

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

PLANNED PARENTHOOD FEDERATION
OF AMERICA, INC.; and PLANNED
PARENTHOOD OF NORTHERN NEW
ENGLAND, INC.,

Plaintiffs,

v.

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

Defendants.

Civil Action No. 1:19-cv-5433 (PAE)
(rel. 1:19-cv-4676; 1:19-cv-5435)

**JOINT MEMORANDUM OF LAW IN
SUPPORT OF PLAINTIFFS' MOTION
FOR PRELIMINARY INJUNCTION**

NATIONAL FAMILY PLANNING AND
REPRODUCTIVE HEALTH
ASSOCIATION; and PUBLIC HEALTH
SOLUTIONS,

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity as
Secretary of the U.S. Department of Health
and Human Services; U.S. DEPARTMENT
OF HEALTH AND HUMAN SERVICES;
ROGER SEVERINO, in his official capacity
as Director of the Office for Civil Rights of
the U.S. Department of Health and Human
Services; OFFICE FOR CIVIL RIGHTS of
the U.S. Department of Health and Human
Services,

Defendants.

Civil Action No. 1:19-cv-5435 (PAE)
(rel. 1:19-cv-4676; 1:19-cv-5433)

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INTRODUCTION

Plaintiff Planned Parenthood Federation of America (“PPFA”) is the leading provider of family planning services to low-income and under- and un-insured people in the country, and Plaintiff Planned Parenthood Northern New England (“PPNNE”) is a member-affiliate of PPFA. Plaintiff National Family Planning and Reproductive Health Association (“NFPRHA”) is a national, non-profit membership association and the leading national advocacy organization for the Title X family planning program, of which Plaintiff Public Health Solutions (“PHS”) and Plaintiff PPNNE are members. Together, Plaintiffs—directly or through their members¹—provide vital reproductive health services and information to millions of people in all 50 states and Washington, D.C. Because the regulation challenged here threatens imminent irreparable harm to Plaintiffs, Plaintiffs respectfully request that this Court preliminarily enjoin its implementation and enforcement by Defendants.

The challenged Rule purports to create broad new rights for health care providers (institutions and individuals) to withhold from and obstruct patient access to a variety of health care services and information, potentially even in emergency situations, due to providers’ moral or religious beliefs. *See* Protecting Statutory Conscience Rights in Health Care, 84 Fed. Reg. 23,263 (May 21, 2019) (to be codified at 45 C.F.R. pt. 88) (the “Refusal of Care Rule” or the “Rule”). Because Plaintiffs receive certain federal funding, they must comply with the Rule’s onerous requirements. For example, the Rule would require Plaintiffs to hire and provide absolute accommodation to individuals who refuse to provide care to their patients, giving these individuals *carte blanche* to refuse to do the jobs they were hired to do and to put personal beliefs over the

¹ Unless otherwise specified, this brief refers to Plaintiff PPFA’s member-affiliates, Plaintiff NFPRHA’s members, and Plaintiffs PPNNE and PHS collectively as “Plaintiffs.”

health and lives of patients. As such, the Rule leaves Plaintiffs with a Hobson's choice: either attempt to comply with the Rule and jeopardize patient health and safety, or lose millions in federal funding on which Plaintiffs rely to provide necessary health care to their patients.

This sweeping and dangerous Rule drastically exceeds the Department of Health and Human Services' ("HHS's") authority and unlawfully expands existing federal law. Moreover, in finalizing the Rule, HHS failed to follow the appropriate regulatory steps. The legal result is a Rule that is unauthorized, conflicts with federal statutes and the U.S. Constitution, and violates basic tenets of the Administrative Procedure Act. The practical result is that patients, particularly those already facing health disparities and systemic barriers to care, will be unnecessarily and unjustly denied access to vital and life-saving health care services.

STATEMENT OF FACTS

A. Statutory Background

As relevant here, the Rule purports "to provide for the implementation and enforcement," 84 Fed. Reg. at 23,263, of three federal statutes—the Church Amendments, 42 U.S.C. § 300a-7; the Coats-Snowe Amendment, 42 U.S.C. § 238n; and the Weldon Amendment² (collectively, the "federal refusal statutes")—concerning health care providers' rights to refuse care on the basis of their beliefs. The statutes vary in terms of what services can be refused, who can refuse to provide those services, the permitted basis for the refusal, and who must honor the refusal.³

The Church Amendments are 1970s-era laws passed in the wake of *Roe v. Wade*, 410 U.S. 113 (1973). *See, e.g.*, 119 Cong. Rec. 9599–9601 (March 27, 1973) (statement of Sen. Church).

