F.3d 486, 498 (2d Cir. 2005). Under this deferential standard of review, "a court is not to substitute its judgment for that of the agency . . . and should uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned . . . ." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513–14 (2009) (citations omitted); *see also FERC v. Elec. Power Supply Ass'n*, 136 S. Ct. 760, 782 (2016) (noting that a court does not determine whether the decision "is the best

one possible or even whether it is better than the alternatives"). The Rule easily satisfies this deferential review.

Plaintiffs make several general arguments in support of their claim that the Rule is "arbitrary" and "capricious." None is persuasive, and none can overcome the presumption of validity to which the agency rulemaking is entitled.

HHS Adequately Explained the Reasons for the Rule

The Rule undeniably revises HHS's approach to enforcing the Federal Conscience Statutes. But HHS is permitted to "consider varying interpretations and the wisdom of its policy on a continuing basis, for example, in response to changed factual circumstances, or a change in administrations." *Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) (internal citation omitted). As the Supreme Court has explained, there is no heightened standard when an agency changes its policy so long as the agency shows that "the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates." *Fox Television v. FCC*, 556 U.S. 502, 515 (2009). HHS has met that standard here.

Contrary to Plaintiffs' position, PP Mem. at 20–23; NY Mem. at 43–44, HHS did acknowledge that it was changing its policy. As HHS explained in the preamble to the Rule, it determined that the preexisting regulatory structure was insufficient to protect the statutory rights and liberty interests of health care entities. *See* 84 Fed. Reg. at 23,228. HHS reasonably judged that the 2011 Rule lacked adequate measures to enforce the Federal Conscience Statutes and promoted confusion, not clarity, about the scope of those statutory protections. The 2011 Rule related to just three of the many Federal Conscience Statutes and did not provide adequate incentives for covered entities to "institute proactive measures to protect conscience, prohibit coercion, and promote nondiscrimination." 84 Fed. Reg. at 23,228. Moreover, the 2011 Rule failed

to provide sufficient information concerning the scope of the various Federal Conscience Statutes, especially regarding their interaction with state laws, including state laws adopted since the promulgation of the 2011 Rule. *Id.*; *see also* NPRM, 83 Fed. Reg. at 3889.

In the same breath that they claim that HHS did not give reasons for the change, Planned Parenthood and NFPRHA also criticize one of HHS's stated reasons—the increase in complaints of alleged violations of the Federal Conscience Statutes. PP Mem. at 21–22. The increase in complaints is, of course just "one of the many metrics used to demonstrate the importance of this rule." 84 Fed. Reg. at 23,229. In addition, the Rule is based on HHS's determination (as explained above) that the existing rule gave too little enforcement authority to HHS to ensure compliance with the Federal Conscience Statutes, and caused confusion about the scope of conscience protections. In any event, the increase in complaints was both real and significant. *See* NPRM, 83 Fed. Reg. at 3886; 84 Fed. Reg. at 23,229. Many of these complaints allege violations of religious and conscience-based beliefs in the medical setting, and while a large subset of them complain of conduct that is outside the scope of the Federal Conscience Statutes and the Rule,[8] some do implicate the relevant statutes, *see*, *e.g.*, Admin. Record (AR) 544,188–207, 544,516, 544,612–23. Further, the complaints overall illustrate the need for HHS to clarify the scope and effect of the Federal Conscience Statutes.

Planned Parenthood and NFPRHA also criticize HHS's conclusion that the Rule will have the benefit of increasing the number of health care providers. PP Mem. at 22–23. That Plaintiffs might give the 2009 poll cited by HHS less weight than HHS did is insufficient to show that the agency acted unreasonably in considering it. *See, e.g.*, *Cablevision Sys. Corp. v. FCC*, 649 F.3d

[8] For example, many complaints were from patients and/or parents who criticized the vaccination policies at schools and medical offices, *see, e.g.*, AR 542,458.

695, 716 (D.C. Cir. 2011) (rejecting arbitrary and capricious challenge premised on agency's alleged overreliance on a "weak and dated" study and agency's inadequate analysis of "whether the study's sample . . . is representative" of the target group). HHS's policy determination relied on its own analysis, the comments it received in response to the NPRM, anecdotal evidence, and, yes, the 2009 poll. 84 Fed. Reg. at 23,247. There was nothing unreasonable, arbitrary, or capricious in HHS considering the poll among other non-empirical evidence. *See Fox Television*, 556 U.S. at 521 ("[E]ven in the absence of evidence, the agency's predictive judgment (which merits deference) makes entire sense. To predict that complete immunity for fleeting expletives, ardently desired by broadcasters, will lead to a substantial increase in fleeting expletives seems to us an exercise in logic rather than clairvoyance."). Planned Parenthood and NFPRHA criticize HHS for not having run studies after the 2011 Rule, but the arbitrary and capricious standard does not permit outsiders to compel the agency to investigate an issue in a particular way. *See Chamber of Commerce of U.S. v. Sec. & Exch. Comm'n*, 412 F.3d 133, 142 (D.C. Cir. 2005). Moreover, HHS scarcely assigned controlling weight to either the 2009 survey or the ramifications of that survey: HHS ultimately concluded merely that it lacked sufficient data to quantify the theoretical effect but that the available data was adequate "to conclude that the rule will increase, or at least not decrease, access to health care providers and services." 84 Fed. Reg. at 23,247; *see also Stand Up for California! v. U.S. Dep't of Interior*, 879 F.3d 1177, 1188 (D.C. Cir. 2018) ("[T]he arbitrary and capricious standard is particularly deferential in matters implicating predictive judgments.") (quoting *Cellular Ass'n v. FCC*, 588 F.3d 1095, 1105 (D.C. Cir. 2009)). HHS also considered other potential benefits of the rule for health care entities, such as the reduction in "harm that providers suffer when they are forced to violate their consciences." 84 Fed. Reg. 23,246 (citing, among other

sources, Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals*, 49 Ariz. Stat. L.J. 549, 565 (2017)).

Whether the Rule would increase or decrease the number of providers is a difficult policy assessment that should be left to the entity with responsibility for making those assessments—HHS. Indeed, "[w]hether [the Court] would have done what the agency did is immaterial," so long as the agency engages in an appropriate decisionmaking process. *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 718 (D.C. Cir. 2016). The court asks only whether the decision "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park*, 401 U.S. at 416. Here, HHS assessed the available evidence and reasonably concluded that the Rule would "increase, or at least not decrease" the number of providers.

HHS's Definitions Were the Product of Reasoned Decisionmaking

As discussed above, HHS crafted each defined term the Rule sets forth in a reasonable exercise of its statutory authority. For similar reasons, the defined terms are also neither arbitrary nor capricious. *See Catskill Mountains*, 846 F.3d at 507. Plaintiffs claim that the definitions of "assist in the performance," "discrimination," "health care entity," and "referral" "so expand the universe of protected persons and prohibited conduct that they present an unworkable situation." NY PI Mem. at 47. In support of this argument, Plaintiffs offer three extreme hypothetical examples of potential outcomes of the Rule. *See id.* But again, Plaintiffs' "challenge is facial, not as-applied, and the fact that [they] can 'point to a hypothetical case in which the rule might lead to an arbitrary result does not render the rule 'arbitrary or capricious.'" *Ass'n of Proprietary Colls. v. Duncan*, 107 F. Supp. 3d 332, 367–68 (S.D.N.Y. 2015) (quoting *Am. Hosp. Ass'n v. NLRB,* 499 U.S. 606, 619 (1991)).

HHS weighed comments that argued that the proposed definitions did not go far enough and others complaining that the definitions were overbroad, and provided thoughtful, detailed explanations for why it believed each of the challenged definitions correctly interpreted the relevant statutes. *See generally* 84 Fed. Reg. 23,186,203; *e.g.*, *id.* at 23,194 (declining to explicitly incorporate "social workers and schools of social work" into the definition of "health care entity" because "it is unclear in many circumstances [whether] such entities deliver healthcare"); *id.* 23,191 (explaining that HHS would not incorporate into the rule the "undue hardship" exception for reasonable accommodations under Title VII because Congress did not adopt such an exception in the applicable statutes). The agency also modified each definition in response to the comments it received, including narrowing and clarifying each definition in significant respects. *See id.* at 23,186–203; *e.g.*, *id.* at 23,186–89 (reviewing several categories of comments asserting that the proposed definition of "assist in the performance of" was overbroad, agreeing in part, and narrowing the definition from "to participate in any activity" with an "articulable connection[,]" to mean "to take an action that has a specific, reasonable, and articulable connection," among other changes and clarifications). HHS thus satisfied its obligations under the APA.

HHS Reasonably Weighed the Costs and Benefits of the Rule

In addition to HHS's purpose of improving knowledge about and enforcement of the Federal Conscience Statutes, HHS identified four primary benefits of the Rule in its cost-benefit analysis: (1) increasing the number of health care providers; (2) improving the doctor-patient relationship; (3) eliminating the harm from requiring health care entities to violate their conscience; and (4) reducing unlawful discrimination in the health care industry and promoting personal freedom. 84 Fed. Reg. at 23,246. Plaintiffs barely contest these advantages. New York

briefly disputes HHS's use of the 2009 study, which was previously addressed above.[9] New York also criticizes HHS for not including "evidence" that the Rule will increase "knowledge of, compliance with, and enforcement of" the underlying statutes. NY Mem. at 41 (quoting 84 Fed. Reg. at 23,175). But an agency need not perform an impossible study to determine the specific effects of a rule that does not yet exist, *see BellSouth Corp. v. FCC*, 162 F.3d 1215, 1221 (D.C. Cir. 1999), and it is clear on its face that the Rule will increase knowledge of, compliance with, and enforcement of, the underlying statutes by providing greater clarity about the Federal Conscience Statutes and HHS's enforcement role. Indeed, the existence of New York's complaint, as well as the complaints of the numerous other plaintiffs challenging the Rule, show that the Rule has already increased knowledge of the underlying statutes, and suggest that even Plaintiffs expect the Rule to increase compliance and enforcement.

Plaintiffs identify a variety of factors that they think HHS should have considered more thoroughly. On some of these issues, the available data were not dispositive, leaving HHS to reach the best conclusions it could through the application of its expertise. Plaintiffs would prefer that they be able to impose their own standard of research on the agency before it can act, but that standard is counter to the APA's lenient standard of review.

Plaintiffs, for example, argue that HHS inadequately considered the effect of the Rule on patient health, PP Mem. at 17–19; NY Mem. at 39–40, but HHS received no data that would "enable[] a reliable quantification of the effect of the rule on access to providers and to care[,]" 84

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[9] New York quibbles that the study does not support HHS's conclusion that "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," NY Mem. at 41 (quoting 84 Fed. Reg. at 23,247 & n.322), but that is an inescapable conclusion of the serious concerns cited by faith-based health care professionals in the 2009 survey.

Fed. Reg. at 23,250. No Plaintiff contests this point; no Plaintiff identifies data that HHS should have considered but did not; no Plaintiff offers *any* quantification of the effects of the Rule on patients. Absent reliable data from which to quantify the effects, HHS was scarcely arbitrary in relying on the data it *did* have—and that data indicated that, if anything, the Rule would increase the number of available providers, which can reasonably be predicted to improve patient care. *See* 84 Fed. Reg. at 23,180; *see also Fox Television*, 556 U.S. at 521.

Furthermore, HHS explicitly sought comments on "whether this final rule would result in unjustified limitations on access to health care." 84 Fed. Reg. at 23,250; NPRM, 83 Fed. Reg. at 3900 (request for comment). Ultimately, and as HHS explained, the majority of the comments it received in response to that request focused on *preexisting* discrimination in health care and did not attempt to answer the question of how the Rule itself would affect access to health care. 84 Fed. Reg. at 23,250. HHS studied academic literature relating to preexisting statutes, but found "insufficient evidence to conclude that conscience protections have negative effects on access to health care." *See id.* at 23,251 & n.345. HHS also considered a report with anecdotal data on discrimination against LGBT patients in states with religious freedom laws. 84. Fed. Reg. at 23,252. But, as HHS explained, that report contained only anecdotal accounts—thus making it unfit for extrapolation—and made no attempt to establish a causal mechanism between the religious freedom laws and the discrimination it reported. *Id.*

Plaintiffs suggest that HHS did not adequately account for the existing effects of Title VII, which Plaintiffs cast as a panacea that has adequately protected the consciences of all health care employees. PP Mem. at 19–20. But Title VII's protections are distinct from the Federal Conscience Statutes that Congress separately enacted. What is more, HHS reasonably concluded that the status quo was not adequately protecting at least some health care providers who object to participating

in certain care, in part due to the increasing number of complaints it was receiving. *See* 84 Fed. Reg. 23,254 (rejecting the option of maintaining the status quo because that would "perpetuate the current circumstances necessitating Federal regulation, which include (1) inadequate to non-existent Federal government frameworks to enforce Federal conscience and antidiscrimination 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 antidiscrimination laws"). And while the Rule adopts the Title VII reasonable-accommodation-of-religion framework in part by recognizing that "when appropriate accommodations are made for objections protected by Federal conscience and antidiscrimination laws, those accommodations do not themselves constitute discrimination[,]" HHS sensibly declined to adopt Title VII's "undue hardship" exception because "Congress chose not to place that limitation on the protections set forth in the [later-in-time] Federal conscience and antidiscrimination laws." 84 Fed. Reg. at 23,191.

Plaintiffs further claim that the agency failed to account for the Rule's purported interference with EMTALA. NY Compl. ¶ 179. But as Defendants have already explained, the Rule does not conflict with EMTALA. Moreover, HHS clearly considered the Rule's effect on the administration of that statute and reiterated its 2008 conclusion that "the requirement under EMTALA that certain hospitals treat and stabilize patients who present in an emergency does not conflict with Federal conscience and antidiscrimination laws," 84 Fed. Reg. 23,183, and "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." *Id.* at 23,188.

New York also argues that HHS has underestimated the number of covered entities and the effort required to comply with the Rule. NY Mem. at 41–42 & n.34. But New York provides no

alternative evidence of its own, no alternative estimate of compliance costs, and no explanation of why it finds HHS's conclusions inadequate.

Many of these questions—the precise effect of the Rule on patient care, the effort that will be required to comply with a new policy—are difficult to answer. Plaintiffs' view seems to be that an agency cannot take an action until it has commissioned or executed studies on every potential repercussion of that action. While that might be a technocrat's dream, it is not what the APA requires. Instead, the APA commits these decisions to the agency's expertise. "Whether [the Court] would have done what the agency did is immaterial[,]" so long as the agency engages in an appropriate decisionmaking process. *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 718 (D.C. Cir. 2016). Where, as here, HHS assessed the available evidence on a subject, and reached a reasonable conclusion, this Court should not accept Plaintiffs' invitation to second-guess the agency's policy conclusions.

E. The Federal Conscience Statutes and the Rule Comply with the Spending Clause

New York alleges that the Rule violates the Spending Clause. NY Mem. at 45–53. More specifically, these plaintiffs allege that the Rule is ambiguous, NY PI Mot. at 46–50; that the Rule is coercive, NY PI Mot. at 50–51; that the Rule's requirements are insufficiently related to the purpose of the Federal Conscience Statutes, NY PI Mot. at 51–53; and that the Rule places unconstitutional conditions on federal funds, NY PI Mot. at 53. All of these contentions are wrong.

As an initial matter, although New York complains that the *Rule* violates the Spending Clause, their real objection is to the underlying substantive law, found in the Federal Conscience Statutes. It is those statutes that attach conditions to the government's offer of funds, and require that such funds not be used to discriminate against health care providers or others for declining to provide certain services (or certain coverage) in accordance with their religious or moral beliefs.

The Rule does not change the substantive law of the Federal Conscience Statutes, as established by Congress. *See* 84 Fed. Reg. 23,256 ("This rule holds States and local governments accountable for compliance with [the Federal Conscience Statutes] 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."). Because Plaintiffs do not challenge the Federal Conscience Statutes themselves, they cannot obtain the relief of having those statutes struck down. *Cf.* NY Compl., Prayer for Relief at 74, ECF No. 3 (requesting relief concerning the Rule exclusively). Instead, Plaintiffs must show that the Rule deviates from the Federal Conscience Statutes in an unconstitutional way. But New York cannot make this showing, because most of their arguments—that the amount of funds with conditions attached is too great and that the government does not have an interest in protecting religious freedom—apply equally to the Rule and the Federal Conscience Statutes. In other instances, the Rule is clearly *less* susceptible to attack than the statutes—for example, Plaintiffs argue that the conditions on federal grants are ambiguous, but the Rule provides greater clarity.

Furthermore, New York's specific objections under the Spending Clause fail on their merits. Article I of the Constitution confers on Congress the authority to "lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defense and general Welfare of the United States." U.S. Const. art. I, § 8, cl. 1. That the Spending Clause authority is "broad" and empowers Congress to "set the terms on which it disburses federal money to the States[.]" *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006); *see also, e.g.*, *S. Dakota v. Dole*, 483 U.S. 203, 206 (1987) (noting that Congress has "repeatedly employed the [spending] power to further broad policy objectives by conditioning receipt of federal moneys

upon compliance by the recipient with federal statutory and administrative directives." (citations omitted)).

As courts have recognized, protecting religious freedom and deterring discrimination against religious practice is the type of governmental interest that can motivate the government's exercise of its Spending Clause power. For example, the Ninth Circuit upheld the Religious Land Use and Institutionalized Persons Act (RLUIPA) against a Spending Clause challenge because "[t]he First Amendment, by prohibiting laws that proscribe the free exercise of religion, demonstrates the great value placed on protecting religious worship from impermissible government intrusion. . . . Moreover, by fostering non-discrimination, RLUIPA follows a long tradition of federal legislation designed to guard against unfair bias and infringement on fundamental freedoms." *Mayweathers v. Newland*, 314 F.3d 1062, 1066–67 (9th Cir. 2002). The Federal Conscience Statutes, and accordingly the Rule, serve a similar interest.

The Federal Conscience Statutes and the Rule Are Unambiguous

One of the discrete limitations attached to the "broad" authority conferred by the Spending Clause is that terms attached to the receipt of federal funds must be "unambiguous[]," and thus enable the potential recipient to "exercise [its] choice" to participate (or not) in the program "knowingly, cognizant of the consequences of [its] participation." *Dole*, 483 U.S. at 207 (citation omitted).

New York makes no attempt to argue that the terms of the Federal Conscience Statutes are ambiguous, likely because each clearly provides unambiguous notice to funding recipients of the anti-discrimination provisions. The Rule—which adds additional clarification and interpretation on top of that provided in the statutes—is necessarily clearer and less ambiguous than the statutes. Either is more than sufficient to pass the ambiguity analysis, which focuses on whether or not potential recipients are aware that the federal government has placed conditions on federal funds,

rather than on whether every detail of the conditions has been set forth.[10] *See, e.g.*, *Mayweathers*, 314 F.3d at 1067 ("[C]onditions may be 'largely indeterminate,' so long as the statute 'provid[es] clear notice to the States that they, by accepting funds under the Act, would indeed be obligated to comply with [the conditions].' Congress is not required to list every factual instance in which a state will fail to comply with a condition. . . . Congress must, however, make the existence of the condition itself . . . explicitly obvious." (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 24–25 (1981))).

Instead, New York's main argument is that the Rule has "significantly alter[ed] the conditions to which [they] initially agreed" by, for example, imposing a certification of compliance requirement. NY Mem. at 47. This argument essentially duplicates Plaintiffs' statutory authority claim (which for the reasons described above fails), and in any event there is no Spending Clause barrier to clarifying the terms on which an entity may receive federal funding. *Cf. NFIB v. Sebelius*, 567 U.S. 519, 582–83 (2012) (holding that the Medicaid statute authorized Congress to modify its terms without creating Spending Clause problems, so long as the modifications did not rise to the level of creating a new program). And it is unclear what Plaintiffs mean by suggesting that the Rule is "retroactive," NY Mem. at 47—HHS does not maintain that it has the authority under the Rule to, for example, claw back funds received in 2004 if it discovers a 2004 violation of one of the Federal Conscience Statutes.

The Federal Conscience Statutes and the Rule Do Not Coerce

A conditional offer of federal funds will be found to be unduly coercive only in the unusual case—"[i]n the typical case we look to the States to defend their prerogatives by adopting 'the

[10] And therefore the fact that the presence of conditions on federal funds is unambiguous is entirely consistent with Defendants' *Chevron* argument.

simple expedient of not yielding' to federal blandishments when they do not want to embrace the federal policies as their own. The States are separate and independent sovereigns. Sometimes they have to act like it." *NFIB*, 567 U.S. at 579 (Roberts, C.J.) (quoting *Massachusetts v. Mellon*, 262 U. S. 447, 482 (1923)).

Here, Plaintiffs attempt to analogize to *NFIB*, in which the Supreme Court concluded that an ACA provision that conditioned all Medicaid funds on a state's agreement to expand its Medicaid program violated the Spending Clause because it "transformed" Medicaid into a new program. 567 U.S. at 583. The Federal Conscience Statutes and the Rule are quite different in two important ways.

First, unlike in *NFIB*, where states were provided with a binary choice—either expand their Medicaid programs, or lose all of their Medicaid funding—it is far from clear that noncompliance with the conscience statues and the Rule would impact all of the funding sources that New York identifies. HHS has a variety of enforcement options when the conditions for its grants are not met, and Plaintiffs have not shown at this early stage that the result of any enforcement proceeding would be the across-the-board loss of HHS funding. Furthermore, the Rule clarifies that HHS will always begin by trying to resolve a potential violation of the Federal Conscience Statutes through informal means. 84 Fed. Reg. at 23,271 ("If an investigation or compliance review indicates a failure to comply with Federal conscience and antidiscrimination laws or this part, OCR will so inform the relevant parties and *the matter will be resolved by informal means whenever possible*." (emphasis added)); 84 Fed. Reg. at 23,222 ("[W]here 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 . . . ."); *see also* 45 C.F.R. § 75.374 (addressing HHS's process

when a non-federal entity fails to comply with conditions on a federal award, and requiring that "[u]pon taking any remedy for non-compliance, the HHS awarding agency must provide the non-Federal entity an opportunity to object and provide information and documentation challenging the suspension or termination action, in accordance with written processes and procedures published by the HHS awarding agency" and "must comply with any requirements for hearings, appeals or other administrative proceedings to which the non-Federal entity is entitled under any statute or regulation applicable to the action involved"); 45 C.F.R. Pt. 16 (describing the procedures of the Departmental Grant Appeals Board, which reviews certain grants disputes as specified in Appendix A to Part 16). Far from the "gun to the head" at issue in *NFIB*, 567 U.S. at 581, this possibility of informal enforcement proceedings is not unduly coercive.

Second, unlike in *NFIB*, the conditions to which New York objects are far from new. The ACA provisions at issue in *NFIB* required the states to adopt an entirely new Medicaid expansion. Many of the Federal Conscience Statutes, in contrast, have been in effect for decades, and any funds that the states have been accepting under the statutes have thus been subject to the Federal Conscience Statutes' conditions for decades. *See, e.g.*, 42 U.S.C. § 300a-7 (Church Amendments, the first of which was enacted in 1973, Pub. L. No. 93-45, 87 Stat. 91); 42 U.S.C. § 238n (Coats-Snowe Amendment, enacted in 1996, Pub. L. No. 104-134, 110 Stat. 1321). Plaintiffs cannot plead surprise that recent events have convinced HHS to step up its enforcement of requirements that have been in effect since the 1970s. *Cf. NFIB*, 567 U.S. at 584 (Roberts, C.J.) (criticizing the Medicaid expansion as an attempt to "enlist[] the States in a new health care program" and "surpris[e] participating States with postacceptance or 'retroactive' conditions" (citation omitted)). Again, Plaintiffs fail to articulate how the Rule is *worse* from a Spending Clause perspective than the Federal Conscience Statutes it implements, which Plaintiffs do not challenge. To the contrary,

the Rule should be an improvement from Plaintiffs' perspective because the Rule provides additional insight into HHS's enforcement processes. Without the Rule, there would be far less transparency and notice.

New York's apocalyptic (and hypothetical) scenarios of complete funding loss—scenarios that have not remotely come to pass in the decades that many of the Federal Conscience Statutes have existed—are of no help. Plaintiffs cannot succeed on their facial challenge by identifying a handful of implausible and speculative circumstances in which the operation of the Federal Conscience Statutes and the Rule *might* have a coercive effect; instead, they must show that the Rule has *no* constitutional applications. *Cf. Copeland v. Vance*, 893 F.3d 101, 110 (2d Cir. 2018). And, the further factual context that would be available if such a scenario did come to pass would be helpful to the Court in evaluating the Spending Clause claims, thus highlighting the lack of ripeness at this time.

The Federal Conscience Statutes and the Rule Are Related to the Federal Interest in Protecting Conscience and Ensuring a Robust Health Care System

New York further allege that the Rule is not adequately related to a governmental purpose. NY Mem. at 51–53. This argument also fails. Again, because it is the Federal Conscience Statutes—not the Rule—that establish the linkage between conscience protections and federal funding, and because Plaintiffs do not challenge the statutes, they can establish a redressable defect only if it can show that the *Rule* rendered the conscience protection requirements less related to a governmental interest than the statutes. As explained above, such a showing is impossible because the Rule does not substantively change the requirements of the Federal Conscience Statutes.

