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

STATE OF NEW YORK, et al. Plaintiffs,	No. 1:19-cv-04676-PAE (rel. 1:19-cv-05433-PAE; 1:19-cv- 05435-PAE)
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.	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.,	No. 1:19-cv-05433-PAE (rel. 1:19-cv-0476-PAE; 1:19-cv-05435- PAE)
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.	

NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION; and PUBLIC HEALTH SOLUTIONS,) No. 1:19-cv-05435-PAE) (rel. 1:19-cv-0476-PAE; 1:19-cv-05433-) PAE)
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.)

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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. 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

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 1397i-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 broadranging, 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." *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 preexisting 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). 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

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.merriamwebster.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 "gardenvariety" 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).

I. 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 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.

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.

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)). 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, 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. 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

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." 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

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]Ithough [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. 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). 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.

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.

Any Relief Should Not Affect Ongoing Investigations Based on the 2011 Rule C.

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.

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Respectfully submitted,

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