² *E.g.*, Dep'ts of Labor, HHS, and Education, and Related Agencies Appropriations Act, 2019, Div. B, § 507(d), Pub. L. No. 115-245, 132 Stat. 2981, 3118 (2018).

³ The full provisions are set forth in Exhibit A, attached to Decl. of Sarah Mac Dougall ("Mac Dougall Decl.").

Specifically, Church (b) specifies that receipt of certain federal funds alone does not obligate private individuals or entities to provide abortion or sterilization services by turning them into state actors. Church (c)(1) prohibits entities receiving specified federal funding from discriminating, in employment and in the extension of staff privileges, against “any physician or other health care personnel[] because” the provider performed or assisted with, or refused to perform or assist with, abortions or sterilization procedures, or because of the provider’s beliefs respecting such procedures. 42 U.S.C. § 300a-7(c)(1).

Congress passed Church (c)(2) and (d) in 1974 as part of the National Research Act, which addressed ethical research involving humans. *See* 119 Cong. Rec. 29,213–32 (Sept. 11, 1973). Church (c)(2) extends the prohibitions in section (c)(1), described above, to certain federal funds for biomedical or behavioral research. 42 U.S.C. § 300a-7(c)(2). Church (d) states: “[n]o individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by [HHS] 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.” *Id.* § 300a-7(d). Unlike Church (c), Church (d) does not include an anti-discrimination provision. The Church Amendments remain largely unchanged since 1979.

In 1996, Congress adopted the Coats-Snowe Amendment, after the Accrediting Council for Graduate Medical Education (“ACGME”) sought to require OB-GYN residency programs to provide opt-out abortion training. *See* 142 Cong. Rec. 5158 (March 19, 1996) (statement of Sen. Coats). Coats-Snowe prohibits the federal government, and state and local governments that receive federal funding, from discriminating against “any health care entity . . . on the basis that” the entity “refuses to undergo training in the performance of induced abortions, to require or

provide such training, to perform such abortions, or to provide referrals for such training or such abortions,” 42 U.S.C. § 238n(a)(1), or “the entity refuses to make arrangements” for any such activities, *id.* § 238n(a)(2). Coats-Snowe has remained unchanged since 1996.

The Weldon Amendment is an appropriations rider attached in similar form since 2004 to the acts funding the departments of Labor, HHS, and Education. It provides that no funds made available in the appropriations act may accrue “to a Federal agency or program, or to a State or local government,” if the 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.” 132 Stat. at 3118.

B. Relevant Rulemaking History

The federal refusal statutes, which have been in place for decades, have been the subject of limited rulemaking. In 2008, HHS promulgated for the first time a rule that purported to implement and enforce the Church, Coats-Snowe, and Weldon Amendments. *See 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”). However, the 2008 Rule was subject to litigation almost immediately after taking effect,⁴ and, shortly thereafter, HHS proposed to rescind it in its entirety, *see Rescission of the Regulation Entitled “Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law,”* 74 Fed. Reg. 10,207 (Mar. 10, 2009). On March 25, 2011, HHS rescinded the 2008 Rule. *See Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws*, 76 Fed. Reg. 9,968-

⁴ *See, e.g., NFPRHA v. Leavitt*, No. 09-cv-00055 (D. Conn. filed Jan. 15, 2009); *PPFA v. Leavitt*, No. 09-cv-00057 (D. Conn. filed Jan. 15, 2009); *State of Connecticut v. United States*, No. 09-cv-00054 (D. Conn. filed Jan. 15, 2009).

02, 9,973–74 (Feb. 23, 2011) (the “2011 Rule”). In so doing, HHS acknowledged that it had “led to greater confusion” about the scope of the underlying statutes, *id.* at 9,969, and could “negatively affect the ability of patients to access care if interpreted broadly,” *id.* at 9,974. HHS retained a provision designating HHS’s Office for Civil Rights (“OCR”) to receive and handle complaints of alleged violations of the federal refusal statutes, *id.* at 9,976–77, and reiterated that this “clear process” would “continue to protect providers after the rescission,” *id.* at 9,974.