Moreover, in the underlying statutes, Congress acted to ensure that federal funds do not subsidize discrimination against individual and institutional health care entities on the basis of their moral or religious beliefs about certain care (or coverage), in service of the government's

interests in protecting the free exercise of religion and in encouraging and overseeing a robust health care system. New York tacitly concedes this governmental interest, objecting only that the Weldon Amendment, by its own terms, places in jeopardy "federal funds not just from HHS, but from the Labor Department and Education Department as well." NY Mem. at 52. But Plaintiffs offers no evidence that Labor or Education funds will actually be at risk. Plaintiffs should not succeed on their *facial* challenge on the convoluted theory that HHS, through its Rule (which applies only to HHS administered, conducted, or funded programs), would somehow bar Plaintiffs from receiving funds provided by the Departments of Labor or Education due to discriminatory actions by, for example, a hospital.

The Federal Conscience Statutes and the Rule Do Not Impose Unconstitutional Conditions

Finally, New York argues that the Rule places unconstitutional conditions on governmental funding recipients by requiring them to violate the Establishment Clause. NY Mem. at 53. This argument fails for the same reason that the Rule does not impermissibly advance religion. *See infra* Part III.F.

F. The Rule Comports with the Establishment Clause

Planned Parenthood and NFPRHA argue that the Rule violates the Establishment Clause, PP Mem. at 39–42, but they overlook the fact that, under their theory, it would be the preexisting Federal Conscience Statutes—which Plaintiffs do not challenge—that violate the Establishment Clause. Those statutes, such as the Church Amendments, are the source of the linkage between eligibility for federal funds and respect for conscience, including religious and moral convictions. And as explained above, the Rule does not change the substantive law of the Federal Conscience Statutes, as established by Congress. *See* 84 Fed. Reg. 23,256.

Plaintiffs, of course, do not challenge the Federal Conscience Statutes, because those statutes do not violate the Establishment Clause. For example, the Ninth Circuit concluded decades ago in *Chrisman v. Sisters of St. Joseph of Peace*, that a provision of the Church Amendments was proper under the Establishment Clause because Congress was seeking to "preserve the government's neutrality in the face of religious differences" rather than to "affirmatively prefer[] one religion over another."[11] 506 F.2d 308, 311 (9th Cir. 1974). The Ninth Circuit analogized the situation to *Sherbert v. Verner*, 374 U.S. 398 (1963), which recognized that a religious adherent's receipt of a government benefit did not establish religion, but rather, "reflects nothing more than the governmental obligation of neutrality in the face of religious differences." *Id.* at 409. Likewise, the Ninth Circuit upheld against an Establishment Clause challenge another of the Federal Conscience Statutes that permitted Medicare and Medicaid payments for the nonmedical care of persons who object to conventional medical care. *See Kong v. Scully*, 341 F.3d 1132 (9th Cir. 2003), *opinion amended on denial of reh'g*, 357 F.3d 895 (9th Cir. 2004) (upholding amendments to 42 U.S.C. § 1320 and 42 U.S.C. § 1395). In passing the remaining Federal Conscience Statutes, the government has similarly done nothing more than preserve its neutrality toward religion. If Plaintiffs accept the constitutionality of the Federal Conscience Statutes (as they appear to), it is nonsensical to claim that the Rule, which merely implements those statutes, violates the Establishment Clause.

Indeed, for all of the same reasons that the Federal Conscience Statutes are in harmony with the Establishment Clause, the Rule is too. "[T]here is ample room for accommodation of

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[11] As explained above, the Church Amendments are a series of conscience-protection provisions enacted in the 1970s and now codified at 42 U.S.C. § 300a-7. 84 Fed. Reg. at 23,171. *Chrisman* addresses one of these provisions, Pub. L. No. 93-45, 87 Stat. 95 § 401 (1973). *Chrisman*, 506 F.2d at 310 & n.6.

religion under the Establishment Clause." *Corp. of Presiding Bishop of Church v. Amos*, 483 U.S. 327, 338 (1987). As the Supreme Court has repeatedly held, "there is room for play in the joints between the Free Exercise and Establishment Clauses, allowing the government to accommodate religion beyond free exercise requirements, without offense to the Establishment Clause." *Cutter v. Wilkinson*, 544 U.S. 709, 713 (2005) (citation omitted). The Rule serves the legitimate secular purpose of alleviating potential burdens of conscience on individual and institutional health care entities, just as the Federal Conscience Statutes do. Additionally, the Rule neither promotes nor subsidizes any religious message or belief; rather, it explains the enforcement processes for ensuring that federal funds will not be used to discriminate against health care entities who act in accordance with their consciences.

Plaintiffs attempt to analogize the Rule to the law at issue in *Thornton v. Caldor, Inc.*, 472 U.S. 703 (1985), but that case is inapposite. First, unlike in *Thornton*, where the law placed an "unyielding weighting in favor of Sabbath observers," *id.* at 710, the Rule is generally neutral between various religions and between religion and nonreligion (because many of the Federal Conscience Statutes apply to conscience objections whether religiously rooted or not). *Cf., e.g.*, 42 U.S.C. § 238n (Coats-Snowe Amendment, the applicability of which does not turn on a religious belief); Pub. L. No. 115-245, Div. B., sec. 507(d) (Weldon Amendment, the applicability of which does not turn on religious belief); 42 U.S.C. § 300a-7 (Church Amendments, which equally protect health care providers from discrimination based on religious beliefs or moral convictions); *Welsh v. United States*, 398 U.S. 333 (1970) (explaining how the Supreme Court has read a statute protecting religious objectors to the draft to include non-religious objections). Second, unlike the law in *Thornton*, the Federal Conscience Statutes and the Rule do not impose an "absolute obligation" on any entities, PP Mem. at 39; rather they simply place conditions on the receipt of

federal funds. If Planned Parenthood and NFPRHA do not wish to adjust their hiring plans, training, or schedules, PP Mem. at 41, as necessary to avoid discriminating against health care providers with conscience objections to providing certain health care services, then they are free to decline HHS funds and make their own unfettered decisions.

Plaintiffs also incorrectly contend that the Rule is inconsistent with the Establishment Clause because it unduly burdens third parties. PP Mem. at 40–41. To begin with, the Establishment Clause does not bar an accommodation of religion merely because it could have an adverse effect on others. For example, in *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327 (1987), the Supreme Court held that Title VII's religious exemption to the prohibition against religious discrimination in employment was consistent with the Establishment Clause even though it allowed an employer to terminate the plaintiff's employment. While the plaintiff was "[u]ndoubtedly" adversely affected, the Court noted, "it was the Church[,] . . . not the Government, who put him to the choice of changing his religious practices or losing his job." 483 U.S. at 337 n.15. Similarly, in *Doe v. Bolton*, the Supreme Court characterized a state statute leaving hospitals, physicians, and other employees free to refrain from participating in abortions as "appropriate protection [for] the individual and [ ] the denominational hospital." 410 U.S. 179, 197–98 (1973). Here, the Federal Conscience Statutes (and, therefore, the Rule) do not directly burden anyone; instead, they simply encourage entities not to discriminate against individual and institutional health care entities that act on their religious, moral, or other objections by making such nondiscrimination a condition of federal funding. If any adverse effects occur, they thus result from the conscience decisions of health care entities, not the government. *See Amos*, 483 U.S. at 337 n.15 (noting plaintiff employee "was not legally obligated" to take the steps necessary to save his job, and that his discharge "was not required by statute").

G. The Rule Does Not Violate the Separation of Powers

New York also asserts that the Rule violates separation of powers principles because it "[d]isregard[s] the careful and deliberate legislation that Congress has enacted." NY Mem. at 44. Not so. As explained above, the Rule does not change the substantive law at all. 84 Fed. Reg. at 23,256. It is not unusual for agencies to enact regulations implementing Congress's funding conditions. *See, e.g.*, Nondiscrimination on the Basis of Race, Color, National Origin, Handicap or Age in Programs or Activities Receiving Federal Financial Assistance; Final Rule, 68 Fed. Reg. 51,334-01 (a regulation by twenty-two agencies implementing Title VI, the Rehabilitation Act, and the Age Discrimination Act). And New York cannot blame the Rule for any refusal by HHS to spend funds that Congress has appropriated when it is the underlying statutes, not the Rule, that compel HHS not to fund programs that do not meet the congressionally dictated criteria. *See, e.g.*, Pub. L. No. 115-245, Div. B, § 507(d), 132 Stat. 2981 (Weldon Amendment, providing that "[n]one of the funds made available in this Act may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.").

H. The Rule Is Not Unconstitutionally Vague

Planned Parenthood and NFPRHA also cannot prevail on their claim that the Rule is unconstitutionally vague. *See* NFPRHA Compl. ¶ 156; PP Compl. ¶ 157. The Rule itself does not impose penalties but instead enforces statutory conditions on government funding. And "when the Government is acting as patron rather than as sovereign, the consequences of imprecision are not constitutionally severe." *Nat'l Endowment for the Arts v. Finley*, 524 U.S. 569, 589 (1998). Accordingly, the Supreme Court has upheld even "opaque" funding provisions that "could raise substantial vagueness concerns" had "they appeared in a criminal statute or regulatory scheme[.]"

Id. at 588; *see also Planned Parenthood of Cent. & N. Ariz. v. Ariz.*, 718 F.2d 938, 948 (9th Cir. 1983) ("Our tolerance should be even greater in a case, such as the one before us, where the consequence of noncompliance with the enactment is not a civil penalty, but merely reduction of a government subsidy.").

The Rule easily clears this lenient vagueness standard. Plaintiffs' vagueness argument boils down to claimed confusion about when and how the Rule might apply in certain hypothetical situations. *See, e.g.*, PP Compl. ¶ 150 ("The Rule does not provide Planned Parenthood with adequate guidance as to what conduct is prohibited and encourages arbitrary enforcement."). But this argument does not get out of the starting gate: Plaintiffs mount a facial challenge, and "speculation about possible vagueness in hypothetical situations not before the Court will not support a facial attack on a [regulation] when it is surely valid in the vast majority of its intended applications[.]" *Hill v. Colorado*, 530 U.S. 703, 733 (2000) (citation omitted). Indeed, even for criminal statutes, "a core of meaning is enough to reject a vagueness challenge, leaving to future adjudication the inevitable questions at the [regulatory] margin." *Trs. of Ind. Univ. v. Curry*, 918 F.3d 537, 541 (7th Cir. 2019). And like HHS grantees in *National Family Planning & Reproductive Health Association, Inc. v. Gonzales*, 468 F.3d 826 (D.C. Cir. 2006), Plaintiffs have "within [their] grasp an easy means for alleviating the alleged uncertainty[,]" namely, to "inquire of HHS exactly how the agency proposes to resolve any of the" purported ambiguities. *Id*. at 831. Thus, even if the Rule, in some hypothetical application, could possibly give rise to borderline situations, that does not render it impermissibly vague as a facial matter. Plaintiffs' facial challenge on the basis of vagueness cannot succeed.

I. The Rule Does Not Violate Patients' Rights to Privacy and Liberty

Planned Parenthood and NFPRHA allege, finally, that the Rule interferes with patients' ability to obtain abortions and therefore violates patients' Fifth Amendment rights to privacy and

liberty recognized by the Supreme Court. *See* NFPRHA Compl. ¶ 157; PP Compl. ¶ 152. The Court should reject this claim out of hand. The Rule contains no restrictions on access to abortion—it merely protects the conscience rights of covered persons and entities who object to participating in or assisting with procedures that they oppose.

In any event, Plaintiffs cannot succeed on their claim that the Rule impermissibly restricts abortion access. "[A]lthough [the] government may not place obstacles in the path" of a woman seeking an abortion, the government "need not remove those not of its own creation." *Harris v. McRae*, 448 U.S. 297, 316 (1980). The Constitution places no "affirmative duty" on the government "to 'commit any resources to facilitating abortions.'" *Rust v. Sullivan*, 500 U.S. 173, 201 (1991) (quoting *Webster v. Reprod. Health Servs.*, 492 U.S. 490, 511 (1998)). That being so, even if a health care entity's objections to performing abortions could be characterized as an obstacle to a women seeking an abortion, the Constitution imposes no duty on the government to remove that obstacle by conscripting unwilling individuals or entities into performing medical procedures to which they object on conscience grounds. Moreover, if these arguments were to prevail, it would also mean that many of the Federal Conscience Statutes also violate the Fifth Amendment—and it is simply implausible that those statutes would have survived, in some instances for decades, if there were any merit to Plaintiffs' argument.

IV. Plaintiffs Will Suffer No Imminent Irreparable Harm

Showing irreparable harm absent a preliminary injunction is "necessary" for Plaintiffs to obtain such relief. *Beacon Hill CBO II, Ltd. v. Beacon Hill Asset Mgmt. LLC*, 89 F. App'x 749, 750 (2d Cir. 2004); *see Winter*, 555 U.S. at 19. And not just any showing will suffice. A party "seeking preliminary relief [must] demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22. Plaintiffs cannot carry that burden.

Putting aside their allegations of constitutional injury, which fail for the reasons described above, Plaintiffs contend that the ability of their health departments to provide quality care will be harmed if they accommodate the conscience rights of providers that Congress has recognized through the various conscience statutes. *See* NY Mem. at 10–12; PP Mem. at 43–46. New York argues, for instance, that medical departments will be unable to make staffing decisions because they will not know which providers are willing to perform which services. NY Mem. at 18–20. And Planned Parenthood and NFPRHA argue that Plaintiffs may have no choice but to attempt to hire additional employees to take over those job functions, and/or require existing employees to cover extended shifts, hours or duties. PP Mem. at 40–41. These alleged harms are purely speculative and based on a misunderstanding of what the Federal Conscience Statutes and the Rule actually require. Contrary to Plaintiffs' characterization, the Rule does, in fact, allow hospitals and other medical departments to make staffing decisions based on the conscience objections of individual providers. *See* 42 C.F.R. § 88.2(4); 84 Fed. Reg. at 23,191–92. Entities may make accommodations, such as moving the individual to a different position, if the individual is willing to do so. *See* 84 Fed. Reg. at 23,191. Only in the limited circumstance where the individual cannot be accommodated without discrimination would a hospital need to consider additional staffing. Moreover, entities subject to the Rule may *require* employees to inform them about potential objections to providing certain services, in order to facilitate such staffing decisions, so long as there is a reasonable likelihood the provider would be asked in good faith to perform those services. *See* 42 C.F.R. § 88.2(5); 84 Fed. Reg. at 23,191. There is, therefore, no basis to accept the parade of horribles that Plaintiffs allege, and no reason to believe that Plaintiffs will be unable to provide adequate health care while still respecting conscience rights. Accordingly, Plaintiffs cannot show any non-speculative, irreparable harm on that basis.

Plaintiffs also claim irreparable injury based on administrative changes they will need to make, and new policies they will need to adopt, in light of the Rule's clarification of the Federal Conscience Statutes. *See* NY Mem. at 11–12; PP Mem. at 44–46. But "ordinary compliance costs are typically insufficient to constitute irreparable harm[,]" *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005) (collecting cases), and Plaintiffs offer no reason why this case should be treated any differently.

Plaintiffs' allegation that they will be "risking the imminent loss" of HHS funding, *see* NY Mem. at 10; *see also* PP Mem. at 46–47, also does not establish irreparable injury, because it is too speculative. As explained above, a long chain of events would have to occur before Plaintiffs would actually lose any HHS funding. HHS would first need to investigate a complaint of a violation, and, if HHS determined that a violation had occurred, it would work with the grantee to try to accomplish compliance. The process for enforcement set out in the Rule is designed to encourage voluntary compliance by recipients and sub-recipients. If OCR concludes a recipient or sub-recipient is not in compliance, it will seek to achieve voluntary compliance through informal means. 42 C.F.R. § 88.7(i)(2). If recipients are unwilling to comply voluntarily, OCR would first take intermediate steps to attempt to achieve compliance, such as imposing additional conditions. There is no reason to believe, therefore, that Plaintiffs face any imminent loss of funding—much less the drastic consequences Plaintiffs describe in their briefs—as soon as the Rule goes into effect.

The remainder of Plaintiffs' arguments address the Rule's purported impact on third parties not before the Court.[12] Plaintiffs lack standing to raise these alleged harms, *see Warth v. Seldin*, 422 U.S. 490, 499 (1975) and, *a fortiori*, Plaintiffs cannot obtain a preliminary injunction based on allegations of third-party harm. Even New York, which arguably represents the interests of its citizens in some circumstances, "does not have standing as *parens patriae* to bring an action against the Federal government." *See Sierra Forest Legacy v. Sherman*, 646 F.3d 1161, 1178 (9th Cir. 2011).

V. The Balance of Equities and The Public Interest Weigh in Favor of Denying Plaintiffs' Preliminary Injunction Motions

On the other side of the ledger, the government "suffers a form of irreparable injury" if it "is enjoined by a court from effectuating statutes enacted by representatives of its people[.]" *Maryland v. King*, 133 S. Ct. 1, 3 (2012) (Rehnquist, J., in chambers) (citation omitted).[13] That is particularly true here, as the government has a compelling interest in ensuring knowledge of, compliance with, and enforcement of, federal conscience and anti-discrimination laws, and in protecting religious liberty and conscience, which the Rule seeks to accomplish. *See Jolly v. Coughlin*, 76 F.3d 468, 482 (2d Cir. 1996).

The need to avoid that harm significantly outweighs any of Plaintiffs' asserted injuries, particularly in light of Defendants' delay of the effective date of the Rule so that this case can be decided on cross-motions for summary judgment.

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[12] *See, e.g.*, PP. Mem. at 47 (hypothesizing regarding the effects on patients in an emergency); *id.* at 46 (alleging that patients will need to travel longer distances for care); NY. Mem. at 15–17 (alleging harms to citizens' health).

[13] When the federal government is the opposing party, the balance of equities and public interest merge. *See Nken v. Holder*, 556 U.S. 418, 435 (2009).

VI. Any Relief Should Be Limited

A. Any Relief Should Be Limited To The Plaintiffs

For the reasons discussed above, the Court should grant summary judgment to Defendants and deny Plaintiffs' motions for a preliminary injunction. But even if the Court were to disagree, any relief should be limited to redressing the injuries of the parties before this Court. As the Supreme Court recently confirmed, any "remedy" ordered by a federal court must "be limited to the inadequacy that produced the injury in fact that the plaintiff has established"; a court's "constitutionally prescribed role is to vindicate the individual rights of the people appearing before it"; and "[a] plaintiff's remedy must be tailored to redress the plaintiff's particular injury." *Gill v. Whitford*, 138 S. Ct. 1916, 1921, 1933–34 (2018) (citation omitted). Equitable principles likewise require that any relief "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Madsen v. Women's Health Ctr., Inc.,* 512 U.S. 753, 765 (1994) (citation omitted); *see also Trump v. Hawaii*, 138 S. Ct. 2392, 2429 (2018) (Thomas, J., concurring) (noting that nationwide injunctions "are legally and historically dubious"). These principles apply with even greater force to a preliminary injunction, an equitable tool designed merely to "preserve the relative positions of the parties" until the merits are resolved. *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981); *accord Zepeda v. U.S. INS*, 753 F.2d 719, 728 n.1 (9th Cir. 1983).

Here, Plaintiffs fail to show that nationwide relief is necessary to redress their alleged injuries. To start, Plaintiffs' choice to bring a facial constitutional challenge does not justify nationwide relief. *See City & Cty. of San Francisco v. Trump*, 897 F.3d 1225, 1244–45 (9th Cir. 2018) (vacating nationwide scope of injunction in facial constitutional challenge to executive order). The Supreme Court recently explained that under Article III, the proper remedy in a constitutional vote-dilution challenge brought by an individual voter involved "revising *only* such

districts as are necessary to reshape the voter's district" rather than "restructuring all of the State's legislative districts[,]" *notwithstanding* that the alleged gerrymandering was "statewide in nature" rather than limited to each plaintiff's particular district. *Gill*, 138 S. Ct. at 1930–31 (emphasis added). That holding confirms that it is the scope of the plaintiff's injury and not the defendant's policy that governs the permissible breadth of any relief under Article III.

Nor does Plaintiffs' decision to bring APA claims necessitate a nationwide remedy. *See, e.g.*, *California v. Azar*, 911 F.3d 558, 582–84 (9th Cir. 2018) (vacating nationwide scope of injunction in facial challenge under the APA). A court "do[es] not lightly assume that Congress has intended to depart from established principles" regarding equitable discretion, *Weinberger v. Romero-Barcelo,* 456 U.S. 305, 313 (1982), and the APA's general instruction that unlawful agency action "shall" be "set aside," 5 U.S.C. § 706(2), is insufficient to mandate such a departure. Indeed, the Supreme Court held that not even a provision directing that an injunction "shall be granted" with respect to a threatened or completed violation of a particular statute was sufficient to displace traditional principles of equitable discretion, *Hecht Co. v. Bowles*, 321 U.S. 321, 328–30 (1944), and Congress is presumed to have been aware of that holding when it enacted the APA two years later. In fact, the APA expressly confirms that, absent a special review statute, "[t]he form of proceeding for judicial review" is simply the traditional "form[s] of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction[,]" 5 U.S.C. § 703, and that the statutory right of review does not affect "the power or duty of the court to . . . deny relief on any . . . appropriate legal or equitable ground," *id.* § 702(1). The Supreme Court therefore has confirmed that, even in an APA case, "equitable defenses may be interposed." *Abbott Labs. v. Gardner*, 387 U.S. 136, 155 (1967). Accordingly, the Court should construe the "set aside" language in Section 706(2) as applying only to the named Plaintiffs, especially as no federal court

had issued a nationwide injunction before Congress's enactment of the APA in 1946, nor would do so for more than fifteen years thereafter, *see Hawaii*, 138 S. Ct. at 2426 (Thomas, J., concurring).

Nationwide relief would be particularly harmful here given that three other district courts in California, Washington, and Maryland are currently considering similar challenges. If the government prevails in all three other jurisdictions, nationwide relief here would render those victories meaningless as a practical matter. It would also preclude appellate courts from testing Plaintiffs' factual assertions against the Rule's operation in other jurisdictions. And, other states—especially ones that have taken additional measures to protect the conscience rights of providers—are likely to welcome the Rule, and there is no reason why Plaintiffs' views on provider conscience protections should govern the rest of the country. *See California*, 911 F.3d at 583 ("The detrimental consequences of a nationwide injunction are not limited to their effects on judicial decisionmaking. There are also the equities of non-parties who are deprived the right to litigate in other forums.").

B. Any Relief Should Be Limited To Specific Provisions

Similarly, should the Court decide to set aside or enjoin any portion of the Rule, the Court should allow the remainder to go into effect. In determining whether severance is appropriate, courts look to both the agency's intent and whether the regulation can function sensibly without the excised provision(s). *MD/DC/DE Broad. Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001).

Here, the intent of the agency is clear: Section 88.10 of the Rule provides that, if a provision of the Rule is held to be invalid or unenforceable, "such provision shall be severable," and "[a] severed provision shall not affect the remainder of this part . . . ." 84 Fed. Reg. at 23,272; *see also id.* at 23,226. Nor is there any functional reason why the entire Rule must fall if the Court agrees with Plaintiffs' attacks on particular provisions. The Rule concerns a variety of statutory provisions protecting conscience, but Plaintiffs have not alleged harms stemming from compliance with the

Rule with respect to each and every one of them. Moreover, the various definitions in Section 88.2 that Plaintiffs challenge can operate independently of one another, as can the other provisions in the Rule. And there is certainly no logical basis for setting aside or enjoining the entire Rule if the Court agrees with only some of Plaintiffs' various challenges.

C. Any Relief Should Not Affect Ongoing Investigations Based on the 2011 Rule or the Federal Conscience Statutes

Finally, if the Court does set aside the Rule or enter an injunction, the Court should make clear that this relief does not prevent HHS from continuing to investigate violations of, and to enforce, federal conscience and anti-discrimination laws under the existing 2011 Rule or the Federal Conscience Statutes themselves. As part of its ordinary enforcement authority, HHS has expended significant resources investigating alleged violations of the Federal Conscience Statutes. Those investigations are independent of the Rule that is the subject of this lawsuit and therefore HHS should not be prevented from continuing to pursue them, or from acting under its existing statutory or regulatory enforcement authority, even if the Court were to otherwise set aside or enjoin the Rule.

CONCLUSION

For the reasons stated above, Defendants respectfully ask that the Court dismiss these cases or, in the alternative, enter judgment in Defendants' favor. Defendants also ask the Court to deny Plaintiffs' motions for a preliminary injunction.

Dated: August 14, 2019

Respectfully submitted,

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, *et al.* *Plaintiffs*, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, *Defendants*, DR. REGINA FROST and CHRISTIAN MEDICAL AND DENTAL ASSOCIATIONS, *Defendants-Intervenors*.	No. 1:19-cv-04676-PAE (consolidated with 1:19-cv-05433-PAE; 1:19-cv-05435-PAE) **NOTICE OF MOTION FOR SUMMARY JUDGMENT**
PLANNED PARENTHOOD FEDERATION OF AMERICA, INC.; and PLANNED PARENTHOOD OF NORTHERN NEW ENGLAND, INC., *Plaintiffs*, v. ALEX M. AZAR II, *in his official capacity as Secretary, United States Department of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROGER SEVERINO, *in his official capacity as Director, Office for Civil Rights, United States Department of Health and Human Services*; and OFFICE FOR CIVIL RIGHTS, United States Department of Health and Human Services, *Defendants*.	No. 1:19-cv-05433-PAE (consolidated with 1:19-cv-0476-PAE; 1:19-cv-05435-PAE)

NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION; and PUBLIC HEALTH SOLUTIONS, *Plaintiffs*, v. ALEX M. AZAR II, *in his official capacity as Secretary of the U.S. Department of Health and Human Services*; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROGER SEVERINO, *in his official capacity as Director of the Office for Civil Rights of the U.S. Department of Health and Human Services*; OFFICE FOR CIVIL RIGHTS of the U.S. Department of Health and Human Services, *Defendants*.	No. 1:19-cv-05435-PAE (consolidated with 1:19-cv-0476-PAE; 1:19-cv-05433-PAE)

PLEASE TAKE NOTICE that, upon the accompanying Memorandum of Law, dated August 14, 2019; the accompanying Declarations of Dr. Regina Frost, Dr. David Stevens, and Erin Norman, all dated August 14, 2019; and such argument as may be received by this Court at the time of a hearing, Defendants-Intervenors Dr. Regina Frost and the Christian Medical and Dental Associations, by and through their undersigned counsel, move this Court before the Honorable Paul A. Engelmayer, United States District Court for the Southern District of New York, 500 Pearl Street, New York, New York, for an order granting summary judgment on all of Plaintiffs' claims in favor of Defendants-Intervenors pursuant to Federal Rule of Civil Procedure 56, and for such further relief as the Court deems just, necessary, and proper.

PLEASE TAKE FURTHER NOTICE that, in accordance with the July 16, 2019 Scheduling Order entered in this action, Dkt. No. 121, Plaintiffs' answering papers are to be filed and served on or before September 5, 2019, and Defendants-Intervenors' reply papers are to be filed and served on or before September 19, 2019.

Dated: August 14, 2019

Respectfully submitted,

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/s/ Allyson N. Ho

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, *et al.* *Plaintiffs*, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, *Defendants*, DR. REGINA FROST and CHRISTIAN MEDICAL AND DENTAL ASSOCIATIONS, *Defendants-Intervenors*.	No. 1:19-cv-04676-PAE (consolidated with 1:19-cv-05433-PAE; 1:19-cv-05435-PAE) **DECLARATION OF DAVID STEVENS, M.D., M.A., IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT, AND IN OPPOSITION TO PLAINTIFFS' MOTIONS FOR PRELIMINARY INJUNCTION**
PLANNED PARENTHOOD FEDERATION OF AMERICA, INC.; and PLANNED PARENTHOOD OF NORTHERN NEW ENGLAND, INC., *Plaintiffs*, v. ALEX M. AZAR II, *in his official capacity as Secretary, United States Department of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROGER SEVERINO, *in his official capacity as Director, Office for Civil Rights, United States Department of Health and Human Services*; and OFFICE FOR CIVIL RIGHTS, United States Department of Health and Human Services, *Defendants*.	No. 1:19-cv-05433-PAE (consolidated with 1:19-cv-0476-PAE; 1:19-cv-05435-PAE)

NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION; and PUBLIC HEALTH SOLUTIONS, *Plaintiffs*, v. ALEX M. AZAR II, *in his official capacity as Secretary of the U.S. Department of Health and Human Services*; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROGER SEVERINO, *in his official capacity as Director of the Office for Civil Rights of the U.S. Department of Health and Human Services*; OFFICE FOR CIVIL RIGHTS of the U.S. Department of Health and Human Services, *Defendants*.	No. 1:19-cv-05435-PAE (consolidated with 1:19-cv-0476-PAE; 1:19-cv-05433-PAE)

1. I, David Stevens, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I submit this Declaration in support of Defendants-Intervenors Dr. Regina Frost and Christian Medical and Dental Associations' ("CMDA") Motion for Summary Judgment, and in Opposition to Plaintiffs' Motions for Preliminary Injunction. I have personal knowledge of the facts set forth herein and if called upon to do so, would testify competently thereto under oath. I have familiarized myself with the recently issued rule entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" ("Final Rule"), to understand its immediate impact upon CMDA and its members.

3. I am a physician and the Chief Executive Officer ("CEO") of CMDA, a position I have held for 25 years. Prior to joining CMDA, I was the Director of World Medical Missions, the medical arm of Samaritan's Purse.

4. Consistent with CMDA's commitment to serving all people with dignity and compassion, I have spent considerable time overseas serving those with little to no access to medical care. Much of this work involved significant personal costs and physical danger. For example:

- From 1981 to 1991, I served in a rural hospital in Kenya that was the only source of healthcare for half a million people. During this time I was Medical Superintendent and then CEO. I was involved in developing the hospital from a "bush hospital" to a 250-bed tertiary center, started a nursing school, a laboratory training school and a large public health program.
- I led a relief team of physicians in Mogadishu, Somalia that treated over 45,000 patients in the midst of a civil conflict and famine in that country.
- I led a medical relief team in Sudan that treated over 25,000 patients and wiped out a deadly epidemic of relapsing fever that had a 50% mortality rate. The country was in the midst of a civil war while we were there, and our team was kidnapped and held hostage for a number of days.

- I supervised the first medical relief team to enter Kigali, Rwanda in 1994, which opened the main hospital in the midst of the genocide in which over a million people were slaughtered.

- I have led medical teams into prisons with deplorable conditions and little to no medical care in Zambia, Peru, and Ecuador.

- I have led medical teams on trips to the Philippines (tsunami relief), Nicaragua (caring for victims of human trafficking) and to Honduras, and Kenya to take care of the poor.

5. In my long medical career, I have treated all patients without discriminating on the basis of race, religion, nationality, sexual orientation, or gender.

6. CMDA was founded in 1931. It educates and equips its nearly 20,000 members to glorify God by fulfilling His Great Commandment and His Great Commission. CMDA members are committed to fulfilling Christ's command to "love your neighbor as yourself." *Matthew* 22:39 (English Standard Version). CMDA encourages its members to take an oath to "love those who come to [them] for healing and comfort" and to "car[e] for the lonely, the poor, the suffering, and the dying."

7. As a Christian organization, CMDA has published over seventy position statements concerning various medical, scientific, ethical and public policy issues. These position statements are informed by CMDA's Christian religious beliefs.

8. For example, CMDA has official position statements regarding—among other things—Abortion, AIDS, the Biblical Model for Medical Ethics, Death, Eugenics and Enhancement, Euthanasia, Healthcare Right of Conscience, Human Life: Its Moral Worth, Human Trafficking, Parental Rights, Patient Refusal of Therapy, Physician-Assisted Suicide, and Sharing Faith in Practice.

9. CMDA has long advocated for legislative and regulatory action to protect conscience rights. CMDA has an official position statement on Healthcare Right of Conscience, which states:

> "Respect for conscientiously held beliefs of individuals and for individual differences is an essential part of our free society. The right of choice is foundational in our healthcare process, and it applies to both healthcare professionals and patients alike. Issues of conscience arise when some aspect of medical care is in conflict with the personal beliefs and values of the patient or the healthcare professional. CMDA believes that in such circumstances the Rights of Conscience have priority."

10. CMDA also has an official position statement on The Healthcare Professional's Right of Conscience, which states:

> "All healthcare professionals have the right to refuse to participate in situations or procedures that they believe to be morally wrong and/or harmful to the patient or others. In such circumstances, healthcare professionals have an obligation to ensure that the patient's records are transferred to the healthcare professional of the patient's choice."

11. CMDA encourages its members to treat all patients. For example, CMDA's official position statement on LGBT patients states, *inter alia*:

> "Because we are guided by Christ, who assisted all who sought his help regardless of sexual or social status, CMDA affirms the obligations of Christian healthcare professionals to care for all patients in need, regardless of sexual orientation, gender identification, or family makeup, with sensitivity and compassion[.] . . . Christian healthcare professionals, in particular, must care for their same-sex-attracted patients in a non-judgmental and compassionate manner, consistent with the humility Jesus modeled and the love Jesus commanded us to show all people."

12. Similarly, CMDA's official position statement on AIDS states:

> "Acquired immunodeficiency syndrome (AIDS) caused by the human immunodeficiency virus (HIV) is a growing epidemic that may surpass the ravages of any plague in human history. We extend compassion to all who have acquired this disease by whatever means. We urge the provision of medical care for them to the same degree that patients with other life-threatening diseases receive it. Christian physicians and dentists, following the example of Christ, should care for HIV-infected persons even at the risk of their own lives. We encourage all healthcare workers to do the same."

13. CMDA also believes that physicians should not hinder the continuity of care, even when they object to a particular procedure. For example, CMDA's position statement on Vegetative States provides that "[i]f a physician, because of moral convictions, is unable to comply with the patient's or surrogate's wishes to withhold or withdraw artificially administered nutrition and hydration, it is appropriate for the physician to withdraw from the care of the patient as soon as another physician assumes that care."

14. In furtherance of its mission to care for all people, CMDA partners with Christian Community Health Fellowshp (CCHF) which encourages, engages and equips healthcare professionals to serve the poor and marginalized. CCHF works with 156 clinics in the United States that focus on serving the neediest members of society, including the uninsured, immigrants, and children.

15. CMDA also operates a short-term medical relief program that conducted 45 one- to two-week service projects in 2018, with 1,041 participants (physicians, dentists, nurses) traveling to Central and South America, the Caribbean, the Middle East, Asia, and Africa. Program participants served 60,060 patients without regard to race, religion, gender, sexual orientation, socio-economic status, or any other factor. Program participants paid their own way and helped to cover the cost of medicines and supplies.

16. CMDA conducted a survey of its members in 2014, and 55.4% of respondents reported that they offer free or steeply discounted care for the poor.

17. Although CMDA believes that healthcare providers should treat all patients, it holds that certain procedures—including elective abortion and euthanasia—are incompatible with the Christian faith.

18. CMDA's official position on euthanasia states:

> "We, as Christian physicians and dentists, believe that human life is a gift from God and is sacred because it bears His image. The role of the physician is to affirm human life, relieve suffering, and give compassionate, competent care as long as the patient lives."

19. Some of CMDA's members have religious objections to other procedures, including sterilization and artificial contraception.

20. CMDA does not have any official policy addressing the ethics of treating an ectopic pregnancy. CMDA understands that the standard of care for treating an ectopic pregnancy is to remove the embryo from the fallopian tubes. Because this procedure is aimed at protecting the health of the mother, and because an embryo cannot survive in the fallopian tubes, CMDA does not have a religious objection to the standard treatments for ectopic pregancies. Ectopic pregnanices sometimes rupture, a dangerous situation that can result in hemmhoraging. CMDA understands that the standard of care for a ruptured ectopic pregnancy is to remove the embryo—if it is still attached to the fallopian tube—and surgically repair the fallopian tube. Because this procedure is aimed at protecting the health of the mother, and because an embryo cannot survive a ruptured ectopic pregnancy, CMDA does not have a religious objection to the standard of care for treating a ruptured ectopic pregnancy. I have personally removed many ectopic pregnancies to protect the life of the mother when I served as a missionary physician in Kenya. I am aware of no faith group that categorically forbids adherents within the medical profession from treating an ectopic pregnancy along the lines described above.

21. According to the Pew Religious Landscape Study, 70.6% of Americans identify as Christian. *See* https://www.pewforum.org/religious-landscape-study/. 20.8% identify as Catholic. *Id.* 46.6% identify as Protestant, with 25.4% identifying as Evangelical Protestant, 14.7% identifying as Mainline Protestant, and 6.5% identifying as Historically Black Protestant. *Id.* The largest Protestant denominations include: the Southern Baptist Convention, United Methodist Church, American Baptist Churches, Evangelical Lutheran Church in America, Na-

tional Baptist Convention, Assemblies of God, Lutheran Church-Missouri Synod, Presbyterian Church USA, The Episcopal Church, and Seventh-day Adventist. *See* https://www.pewforum.org/2015/05/12/chapter-1-the-changing-religious-composition-of-the-u-s/pr_15-05-12_rls_chapter1-03/.

22. My understanding is that every single one of those religious groups permit removal of ectopic pregnancies, particularly where necessary to save the life or health of the mother. Many groups allow abortions in many more circumstances. I have reviewed the following statements from each religious group:

a) Roman Catholic Church, *New Charter for Health Care Workers*, Pontifical Council for Pastoral Assistance to Health Care Workers ¶ 57 (2016), *available at* https://www.ncbcenter.org/resources/church-documents-bioethics/new-charter-health-care-workers/;

b) Southern Baptist Convention, http://www.sbc.net/resolutions/2289/on-reaffirming-the-full-dignity-of-every-human-being, http://www.sbc.net/resolutions/24/resolution-on-the-freedom-of-choice-act-hyde-amendment, http://www.sbc.net/resolutions/23/resolution-on-encouraging-laws-regulating-abortion;

c) United Methodist Church, http://www.umc.org/what-we-believe/the-nurturing-community#abortion;

d) American Baptist Churches USA, https://www.abc-usa.org/wp-content/uploads/2019/02/Abortion-and-Ministry-in-the-Local-Church.pdf;

e) Evangelical Lutheran Church in America, http://download.elca.org/ELCA%20Resource%20Repository/AbortionSS.pdf?_ga=2.56332776.293390546.1565119472-1956408064.1565119472;

f) Assemblies of God, https://ag.org/Beliefs/Position-Papers/Abortion-Sanctity-of-Human-Life;

g) Lutheran Church-Missouri Synod, https://www.lcms.org/about/beliefs/faqs/lcms-views#abortion, http://www.lcms.org/Document.fdoc?src=lcm&id=363;

h) Presbyterian Church USA, https://www.presbyterianmission.org/blog/2016/02/23/abortion-issues-2/;

i) Episcopal Church, https://episcopalarchives.org/cgi-bin/acts/acts_resolution.pl?resolution=1994-A054; https://www.vbinder.net/resolutions/D032?house=hd&lang=en;

j) Seventh-day Adventists, https://www.adventist.org/en/information/official-statements/guidelines/article/go/0/abortion/;

23. I have also reviewed the statements of faith and reported beliefs of other faith groups, including the Church of Jesus Christ of Latter-Day Saints, Judaism, Buddhism, and Hinduism:

a) the Church of Jesus Christ of Latter-Day Saints, https://www.churchofjesuschrist.org/study/manual/gospel-topics/abortion?lang=eng&_r=1;

b) Orthodox Judaism https://rabbis.org/rca-opposes-new-york-states-reproductive-health-act/;

c) Reform Judaism, https://urj.org/what-we-believe/resolutions/reproductive-rights;

d) Conservative Judaism, https://www.rabbinicalassembly.org/story/resolution-reproductive-freedom-united-states;

e) Buddhism https://www.pewforum.org/2013/01/16/religious-groups-official-positions-on-abortion/; and

f) Hinduism, https://www.pewforum.org/2013/01/16/religious-groups-official-positions-on-abortion/.

24. CMDA recognizes that miscarriages are an unfortunate fact of life. In some cases, a woman who has suffered a miscarriage may need medical intervention to remove the fetal tissue to prevent infection. Because this procedure is aimed at protecting the health of the mother and does not terminate a human life, CMDA has no religious objection to this procedure for treating miscarriages. I have personally performed numerous D&C procedures to remove the products of a miscarriage. I am not aware of any other religious tradition that opposes the provision of care to a mother experiencing a miscarriage.

25. CMDA does not agree with all of the ethics guidelines adopted by the American Medical Association ("AMA"). In particular, CMDA does not believe that the AMA's guidelines adequately protect the right of conscience. The AMA's Code of Medical Opinion 1.1.7, Physician Exercise of Conscience, is particularly deficient, as it would impose an obligation on doctors to perform procedures against their religious beliefs when there is a risk even to the patient's "emotional well-being." CMDA does not believe that physicians should ever be required to perform procedures that violate their firmly held religious beliefs.

26. Rather, CMDA is convinced that forcing a physician to perform procedures that violates his or her beliefs degrades the quality of care to patients. In our experience, patients want their physicians to act in accordance with conscience.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 14 day of August, 2019.

David Stevens MD, MACEthics

David Stevens

CEO, Christian Medical and Dental Associations

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, *et al.* *Plaintiffs*, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, *Defendants*, DR. REGINA FROST and CHRISTIAN MEDICAL AND DENTAL ASSOCIATIONS, *Defendants-Intervenors*.	No. 1:19-cv-04676-PAE (consolidated with 1:19-cv-05433-PAE; 1:19-cv-05435-PAE) **DECLARATION OF REGINA RENEE FROST, M.D., IN SUPPORT OF INTERVENORS' MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTIONS FOR PRELIMINARY INJUNCTION**
PLANNED PARENTHOOD FEDERATION OF AMERICA, INC.; and PLANNED PARENTHOOD OF NORTHERN NEW ENGLAND, INC., *Plaintiffs*, v. ALEX M. AZAR II, *in his official capacity as Secretary, United States Department of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROGER SEVERINO, *in his official capacity as Director, Office for Civil Rights, United States Department of Health and Human Services*; and OFFICE FOR CIVIL RIGHTS, United States Department of Health and Human Services, *Defendants*.	No. 1:19-cv-05433-PAE (consolidated with 1:19-cv-0476-PAE; 1:19-cv-05435-PAE)

NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION; and PUBLIC HEALTH SOLUTIONS, *Plaintiffs*, v. ALEX M. AZAR II, *in his official capacity as Secretary of the U.S. Department of Health and Human Services*; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROGER SEVERINO, *in his official capacity as Director of the Office for Civil Rights of the U.S. Department of Health and Human Services*; OFFICE FOR CIVIL RIGHTS of the U.S. Department of Health and Human Services, *Defendants*.	No. 1:19-cv-05435-PAE (consolidated with 1:19-cv-0476-PAE; 1:19-cv-05433-PAE)

1. I, Dr. Regina Renee Frost, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I submit this Declaration in support of Defendants-Intervenors' Motion for Summary Judgment and in Opposition to Plaintiffs' Motions for Preliminary Injunction. I have personal knowledge of the facts set forth herein and if called upon to do so, would testify competently thereto under oath.

3. I graduated from the University of Michigan with a BA in Psychology in 2000. I graduated from Wayne State University School of Medicine in 2004. I was an Obstetrics and Gynecology Resident at St. John Hospital and Medical Center in Detroit, Michigan from 2004 to 2008. During my last year of residency I was the Chief Administrative Resident.

4. From 2008 to 2009 I worked in private practice as an OBGYN at the Medical Resources Group. From 2010 to 2013 I was part-time faculty at St. John Hospital and Medical Center. From 2010 to 2017 I was a solo-practitioner operating Compassionate Women's Healthcare. From 2018 to the present I have worked at St. John ObGyn Associates with the Ascension Medical Group. I served as a Clinical Assistant Professor for Michigan State University in the Department of Osteopathic Surgical Specialties from 2011 to 2017.

5. I am a Christian and have been a member of the Christian Medical Association since 2014.

6. My Christian faith has given me a passion for missions and helping those in need. For example, during medical school, I served on a mobile medical team in Nyahururu, Kenya, attending to the needs of women, children, and the elderly. I pray with my patients when appropriate and offer words of encouragement to lift their spirits.

7. I have helped lead Women Physicians in Christ ("WPC"), a ministry of CMDA,

since 2014. The mission of WPC is to build relationships among female physicians so that they can encourage and support one another in the profession. I lead a Bible study for a local WPC group that I started in 2014.

8. My work as an OBGYN, my service to those in need, and my leadership of a ministry to women physicians all flow directly from my Christian faith. *See 1 Corinthians* 10:31 ("So whether you eat or drink or whatever you do, do it all for the glory of God."). I sincerely believe that Christians should feed the hungry, give water to the thirsty, provide homes to strangers, clothe the needy, care for the sick, and visit prisoners. *Matthew* 25:31-46. By serving others, we serve and honor God. *Id.* ("Truly I tell you, whatever you did for one of the least of these brothers and sisters of mine, you did for me."). I believe that God is just as interested in what I do to serve others, including as a doctor, as He is in what I do on Sunday mornings at church. *Isaiah* 58:1-12 ("Is this not the kind of fasting that I have chosen: to loose the chains of injustice and untie the cords of the yoke, to set the oppressed free and to break every yoke?").

9. I am committed to treating every patient with dignity and love, without regard to race, religion, sexual orientiation, or gender. That is because I believe that every person is created in the image of God, and possesses inherent dignity. *Genesis* 1:27 ("God created man in his own image."). And Christ commands us to love our neighbor as ourselves. *Matthew* 22:39.

10. As a Christian, I have religious objections to providing or participating in certain procedures, including abortion and sex reassignment surgery, which I believe to be contrary to God's will and inconsistent with my best medical judgment for my patients.

11. These religious objections are based on the teachings of my faith. I believe, for instance, that the unborn are persons created by God who deserve my respect. *See, e.g., Jeremiah* 1:4-5 ("'Before I formed you in the womb I knew you, and before you were born I consecrat-

ed you; I appointed you a prophet to the nations.'"); *Psalm* 139:13-16 (noting that God "formed my inward parts . . . knitted me together in my mother's womb," and knew "the days that were formed for me, when as yet there was none of them"). I believe it would be wrong for me to personally participate in causing their death. *See*, *e.g.*, *Matthew* 5:21 and 19:18 (affirming the commandments against taking innocent human life).

12. Any patient who asks about abortion is informed that I do not perform that procedure. If my employer or the government ever directed or pressured me to perform a procedure to which I have a religious objection, I would be compelled to resign or to leave the practice of medicine, because I will not perform any procedure that my faith teaches is wrong or which I believe is not in the best interests of my patient.

13. I believe that the federal government should protect healthcare providers' conscience rights to ensure that no employer, or state or municipal government, can require healthcare professionals to perform or facilitate procedures to which they have sincere religious objections, or punish healthcare professionals for refusing to perform or facilitate such procedures. I have heard from several physicians who have been terminated or faced significant opposition because of their religious beliefs, and I am concerned that one day I too could be pressured to perform a medical procedure that I find morally objectionable. I am especially concerned about that in this case, given that my home state of Michigan is a plaintiff in this lawsuit. Without the conscience protections afforded by the regulation challenged in this lawsuit—*Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 84 Fed. Reg. 23,170 (May 21, 2019) ("Conscience Rule")—I would likely be subject to discrimination or termination in such an instance on account of my religious beliefs. Invalidating the Conscience Rule would thus harm me and other healthcare professionals with religious objections to certain procedures.

14. As an OBGYN, I have treated many women diagnosed with ectopic pregnancies, which describes a situation where the embryo implants in the fallopian tube (or, less commonly, in other locations, such as the cervix or abdomen) rather than the uterus. Ectopic pregnancies are typically diagnosed within the first 4-8 weeks of pregnancy. Many ectopic pregnancies resolve naturally when the embryo detaches and is expelled from the body. However, ectopic pregnancies can cause the fallopian tube to rupture, which results in hemorrhaging that can threaten the mother's life. Because of this risk, the standard of care for women diagnosed with an ectopic pregnancy is to remove the embryo. If it is diagnosed early and the patient is stable, an ectopic pregnancy can be treated medically by administering methotrexate, which avoids surgery and preserves the fallopian tubes. If that is not an option, surgery is usually scheduled immediately after a woman is diagnosed, but the timing of the procedure is based on the operating room's availability and the patient's clinical status. Because this procedure is aimed at protecting the mother's health, and because an embryo cannot survive in the fallopian tubes, I do not have a religious objection to this procedure. I have performed this procedure on many of my patients after diagnosing them with an ectopic pregnancy. I am not aware of any OBGYNs that have a religious objection to removing an ectoptic pregnancy, though I understand that there may be disagreements over the most appropriate type of treatment.

15. If an ectopic pregnancy ruptures, the standard of care is immediate surgery to remove the embryo—if it remains in place—and to surgically repair the ruptured fallopian tube. Because a ruptured ectopic pregnancy is an emergency that endangers the life of the mother, and because the life of the embryo cannot be saved, I do not have a religious objection to this procedure. I have performed this procedure on my patients. I am not aware of any physician who has a religious objection to this procedure.

16. I have also treated many patients who have suffered from miscarriages. A miscarriage results in the death of the fetus by natural means. In most instances, a miscarriage will not require medical intervention because the fetal tissue will pass naturally. In some cases, however, the woman's body does not expel the fetal tissue, which puts her at risk of infection. The standard of care in this situation is a procedure to remove the fetal tissue. Because this procedure does not terminate a human life, and is aimed at protecting the mother's health, I do not have a religious objection to it. I have performed this procedure on many of my patients. I am not aware of any OBGYNs who have religious objections to treating a woman who has suffered a miscarriage.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 14 day of August, 2019.