C. The 2019 Refusal of Care Rule

In January 2018, HHS published a Notice of Proposed Rulemaking outlining its intent to create broad rights for a wide array of individuals and institutions to refuse health care services on the basis of “religious, moral, ethical, or other reasons.” Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3,880, 3,923 (proposed Jan. 26, 2018) (the “Proposed Rule”). HHS received comments in opposition to the Rule submitted by numerous states (including New York), Plaintiffs PPFA and NFPRHA on behalf of their members, and major health care organizations and health care provider associations.⁵

President Trump announced the final Rule on May 2, 2019, and it was published in the Federal Register on May 21, 2019. *See* 84 Fed. Reg. at 23,170. As set forth *infra*, the final Rule

⁵ *See, e.g.*, Comment Letter from Am. Med. Ass’n (“AMA Comments”) (Mar. 27, 2018), <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70564>; Comment Letter from Ass’n of Am. Med. Colleges (Mar. 26, 2018), <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-67592>; Comment Letter from National Family Planning & Reproductive Health Association, (Mar. 27, 2018), <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70260>; Comment Letter from Planned Parenthood Fed’n of Am. (“PPFA Comments”) (Mar. 27, 2018), <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71810>; Comment Letter from Am. Coll. of Obstetricians & Gynecologists (Mar. 27, 2018), <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70647>; Comment Letter from Am. Acad. of Pediatrics (Mar. 27, 2018), <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71048>; Comment Letter from Am. Acad. of Physician Assistants (Mar. 26, 2018), <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-65085>.

creates broad exemptions that purport to allow health care providers and other individuals working in a health care setting receiving federal funds—from clinicians to receptionists to ambulance drivers—to deny patients basic health care services and information, including in emergencies. The Rule would allow such individuals to refrain from even informing patients about treatment options that they find objectionable—violating principles of medical ethics and informed consent—and to refrain from referring the patient to a medical professional who has no such objection to providing the patient with needed care.

The Rule abandons the long-standing balancing framework under Title VII of the Civil Rights Act of 1964, which requires accommodations of religious beliefs only when they do not impose undue hardship on the employer’s operations. 42 U.S.C. §§ 2000e-2(a), 2000e(j). Indeed, the Rule expressly provides that it does not incorporate *any* assessment of undue hardship or other burden on employers. 84 Fed. Reg. at 23,190–91. As a result, the Rule appears to require health care employers like Plaintiffs to provide absolute accommodation to individuals who refuse to provide certain information and services to their patients, even when providing such information and services is one of the primary duties of the job and even in emergencies. The Rule also prohibits health care employers from asking prospective employees whether they are willing to perform the essential functions of the job they are seeking, and prohibits asking employees if they object to the performance of any of their job functions more than once per calendar year absent an undefined “persuasive justification.” *Id.* at 23,263. The Department even explicitly declined to state that health care employers subject to the Rule are permitted to reject job candidates who refuse to perform or assist in the performance of a health service that comprises “the primary or substantial majority of the duties of the position.” *Id.* at 23,192. Should a health care employer seek to inform their patients of their right to receive full information about all of their options by

posting a notice to patients informing them that there is a staff member who refuses to provide certain care, the Rule states this could be deemed “discrimination” against the objecting employee. *Id.* at 23,263.

As is also discussed *infra*, HHS further expands its regulatory reach by assigning to itself extraordinarily broad and coercive enforcement power. The Rule allows HHS to terminate, withhold, deny, suspend, or claw back *all* federal funds received by a health care provider subject to the requirements of the Rule, if HHS determines “there is a failure to comply” with the Rule or the federal refusal statutes. *See* 84 Fed. Reg. at 23,271–72 (to be codified at 45 C.F.R. § 88.7(i)).⁶ The Rule does not appear to require any nexus between the funding subject to termination and the alleged violation.

D. Plaintiffs and Their Patients

Plaintiff PPFa is a not-for-profit corporation that strives to ensure access to comprehensive reproductive health care services, advocates for public policies that support access to health care—especially for individuals who are low-income or from underserved communities—and provides educational programs relating to reproductive and sexual health. Decl. of Kimberly Custer in Supp. of Pls.’ Mot. for a Prelim. Inj. (“Custer Decl.”) ¶ 11, attached as Ex. B to Mac Dougall Decl. Medical services are provided by 53 PPFa affiliates, including Plaintiff PPNNE, in 48 states and the District of Columbia. *Id.* ¶ 12. These affiliates operate more than 600 health centers across the nation, providing services to millions of patients from all 50 states and the District of Columbia each year. *Id.* In 2018, Planned Parenthood affiliates provided more than 9.8 million services to approximately 2.4 million patients during approximately 4 million visits. This included more than

⁶ While the Rule states that determinations of noncompliance may “be resolved by informal means,” it expressly authorizes the Department to terminate a recipient’s federal funds even during the pendency of good-faith voluntary compliance efforts. 84 Fed. Reg. at 23,271–72.