Dr. Regina Renee Frost

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, *et al.* *Plaintiffs*, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, *Defendants*, DR. REGINA FROST and CHRISTIAN MEDICAL AND DENTAL ASSOCIATIONS, *Defendants-Intervenors*.	No. 1:19-cv-04676-PAE (consolidated with 1:19-cv-05433-PAE; 1:19-cv-05435-PAE) **DECLARATION OF ERIN NORMAN, IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT, AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**
PLANNED PARENTHOOD FEDERATION OF AMERICA, INC.; and PLANNED PARENTHOOD OF NORTHERN NEW ENGLAND, INC., *Plaintiffs*, v. ALEX M. AZAR II, *in his official capacity as Secretary, United States Department of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROGER SEVERINO, *in his official capacity as Director, Office for Civil Rights, United States Department of Health and Human Services*; and OFFICE FOR CIVIL RIGHTS, United States Department of Health and Human Services, *Defendants*.	No. 1:19-cv-05433-PAE (consolidated with 1:19-cv-0476-PAE; 1:19-cv-05435-PAE)

NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION; and PUBLIC HEALTH SOLUTIONS, *Plaintiffs*, v. ALEX M. AZAR II, *in his official capacity as Secretary of the U.S. Department of Health and Human Services*; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROGER SEVERINO, *in his official capacity as Director of the Office for Civil Rights of the U.S. Department of Health and Human Services*; OFFICE FOR CIVIL RIGHTS of the U.S. Department of Health and Human Services, *Defendants*.	No. 1:19-cv-05435-PAE (consolidated with 1:19-cv-0476-PAE; 1:19-cv-05433-PAE)

1. I, Erin Norman, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I submit this Declaration in support of Defendants-Intervenors Dr. Regina Frost and Christian Medical and Dental Associations' ("CMDA") Motion for Summary Judgment, and in Opposition to Plaintiffs' Motions for Preliminary Injunction. I have personal knowledge of the facts set forth herein and if called upon to do so, would testify competently thereto under oath.

3. I graduated in 2005 from Questrom School of Business at Boston University with a BSBA in Marketing and Business Law. I also received a Masters in Public Policy from William & Mary in 2010.

4. I am currently a Senior Solutions Consultant for Public Policy at Heart+Mind Strategies, a research-led consulting firm. I develop, execute, and modify project management plans for all aspects of qualitative and quantitave research engagements and oversee all aspects of the research process. I also provide consultative advice to clients about research implementation and provide subject matter expertise on policy related topics.

5. I designed and executed a survey on behalf of the CMDA to survey its membership and other religious medical professionals on questions related to their moral and religious approaches to medicine and their views on conscience protection. The survey was intended to demonstrate the views and opinions of the individuals surveyed.

6. The survey was live from July 18-29, 2019. The survey was sent to members of the Christian Medical and Dental Associations (CMDA), the Catholic Medical Association (CMA), Nurses Christian Fellowship (NCF), and Christian Pharmacists Fellowship International (CPFI). Members of these organizations received a pre-survey communication letting them

know the study would be happening and that the organizations were partnering with Heart+Mind Strategies. A few days later, members were sent a link to the survey by each partnering organization. Those who did not open the original email were sent a reminder email 4-5 days later.

7. A total of 1,732 individuals responded to the survey. Of those, 1,297 were CMDA members, 10 were CMA members, 170 were NCF members, and 111 were CPFI members.

8. All sample surveys and polls may be subject to multiple sources of error including sampling error, coverage error, error associated with nonresponse, error associated with question wording and response options, and post-survey weighting and adjustments. As such, Heart+Mind Strategies considers anything above 85% to be a strong population consensus.

9. The survey shows that 97% of respondents support—and 93% strongly support—conscience protection for medical professionals who decline to participate in healthcare procedures, like abortion and assisted suicide, to which they object on moral or religious grounds. [Q220]

10. The survey shows that 97% of respondents think conscience protections are necessary, and 93% think they are very necessary. [Q225]

11. The survey shows that 91% of respondents agreed—and 73% strongly agreed—with the statement that "I would rather stop practicing medicine altogether than be forced to violate my conscience." [Q280]

12. The survey shows that 97% of respondents agreed—and 93% strongly agreed—with the statement that "All healthcare professionals have the right to decline to participate in situations or procedures that they believe to be morally wrong and/or harmful to the patient or others." [Q280]

13. The survey shows that 97% of respondents agreed—and 92% strongly agreed—with the statement, "I care for all patients in need, regardless of sexual orientation, gender identification, or family makeup, with sensitivity and compassion, even when I cannot validate their choices."

14. The survey shows that 60% of respondents thought that it was somewhat or very common for "doctors, medical students or other healthcare professionals" to "face discrimination for declining to participate in activities or provide medical procedures to which they have moral or religious objections," where "discrimination" was defined to include "loss of opportunity, promotion or position; unjust ethics charges; and other overt and subtle penalties, coercions, and pressures." [Q210]

15. The survey shows that 23% of respondents have suffered discrimination because of their moral or religious beliefs, and another 42% have seen or known someone who has suffered discrimination because of their moral or religious beliefs. [Q212]

16. The survey shows that 76% of respondents believe that "the number of medical professionals being pressured to compromise their moral, ethical, or religious beliefs in their practice has increased" "over the course of [their] professional experience." Only 1% of respondents believed that the number has decreased. [Q250]

17. The survey shows that 33% of respondents have been pressured or forced to "participate in training, perform a procedure, or write a prescription to which [they] had moral, ethical, religious objections," and another 2% reported being punished for refusing to participate. [Q270]

18. The survey shows that 33% of respondents have been pressured or forced to "refer a patient for a procedure to which [they] had moral, ethical, or religious objections," and another 1% reported being punished for refusing to refer. [Q270]

19. The survey shows that 62% of respondents are "currently involved in serving poor and medically-underserved populations, either domestically or overseas." Of these, 18% of respondents are serving in full-time capacity, 24% are serving in a part-time capacity, and 21% are serving in short-term missions or projects. Another 15% of respondents are not currently involved in serving poor and medically-underserved populations but plan to be.

20. The survey shows that 70% of respondents think that fewer doctors would be practicing medicine if the conscience protection regulation is eliminated, and 60% think there would be decreased access to healthcare providers, services, and/or facilities for patients in rural and low-income areas.

21. The survey shows that 20% of respondents chose not pursue a career in a particular specialty because of "attitudes prevalent in that specialty that are not considered tolerant of [their] moral, ethical, or religious beliefs." Of those 20%, 80% indicated that the specialty they did not pursue was OBGYN.

22. The full results of the survey and a description of its methodology are publicly available at https://www.freedom2care.org/polling.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 14th day of August, 2019.

Erin Norman

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, et al., Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	19 Civ. 4676 (PAE) (lead) 19 Civ. 5433 (PAE) (consolidated) 19 Civ. 5435 (PAE) (consolidated)

PLAINTIFFS' NOTICE OF MOTION
(Fed. R. Civ. P. 56, Fed. R. Civ. P. 65, and 5 U.S.C. § 705)

PLEASE TAKE NOTICE that pursuant to Federal Rule of Civil Procedure 56, and this Court's July 16, 2019 Order, Dkt. 121, Plaintiffs hereby move the Court for summary judgment with respect to all six claims for relief in Plaintiffs' complaint in this action challenging the Final Rule entitled *Protecting Statutory Conscience Rights in Health Care: Delegations of Authority*, 84 Fed. Reg. 23,170 (May 21, 2019). *See* Compl. ¶¶ 159-201, Dkt. 3.

Plaintiffs request that the Court declare that the Final Rule is in excess of the Department's statutory jurisdiction, authority, or limitations, or short of statutory right within the meaning of 5 U.S.C. § 706(2)(C); declare that the Final Rule is arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with law within the meaning of 5 U.S.C. § 706(2)(A); declare that the Final Rule is unconstitutional in violation of the constitutional separation of powers, and the Spending and Establishment Clauses of the United States Constitution; vacate and set aside the Final Rule; and grant other such relief as this Court may deem proper.

Alternatively, pursuant to Federal Rule of Civil Procedure 65 and this Court's July 16

Order, Plaintiffs hereby move the Court for a preliminary injunction to enjoin Defendants from implementing, applying, or taking any action under the Final Rule in order to preserve the status quo until this case is decided on the merits and final judgment is entered.

Alternatively, pursuant to 5 U.S.C. § 705 and this Court's July 16 Order, Plaintiffs move for a stay postponing the effective date of the Final Rule until this case is decided on the merits and final judgment is entered.

In support of this motion, Plaintiffs rely on the accompanying Memorandum of Law; the Declaration of Matthew Colangelo dated September 5, 2019; the exhibits attached to that Declaration; the pleadings and papers on file in this action; and any argument and evidence that is presented on the hearing of this motion. In addition, pursuant to this Court's July 16 Order, Plaintiffs rely on:

- The Memorandum of Law in Support of Plaintiffs' Motion for Preliminary Injunction, Dkt. 45 (filed June 14, 2019);
- The Declaration of Matthew Colangelo and the exhibits attached to that Declaration, Dkt. 43 (filed June 14, 2019);
- The exhibit to Plaintiffs' Notice of Filing of Corrected Exhibit, Dkt. 44 (filed June 14, 2019);
- The Joint Memorandum of Law in Support of [Provider] Plaintiffs' Motion for Preliminary Injunction, 19 Civ. 5433 (PAE), Dkt. 20 (filed June 17, 2019);
- The Memorandum of Law in Support of [Provider] Plaintiffs' Cross-Motion for Summary Judgment, in Opposition to Defendants' Motion for Summary Judgment, and Reply in Support of Plaintiffs' Motion for Preliminary Injunction, Dkt. __ (filed Sept. 5, 2019).

DATED: September 5, 2019

Respectfully submitted,

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, et al., Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	19 Civ. 4676 (PAE) (lead) 19 Civ. 5433 (PAE) (consolidated) 19 Civ. 5435 (PAE) (consolidated)

DECLARATION OF MATTHEW COLANGELO

Matthew Colangelo, pursuant to penalty of perjury under 28 U.S.C. § 1746, does hereby state the following:

I am an attorney in the Office of the New York State Attorney General and counsel to Plaintiffs in this action. I submit this Declaration in support of Plaintiffs' motion for a preliminary injunction and cross-motion for summary judgment, and in opposition to Defendants' motion to dismiss and for summary judgment.

Attached to this Declaration are true and correct copies of the following numbered exhibits, including parts of the administrative record produced by Defendants in this action:

67. Complaints in the Administrative Record per excel list that Defendants provided to Plaintiffs on August 19, 2019 (AR 541798-546163; AR 548439-548443; 549903-549940).

68. Comment, N.Y. Dep't of Fin. Servs. (AR 52459)

69. Comment, Oregon Found. for Reprod. Health (AR 55622)

70. Comment, Am. Nurses Ass'n (AR 56915)

71. Comment, Raising Women's Voices (AR 66545)

72. Comment, State of Washington Dep't of Health (AR 67173)

73. Comment, Am. Hosp. Ass'n (AR 67413)

74. Comment, In Our Own Voice: Nat'l Black Women's Reprod. Justice Agenda (AR 67666)

75. Comment, Nat'l Ass'n of Councils on Developmental Disabilities (AR 68426)

76. Comment, Ass'n of Am. Med. Colls. (AR 71138)

77. Comment, Health Care for All (AR 71476)

78. Comment, Consumer Health First (AR 71569)

79. Comment, LHI-Houston (AR 71750)

80. Comment, Nat'l Ctr. For Lesbian Rights (AR 134728)

81. Comment, San Francisco Dep't of Pub. Health (AR 134791)

82. Comment, Kentucky Voices for Health (AR 135566)

83. Comment, Callen-Lorde Comm. Health Ctr. (AR 135824)

84. Comment, Ohio Hosp. Ass'n (AR 137611)

85. Comment, New Voices for Reprod. Justice (AR 137857)

86. Comment, Calif. Dep't of Justice (AR 137905)

87. Comment, Attorneys General of New York, et al. (AR 137920)

88. Comment, Community Catalyst (AR 138088)

89. Comment, Nat'l Family Planning & Reprod. Health Ass'n (AR 138102)

90. Comment, Boston Med. Ctr. (AR 139287)

91. Comment, Am. Med. Ass'n (AR 139587)

92. Comment, Kaiser Permanente (AR 139639)

93. Comment, Alameda County (AR 139746)

94. Comment, Am. Coll. Of Obstetricians & Gynecologists (AR 139749)

95. Comment, Nat'l Council of Jewish Women (AR 140183)

96. Comment, BlueCross BlueShield Ass'n (AR 140265)

97. Comment, Calif. Dep't of Insurance (AR 140350)

98. Comment, Am. Acad. of Pediatrics (AR 140460)

99. Comment, N.Y. City Comm'n on Human Rights, et al. (AR 140484)

100. Comment, American Civil Liberties Union (AR 147746)

101. Comment, Greater New York Hosp. Ass'n (AR 147824)

102. Comment, Massachusetts Health & Hosp. Ass'n (AR 147871)

103. Comment, Anne Arundel Med. Ctr. (AR 147890)

104. Comment, The Disability Coal. (AR 147952)

105. Comment, Ass'n of Women's Health, Obstetric & Neonatal Nurses (AR 147963)

106. Comment, Am. Coll. of Emergency Physicians (AR 147981)

107. Comment, Nat'l Immigration Law Ctr. (AR 148056)

108. Comment, N.Y. State LGBT Health & Hum. Servs. Network (AR 148072)

109. Comment, Nat'l Ctr. For Transgender Equality (AR 148096)

110. Comment, Nat'l Women's Law Ctr. (AR 149141)

111. Comment, California Med. Ass'n (AR 151666)

112. Comment, GLMA: Health Professionals Advancing LGBT Equality (AR 160566)

113. Comment, Planned Parenthood Fed. of Am. (AR 160751)

114. Comment, Ctr. for Reproductive Rights (AR 160801)

115. Comment, Medicare Rights Ctr. (AR 161033)

116. Comment, Inst. For Policy Integrity (AR 161178)

117. Comment, Lambda Legal (AR 161476)

118. Christian Medical Ass'n, Summary of Online Survey of Faith-Based Medical Professionals (AR 537609)

119. Closure Letter, Compl. 11-122388 (AR 541805)

120. Closure Letter and PIMS, Compl. 17-259696 (AR 541967)

121. Compl. 18-293704 (AR 542414)

122. Compl. 18-293773 (AR 542449)

123. Compl. 18-294058 (AR 542627)

124. Compl. 18-294456 (AR 543082)

125. Compl. 18-296732 (AR 543879)

126. Compl. 18-297792 (AR 544035)

127. Compl. 18-298614 (AR 544188)

128. Compl. 18-298848 (AR 544235)

129. Compl. 18-304776 (AR 544516)

130. Compl. 18-306427 (AR 544612)

131. Compl. 18-316861 (AR 544753)

132. Compl. 14-191081 (AR 545712)

133. Compl. 16-224756 (AR 545736)

134. Lori R. Freedman, *Where There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, 98 Am. Journal of Pub. Health No. 10 (October 2008) (AR 548500)

135. Declaration of Kristen Miller and accompanying Exhibits A-H

136. Result of TAGGS, Recipient Search, https://taggs.hhs.gov/SearchRecip (visited and exported on Sept. 5, 2019), by filtering "Fiscal Year" to "2018," "Recipient Class" to "State Government," and "State" to each State Plaintiff represented in this lawsuit

Dated: September 5, 2019

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Exhibit 67

Slipsheet

(Exhibit 67 contains files too large to be docketed on ECF; produced on CD-ROM to the Court and all counsel)

Exhibit 68

NEW YORK STATE
DEPARTMENT of
FINANCIAL SERVICES

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March 21, 2018

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RIN 0945-ZA03

Re: Comments on Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Mr. Hargan:

The New York Department of Financial Services (NYDFS) submits the following comments on the proposed rule 45 CFR 88, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority [HHS-OCR-2018-0002] (Proposed Rule). As set forth below, the Proposed Rule impermissibly attempts to restrict women's access to abortion services and attempts to veil such blatant discrimination of women as conscience rights. NYSDFS urges the retraction of the Proposed Rule.

Specifically, Section 88.3(c) in the Proposed Rule unlawfully deviates from the plain language of the Weldon Amendment – see, e.g., Pub. L. 115-31, Div. H, sec. 507(d) – by expanding the definition of health care entities that are subject to the amendment and by incorporating a definition of the term "discrimination" that far exceeds the recognized, legal meaning of that term. The Proposed Rule also attempts to interfere unlawfully with the operation of State law with respect to ensuring that women have access to medical services. NYDFS strongly supports the compelling governmental interest in providing women access to all medical services, including abortion services, to promote women's health and gender equality. Consistent with this compelling governmental interest, New York law requires that all health insurance plans issued in the state include coverage for medically necessary abortions. Any Department of Health and Human Services ("HHS") proposed rule that seeks to undermine

New York's right to promote and protect women's health and gender equality, violates of the Affordable Care Act ("ACA") and bedrock constitutional principles. NYDFS strongly objects to the unconstitutional, unreasonable, and discriminatory Proposed Rule which takes a drastic step backwards and unnecessarily attempts to curtail women's access full to medical services.

The Proposed Rule Discriminates Against Women

The Proposed Rule discriminates against women by hindering their access to abortion and other medically necessary health care services. The U.S. Supreme Court has held that the right to terminate a pregnancy is a fundamental privacy right, protected as a liberty interest under the Fourteenth Amendment of the U.S. Constitution.[1] The number of abortion providers are already in decline,[2] and many states have enacted cumbersome barriers, forcing women to travel to obtain abortion services necessary for their health.[3] The Proposed Rule exacerbates the problem, by not only expanding the persons who may object beyond any by reasonable definition, and also increasing the categories of behavior protected under its scope. Under the Proposed Rule, employers could impose their will on their employees by forcing insurers to deny abortion coverage to women; pharmacists may not need to dispense emergency contraception; objecting health care providers could choose not to refer patients to non-objecting providers, or provide abortion funding information; and pregnant women could be denied life-saving options during an emergency. These provisions are unlawful, discriminatory, and not permissible by regulatory fiat.

The Supreme Court has ruled that an obstacle is substantial when it is created to impede rather than inform a woman of her choices.[4] By allowing plan sponsors and health care providers to obstruct the patient from being able to obtain coverage for or afford abortion services; from receiving medication that her doctor prescribed for her; by limiting medical information or options that patients have a right to know about; or by preventing women from receiving medically necessary procedures, the HHS is creating substantial obstacles and unjustifiably limiting access to the breadth of health services to which women are lawfully entitled.[5] It is neither the government nor employers that have the legal right or moral superiority over women's health care decisions as prescribed by their physicians.

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[1] Roe v. Wade, 410 U.S. 113, 153 (1973); see also Planned Parenthood of Se. Pennsylvania v. Casey, 505 U.S. 833 (1992).

[2] The number of clinics providing abortions declined 6% between 2011 and 2014, and declines were steepest in the Midwest (22%) and the South (13%). Rachel K. Jones, Jenna Jerman, Abortion Incidence and Service Availability, National Center for Biotechnology Information (January 17, 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5487028/.

[3] Angie Leventis Lourgos, More Women Seem to be Crossing State Lines to have Abortions in Illinois, Chicago Tribune (February 27, 2018), http://www.chicagotribune.com/news/ct-met-abortion-numbers-illinois-20180222-story.html.

[4] "And a statute which, while furthering the interest in potential life or some other valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends." Planned Parenthood of Se. Pennsylvania v. Casey, 505 U.S. 833, 877 (1992).

[5] "All health care providers must provide accurate and unbiased information so that patients can make informed decisions. Where conscience implores physicians to deviate from standard practices, they must provide potential

Moreover, the Proposed Rule favors the rights of a non-protected class over the rights of a protected class. HHS stated in the Proposed Rule that "conscience objectors" should be "allowed a level playing field, and that their beliefs not be held to disqualify them from participation in a program or benefit." HHS erroneously claims that this alleged form of discrimination against conscience objectors "parallels the type of discrimination typically prohibited with respect to other characteristics such as race, color, or national origin." Under the law, "conscience objectors" are not a protected class; therefore, they are not entitled to the same level of protection as other federally protected classes, and, such as gender and race. The Proposed Rule defines "discriminate" as "to withhold, reduce, exclude, terminate, restrict, or otherwise make unavailable or deny any benefit or privilege." In reducing and restricting women's access to abortions, by its own definition, HHS is discriminating against women. HHS compounds the problem by giving employers the new right to invade the confidentiality of women's health care relationship with her doctor, broadening the scope of any possible religious exemption to a "conscience objector" which finds no support in law or health care policy.

The Proposed Rule Is Inconsistent with the Plain Language of the Weldon Amendment

Since 2005, HHS appropriations have included a provision that restricted states and other recipients of HHS appropriations from discriminating against a "health care entity" on the ground that the entity does not provide, pay for, provide coverage of, or refer for abortions. The entirety of this restriction – commonly referred as the Weldon Amendment – includes the following two clauses:

> (1) None of the funds made available in this Act may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.
>
> (2) In this subsection, 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.

See Pub. L. 115-31, Div. H, sec. 507(d).

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patients with accurate and prior notice of their personal moral commitments. Physicians and other health care providers have the duty to refer patients in a timely manner to other providers if they do not feel that they can in conscience provide the standard reproductive services that patients request. The Limits of Conscientious Refusal in Reproductive Medicine." Committee on Ethics, The Limits of Conscientious Refusal in Reproductive Medicine, The American College of Obstetricians and Gynecologists, Number 385 (reaffirmed in 2016), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/The-Limits-of-Conscientious-Refusal-in-Reproductive-Medicine.

Section 88.3(c) in the Proposed Rule, were it to be adopted (and it should not be), would unlawfully and illegally expand the restrictions in the Weldon Amendment in two material respects.

First, the definition of "health care entity" used in the Proposed Rule is impermissibly broader than the definition included in the Weldon Amendment. In the Proposed Rule, the definition of "health care entity" has been expanded to include "a plan sponsor" in addition to various other impermissible additions. The inclusion of "a plan sponsor" in the Proposed Rule's definition would mean that employers that merely purchase or sponsor a group health plan would be subject to the Weldon Amendment, an extension that violates the law. Indeed, this proposed definitional expansion is contrary to the plain language of the Weldon Amendment and its legislative history, which shows that the purpose of the Weldon Amendment was to respect the religious and moral viewpoint of those directly engaged in the delivery of health care services (i.e., doctors and hospitals). Employers or other plan sponsors are not health care entities under any stretch of the term. The proposed regulatory expansion of the Weldon Amendment to cover all employers who merely purchase or sponsor a group health insurance plan for employees is far beyond the plain language and intended scope of the amendment and would impermissibly sanction employers' intervention into private health care decisions. Given that employers (or "plan sponsors") are clearly not included in the definition of "health care entity" in the Weldon Amendment and cannot be characterized as a health care facility, organization or plan, the definition of "health care entity" used in the Proposed Rule is contrary to law and policy. Indeed, all of the additions in the Proposed Rule to the definition of "health care entity" that do not appear in the Weldon Amendment must be removed as illegal.

Second, the definition of "discrimination" in the Proposed Rule is contrary to federal law. As noted above, the Weldon Amendment prevents a state from discriminating against a "health care entity" on the ground that the entity does not provide, pay for, provide coverage of, or refer for abortions. Yet, Section 88.2 of the Proposed Rule would include in the definition of "discriminate or discrimination" the "enactment, application, or enforcement of laws, regulations, policies, procedures … that tends to subject individuals or entities protected under this part to any adverse effect." This newly-minted definition of "discrimination" in the Proposed Rule attempts to prevent a state from enacting, applying or enforcing a neutral law of general applicability that would require coverage for abortion services, which is clearly contrary to federal law. Under applicable Supreme Court precedent, neutral laws of general applicability, including state laws mandating coverage of all medically necessary surgical services including abortions, by definition, are non-discriminatory:

> We have never held that an individual's religious beliefs excuse him from compliance with an otherwise valid law prohibiting conduct that the State is free to regulate. On the contrary, the record of more than a century of our free exercise jurisprudence contradicts that proposition. . . . Conscientious scruples have not, in the course of the long struggle for religious toleration, relieved the individual from obedience to a general law not aimed at the promotion or restriction of religious beliefs. The mere possession of religious

> convictions which contradict the relevant concerns of a political society does not relieve the citizen from the discharge of political responsibilities.

Emp't Div. v. Smith, 494 U.S. 872, 878-79, 110 S. Ct. 1595, 1600 (1990) (emphasis added; internal quotation omitted). The Court in Smith, examining conscience objections, made clear that neutral laws of general applicability do not rise to the level of discrimination. See id. at 886 n 3. The definition of "discrimination" used in the Proposed Rule therefore does not accord with federal law or the U.S. Constitution.

In addition, the definition of "discrimination" in the Proposed Rule does not, in fact, prohibit discrimination. Discrimination is the disparate treatment of an individual or entity. The Proposed Rule actually mandates discrimination by preventing the equal application and enforcement of neutral state laws. The definition of "discrimination" in the Proposed Rule would impermissibly require a state to modify its laws to accommodate religious or moral beliefs of regulated entities. Such an accommodation would result in the disparate treatment of similarly situated individuals, and entities – the textbook definition of discrimination. Such a requirement is far outside the boundary of a non-discrimination rule and renders the definition in the Proposed Rule contrary to law. If the rule proceeds, at a minimum, the definition of discrimination in the Proposed Rule should be revised to correct this legal deficiency.

The Proposed Rule Violates the Affordable Care Act

The Affordable Care Act (ACA) expressly authorizes a state to require coverage for medically necessary abortions in health insurance policies issued in the state. See 42 U.S.C. 18023(c)(1) ("[n]othing 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"). In other words, state laws requiring coverage for medically necessary abortion services in insurance policies are expressly permissible under the ACA. The Proposed Rule – which unlawfully attempts to prevent the application and enforcement of abortion coverage mandates in state law – would clearly violate the provision in the ACA by attempting to prevent New York from enforcing its abortion coverage mandates on health insurance policies issued in New York.

In 2010, when the ACA was enacted, the Weldon Amendment had already been included in HHS's appropriation bills for five years. Had the Weldon Amendment prevented (or was intended to prevent) states from enforcing neutral laws that mandate abortion coverage, the ACA could not have included the provision quoted above as it would immediately have been rendered meaningless. Indeed, prior to the release of the Proposed Rule, neither HHS nor any arm of the federal government had ever suggested that the Weldon Amendment prevented a state from enacting, applying or enforcing a neutral law of general applicability that would require coverage for abortion services. The Proposed Rule's attempted expansion of the Weldon Amendment to do just that not only violates the plain language of the statute but also undermines this key provision in the ACA, and therefore lacks a legal foundation.

The Proposed Rule is an Unconstitutional Violation of the Federal Spending Clause

The Proposed Rule delegates full enforcement authority to HHS's Office for Civil Rights (OCR) and states that if compliance is not achieved, then HHS would consider all legal options available, including "termination of relevant [federal] funding, in whole or in part, claw backs, referral to the Department of Justice, or other measures." Under settled law, 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.[6] As OCR itself noted in June 2016, it is highly questionable whether the Weldon Amendment is enforceable at all when interpreted consistent with the Proposed Rule, since the revocation of federal funds would violate the Constitution's prohibition on the federal government attempting to compel a State to regulate.[7] Further, the Proposed Rule does not provide a clear methodology for withholding federal funding, or any guidance on how the punitive measures would be warranted, leaving enforcement arbitrary and the Proposed Rule unenforceable. It is clear that the Proposed Rule is intended to force states to adopt a policy of regulation of their health insurance markets in a manner in line with the views of the current federal executive "while the federal officials who devised the regulatory program may remain insulated from the electoral ramifications of their decision."[8] The Supreme Court has consistently held that the use of the Congressional Spending Clause power to coerce states into regulating in accordance with federal policy is an unconstitutional intrusion on the independent sovereignty of the states.[9] Therefore, even if the Proposed Rule were a permissible reading of the statutes it purports to interpret—which it is not—such a reading renders those statutes unconstitutional, and the Proposed Rule must fall with them.

The Proposed Rule Did Not Adequately Assess the Impact on Families

Under federal rulemaking rules, prior to proposing a new rule, HHS is required to determine whether a proposed policy or regulation could affect family well-being and, if affirmative, prepare an impact assessment. Yet, HHS determined that the Proposed Rule will not negatively impact family well-being. The commentary states that, "[i]t is unlikely that this proposed rule will negatively impact the stability of the family. . ." The commentary further states, "[i]n addition, the proposed rule has no bearing on the disposable income or poverty of families and children. . ." These statements are patently false. Interfering with a women's access to safe abortion services will adversely impact her health and correspondingly the well-being of her family. In addition, limiting health insurance coverage of abortion services will directly impact the disposable income of families, as women will be forced to pay for abortion services out-of-pocket, when other medical procedures are covered for men. Importantly, the

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[6] South Dakota v. Dole, 483 U.S. 203, 204 (1987).
[7] Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 577-78, 132 S. Ct. 2566, 2602 (2012) ("[W]hen pressure turns into compulsion, the legislation runs contrary to our system of federalism. The Constitution simply does not give Congress the authority to require the States to regulate." quoting New York v. United States, 505 U.S. 144, 178 (1992) internal quotations omitted).
[8] New York v. United States, 505 U.S. 144, 169, 112 S. Ct. 2408, 2424 (1992).
[9] See e.g., Sebelius, 567 U.S. at 577-85.

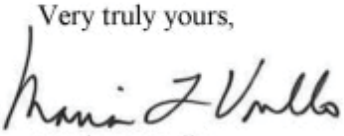
Proposed Rule would have a disparate impact on lower income women who do not have the financial means to pay for an abortion. The Proposed Rule fails for these additional reasons.

Conclusion

NYSDFS strongly urges HHS to reconsider adopting this unconstitutional, unlawful, unreasonable, discriminatory, and impermissible Proposed Rule. Women must have access to medical services to ensure their health, well-being, and gender equality. The federal government may not infringe on the independent sovereignty of the states and the states must be accorded their traditional and Congressionally recognized power over the regulation of health insurance business within their borders. The Proposed Rule unlawfully and impermissibly attempts to curtail women's rights and powers of the state. It should not be adopted.

We appreciate the Department's consideration of these comments.

Very truly yours,



Maria T. Vullo
Superintendent of Financial Services

Exhibit 69

March 27, 2018
U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Public Comment in Response to the Proposed Regulation, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

To Whom It May Concern:

I am writing on behalf of the Oregon Foundation for Reproductive Health in response to the request for public comment on the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26.[1] The Oregon Foundation for Reproductive Health (OFRH) is a non-profit advocacy organization located in Portland, that provides a channel for Oregon women's voices from all over the state to be heard, particularly those historically under-served. We believe that all people should have the power and resources to make healthy decisions about their bodies, sexuality, and reproduction for themselves and their families without fear of discrimination, exclusion, or harm. We will work to break down barriers to health care so that all people have the opportunity to thrive. Our mission is to improve access to comprehensive reproductive health care, such as preventing unintended pregnancy and planning healthy families, and we are committed to advancing reproductive rights and advocating for reproductive health equity in all Oregon communities.

This proposed regulation would exacerbate the challenges that many patients—especially women, LGBTQ people, people of color, immigrants and low-income people—already face in getting the health care they need in a timely manner and at an affordable cost. The rule would expose vulnerable patients to increased discrimination and denials of medically-indicated care by broadening religious health care provider exemptions beyond the existing limited circumstances allowed by law. Moreover, while protecting health providers who deny care, the rule would provide *no protections for patients who are being denied care—even in emergencies*. As drafted, the rule would not even require that patients be informed of all their potential treatment options or referred to alternative providers of needed care.

[1] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (proposed Jan. 26, 2018) (*to be codified at* 45 C.F.R. pt. 88) [*hereinafter* Rule].

Indeed, this proposal runs in the opposite direction of everything the American health system is striving to achieve in the pursuit of "patient-centered care." We urge the administration to put patients first, and withdraw the proposed regulation because of the serious problems enumerated below.

1. The rule improperly seeks to expand on existing religious refusal exemptions to potentially allow denial of any health care service based on a provider's personal beliefs or religious doctrine.

Existing refusal of care laws (such as those for abortion and sterilization services) are already being used across the country to deny patients the care they need.[2] The proposed rule attempts to expand on these laws in numerous ways that are directly contrary to the stated purpose of the existing laws. Specifically, the Department and its Office for Civil Rights (OCR) are attempting to require a broad swath of entities to allow individuals to refuse "*any* lawful health service or activity based on religious beliefs or moral convictions (emphasis added)."[3]

This expansive interpretation could lead to provider denials based on personal beliefs that are biased and discriminatory, such as objections to providing care to people who are transgender or in same-sex relationships. We are aware of cases in which this type of unjust denial of care has occurred, such as a California physician's denial of donor insemination to a lesbian couple, even though the doctor routinely provided the same service to heterosexual couples. [4]

We are also concerned about potential enabling of care denials by providers based on their non-scientific personal beliefs about other types of health services. For example, certain religiously-affiliated hospitals and individual clinicians have refused to provide rape victims with emergency contraception to prevent pregnancy[5] based on the belief that it can cause an abortion, even though there is no scientific evidence that this is the case.

2. The rule would protect refusals by anyone who would be "assisting in the performance of" a health care service to which they object, not just clinicians.

The rule seeks to protect refusals by any "member of the workforce" of a health care institution whose actions have an "articulable connection to a procedure, health services or health service program, or research activity." The rule includes examples such as "counseling, referral, training and other arrangements for the procedure, health service or research activity."

An expansive interpretation of "assist in the performance of" thus *could conceivably allow an ambulance driver to refuse to transport a patient to the hospital for care he/she finds objectionable*. It

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[2] *See, e.g., Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Uttley, L., et al, *Miscarriage of Medicine,* MergerWatch and the ACLU (2013), https://www.aclu.org/report/miscarriage-medicine.

[3] *See* Rule *supra* note 1, at 12.

[4] Hardaway, Lisa, *Settlement Reached in Case of Lambda Legal Lesbian Client Denied Infertility Treatment by Christian Fundamentalist Doctors,* Lambda Legal, September 29, 2009, accessed at https://www.lambdalegal.org/news/ca_20090929_settlement-reached.

[5] Erdely, Sabrina, *Doctors' beliefs can hinder patient care*, SELF magazine, June 22, 2007, accessed at http://www.nbcnews.com/id/19190916/print/1/displaymode/1098/

could mean a hospital admissions clerk could refuse to check in a patient for treatment the clerk finds objectionable or a technician could refuse to prepare surgical instruments for use in a service.

On an institutional level, the right to refuse to "assist in the performance of" a service could mean *a* religiously-affiliated hospital or clinic could deny care, and *then also refuse to provide a patient with a referral or transfer to a willing provider* of the needed service.

The proposed rule thus could be read as allowing health providers to refuse to inform patients of all potential treatment options. A 2010 publication of the National Health Law Program, "Health Care Refusals: Undermining Quality of Care for Women," noted that "refusal clauses and institutional restrictions can operate to deprive patients of the complete and accurate information necessary to give informed consent."[6]

3. The rule does not address how a patient's needs would be met in an emergency situation.

There have been reported instances in which pregnant women suffering medical emergencies—including premature rupture of membranes (PPROM) and ectopic pregnancies[7]—have gone to hospital emergency departments and been denied prompt, medically-indicated care because of institutional religious restrictions.[8] The proposed rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility.[9] Under EMTALA, every hospital is required to comply – even those that are religiously affiliated.[10] Because the proposed rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

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[6] The NHeLP publication noted (at page 21) that the Ethical and Religious Directives for Catholic Healthcare Services, which govern care at Catholic hospitals, limit the information a patient can be given about treatment alternatives to those considered "morally legitimate" within Catholic religious teachings. (Directive No. 26).

[7] Foster, AM, and Smith, DA, *Do religious restrictions influence ectopic pregnancy management? A national qualitative study*, Jacob Institute for Women's Health, Women's Health Issues, 2011 Mar-Apri; 21(2): 104-9, accessed at https://www.ncbi.nlm.nih.gov/pubmed/21353977

[8] Stein, Rob, *Religious hospitals' restrictions sparking conflicts, scrutiny,* The Washington Post, January 3, 2011, accessed at https://www.washingtonpost.com/health-environment-science/religious-hospitals-restrictions-sparking-conflicts-scrutiny/2011/01/03/ABVVxmD_story.html?utm_term=.cc34abcbb928

[9] 42 U.S.C. § 1295dd(a)-(c) (2003).

[10] In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. *See, e.g., Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220, 228 (3rd Cir. 2000); *In re Baby K*, 16 F.3d 590, 597 (4th Cir. 1994); *Nonsen v. Medical Staffing Network, Inc.* 2006 WL 1529664 (W.D. Wis.); *Grant v. Fairview Hosp.*, 2004 WL 326694, *93 Fair Empl. Prac. Cas.* (BNA) 685 (D. Minn. 2006); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); *Barris v. County of Los Angeles*, 972 P.2d 966, 972 (Cal. 1999).

4. **Health care institutions would be required to notify employees that they have the right to refuse to provide care, *but would not be required to notify patients about the types of care they will not be able to receive at that hospital, pharmacy, clinic or doctor's office*.**

The rule sets forth extensive requirements for health care institutions, such as hospitals, to notify employees about their refusal rights, including how to file a discrimination complaint with OCR. The rule requires posting of such notices on the employer's website and in prescribed physical locations within the employer's building. The rule also sets forth the expectation that OCR would investigate or conduct compliance reviews of whether health care institutions are following the posting rule.[11]

By contrast, the rule contains no requirement that patients be notified of institutional restrictions on provision of certain types of care. Such notification is essential because research has found that patients often are unaware of service restrictions at religiously-sponsored health care institutions. [12]

5. The rule conflicts with other existing federal laws, including the Title VII framework for accommodation of employees' religious beliefs.

The Proposed Rule generates chaos through its failure to account for existing laws that conflict with the refusals of care it would create. For example, the proposed rule makes no mention of Title VII,[13] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[14] Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.[15] The proposed rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both.

5. There is no provision protecting the rights of health care providers with religious or moral convictions to *provide* (not deny) services their patients need.

The proposed rule ignores those providers with deeply held moral convictions that motivate them to provide patients with health care, including abortion, transition-related care, and end-of-life care. The

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[11] The notice requirement is spelled out in section 88.5 of the proposed rule.
[12] *See*, for example, Freedman, Lori R., Luciana E. Hebert, Molly F. Battistelli, and Debra B. Stulberg, *Religious hospital policies on reproductive care: what do patients want to know?* American Journal of Obstetrics & Gynecology 218, no. 2 (2018): 251-e1, accessed here: http://www.ajog.org/article/S0002-9378(17)32444-4/fulltext; also Guiahi, Maryam, Jeanelle Sheeder, and Stephanie Teal, *Are women aware of religious restrictions on reproductive health at Catholic hospitals? A survey of women's expectations and preferences for family planning care*, Contraception and Stulberg, D., et all, accessed here: http://www.contraceptionjournal.org/article/S0010-7824(14)00358-8/fulltext; *Do women know when their hospital is Catholic and how this affects their care? Restrictions in Catholic Hospitals (PARRCH) national survey*, Contraception, Volume 96, Issue 4, 268-269,accessed here: http://www.contraceptionjournal.org/article/S0010-7824(17)30235-4/fulltext; a
[13] 42 U.S.C. § 2000e-2 (1964).
[14] *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.
[15] *See id.*

rule fails to acknowledge the Church Amendment's protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[16]

Doctors are, in effect, forced to abandon their patients when they are prevented by health care institutions from providing a service they believe is medically-indicated. This was the case for a doctor in Sierra Vista, Arizona, who was prevented from ending a patient's wanted, but doomed, pregnancy after she suffered premature rupture of membranes. The patient had to be sent to the nearest non-objecting hospital, which was 80 miles away, far from her family and friends. The physician described the experience as "a very gut wrenching thing to put the staff through and the patient, obviously."[17]

6. The proposed rule carries severe consequences for patients and will exacerbate existing inequities.

a. Refusals of care make it difficult for many individuals to access the care they need

Across the country, refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need.[18] One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously-affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care.[19] Another woman experiencing pregnancy loss was denied care for 10 days at a religiously affiliated hospital outside Chicago, Illinois.[20] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[21] Another patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic hospital provider refused to give her the procedure.[22] Another woman was sent home by a religiously-affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options.[23]

b. Refusals of care are especially dangerous for those already facing barriers to care

Refusals of care based on personal beliefs already make it difficult for many individuals to access health care and have real consequences for those denied the care they need because of a provider or hospital's religious beliefs. When women and families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another

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[16] *See* The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).
[17] Uttley, L, et all, *Miscarriage of Medicine,* MergerWatch and the ACLU (2013), p. 16, https://www.aclu.org/report/miscarriage-medicine.
[18] *See, e.g., supra* note 2.
[19] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[20] *See* Julia Kaye, et al., *Health Care* Denied, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.
[21] *See* Kira Shepherd, et al., *supra* note 19, at 29.
[22] *See The Patient Should Come First: Refusals to Provide Reproductive Health Care*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/05/Refusals-FS.pdf; Sandhya Somashekhar, *A Pregnant Woman Wanted her Tubes Tied. Her Catholic Hospital Said No.*, WASH. POST (Sept. 13, 2015), https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2_story.html?utm_term=.8c022b364b75.
[23] *See* Kira Shepherd, et al., *supra* note 19, at 27.

location, refusals bar access to necessary care.[24] This is especially true for immigrant patients who often lack access to transportation and may have to travel great distances to get the care they need.[25] In rural areas there may be no other sources of health and life preserving medical care.[26] When these individuals encounter refusals of care, they may have nowhere else to go.

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that In 19 states, women of color are more likely than white women to give birth in Catholic hospitals.[27] Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provide guidance on a wide range of hospital matters, including reproductive health care, and can keep providers from offering the standard of care.[28] The reach of this type of religious refusal of care is growing with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.[29]

7. The Department is abdicating its responsibility to patients

If finalized, the proposed rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care and eliminate health disparities

The proposed rule seeks to divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. For example, Black women are three to four times more likely than white women to die during or after childbirth.[30] Lesbian, gay, bisexual and transgender individuals also encounter high rates of discrimination in health care.[31] Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a health care provider had refused to see them because of their actual or perceived sexual orientation or gender identity in the year before the survey.[32] OCR must work to address these disparities, yet the proposed rule is antithetical to OCR's mission.

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[24] In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. *Women's Health Insurance* Coverage, KAISER FAMILY FOUND. 1, 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage.

[25] Athena Tapales et al., *The Sexual and Reproductive Health of Foreign-Born Women in the United States*, CONTRACEPTION 8, 16 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf; Nat'l Latina Inst. For Reproductive Health & Ctr. For Reproductive Rights, *Nuestra Voz, Nuestra Salud, Nuestro Texas: the Fight for Women's Reproductive Health in the Rio Grande Valley* 1, 7 (2013), http://www.nuestrotexas.org/pdf/NT-spread.pdf.

[26] Since 2010, eighty-three rural hospitals have closed. *See Rural Hospital Closures: January 2010 – Present*, THE CECIL G. SHEPS CTR FOR HEALTH SERVS. RES. (2018), http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

[27] *See* Kira Shepherd, et al., *supra* note 19, at 12.

[28] *See id.* at 10-13.

[29] *See, e.g.*, *Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.

[30] *See* Nina Martin, *Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why*, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why.

[31] *See, e.g.*, *When Health Care Isn't Caring*, LAMBDA LEGAL 5 (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring_1.pdf.

[32] *See* Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NAT'L GAY AND LESBIAN TASK FORCE & NAT'L CTR. FOR TRANSGENDER EQUALITY, http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.

8. The proposed rule will make it harder for states to protect their residents

The proposed rule will have a chilling effect on the enforcement and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. Moreover, the proposed rule invites states to further expand refusals of care by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.[33]

Conclusion

The proposed pule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The proposed rule is discriminatory, violates multiple federal statutes and the Constitution, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons the Oregon Foundation for Reproductive Health calls on the Department to withdraw the proposed rule in its entirety.

[33] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.

Exhibit 70

ANA
AMERICAN NURSES ASSOCIATION

AMERICAN ACADEMY OF NURSING
transforming health policy and practice through nursing knowledge

March 23, 2018

Office for Civil Rights
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Constitution Avenue, NW
Washington, DC 20210

Attention: Conscience Notice of Proposed Rule Making (NPRM), RIN 0945-ZA03

Submitted electronically to www.regulations.gov

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority
[HHS-OCR-2018-0002; RIN 0945-ZA03]

Dear Sir/Madam:

The American Nurses Association (ANA) and the American Academy of Nursing (AAN) submit the following comments in response to the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) Proposed Rule: *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*. This proposed rule requests comment on a number of provisions contained therein, and ANA and AAN through this comment letter seek to highlight the potential negative and unintended impacts which might follow from the final implementation of such, and offers policy recommendations. ANA is the premier organization representing the interests of the nation's 3.6 million registered nurses (RNs), through its state and constituent member associations, organizational affiliates, and individual members. ANA advances the nursing profession by fostering high standards of nursing practice, promoting a safe and ethical work environment, bolstering the health and wellness of nurses, and advocating on health care issues that affect nurses and the public. AAN serves the public and the nursing profession by advancing health policy and practice through the generation, synthesis, and dissemination of nursing knowledge. The Academy's more than 2,400 fellows are nursing's most accomplished leaders in education, management, practice, and research.

ANA and AAN strongly support the right and prerogative of nurses - and all healthcare workers – to heed their moral and ethical values when making care decisions. However, the primacy of the patient in nursing practice is paramount, and the moral and ethical considerations of the nurse should never, under any circumstance, result in the inability of the patient to receive quality, medically necessary, and compassionate care.

ANA and AAN are concerned that this proposed rule, in strengthening the authority of OCR to enforce statutory conscience rights under the Church Amendments, the Coats-Snowe Amendment, the Weldon Amendment, and other federal statutes, could lead to inordinate discrimination against certain patient populations – namely individuals seeking reproductive

health care services and lesbian, gay, bisexual, transgender, and queer or questioning (LGBTQ) individuals. Proliferation of such discrimination – which in the case of LGBTQ individuals is unlawful under Section 1557 of the Affordable Care Act (ACA) – could result in reduced access to crucial and medically necessary health care services and the further exacerbation of health disparities between these groups and the overall population.

Discrimination in health care settings remains a grave and widespread problem for many vulnerable populations and contributes to a wide range of health disparities. Existing religion-based exemptions already create hardships for many individuals. The mission of HHS is to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, patient care, public health, and social services. This proposed rule fails to ensure that all people have equal access to comprehensive and nondiscriminatory services, and dangerously expands the ability of institutions and entities, including hospitals, pharmacies, doctors, nurses, even receptionists, to use their religious or moral beliefs to discriminate and deny patients health care. All patients deserve universal access to high quality care and we as health care providers must guard against any erosion of civil rights protections in health care that would lead to denied or delayed care.

ANA and AAN believe that HHS should rescind this proposed rule and instead, through OCR, should create a standard for health systems and individual practices to ensure prompt, easy access to critical health care services if an individual provider has a moral or ethical objection to certain health care services; such a standard should build on evidence-based and effective mechanisms to accommodate conscientious objections to services including abortion, sterilization, or assisted suicide as cited in the proposed rule. ANA and AAN also believe that in no instance should a nurse – or any health care provider – refuse to treat a patient based on that patient's individual attributes; such treatment violates one of the central tenets of the professional *Code of Ethics for Nurses*. No patient should ever be deprived of necessary health care services or of compassionate health care; it is incumbent upon HHS to work to create accommodations to that end.

Code of Ethics for Nurses and Moral and Ethical Obligations

The critical importance of the relationship between the patient and the nurse is inherent in the fact that Provision 1 and Provision 2 of the *Code of Ethics for Nurses*[1] deal explicitly with these topics.

Affirming Health through Relationships of Dignity and Respect: *Provision 1 of the Code of Ethics:* states that "The nurse practices with compassion and respect for the inherent dignity, worth, and unique attributes of every person."[2] This includes respect for the human dignity of the patient and the demand that nurses must never behave prejudicially – which is to say, with

[1]American Nurses Association. *Code of Ethics for Nurses with Interpretive Statements*. 2015: Second Edition.
[2]Ibid: Pg. 1.

unjust discrimination. Nurses can and should base patient care on individual attributes, but only in the sense that those individual attributes inform the patient's care plan; nurses must always respect the dignity of such individual attributes.

Health care professionals work within a matrix of legal, institutional, and professional constraints and obligations, and their primary commitment to patients remains the foundational responsibility of health care.[3] *Provision 2* states that "The nurse's primary commitment is to the patient, whether an individual, family, group, community, or population."[4] Provision 2 explicitly establishes the primacy of the patient's interests in health care settings; this principle also situates the nurse-patient relationship within a larger "ethic of care" which encompasses the entire relational nexus in which the nurse and patient are situated, including the patient, the patient's family or close relationships, the nurse, the healthcare team, the institution or agency, and even societal expectations of care."[5]

While the primacy of the patient is not the only consideration when a nurse makes a care decision, it is the consideration which carries by far the most relative weight. Nurses then must base care decisions primarily on patients' needs. If a nurse feels that a moral or ethical consideration prevents him or her from delivering health care services, then the nurse, the full medical team, and/or the practice, institution, health system, or agency, should make an exhaustive and good-faith effort to ensure that the patient easily and promptly receives those health care services. In addition to the provisions contained within this proposed rule, OCR must implement guidelines by which the aforementioned stakeholders must ensure access to essential and quality health care services for all patients.

Considerations for Access to Reproductive Health Care Services

In addition to providing competent, professional and high quality care, there is also an emphasis on providing evidence-informed patient education and support as part of the nursing standard of care. The nursing profession holds sacred the patient's right of autonomy to make informed decisions to direct his or her care, as well as the crucial role that nurses play in supporting the patient. Patient education and advocacy are essential elements of the nursing process. Thus, it is the patients' decisions, regardless of faith or moral convictions, that should guide healthcare providers' care of patients, as articulated in the Code of Ethics for Nurses with Interpretive Statements.

For nurses who have concerns about the provision of specific healthcare services, existing laws and ethical guidelines are more than adequate to protect the rights of health care providers to follow their moral and religious convictions. There already exist effective models to accommodate providers' moral and religious beliefs in training and practice, while striking a

[3]Stahl, Ronit Y. and Emanuel, Ezekiel J. *Physicians, Not Conscripts — Conscientious Objection in Health Care*. The New England Journal of Medicine: 2017 April; 376: 1380-1385.
[4]American Nurses Association. Code *of Ethics for Nurses*: Pgs. 25-26.
[5]Ibid: Pg. 28.

crucial balance with delivering evidence-based, patient-centered care.[6] This proposed rule skews that balance, lowers the bar for care necessary for patients in vulnerable populations, and exposes women who seek reproductive health care to discrimination and harmful delays.[7] Such discrimination is well-documented – one study notes that 24% of women were denied treatment by a health care provider for pregnancy termination.[8] The proposed rule defines "discrimination" for the first time in a way that subverts the language of landmark civil rights statutes to shield those who discriminate, rather than protecting against discrimination.[9]

The proposed rule provides a broad definition of "assist in the performance" of an activity to which an individual can refuse to participate. The definition allows for blanket discrimination by permitting a broad interpretation of not only what type of services that can be refused but also the individuals who can refuse. For example, under this proposed rule, a receptionist can refuse to schedule a patient's pregnancy termination or appointment for contraception consultation. This expansion violates the plain meaning of the existing law and goes against the stated mission of HHS.

Data suggest that health care providers believe that even when they are morally opposed to offering care, they are willing to make referrals and coordinate care according to care coordination standards to ensure adequate, timely and safe care, as well as full information about standard of care and available services, is provided for all patients.[10] Yet, the proposed rule creates a definition of "referral" that allows refusal to provide any information that could help the patient receive the proper care necessary; withholding information or complete care recommendations (e.g., professionals withholding diagnostic or treatment information) is unethical.

International professional associations such as the World Medical Association, as well as national medical and nursing societies and groups such as the American Congress of Obstetricians and Gynecologists and the Royal College of Nursing, Australia, have similarly agreed that the provider's right to conscientiously refuse to provide certain services must be secondary to his or her first duty, which is to the patient.[11] This right to refuse must be bound

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[6]National Women's Law Center. *Trump Administration Proposes Sweeping Rule to Permit Personal Beliefs to Dictate Health Care.* February 16, 2018. Web: https://nwlc.org/resources/trump-administration-proposes-sweeping-rule-to-permit-personal-beliefs-to-dictate-health-care/

[7]Ibid.

[8]Biggs, M. Antonia and John M. Neuhaus and Diana G. Foster. *Mental Health Diagnoses 3 Years After Receiving or Being Denied an Abortion in the United States.* The American Journal of Public Health: 2015 December; 105(12): 2557-2563.

[9]National Women's Law Center. *Trump Administration Proposes Sweeping Rule to Permit Personal Beliefs to Dictate Health Care.*

[10]Harris, LH et al. *Obstetrician-gynecologists' objections to and willingness to help patients obtain an abortion.* Obstetrics and Gynecology: 2011 October; 118(4): 905-912.

[11]Chavkin, W. et al. *Conscientious objection and refusal to provide reproductive healthcare: a White Paper examining prevalence, health consequences, and policy responses.* The International Journal of Gynaecology and Obstetrics: 2013 December; 123 Supplement 3: S41-56.

by obligations to ensure that the patient's autonomous rights to information and services are not infringed upon.[12]

Considerations for the Protection of LGBTQ Access to Health Care Services

LGBTQ populations experience a significant rate of discrimination in health care settings, and also experience negative health outcomes compared with the overall population. The reasons for this are complex and varied, but many stem from a pattern of societal stigma and discrimination[13] exacerbated by the historical designation of homosexuality as a mental disorder[14], the onset of the HIV/AIDS epidemic[15], religious prejudice with respect to homosexuality[16], and government policy such as *Don't Ask, Don't Tell*.[17] Indeed, the current administration filed a brief in federal court with the U.S. Court of Appeals for the 2nd Circuit in the case of *Zarda v. Altitude Express* arguing that sex discrimination provisions under Title VII of the 1964 Civil Rights Act do not protect employees from discrimination based on sexual orientation.[18]

HHS in May 2016 issued a rule to implement Section 1557 of the ACA, which clarifies that discrimination based on sex stereotyping and gender identity is impermissible sex discrimination under the law.[19] The current administration has failed to defend this regulation in federal court in the case of *Franciscan Alliance v. Burwell* (a different federal court recently ruled that Section 1557 *ipso facto* provides for the rule's aforementioned protections);[20] this seems to point to a preferential pattern of treatment in favor of religious conscience objections over the civil rights of LGBTQ populations despite consistent federal court opinions to the contrary.

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[12]Ibid.
[13]U.S. Centers for Disease Control and Prevention. *Gay and Bisexual Men's Health: Stigma and Discrimination.* February 29, 2016. Web: https://www.cdc.gov/msmhealth/stigma-and-discrimination.htm
[14]Burton, Neel. *When Homosexuality Stopped Being a Mental Disorder.* Psychology Today (Blog). September 18, 2015. Web: https://www.psychologytoday.com/blog/hide-and-seek/201509/when-homosexuality-stopped-being-mental-disorder
[15]Barnes, David M. and Meyer, Ilan H. *Religious Affiliation, Internalized Homophobia, and Mental Health in Lesbians, Gay Men, and Bisexuals.* American Journal of Orthopsychiatry: 2012 October; 82(4): 505-515.
[16]DeCarlo, Pamela and Ekstrand, Maria. *How does stigma affect HIV prevention and treatment*? University of California, San Francisco: October 2016. Web: https://prevention.ucsf.edu/library/stigma
[17]U.S. Department of Defense. *Don't Ask, Don't Tell Is Repealed.* September 2011. Web: http://archive.defense.gov/home/features/2010/0610_dadt/
[18]Feuer, Alan and Weiser, Benjamin. *Civil Rights Act Protects Gay Workers, Appeals Court Rules.* The New York Times: February 26, 2018. Web: https://www.nytimes.com/2018/02/26/nyregion/gender-discrimination-civil-rights-lawsuit-zarda.html
[19]Gruberg, Sharita and Bewkes, Frank J. *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial.* Center for American Progress: March 7, 2018: Pg. 1. Web: https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/
[20]Ibid: Pg. 2.

OCR is responsible for accepting and investigating such complaints under Section 1557; the Center for American Progress in 2018 conducted an independent analysis of such complaints from May 2010 to January 2017 and found the following breakdown of complaint issues:[21]

- Denied care because of gender identity – non-transition related (24.3%)
- Misgendering or other derogatory language (18.9%)
- Denied insurance coverage for transition care (13.2%)
- Provider denied transition care (10.8%)
- Inadequate care because of gender identity (10.8%)
- Other discrimination based on sexual orientation (8.1%)
- Denied insurance coverage because of gender identity – non-transition-related (5.4%)
- Denied care because of sexual orientation or HIV status (5.4%)
- Inadequate care because of sexual orientation (2.7%)

It is worth noting that the number of Section 1557 complaints during this 7-year period (34) is comparable to the number of health care conscience complaints (44) during the 10-year period cited in the proposed rule. This comparison not only highlights the balance that must be struck between these two types of complaints, but also raises the question as to how such discrimination translates to actual health outcomes.

Negative health outcomes that disproportionately impact LGTBQ individuals include: increased instances of mood and anxiety disorders and depression, and an elevated risk for suicidal ideation and attempts; higher rates of smoking, alcohol use, and substance use; higher instances of stigma, discrimination, and violence; less frequent use of preventive health services; and increased levels of homelessness among LGBTQ youth.[22] Men who have sex with men (MSM) and transgender women also experience significantly higher rates of HIV/AIDS infections, complications, and deaths; this burden falls particularly heavily on young, African-American MSM and transgender women. As evidenced in the Section 1557 complaints above, this disease burden is itself known to contribute to discrimination against LGBTQ individuals. Transgender individuals also face particularly severe discrimination in health care settings: 33% of transgender patients say that a health care provider turned them away because of being transgender.[23]

As noted in the "*Code of Ethics for Nurses and Moral and Ethical Obligations*" section of this comment letter, nurses are obligated to respect the human dignity of all patients and to ensure that all patients receive quality, medically necessary, and compassionate care that is timely and safe. The health disparities highlighted in this section demonstrate the negative outcomes

[21] Ibid: Pg. 5.
[22] U.S. Institute of Medicine Committee on Lesbian, Gay, Bisexual, and Transgender Health Issues and Research Gaps and Opportunities. *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding.* Washington, DC: National Academies Press; 2011.
[23] James, Sandy E. et al. *The Report of the U.S. Transgender Survey.* 2016: 96-97. Web: www.ustranssurvey.org/report

associated with failure to provide such care. The civil rights of LGBTQ individuals – including the accessibility of quality health care services for LGBTQ individuals – should be protected in a manner consistent with the statutory conscience rights of health care workers under this proposed rule; the protection of such conscience rights should never impede the ability of LGBTQ individuals to access health care services.

Policy Recommendations and Conclusion

ANA and AAN do not wish to diminish the role of moral and ethical considerations in patient care. In fact, the *Code of Ethics for Nurses* acknowledges both implicitly and explicitly that such considerations play critical roles when it comes to a patient's care plan. ANA and AAN do, however, reiterate the primacy of the patient in nursing care; ensuring that all patients are able to access quality, medically necessary, and compassionate care is paramount to nursing practice. ANA and AAN also acknowledge the dual roles that OCR plays with respect to simultaneously enforcing the ACA's Section 1557 provisions and the statutory conscience rights provisions referenced in the proposed rule, including those under the Church Amendments, the Coats-Snowe Amendment, and the Weldon Amendment.

To this end, ANA and AAN believe that in order to accommodate both priorities, OCR should implement guidelines for individual providers, practices, agencies, health systems, and institutions to accommodate both employees and patients. Namely, these guidelines must ensure that if any of the aforementioned stakeholders has a moral or ethical objection to providing certain health care services, they must have in place an organized plan by which the patient – without creating or exacerbating inequities - is able to easily access the quality, affordable, compassionate, and comprehensive health care that they need. Such guidelines reflect the primacy of the patient while at the same time recognizing that various federal statutes protect the conscience rights of health care workers. HHS and OCR must also work with stakeholders to implement existing, evidence-based models that facilitate a standard of care that integrates timely care coordination when health care providers or their employers exhibit a moral or ethical objection to providing certain health care services; such models must also protect the ability of the patient to access evidence-informed care and must not expose women and other marginalized populations to discrimination.

ANA and AAN also reiterate in no uncertain terms that nurses (or any other health care provider) cannot cite conscience rights protections as a reason for refusing to treat certain patient populations, including women seeking reproductive health care and LGBTQ populations. Such refusals go far beyond the provisions of any of the federal statutes cited in the proposed rule, a fact again borne out consistently in federal court opinions. As noted above, the nurse's primary concern is the patient's care. To provide inequitable care for an individual, or to refuse to provide that care entirely, would demonstrate unjust discrimination toward that patient. Such care (or lack thereof) directly contradicts one of the central tenets of nursing practice, violates federal law – including Section 1557 of the ACA – and leads to negative health outcomes and population health disparities.

ANA and AAN believe that this proposed rule should be rescinded and that HHS should develop a standard for accommodation for conscientious objection to certain services which in no way limits the ability of the patient to receive timely, affordable, quality, and compassionate care. This proposed rule is restrictive with respect to ensuring such care. Given the current administration's track record when it comes to defending religious objections at the expense of individual rights, it seems to follow that this proposed rule would represent a significant lurch toward such defense in the health care field. This is unacceptable; in health care practice, patients come first, and HHS must make every attempt to strike an equitable balance between conscientious objections and patients' inalienable rights.

ANA and AAN welcome an opportunity to further discuss the issue of statutory conscience rights protections for health care workers. If you have questions, please contact Liz Stokes, Director, Center for Ethics and Human Rights (liz.stokes@ana.org) or Mary Beth Bresch White, Director, Health Policy (marybreschwhite@ana.org).

Sincerely,

Pamela F. Cipriano, PhD, RN, NEA-BC, FAAN
President
American Nurses Association

Karen S. Cox, PhD, RN, FACHE, FAAN
President
American Academy of Nursing

cc: Debbie Hatmaker, PhD, RN, FAAN, Interim Chief Executive Officer, American Nurses Assoc.
Cheryl G. Sullivan, MSES, Chief Executive Officer, American Academy of Nursing

Exhibit 71

March 27, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Public Comment in Response to the Proposed Regulation, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03 (Submitted electronically)

To Whom it May Concern:

We are writing on behalf of Raising Women's Voices for the Health Care We Need (Raising Women's Voices) in response to the request for public comment on the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26.[1]

Raising Women's Voices is a national initiative with 30 regional coordinator organizations in 29 states working to ensure that the health care needs of women and our families are addressed in federal and state health policies. We have a special mission of engaging women who are not often invited into health policy discussions: women of color, low-income women, immigrant women, young women, women with disabilities, and members of the LGBTQ community.

This proposed regulation would exacerbate the challenges that many patients -- especially women, LGBTQ people, people of color, immigrants and low-income people -- already face in getting the health care they need in a timely manner and at an affordable cost. The rule would expose vulnerable patients to increased discrimination and denials of medically-indicated care by broadening religious health care provider exemptions beyond the existing limited circumstances allowed by law. Moreover, while protecting health providers who deny care, the rule would provide *no protections for patients who are being denied care – even in emergencies*. As drafted, the rule would not even require that patients be informed of all their potential treatment options and referred to alternative providers of needed care.

[1] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (proposed Jan. 26, 2018) (*to be codified at* 45 C.F.R. pt. 88) [*hereinafter* Rule].

Indeed, this proposal runs in the opposite direction of everything we believe the American health system must do to achieve "patient-centered care." We urge the administration to put patients first, and withdraw the proposed regulation because of the serious problems enumerated below.

1. The rule improperly seeks to expand on existing religious refusal exemptions to potentially allow denial of any health care service based on a provider's personal beliefs or religious doctrine.

Existing refusal of care laws (such as for abortion and sterilization services) are already being used across the country to deny patients the care they need.[2] The proposed rule attempts to expand on these laws in numerous ways that are directly contrary to the stated purpose of the existing laws. Specifically, the Department and its Office for Civil Rights (OCR) are attempting to require a broad swath of entities to allow individuals to refuse "*any* lawful health service or activity based on religious beliefs or moral convictions (emphasis added)."[3]

This expansive interpretation could lead to provider denials based on personal beliefs that are biased and discriminatory, such as objections to providing care to people who are transgender or in same-sex relationships. We are aware of cases in which this type of unjust denial of care has occurred, such as a California physician's denial of donor insemination to a lesbian couple, even though the doctor routinely provided the same service to heterosexual couples. [4]

We are also concerned about potential enabling of care denials by providers based on their non-scientific personal beliefs about other types of health services. For example, certain religiously-affiliated hospitals and individual clinicians have refused to provide rape victims with emergency contraception to prevent pregnancy[5] based on the belief that it can cause an abortion, even though there is no scientific evidence that this is the case. Providers could conceivably be motivated by the proposed rule to object to administering vaccinations or refuse to prescribe or dispense Pre-exposure Profylaxis (PrEP) medication to help gay men reduce the risk of HIV transmission through unprotected sex.

2. The rule would protect refusals by anyone who would be "assisting in the performance of" a health care service to which they object, not just clinicians.

The rule seeks to protect refusals by any "member of the workforce" of a health care institution whose actions have an "articulable connection to a procedure, health services or health service program, or research activity." The rule includes examples such as "counseling, referral, training and other arrangements for the procedure, health service or research activity."

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[2] *See, e.g., Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Uttley, L., et al, *Miscarriage of Medicine,* MergerWatch and the ACLU (2013), https://www.aclu.org/report/miscarriage-medicine.

[3] *See* Rule *supra* note 1, at 12.

[4] Hardaway, Lisa, *Settlement Reached in Case of Lambda Legal Lesbian Client Denied Infertility Treatment by Christian Fundamentalist Doctors,* Lambda Legal, September 29, 2009, accessed at https://www.lambdalegal.org/news/ca_20090929_settlement-reached.

[5] Erdely, Sabrina, *Doctors' beliefs can hinder patient care*, SELF magazine, June 22, 2007, accessed at http://www.nbcnews.com/id/19190916/print/1/displaymode/1098/

An expansive interpretation of "assist in the performance of" thus *could conceivably allow an ambulance driver to refuse to transport a patient to the hospital for care he/she finds objectionable*. It could mean a hospital admissions clerk could refuse to check a patient in for treatment the clerk finds objectionable or a technician could refuse to prepare surgical instruments for use in a service.

On an institutional level, the right to refuse to "assist in the performance of" a service could mean *a* religiously-affiliated hospital or clinic could deny care, and *then also refuse to provide a patient with a referral or transfer to a willing provider* of the needed service. Indeed, the proposed rule's definition of "referral" goes beyond any common understanding of the term, allowing refusals to provide *any information,* including location of an alternative provider, that could help people get care they need.[6]

The proposed rule thus could be read as allowing health providers to refuse to inform patients of all potential treatment options. A 2010 publication of the National Health Law Program, "Health Care Refusals: Undermining Quality of Care for Women," noted that "refusal clauses and institutional restrictions can operate to deprive patients of the complete and accurate information necessary to give informed consent."[7]

3. The rule does not address how a patient's needs would be met in an emergency situation.

There have been reported instances in which pregnant women suffering medical emergencies – including premature rupture of membranes (PPROM) and ectopic pregnancies[8] -- have gone to hospital emergency departments and been denied prompt, medically-indicated care because of institutional religious restrictions.[9] This lack of protections for patients is especially problematic in regions of the country, such as rural areas, where there may be no other nearby hospital to which a patient could easily go without assistance and careful medical monitoring enroute.[10]

The proposed rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person

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[6] *See* Rule *supra* note 1, at 183.

[7] The NHeLP publication noted (at page 21) that the Ethical and Religious Directives for Catholic Healthcare Services, which govern care at Catholic hospitals, limit the information a patient can be given about treatment alternatives to those considered "morally legitimate" within Catholic religious teachings. (Directive No. 26).

[8] Foster, AM, and Smith, DA, *Do religious restrictions influence ectopic pregnancy management? A national qualitative study*, Jacob Institute for Women's Health, Women's Health Issues, 2011 Mar-Apri; 21(2): 104-9, accessed at https://www.ncbi.nlm.nih.gov/pubmed/21353977

[9] Stein, Rob, *Religious hospitals' restrictions sparking conflicts, scrutiny,* The Washington Post, January 3, 2011, accessed at https://www.washingtonpost.com/health-environment-science/religious-hospitals-restrictions-sparking-conflicts-scrutiny/2011/01/03/ABVVxmD_story.html?utm_term=.cc34abcbb928

[10] For example, a 2016 study found there were 46 Catholic-affiliated hospitals that were the federally-designated "sole community providers" of hospital care for their geographic regions. Women needing reproductive health services that are prohibited by Catholic health restrictions would have no other easily accessible choice of hospital care. Uttley, L., and Khaikin, C., *Growth of Catholic Hospitals and Health Systems,* MergerWatch, 2016, accessed at www.MergerWatch.org

to another facility.[11] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[12] Because the proposed rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

4. **Health care institutions would be required to notify employees that they have the right to refuse to provide care, *but would not be required to notify patients about the types of care they will not be able to receive at that hospital, pharmacy, clinic or doctor's office*.**

The rule sets forth extensive requirements for health care institutions, such as hospitals, to notify employees about their refusal rights, including how to file a discrimination complaint with OCR. The rule requires posting of such notices on the employer's website and in prescribed physical locations within the employer's building. The rule also sets forth the expectation that OCR would investigate or do compliance reviews of whether health care institutions are following the posting rule.[13]

By contrast, the rule contains no requirement that patients be notified of institutional restrictions on provision of certain types of care. Such notification is essential because research has found that patients often are unaware of service restrictions at religiously-sponsored health care institutions. [14]

5. The rule conflicts with other existing federal laws, including the Title VII framework for accommodation of employee's religious beliefs.

The Proposed Rule generates chaos through its failure to account for existing laws that conflict with the refusals of care it would create. For example, the proposed rule makes no mention of Title VII,[15] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[16] Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.[17] For decades, Title VII has

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[11] 42 U.S.C. § 1295dd(a)-(c) (2003).

[12] In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. *See, e.g., Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220, 228 (3rd Cir. 2000); *In re Baby K*, 16 F.3d 590, 597 (4th Cir. 1994); *Nonsen v. Medical Staffing Network, Inc.* 2006 WL 1529664 (W.D. Wis.); *Grant v. Fairview Hosp.*, 2004 WL 326694, *93 Fair Empl. Prac. Cas.* (BNA) 685 (D. Minn. 2006); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); *Barris v. County of Los Angeles*, 972 P.2d 966, 972 (Cal. 1999).

[13] The notice requirement is spelled out in section 88.5 of the proposed rule.

[14] *See*, for example, Freedman, Lori R., Luciana E. Hebert, Molly F. Battistelli, and Debra B. Stulberg, *Religious hospital policies on reproductive care: what do patients want to know?* American Journal of Obstetrics & Gynecology 218, no. 2 (2018): 251-e1, accessed here: http://www.ajog.org/article/S0002-9378(17)32444-4/fulltext; also Guiahi, Maryam, Jeanelle Sheeder, and Stephanie Teal, *Are women aware of religious restrictions on reproductive health at Catholic hospitals? A survey of women's expectations and preferences for family planning care*, Contraception and Stulberg, D., et all, accessed here: http://www.contraceptionjournal.org/article/S0010-7824(14)00358-8/fulltext; *Do women know when their hospital is Catholic and how this affects their care? Restrictions in Catholic Hospitals (PARRCH) national survey*, Contraception, Volume 96, Issue 4, 268-269,accessed here: http://www.contraceptionjournal.org/article/S0010-7824(17)30235-4/fulltext; a

[15] 42 U.S.C. § 2000e-2 (1964).

[16] *Title VII of the Civil Rights Act of 1964*, U.S. Equal Emp't. Opportunity Comm'n (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.

[17] *See id.*

established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal obligations. The proposed rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[18]

Furthermore, the language in the proposed rule would seem to put health care entities in the position of being forced to hire people who intend to refuse to perform essential elements of a position, even though Title VII would not require such an "accommodation." For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the applicant refuses to provide non-directive options counseling, even though the employer would not be required to do so under Title VII.[19] It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

6. There is no provision protecting the rights of health care providers with religious or moral convictions to *provide* (not deny) services their patients need.

The proposed rule ignores those providers with deeply held moral convictions that motivate them to provide patients with health care, including abortion, transition-related care and end-of-life care. The rule fails to acknowledge the Church Amendment's protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[20]

Doctors are, in effect, forced to abandon their patients when they are prevented by health care institutions from providing a service they believe is medically-indicated. This was the case for a doctor in Sierra Vista, Arizona, who was prevented from ending a patient's wanted, but doomed, pregnancy after she suffered premature rupture of membranes. The patient had to be sent to the nearest non-objecting hospital, which was 80 miles away, far from her family and friends. The physician described the experience as "a very gut wrenching thing to put the staff through and the patient, obviously."[21]

7. The proposed rule carries severe consequences for patients and would exacerbate existing inequities.

a. *Refusals of care make it difficult for many individuals to access the care they need*

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[18] Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), *available at* https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html.
[19] *See* Rule *supra* note 1, at 180-181.
[20] *See* The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).
[21] Uttley, L, et all, *Miscarriage of Medicine,* MergerWatch and the ACLU (2013), p. 16, https://www.aclu.org/report/miscarriage-medicine.

Across the country, refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need.[22] One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care.[23] Another woman experiencing pregnancy loss was denied care for 10 days at a religiously affiliated hospital outside Chicago, Illinois.[24] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[25] Another patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic hospital provider refused to give her the procedure.[26] Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options.[27]

b. *Refusals of care are especially dangerous for those already facing barriers to care*

Refusals of care based on personal beliefs already make it difficult for many individuals to access health care and have real consequences for those denied the care they need because of a provider or hospital's religious beliefs. When women and families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another location, refusals bar access to necessary care.[28] This is especially true for immigrant patients who often lack access to transportation and may have to travel great distances to get the care they need.[29] In rural areas there may be no other sources of health and life preserving medical care.[30] When these individuals encounter refusals of care, they may have nowhere else to go.

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[22] *See, e.g.*, *supra* note 2.

[23] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[24] *See* Julia Kaye, et al., *Health Care* Denied, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

[25] *See* Kira Shepherd, et al., *supra* note 23, at 29..

[26] *See The Patient Should Come First: Refusals to Provide Reproductive Health Care*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/05/Refusals-FS.pdf; Sandhya Somashekhar, *A Pregnant Woman Wanted her Tubes Tied. Her Catholic Hospital Said No.*, WASH. POST (Sept. 13, 2015), https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2_story.html?utm_term=.8c022b364b75.

[27] *See* Kira Shepherd, et al., *supra* note 23, at 27..

[28] In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. *Women's Health Insurance* Coverage, KAISER FAMILY FOUND. 1, 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage.

[29] Athena Tapales et al., *The Sexual and Reproductive Health of Foreign-Born Women in the United States*, CONTRACEPTION 8, 16 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf; Nat'l Latina Inst. For Reproductive Health & Ctr. For Reproductive Rights, *Nuestra Voz, Nuestra Salud, Nuestro Texas: the Fight for Women's Reproductive Health in the Rio Grande Valley* 1, 7 (2013), http://www.nuestrotexas.org/pdf/NT-spread.pdf.

[30] Since 2010, eighty-three rural hospitals have closed. *See Rural Hospital Closures: January 2010 – Present*, THE CECIL G. SHEPS CTR FOR HEALTH SERVS. RES. (2018), http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that In 19 states, women of color are more likely than white women to give birth in Catholic hospitals.[31] Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provide guidance on a wide range of hospital matters, including reproductive health care, and can keep providers from offering the standard of care.[32] Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women were delayed care or transferred to other facilities at great risk to their health.[33] The reach of this type of religious refusal of care is growing with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.[34]

We concur with the comments submitted by the National Health Law Program (NHeLP) that the regulations fail to consider the impact of refusals on persons suffering from substance use disorders. Rather than promoting the evidence-based standard of care, the rule could allow practitioners to refuse to provide, or even recommend, Medication Assisted Treatment (MAT) and other evidence-based interventions due simply to a personal objection.

Stigma associated with drug use stands in the way of saving lives.[35] America's prevailing cultural consciousness -- after decades of treating the disease of addiction as largely a criminal justice and not the public health issue it is -- generally perceives drug use as a moral failing and drug users as less deserving of care. For example, a needle exchange program designed to protect injection drug users from contracting blood borne illnesses such as HIV, Hepatitis C, and bacterial endocarditis was shut down in October 2017 by the Lawrence County, Indiana County Commission due to their moral objection to drug use, despite overwhelming evidence that these programs are effective at reducing harm and do not increase drug use.[36] One commissioner even quoted the Bible as he voted to shut it down. Use of MAT to reverse overdose has been decried as "enabling these people" to go on to overdose again.[37]

In this frame of mind, only total abstinence is seen as successful treatment for substance use disorders, usually as a result of a 12-step or faith-based program, even though evidence for 12-step

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[31] *See* Kira Shepherd, et al., *supra* note 23, at 12.
[32] *See id.* at 10-13.
[33] Lori R. Freedman, *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.
[34] *See, e.g.*, *Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.
[35] Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance*, 13 J. HEALTH CARE L. & POL'Y 49, 56 (2010); German Lopez, *There's a highly successful treatment for opioid addiction. But stigma is holding it back.*, https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone.
[36] German Lopez, *An Indiana county just halted a lifesaving needle exchange program, citing the Bible*, VOX, Oct. 20, 2017, https://www.vox.com/policy-and-politics/2017/10/20/16507902/indiana-lawrence-county-needle-exchange.
[37] Tim Craig & Nicole Lewis, *As opioid overdoses exact a higher price, communities ponder who should be saved*, WASH. POST, Jul. 15, 2017, https://www.washingtonpost.com/world/as-opioid-overdoses-exact-a-higher-price-communities-ponder-who-should-be-saved/2017/07/15/1ea91890-67f3-11e7-8eb5-cbccc2e7bfbf_story.html?utm_term=.4184c42f806c.

programs is weak. The White House's own opioid commission found that "negative attitudes regarding MAT appeared to be related to negative judgments about drug users in general and heroin users in particular."[38]

People with substance use disorders already suffer due to stigma and have a difficult time finding appropriate care. This rule, which allows misinformation and personal feelings to get in the way of science and lifesaving treatment, would not help achieve the goals of the administration; it could instead trigger countless numbers of deaths.

By expanding refusals of care, the proposed rule will exacerbate the barriers to health care services patients need. It is evident that the harm caused by this proposed rule will fall hardest on those most in need of care. The Department should remember, under Executive Order 13563, an agency may only propose regulations where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on society."[39] The proposed rule plainly fails on both counts. Although the proposed rule attempts to quantify the costs of compliance, it completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs.[40]

Moreover, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant religious exemptions and, in fact, bars granting an exemption when it would detrimentally affect any third party.[41] Because the proposed rule would cause substantial harm, including to patients, it would violate the Establishment Clause.[42]

8. The Department is abdicating its responsibility to patients

The proposed rule exceeds OCR's authority by abandoning OCR's mission to address health disparities and discrimination that harms patients.[43] Instead, the proposed rule appropriates language from civil

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[38] Report of the President's Commission on Combating Drug Addiction and the Opioid Crisis, Nov. 1, 2017, https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf

[39] *Improving Regulation and Regulatory Review*, Executive Order 13563 (Jan. 18, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review.

[40] *See* Rule *supra* note 1, at 94-177.

[41] U.S. Const. amend. I; *Cutter v. Wilkinson*. 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment Clause, courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985)); *see also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).

[42] Respecting religious exercise may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *See Burwell v. Hobby Lobby*, 134 S. Ct. at 2787. When considering whether the birth control coverage requirement was the least restrictive means in Hobby Lobby, the Court considered that the accommodation offered by the government ensured that affected employees "have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing coverage." *See id.* at 2759. In other words, the effect of the accommodation on women would be "precisely zero." *Id.* at 2760.

[43] *OCR's Mission and Vision*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html ("The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS

rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the proposed rule creates a regulatory scheme that is not only nonsensical but is affirmatively harmful. For example, the notice and certification of compliance and assurance requirements simply do not make sense when applied to the laws the proposed rule seeks to enforce.[44]

The Department, including OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities.[45] If finalized, however, the proposed rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care, and eliminate health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.[46]

Nevertheless, there is still work to be done, and the proposed rule seeks to divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color.[47] Black women are three to four times more likely than white women to die during or after childbirth.[48] According to a recent report, doctors often fail to inform Black women of the full range of reproductive health options regarding labor or delivery, possibly due to stereotypes about Black women's sexuality and reproduction.[49] Young Black women said they felt they were shamed by

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programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

[44] *See* Rule *supra* note 1, at 203-214.

[45] As one of its first official acts in 1967, the Office of Equal Health Opportunity undertook the massive effort of inspecting 3,000 hospitals to ensure they were complying with Title VI's prohibition against discrimination on the basis of race, color, or national origin. 42. U.S.C. § 2000d (1964). After this auspicious start, the Office of Equal Health Opportunity which would eventually become OCR would go on to ensure that health programs and activities it regulated complied with key anti-discrimination laws including Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (1973), Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 (1972), the Age Discrimination Act of 1976, 42 U.S.C. § 6101 (1976), and Section 1557 of the Affordable Care Act, 42 U.S.C. §18116 (2010), among others. Through robust enforcement of these laws, OCR has worked to reduce discrimination in health care.

[46] *See, e.g., Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html; *Protecting the Civil Rights and Health Information Privacy Rights of People Living with HIV/AIDS*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html; *National Origin Discrimination*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/index.html; *Health Disparities*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

[47] *See* Skinner et al., *Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans*, NAT'L INSTIT. OF HEALTH 1 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf.

[48] *See* Nina Martin, *Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why*, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why.

[49] CTR. FOR REPROD. RIGHTS, NAT'L LATINA INST. FOR REPROD. HEALTH & SISTERSONG WOMEN OF COLOR REPROD. JUSTICE COLLECTIVE, *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care* 20-22 (2014), *available at*

providers when seeking sexual health information and contraceptive care, due to their age and in some instances, sexual orientation.[50]

Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[51] Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a health care provider had refused to see them because of their actual or perceived sexual orientation or gender identity in the year before the survey.[52]

As NHelP's comments note, many people with disabilities receive home and community-based services (HCBS), including residential and day services, from religiously-affiliated providers. Historically, people with disabilities who rely on these services have sometimes faced discrimination, exclusion, and a loss of autonomy due to provider objections. Group homes have, for example, refused to allow residents with intellectual disabilities who were married to live together in the group home.[53] Individuals with HIV – a recognized disability under the ADA – have repeatedly encountered providers who deny services, necessary medications, and other treatments citing religious and moral objections. One man with HIV was refused care by six nursing homes before his family was finally forced to relocate him to a nursing home 80 miles away.[54] Given these and other experiences, the extremely broad proposed language at 45 C.F.R. § 88.3(a)(2)(vi) that would allow any individual or entity with an "articulable connection" to a service, referral, or counseling described in the relevant statutory language to deny assistance due to a moral or religious objection is extremely alarming and could seriously compromise the health, autonomy and well-being of people with disabilities.

OCR must work to address these disparities, yet the proposed rule seeks to prioritize the expansion of existing religious refusal laws beyond their statutory requirements and create new religious exemptions where none had previously existed rather than using already limited resources to protect patient access to health care. The proposed rule will harm patient care and is antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality.[55]

9. The proposed rule will make it harder for states to protect their residents

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https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD_Shadow_US_6.30.14_Web.pdf [hereinafter *Reproductive Injustice*]; IN OUR OWN VOICE: NAT'L BLACK WOMEN'S REPROD. JUSTICE AGENDA, *The State of Black Women & Reproductive Justice* 32-33 (2017), *available at* http://blackrj.org/wp-content/uploads/2017/06/FINAL-InOurVoices_Report_final.pdf.

[50] *Reproductive Injustice*, *supra* note 10, at 16-17.

[51] *See, e.g.*, *When Health Care Isn't Caring*, LAMBDA LEGAL 5 (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring_1.pdf.

[52] *See* Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NAT'L GAY AND LESBIAN TASK FORCE & NAT'L CTR. FOR TRANSGENDER EQUALITY, http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.

[53] See *Forziano v. Independent Grp. Home Living Prog.*, No. 13-cv-00370 (E.D.N.Y. Mar. 26, 2014) (dismissing lawsuit against group homes, including a religiously affiliated group home, that refused to allow married couple with intellectual disabilities live together). Recent regulations have reinforced protections to ensure available choice of roommates and guests. 42 C.F.R. §§ 441.301(c)(4)(vi)(B) & (D).

[54] NAT'L WOMEN'S LAW CTR., *Fact Sheet: Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS*, (May 2014), *available at* https://nwlc.org/wp-content/uploads/2015/08/lgbt_refusals_factsheet_05-09-14.pdf.

[55] *See supra* note 42.

The proposed rule will have a chilling effect on the enforcement of and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. The preamble of the proposed rule discusses at length state laws that the Department finds objectionable, such as state laws that require anti-abortion counseling centers to provide information about where reproductive health care services can be obtained or whether facilities have licensed medical staff, as well as state laws that require health insurance plans to cover abortion.[56] Moreover, the proposed rule invites states to further expand refusals of care by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.[57]

10. The proposed rule will undermine critical federal health programs, including Title X

The proposed rule would seemingly allow health care entities to receive grants and contracts under HHS-funded programs or other federal health programs, such as Title X, the only domestic family planning program, while refusing to provide key services required by those programs.[58] For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[59] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[60] Under the Proposed Rule, the Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such funds are generally conditioned.[61] The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the sub-recipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.[62] When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objectives. Every year millions of low-income, including under-insured, and uninsured individuals, rely on Title X clinics to access services they otherwise might not be able to afford.[63]

Conclusion

The proposed rule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The proposed rule is discriminatory, violates multiple federal statutes and the

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[56] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.
[57] *See id.*
[58] *See* Rule *supra* note 1, at 180-181, 183. *See also Title X Family Planning*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (2018), https://www.hhs.gov/opa/title-x-family-planning/index.html; *Title X an Introduction to the Nation's Family Planning Program*, NAT'L FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOC. (2017) (*hereinafter* NFPRHA), https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf.
[59] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).
[60] *See* What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).
[61] *See, e.g.*, Rule *supra* note 1, at 180-185.
[62] *See* NFPRHA *supra* note 34.
[63] *See id.*

Constitution, ignores congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons, Raising Women's Voices calls on the Department to withdraw the proposed rule in its entirety.

If you have any questions regarding these comments, please contact Lois Uttley, co-founder of Raising Women's Voices and Women's Health Program Director for Community Catalyst, at luttley@communitycatalyst.org.

Respectfully submitted,

Raising Women's Voices for the Health Care We Need

Exhibit 72

STATE OF WASHINGTON
DEPARTMENT OF HEALTH

March 26, 2018

U.S. Department of Health and Human Services, Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, D.C. 20201

The Washington State Department of Health (DOH) appreciates the opportunity to comment on the proposed rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," printed in the Federal Register on January 26, 2018 (83 FR 3880). We are specifically responding to the request for feedback on the rule's potential to improve or worsen health outcomes.

The proposed rule significantly broadens the criteria by which people or entities can claim conscience objections to deny patients care, the types of entities that must accommodate their employees' or volunteers' objections, and the types of activities to which an entity can object. This threatens to directly reduce access to essential health care services, especially for vulnerable populations—including those living in rural areas—and thereby worsen health outcomes. In addition, the proposed rule conflicts with program requirements in existing successful HHS programs (e.g., immunizations and family planning) that have been shown to improve outcomes. This change will jeopardize the integrity of and funding for these programs. This would further reduce access to care and lead to poorer health outcomes and wider inequities.

The proposed rule does not appropriately balance the conscience rights of providers with health outcomes of their patients or the public health system's role to ensure access to health care services for *all* people.

For these reasons, we recommend HHS withdraw the proposed rule.

If not withdrawn, we strongly urge HHS to revise the language to:

- Allow entities, including states, health systems, clinics, providers, and insurers, to consider significant public health concerns, such as patient access to care, when managing conscience objections.
- Remove requirements for accommodations when they directly conflict with the statutory requirements of HHS programs as determined by the U.S. Congress.

The rule proposes definitions that broaden the type of entity who can claim a conscience objection and the types of activities for which a moral or religious objection could be made, including referrals. The proposed definitions for "assist in the performance," "health care entity,"

and "referral/refer for," taken in conjunction with one another, significantly broaden the number of entities or persons who have a basis to file a complaint and will lead to significant unintended consequences.

First, the broadening of these definitions will make it difficult for some organizations to manage conscience objections without harming their business operations. Small clinics cannot afford multiple schedulers, billers, or assistants who may raise moral or religious objections, which previously were accommodated only for healthcare providers.

It is also our expectation these expanded definitions would create substantial gaps in access to preventive services and limit referrals to services that are provided elsewhere. These gaps could be especially harmful for vulnerable populations such as women and families with low incomes; people who are lesbian, gay, bisexual, or transgender (LGBT); people of color; and people living in rural or otherwise underserved areas. While 20 percent of the population lives in rural areas, less than 10 percent of physicians practice in rural areas. As a result, many individuals across the U.S. already have limited options to receive medical care, including preventive services such as family planning or vaccinations. If the only provider in an area does not administer vaccines because it is against his or her personal religious beliefs, for example, entire communities could be left vulnerable to devastating infectious diseases. Similarly, all women in a given community could find themselves without access to contraception or other reproductive health care if the only provider in the area asserts moral or religious objections.

Finally, the broadening of these definitions may create confusion or be interpreted in a way that facilitates discrimination against women, low-income individuals, LGBT people, or people of color, under the guise of a conscience objection. These groups already face barriers to care and experience health inequities. The proposed rule could further decrease their access to necessary health care and worsen health outcomes and disparities. This clearly runs counter to the mission of HHS "to enhance and protect the health and well-being of all Americans," and it neglects the responsibility of our public health system to ensure access to quality health services.

The proposed rule conflicts with existing requirements in HHS programs.

Definitions in the proposed rule allow for refusals that conflict with the requirements of some existing HHS programs. These programs have a documented history of providing quality preventive health care services, improving health outcomes, and saving costs. This proposed rule will jeopardize the integrity and continued success of these programs, funding for them, and the delivery of the quality services they provide.

- The Vaccines for Children program requires participating healthcare providers to offer all routinely recommended vaccines to eligible at-risk children (42 USC 1396s(c)(2)(B)(i)). Under this proposed rule change, a person or entity may object to administering a vaccine. States and health care providers may struggle to comply with federal requirements for at-risk children to access and receive the recommended standard-of-care vaccines, because of an expanded number and basis for conscience objections.

- The Title X family planning projects are designed to "consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children" (42 CFR 59.1). The Title X statute specifically requires that "all pregnancy counseling shall be nondirective" (Public Law 112-74, p. 1066-1067), and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination (42 CFR 59.5(a)(5)).

The proposed rule protects individuals and entities who refuse to provide some essential services or provide complete information about all of a woman's pregnancy options. The proposed rule could force the Washington State Department of Health and Title X sub-recipients to choose between violating the Title X requirements or violating the proposed rule.

The Emergency Medical Treatment and Active Labor Act (EMTALA) requires emergency department to provide emergency treatment to *anyone* seeking treatment. The proposed rule could potentially conflict with EMTALA statutory requirements. For example, a hospital or provider could decline service to a woman with possible complications following an abortion. These proposed rules could jeopardize patient lives.

Preserving religious freedom in the U.S. is important, and so is our responsibility as government leaders to ensure access to health care services for all people. Existing laws have sought to preserve balance between conscience objections based on sincerely held religious beliefs and moral convictions, and the needs of patients and the public health. It is imperative to the nation's health and well-being that this rule does the same. Unfortunately, the rule as written fails to strike an appropriate balance, clearly placing the health of patients and the public at risk. I urge you to withdraw it.

Sincerely,

John Wiesman, DrPH, MPH
Secretary of Health

Exhibit 73

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March 26, 2018

Roger Severino
Director, Office for Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 515F
Washington, DC 20201

Re: HHS—OCR—2018—0002, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority; Proposed Rule (Vol. 83, No. 18) Jan. 26, 2018.

Dear Mr. Severino:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinical partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Department of Health and Human Services (HHS) Office for Civil Rights' (OCR) proposed rule regarding certain statutory conscience protections.

Hospitals and health systems are committed to respecting the conscience objections of hospital employees and medical staff. Conscience protections for health care professionals are long-standing and deeply rooted in our health care delivery system. For decades, the AHA and its members have supported policies to accommodate the differing convictions of our employees and medical staff by making provisions for them to decline to participate in delivering services they say they cannot perform in good conscience. Existing federal and state laws protect health care workers who express religious objections related to performing certain procedures.

At the same time, hospitals and health systems have obligations to their patients and are committed to providing the care they need. Existing laws create protections for patients and impose certain obligations on providers to ensure that patients have access to necessary care. Hospitals and health systems value every individual they have the opportunity to serve, and oppose discrimination against patients based on characteristics such as race, religion, national origin, sexual orientation or gender identity.

The intersection of these equally important obligations can present unique challenges. Neither obligation can or should be addressed in a vacuum. OCR's framework for enforcing the conscience protections at issue should account for this intersection of hospitals' obligation to ensure needed care for patients and the obligation to honor conscience objections of employees.

With this as a backdrop, we make the following recommendations.

THE POLICIES, PRACTICES, AND COURT PRECEDENT GOVERNING ENFORCEMENT OF OTHER CIVIL RIGHTS PROTECTIONS SHOULD BE THE MODEL FOR ENFORCEMENT OF THE CONSCIENCE PROTECTIONS AT ISSUE.

OCR observes that the conscience protections at issue are civil rights to be enforced no less than other civil rights protections. The AHA agrees that the conscience protections are among the civil rights of hospital employees and medical staff. They should, therefore, be duly protected.

In keeping with the principle that the conscience protections should be treated akin to other civil rights, the AHA urges OCR to ensure that the enforcement policies and practices applicable to the conscience protections are comparable to the long-standing policies and practices applicable when guaranteeing other civil rights protections for employees and staff. OCR should not invent new, distinct, or additional policies and practices that add unnecessary complexity and burden or prefer conscience protections over other civil rights. Rather, OCR should use existing civil rights frameworks as the model for the conscience protections at issue. This not only would place the conscience protections on a level playing field with other civil rights, but would ensure that the conscience protections are guaranteed through an enforcement framework that already has proven effective in analogous civil rights contexts.

To this end, **OCR should explicitly adopt a reasonable accommodation framework that provides the flexibility for HHS to take into account particular facts and circumstances to determine that a hospital has done all it reasonably could under the circumstances to accommodate conscience objections of employees or medical staff** (*Bruff v. North Miss. Health Servs.*, 244 F.3d 495 (5th Cir. 2001)).

Employment discrimination on the basis of religion is prohibited and employers are required to reasonably accommodate the sincerely held religious beliefs of employees, absent a showing of undue hardship on the employer (*See* 29 C.F.R. § 1605.2). This has been true for over a half century, and this framework has successfully protected employees, including those of hospitals and health systems, from religious discrimination. Analogous reasonable accommodation frameworks also have been successfully employed in other civil rights contexts, such as the Rehabilitation Act of 1973.

This framework has proven successful in the hospital context, in part, because it allows for an assessment of the reasonableness of a requested accommodation in context. The requirement of reasonably accommodating the sincerely held religious beliefs of employees and medical staff, absent a showing of undue hardship, guarantees robust protections for the religious beliefs of hospital employees and medical staff.

Consistent with this framework, a hospital should be responsible for providing *reasonable* conscience-based accommodations and an employee is responsible for providing fair notice of a specific and sincerely held religious or moral objection. A hospital should not be sanctioned for failing to accommodate the moral or religious beliefs of an employee or medical staff where, despite being on notice of his or her right to do so, the individual did not give the hospital advance notice of his or her objection (*Wessling v. Kroger Co.*, 554 F. Supp. 548 (E.D. Mich. 1982) (no Title VII violation when the employee did not give the employer notice of a desire for a religious accommodation)).

Adoption of this framework in the conscience rule would assure hospitals that they may continue with a time-tested way of honoring their responsibilities to ensure access to necessary care for all patients, while effectively protecting the religious and other conscience rights of employees and medical staff. It also would avoid the unnecessary and duplicative administrative burdens for hospitals that imposing an additional and different framework would create.

Hospitals have existing policies, procedures, and best practices. They also have decades of experience with how to meet their responsibility to provide reasonable accommodations. Adopting a parallel framework for the conscience protections would enable hospitals to seamlessly incorporate the conscience rights of employees and medical staff into the existing compliance frameworks. The religious and moral beliefs of hospital employees and medical staff would be protected, while reducing the complexity and burden for hospitals. **OCR should expressly affirm these guiding principles.**

DUE PROCESS PROTECTIONS SHOULD BE EXPLICITLY INCLUDED IN THE REGULATIONS.

The proposed regulations are silent on procedural protections for a recipient of funding before the Department may take an adverse action. OCR should affirmatively recognize the due process rights of recipients of federal funds. The regulations should reinforce those rights with a clear acknowledgement of the procedural protections applicable to any action by the Department that would adversely affect a recipient's continued receipt of, or future eligibility for, federal funding. For example, the Social Security Act controls whether participation in, or receipt of funding from, the Medicare program may be limited or terminated; the Medicare law and regulations control the procedural protections for providers.

As discussed above, there are existing and proven civil rights policies and practices that should apply equally here. In particular, the conscience regulations should expressly adopt the longstanding due process protections for Title VI enforcement. The same protections should apply for challenges to any finding of noncompliance with the conscience protections that OCR may make or any penalty or other adverse action for noncompliance with the conscience protections that OCR may seek to impose.

Additionally, the regulations should be explicit about the grounds for imposing any contemplated sanction and the procedural protections. The proposed regulation lists numerous potential adverse actions available to OCR or the Department without delineating the specific circumstances that must occur before taking any such action. The implication is that they are

available at OCR's or the Department's discretion, without reference to any reasonable standards. The regulation should expressly identify which sanction is applicable under which circumstances. It also should identify the related procedural protections, including notice and hearing rights. This would further the government's interests in not only ensuring fundamental fairness but also avoiding inappropriate disruption of health services that are federally funded.

REGULATORY BURDEN SHOULD BE EASED WHEREVER POSSIBLE.

The proposed requirement that a recipient report reviews, investigations, and complaints to any component of the Department from which it receives funding is burdensome and unnecessary. So, too, is the proposed requirement that a recipient seeking new or renewed funding report reviews, investigations, and complaints from the prior five years. No such requirements apply in other civil rights contexts. Because OCR will know of all such reviews, investigations, and complaints, OCR should instead be the source of this information within the Department. OCR will be the central repository of all such data and can make it readily available to other Departmental components, greatly reducing unnecessary burden on regulated parties.

Additionally, the sweep of these proposed disclosures is problematic. There is no distinction in the proposed treatment of, for example, general compliance reviews (unprompted by any particular concern), rejections of frivolous complaints, findings of compliance, or cases where a sanction is ultimately overturned. With new, renewed, or continuing funding at stake, the proposed reporting requirement risks inappropriately suggesting to the decision-maker that there is a cause for concern when there is in fact none, improperly biasing the decision-making against the recipient. The regulation should not effectively create a presumption of noncompliance. **The proposed reporting requirement should not be finalized.**

We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Maureen Mudron, AHA deputy general counsel, at (202) 626-2301 or mmudron@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President

Exhibit 74

March 26, 2018

Submitted via www.regulations.gov
Docket ID # HHS-OCR-2018-002

Roger Severino
Director
Office of Civil Rights, Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW., Room 509F
Washington, DC 20201

Attention: Conscience NPRM, RIN 0945-ZA03

Re: **Protecting Statutory Conscience Rights in Health Care; Delegations of Authority**

Dear Director Severino:

On behalf of *In Our Own Voice: National Black Women's Reproductive Justice Agenda*, we welcome the opportunity to comment on the Department of Health and Human Services' (the "Department") proposed rule ("Proposed Rule") which seeks to permit discrimination in all aspects of health care.[1] *In Our Own Voice: National Black Women's Reproductive Justice Agenda* believes a health care provider's personal beliefs should never determine the care a patient receives, which leads us to strongly oppose the Department's Proposed Rule.

The Proposed Rule seeks to unlawfully expand refusals to provide care by attempting to allow individuals and health care entities that receive federal funding to refuse to provide *any* part of a health service or program. In addition, the Proposed Rule unlawfully attempts to create new refusals seemingly out of thin air. Such expansions exceed the Department's authority; violate the Constitution; undermine the ability of states to protect their citizens; undermine critical HHS programs like Title X; interfere with the provider-patient relationship; and threaten the health and well-being of people across the country and around the world. Plainly said, this Proposed Rule attempts to curtail women's autonomy and access to contraception.

By issuing the Proposed Rule and creating a new division within the Office of Civil Rights ("OCR") – the new "Conscience and Religious Freedom Division" – the Department seeks to inappropriately use OCR's limited resources in order to affirmatively allow institutions,

[1] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (proposed

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insurance companies, and almost anyone involved in patient care to use their personal beliefs to deny people the care they need. For these reasons, *In Our Own Voice: National Black Women's Reproductive Justice Agenda* calls on the Department and OCR to withdraw the Proposed Rule in its entirety.

In Our Own Voice: National Black Women's Reproductive Justice Agenda

In Our Own Voice: National Black Women's Reproductive Justice Agenda is a national Reproductive Justice organization focused on increasing the visibility of Black women at the national and regional levels in our ongoing policy fight to secure Reproductive Justice for all women and girls. *In Our Own Voice* is a national-state partnership with eight Black women's reproductive justice organizations: the Afiya Center in Texas, Black Women for Wellness in California, Black Women's Health Imperative, a national organization, New Voices for Reproductive Justice in Pennsylvania and Ohio, SisterLove, Inc., in Georgia, Sister Reach in Tennessee, SPARK Reproductive Justice NOW in Georgia and Women with a Vision in Louisiana.

In Our Own Voice provides an opportunity to have Black women and girls speak for ourselves and present a proactive strategy to advance reproductive health, rights and justice, including the right to safe and legal abortions, contraceptive equity and comprehensive sex education. Reproductive Justice will be attained when all people have the economic, social, and political power and means to make decisions about their bodies, sexuality, health, and family, with dignity and self-determination. Our health, safety and wellbeing are intrinsically linked. The Proposed Rule seeks to strip black women of the power to access quality health services and programs by allowing individuals or institutions to deny someone contraceptive access by stating that those services violate their religious beliefs.

The Proposed Rule Unlawfully Exceeds the Department's Authority by Impermissibly Expanding Religious Refusals to Provide Care

The Proposed Rule attempts to expand the reach not only of existing harmful refusal of care laws but also to create new refusals of care where none were intended.

a. *The Proposed Rule Seeks to Allow the Refusal of any Health Service Based on Personal Belief*

The Proposed Rule will exacerbate health inequities by expanding the ability to refuse critical services, including abortion and transition-related care. Specifically, the Department and OCR are attempting to require a broad swath of entities to allow individuals to refuse "*any* lawful health service or activity based on religious beliefs or moral convictions (emphasis added)."[2] Read in conjunction with the rest of the Proposed Rule, it is clear this is intended to allow any entity involved in a patient's care—from a hospital board of directors to the receptionist that

[2] *See id.* at 12.

schedules procedures—to use their personal beliefs to determine a patient's access to care. What we at *In Our Own Voice* know to be tried and true is that only women should be making decisions about their health care. Reproductive justice will be attained when all people have the economic, social and political power and means to make fully informed decisions about their bodies, sexuality, health and families.

b. The Proposed Rule Unlawfully Expands Already Harmful Abortion/Sterilization Refusal of Care Laws

Already existing refusal of care laws are used across the country to deny patients the care they need.[3] The Proposed Rule attempts to expand these laws in numerous ways that are directly contrary to the stated purpose of the existing laws. For example, one provision of the Church Amendments allows individuals who work for or with entities receiving grants or contracts for biomedical or behavioral research entities to refuse to participate in "any lawful health services or research activity" based on religious beliefs or moral convictions specifically related to the service or research activity to which they object.[4] But the Proposed Rule attempts to broaden this provision to allow individuals to refuse to perform aspects of their jobs based on a mere reference to a religious or moral belief regardless of whether it relates to the specific biomedical or behavioral service or research activity they are working on.[5] Such an attempted expansion goes beyond what the statute enacted by Congress allows. Furthermore, the Proposed Rule would expansively apply other provisions of the Church Amendments to, among other things, individuals working under global health programs funded by the Department thereby allowing global health providers and entities to refuse individuals the care they need contrary to the very purpose of such programs.

Similarly, the Proposed Rule defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. For example, the definition of "assist in the performance" greatly expands the types of services that can be refused to include merely "making arrangements for the procedure" no matter how tangential.[6] This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees, can now assert a new right to refuse. The Proposed Rule's definition of "referral" similarly goes beyond any

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[3] *See, e.g.*, *Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Catherine Weiss, et al., *Religious Refusals and Reproductive* Rights, AM. CIVIL LIBERTIES UNION (2002), https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report; Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf; Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[4] The Church Amendments, 42 U.S.C. § 300a-7 (2018).

[5] *See* Rule *supra* note 1, at 185.

[6] *Id.* at 180.

understanding of the term, allowing refusals to provide any information, including location or funding, that could help an individual to get the care they need.[7]

Furthermore, the Proposed Rule's new and unwarranted expanded definitions often exceed, or are not in accordance with, existing definitions contained within the statutes the Proposed Rule seeks to enforce. Specifically, under the Coats and Weldon Amendments "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in the delivery of health care.[8] The Proposed Rule attempts to combine separate definitions of "health care entity" found in different statutes and applicable in different circumstances into one broad term.[9] Such an attempt to expand the meaning of a statutory term Congress already took the time to define not only fosters confusion, but goes directly against congressional intent. By expressly defining the term "health care entity" Congress implicitly rejected the inclusion of the other terms the Department now attempts to insert.[10]

When these impermissibly broad definitions are combined with the expansive interpretations of the underlying statutes, they work together to further expand refusals of care to allow more individuals and entities to refuse to provide access to health care. For example, one way the Weldon Amendment is expanded under the Proposed Rule is through the definition of "discrimination."[11] In particular, the Proposed Rule defines "discrimination" against a health care entity broadly to include a number of activities, including denying a grant or employment as well as an unspecified catch-all phrase "any activity reasonably regarded as discrimination."[12] In a Proposed Rule that seeks to protect those who want to discriminate, this broad definition is nonsensical and inappropriate. Further such a vague and inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements, thereby fostering confusion.

The Proposed Rule Carries Severe Consequences for Patients and will Exacerbate Already Existing Inequities

a. Refusals of Care Make it Difficult for Many Individuals to Access the Care They Need

Across the country refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need.[13] Fundamental human rights are violated when patients must endure preventable suffering, including death, health complications, mistreatment, discrimination, and denials of information and bodily autonomy. Religiously affiliated hospitals

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[7] *Id.* at 183.
[8] The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018).
[9] *See* Rule *supra* note 1, at 182.
[10] The doctrine of expression unius est exclusion alterius (the expression of one thing implies the exclusion of others) as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.
[11] *See* Rule *supra* note 1, at 180.
[12] *Id.*
[13] *See, e.g.*, *supra* note 3.

are often the only local health care provider, particularly in rural states, and are likely to be the provider of last resort for uninsured women. This is particularly important for Black women, who are more likely not to have health insurance. One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care.[14] Another woman experiencing pregnancy loss was denied care for ten days at a religiously affiliated hospital outside Chicago, Illinois.[15] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[16] Another patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic hospital provider refused to give her the procedure.[17] Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options.[18]

All patients should be fully informed and understand their health care options, regardless of the religious beliefs of providers. HHS must work to ensure that policies reflect the health needs and decisions of the patient.

b. Refusals of Care are Especially Dangerous for Those Already Facing Barriers to Care

Black women already receive disparate care and face increased barriers when accessing care compared to white women, often due to systemic racism and sexism. Historically, Black women and other women of color have been the targets of coercive health practices and policies, unethical testing, and misinformation.[19] Refusals of care based on personal beliefs are an added burden for many individuals to access health care and have real consequences for those denied the care they need because of a provider or hospital's religious beliefs. When women and

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[14] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[15] *See* Julia Kaye, et al., *Health Care* Denied, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

[16] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 29 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[17] *See The Patient Should Come First: Refusals to Provide Reproductive Health Care*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/05/Refusals-FS.pdf; Sandhya Somashekhar, *A Pregnant Woman Wanted her Tubes Tied. Her Catholic Hospital Said No.*, WASH. POST (Sept. 13, 2015), https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2_story.html?utm_term=.8c022b364b75.

[18] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 27 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[19] Dorethy Roberts, *Killing the Black Body: Race, Reproduction, and the Mean of Liberty*, NEW YORK: VINTAGE PRESS (2017).

families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another location, refusals bar access to necessary care.[20] This is especially true for immigrant patients who often lack access to transportation and may have to travel great distances to get the care they need.[21] In rural areas there may be no other sources of health and life preserving medical care.[22] In developing countries where many health systems are weak, health care options and supplies are often unavailable.[23] When these individuals encounter refusals of care, they may have nowhere else to go.

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that women of color in many states disproportionately receive their care at Catholic hospitals. In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals.[24] These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provides guidance on a wide range of hospital matters, including reproductive health care and can keep providers from offering the standard of care.[25] Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women were delayed care or transferred to other facilities at great risk to their health.[26] The reach of this type of religious refusal of care is growing with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.[27]

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[20] In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. *Women's Health Insurance* Coverage, KAISER FAMILY FOUND. 1, 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage.

[21] Athena Tapales et al., *The Sexual and Reproductive Health of Foreign-Born Women in the United States*, CONTRACEPTION 8, 16 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf; Nat'l Latina Inst. For Reproductive Health & Ctr. For Reproductive Rights, *Nuestra Voz, Nuestra Salud, Nuestro Texas: the Fight for Women's Reproductive Health in the Rio Grande Valley* 1, 7 (2013), http://www.nuestrotexas.org/pdf/NT-spread.pdf.

[22] Since 2010, eighty-three rural hospitals have closed. *See Rural Hospital Closures: January 2010 – Present*, THE CECIL G. SHEPS CTR FOR HEALTH SERVS. RES. (2018), http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

[23] *See* Nurith Aizenman, *Health Care Costs Push a Staggering Number of People into Extreme Poverty*, NPR (Dec. 14, 2017), https://www.npr.org/sections/goatsandsoda/2017/12/14/569893722/health-care-costs-push-a-staggering-number-of-people-into-extreme-poverty; *Tracking Universal Health Coverage: 2017 Global Monitoring Report*, WORLD HEALTH ORG. & THE WORLD BANK (2017), http://documents.worldbank.org/curated/en/640121513095868125/pdf/122029-WP-REVISED-PUBLIC.pdf.

[24] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 12 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[25] *See id.* at 10-13.

[26] Lori R. Freedman, *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.

[27] *See, e.g.*, *Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.

In addition, in many of the countries where the Department implements global AIDS programs, many of the patients served already face numerous barriers to care, including a broad and harmful refusal provision contained within the statute governing such programs.[28]

c. *In Proposing this Rule, the Agency has Abandoned its Legal Obligations to Adequately Account for Harm to Patients*

By expanding refusals of care the Proposed Rule will exacerbate the barriers to health care services patients need. It is evident that the harm caused by this Proposed Rule will fall hardest on those most in need of care by allowing individuals and health care entities to use their personal beliefs to dictate patient care. The Department should remember, under Executive Order 13563, an agency may only propose regulations where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on society."[29] The Proposed Rule plainly fails on both counts. Although the Proposed Rule attempts to quantify the costs of compliance, it completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs.[30]

Moreover, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant religious exemptions and, in fact, bars granting an exemption when it would detrimentally affect any third party.[31] Because the Proposed Rule would cause substantial harm, including to patients, it would violate the Establishment Clause.[32]

The Proposed Rule Will Undermine Critical Federal Health Programs, including Title X

The Proposed Rule would seemingly allow health care entities to receive grants and contracts under HHS-funded programs or other federal health programs, such as Title X, the only domestic

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[28] *See The Mexico City Policy: An Explainer*, KAISER FAMILY FOUND. (June 1, 2017), https://www.kff.org/global-health-policy/fact-sheet/mexico-city-policy-explainer/.

[29] Improving Regulation and Regulatory Review, Executive Order 13563 (Jan. 18, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review.

[30] *See* Rule *supra* note 1, at 94-177.

[31] U.S. Const. amend. I; *Cutter v. Wilkinson*. 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment Clause, courts "must take adequate account of the burdens a requested accommodation may impose on non-beneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985)); *see also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).

[32] Respecting religious exercise may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *See Burwell v. Hobby Lobby*, 134 S. Ct. at 2787. When considering whether the birth control coverage requirement was the least restrictive means in Hobby Lobby, the Court considered that the accommodation offered by the government ensured that affected employees "have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing coverage." *See id.* at 2759. In other words, the effect of the accommodation on women would be "precisely zero." *Id.* at 2760.

family planning program, while refusing to provide key services required by those programs.[33] For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[34] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[35] Under the Proposed Rule, the Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such funds are generally conditioned.[36] The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the sub-recipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.[37] When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objectives. Every year millions of low-income, including under-insured, and uninsured individuals, 21% of whom are black women,[38] rely on Title X clinics to access services they otherwise might not be able to afford.[39]

The Proposed Rule Will Carry Severe Consequences for Providers and Undermine the Provider-Patient Relationship

Existing refusals of care based on personal beliefs already undermine open communication between providers and patients, interfere with providers' ability to provide care according to medical standards, and ignore the reality that many providers want to provide comprehensive care. Hospital systems across the country use religious beliefs to prevent their employees from treating patients regardless of the professional, ethical, or moral convictions of these providers.[40] The Proposed Rule would exacerbate these problems by emboldening health care entities and institutions, including foreign and international organizations, to bind the hands of providers and attempt to limit the types of care they can provide.

The Proposed Rule threatens informed consent, a necessary principle of patient-centered decision-making intended to help balance the power dynamics between health providers and

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[33] *See* Rule *supra* note 1, at 180-181, 183. *See also Title X Family Planning*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (2018), https://www.hhs.gov/opa/title-x-family-planning/index.html; *Title X an Introduction to the Nation's Family Planning Program*, NAT'L FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOC. (2017) (*hereinafter* NFPRHA), https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf.
[34] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).
[35] *See* What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).
[36] *See, e.g.*, Rule *supra* note 1, at 180-185.
[37] *See* NFPRHA *supra* note 34.
[38] *See* Title X: America's Family Planning Program, https://www.plannedparenthoodaction.org/issues/health-care-equity/title-x.
[39] *See id.*
[40] *See* Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

patients and ensure patient-centered decision-making.[41] Informed consent requires providers disclose relevant and medically accurate information about treatment choices and alternatives so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.[42] By allowing providers, including hospital and health care institutions, to refuse to provide patients with information, the Proposed Rule makes it impossible for patients to have full information regarding treatment options. While the Department claims the Proposed Rule improves communication between patients and providers, in truth it will deter open, honest conversations that are vital to ensuring that a patient can control their medical circumstances.[43]

The Proposed Rule also disregards standards of care established by the medical community by allowing providers to opt out of providing medical care. Medical practice guidelines and standards of care establish the boundaries of medical services that patients can expect to receive and that providers should be expected to deliver. Yet, the Proposed Rule seeks to allow providers and institutions to ignore the standards of care, particularly surrounding reproductive and sexual health. Information, counseling, referral and provision of contraceptive and abortion services are part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer.[44] Individuals seeking reproductive health care, regardless of their reasons for needing these services, should be treated with dignity and respect. Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care to patients harms them and impairs their ability to make the health care decision that is right for them.

In addition, the Proposed Rule ignores the many providers with deeply held moral convictions that affirmatively motivate them to provide patients with health care, including abortion, transition-related care, and end-of-life care. Moreover, the Proposed Rule fails to acknowledge the Church Amendments' protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[45] No health care professional should face discrimination from their employer because they treated or provided information to a patient seeking an abortion.

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[41] *See* TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); CHARLES LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).

[42] *See id.*

[43] *See* Rule *supra* note 1, at 150-151.

[44] For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care. Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant. AM. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE § 114-15, S117 (2017), available at http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf. The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival. AM. ACAD. OF PEDIATRICS & AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).

[45] *See* The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).

The Department is Abdicating its Responsibility to Patients

The Proposed Rule exceeds OCR's authority by abandoning OCR's mission to address health disparities and discrimination that harms patients.[46] Instead, the Proposed Rule appropriates language from civil rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the Proposed Rule creates a regulatory scheme that is not only nonsensical but is affirmatively harmful. For example, the notice and certification of compliance and assurance requirements simply do not make sense when applied to the laws the Proposed Rule seeks to enforce.[47] They will place a significant and burdensome requirement on health care providers and impose unique challenges for those working in other countries by taking resources away from patient care without adding any benefit.

The Department, including OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities.[48] If finalized, however, the Proposed Rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care, and eliminate health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.[49] These were immense steps in ensure equitable access to health care, particularly for black women.

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[46] *OCR's Mission and Vision*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html ("The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

[47] *See* Rule *supra* note 1, at 203-214.

[48] As one of its first official acts in 1967, the Office of Equal Health Opportunity undertook the massive effort of inspecting 3,000 hospitals to ensure they were complying with Title VI's prohibition against discrimination on the basis of race, color, or national origin. 42. U.S.C. § 2000d (1964). After this auspicious start, the Office of Equal Health Opportunity which would eventually become OCR would go on to ensure that health programs and activities it regulated complied with key anti-discrimination laws including Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (1973), Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 (1972), the Age Discrimination Act of 1976, 42 U.S.C. § 6101 (1976), and Section 1557 of the Affordable Care Act, 42 U.S.C. §18116 (2010), among others. Through robust enforcement of these laws, OCR has worked to reduce discrimination in health care.

[49] *See, e.g., Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html; *Protecting the Civil Rights and Health Information Privacy Rights of People Living with HIV/AIDS*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html; *National Origin Discrimination*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/index.html; *Health Disparities*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

Black women already face significant barriers to accessing reproductive health care. Black women have been systematically denied resources, services and information needed to make important personal decisions about their health. Black women are more likely to lack access to comprehensive sex education and contraception. And as a consequence, they experience higher rates of unintended pregnancy than women of any other ethnic or racial group. Black women are also more likely to experience pregnancy-related complications, or become gravely ill or die in childbirth. The Proposed Rule will exacerbate disparities as medical providers are allowed to withhold important information and health services from patients.

In addition to medical and public health practitioner bias, politics and bias continue to infringe upon the reproductive health rights of women, with constant and persistent threats to defund or limit federal allocations for family planning services, including contraceptives. The Proposed Rule would further divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color.[50] And these disparities do not occur in isolation. Black women, for example, are three to four times more likely than white women to die during or after childbirth.[51] Further, the disparity in maternal mortality is growing rather than decreasing,[52] which in part may be due to the reality that women have long been the subject of discrimination in health care and the resulting health disparities. For example, women's pain is routinely undertreated and often dismissed.[53] And due to gender biases and disparities in research, doctors often offer women less aggressive treatment, or even no treatment, for conditions such as heart disease.[54]

Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[55] Barriers from homophobia and transphobia impede access to care, particularly in

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[50] *See* Skinner et al., *Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans*, NAT'L INSTIT. OF HEALTH 1 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf.

[51] *See* Nina Martin, *Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why*, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why.

[52] *See id.*

[53] *See, e.g.*, Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29:1 J. OF L., MED., & ETHICS 13, 13-27 (2001).

[54] *See, e.g.*, Judith H. Lichtman et al., *Symptom Recognition and Healthcare Experiences of Young Women with Acute Myocardial Infarction*, 10 J. of the Am. Heart Ass'n 1 (2015).

[55] *See, e.g.*, *When Health Care Isn't Caring*, LAMBDA LEGAL 5 (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring_1.pdf. A survey examining discrimination against LGBTQ people in health care more than half of respondents reported that they have experienced at least one of the following types of discrimination in care: being refused needed care; health care professionals refusing to touch them or using excessive precautions; health care professionals using harsh or abusive language; being blamed for their health care status; or health care professionals being physically rough or abusive.

rural communities with shortages of health care providers and facilities.[56] Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a doctor or other health care provider had refused to see them because of their actual or perceived sexual orientation or gender identity in the year before the survey.[57]

OCR must work to address these disparities, yet the Proposed Rule seeks to prioritize the expansion of existing religious refusal laws beyond their statutory requirements and create new religious exemptions where none had previously existed rather than using already limited resources to protect patient access to health care. The Proposed Rule will harm patient care and is antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality.[58]

The Proposed Rule Conflicts with Other Existing Federal Law

The Proposed Rule generates chaos through its failure to account for existing laws that conflict with the refusals to care it would create.

For example, the Proposed Rule makes no mention of Title VII,[59] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[60] With respect to religion, Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.[61] For decades, Title VII has established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal obligations. The Proposed Rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[62]

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[56] Barry D, Esenstad A, Ensuring Access to Family Planning for All, Washington, DC: Center for American Progress, 2014. Online: https://www.americanprogress.org/ issues/women/reports/2014/10/23/99612/ ensuring-access-to-family-planning-services-for-all/

[57] *See* Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NAT'L GAY AND LESBIAN TASK FORCE & NAT'L CTR. FOR TRANSGENDER EQUALITY, http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.

[58] *See supra* note 46.

[59] 42 U.S.C. § 2000e-2 (1964).

[60] *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.

[61] *See id.*

[62] Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), *available at* https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html.

Furthermore, the language in the Proposed Rule would seem to put health care entities in the position of being forced to hire people who intend to refuse to perform essential elements of a position even though Title VII would not require such an "accommodation." For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the applicant refuses to provide non-directive options counseling even though the employer would not be required to do so under Title VII.[63] It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

In addition, the Proposed Rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. For example, in 2016, a 31-year-old woman was sent home from the emergency room although she was experiencing an ectopic pregnancy that would later burst and she was pressured into having a cesarean section. She was denied access to life-saving information about all available health options.[64] The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility.[65] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[66] Because the Proposed Rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

The Proposed Rule Will Make It Harder for States to Protect their Residents

The Proposed Rule will have a chilling effect on the enforcement of and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. The HHS regulations explicitly target laws in specific states that require many health insurance plants to cover abortion care. The preamble of the Proposed Rule discusses at length state laws that the Department finds objectionable, such as state laws that require anti-abortion counseling centers to provide information about where reproductive health care services can be

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[63] *See* Rule *supra* note 1, at 180-181.

[64] *See* In Our Own Voice: National Black Women's Reproductive Justice Agenda, *Our Bodies, Our Lives, Our Voices: The State of Black Women & Reproductive Justice* (pp. 32-33, Rep.).

[65] 42 U.S.C. § 1295dd(a)-(c) (2003).

[66] In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. *See, e.g.*, *Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220, 228 (3rd Cir. 2000); In In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); *Nonsen v. Medical Staffing Network, Inc.* 2006 WL 1529664 (W.D. Wis.); *Grant v. Fairview Hosp.*, 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); *Barris v. County of Los Angeles*, 972 P.2d 966, 972 (Cal. 1999).

obtained or whether facilities have licensed medical staff, as well as state laws that require health insurance plans to cover abortion.[67] Moreover, the Proposed Rule invites states to further expand refusals of care by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.[68]

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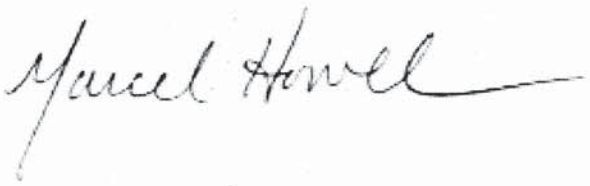
The Proposed Rule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The Proposed Rule is discriminatory, violates multiple federal statutes and the Constitution, ignores congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons *In Our Own Voice: National Black Women's Reproductive Justice Agenda* calls on the Department to withdraw the Proposed Rule in its entirety.

If you require additional information about the issues raised in this letter, please contact Jessica Pinckney, Deputy Director of Government Affairs at jessica@blackrj.org.

Sincerely,



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[67] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.
[68] *See id.*