4.9 million STI tests and more than 560,000 cancer screenings and preventive services such as breast exams and cervical screens. *Id.* ¶¶ 18–19. Most of Plaintiffs’ patients have low incomes and/or are uninsured; approximately 73% have incomes at or below 150% of the federal poverty level. *Id.* ¶ 26.⁷ PPFA affiliates, including PPNNE, also serve a significant number of rural patients. *Id.*; Decl. of Megan Gallagher in Supp. of Pls.’ Mot. for a Prelim. Inj. (“Gallagher Decl.”) ¶ 13, attached as Ex. C to Mac Dougall Decl. Many of Planned Parenthood’s patients depend upon Planned Parenthood as their sole source of critical medical care, including reproductive health care.

PPFA affiliates, including PPNNE, depend on multiple sources of federal funding to provide health services, particularly for low-income patients. For example, almost all PPFA affiliates participate in Title XIX of the Social Security Act, known as Medicaid, Custer Decl. ¶¶ 28–29, which allows affiliates to provide medical assistance to individuals with low incomes. In 2017, Planned Parenthood affiliates received over \$418 million for services in Medicaid funds, *id.* ¶ 29, and PPNNE in particular receives about \$2.7 million a year in Medicaid and Medicare funds, Gallagher Decl. ¶¶ 11, 24. PPFA affiliates also depend on federal funding through the Title X program, which funds family planning services to low-income people. Custer Decl. ¶ 30. In 2017, PPFA affiliates received over \$67 million in Title X grants and subgrants, *id.* ¶ 31, and PPNNE received \$1.9 million. Gallagher Decl. ¶ 21. PPFA affiliates also receive federal funding from other programs, including the Social Security Block Grant (“SSBG” or “Title XX”) program,

⁷ The federal poverty level (“FPL”) for a single person is \$12,490 and \$25,750 for a family of four in the 48 contiguous states and District of Columbia. HHS, Office of the Secretary, Annual Update of the HHS Poverty Guidelines, 84 Fed. Reg. 1,167–68 (Feb. 1, 2019). Two hundred percent of the FPL for a single person is \$24,980 per year, and \$51,500 for a family of four.

42 U.S.C. § 1397 *et seq.* Custer Decl. ¶ 32. PPNNE stands to lose more than \$6.7 million, or approximately 28% of its revenue, if found out of compliance with the Rule. Gallagher Decl. ¶ 26.

Plaintiff NFPRHA is a national, non-profit membership association and the lead national advocacy organization for the Title X family planning program. Decl. of Clare M. Coleman in Supp. of Pls.’ Mot. for a Prelim. Inj. (“Coleman Decl.”) ¶¶ 9–12, attached as Ex. D to Mac Dougall Decl. NFPRHA’s members include more than 850 health care organizations—including state, county, and local health departments; private non-profit family planning organizations; hospital-based health practices; and federally qualified health centers—in all 50 states, the District of Columbia, and the U.S. territories. *Id.* ¶ 11. NFPRHA member organizations operate or fund a network of more than 3,500 health centers (93% of Title X-funded service sites) that provide family planning services to nearly 3.7 million Title X patients (94% of patients served in Title X-funded sites) each year. *Id.* ¶ 12. The majority of Title X users have income levels at or below the poverty line and are uninsured or underinsured. *Id.* ¶ 13. Additional federal funding sources administered by HHS help finance services provided by many NFPRHA members. *Id.* ¶¶ 15–17. Plaintiffs PPNNE and PHS are NFPRHA members. *Id.* ¶ 11; Decl. of Lisa David in Supp. of Pls.’ Mot. for a Prelim. Inj. (“David Decl.”) ¶ 4, attached as Ex. E to Mac Dougall Decl.

PHS was first established in 1957 and is currently the largest public health nonprofit serving New York City. David Decl. ¶ 3. PHS uses a client-centered approach to address critical public health issues, which is core to its mission. *Id.* ¶ 18. In 2018, PHS served 105,000 individuals and families across New York City through various direct services programs, including its two sexual and reproductive health centers which have been a stable and trusted presence in their communities for over 50 years. *Id.* ¶¶ 3, 18. Approximately 70% of PHS patients are below 100% of the poverty level, 76% are below the 200% of the poverty level, and 26% lack health insurance.

Id. ¶ 23. PHS is also New York City’s largest grantee for the Title X program. *Id.* ¶ 3. PHS receives a \$4.6 million Title X grant, approximately 86% of which (\$3.9 million) is dispersed to its five delegate agencies, as well as PHS’s own two health centers, to provide family planning services to low-income and uninsured New Yorkers. *Id.* ¶ 8. With respect to reproductive health care, in particular, PHS and its sub-recipients provide prenatal and family planning services to over 40,000 at-risk patients annually throughout New York City. *Id.* ¶ 20. In total, PHS receives \$182 million in federal funds—\$138 million of which are from HHS—to provide essential health care services. *Id.* ¶ 14.

Plaintiffs reasonably fear that the Rule will undermine their ability to provide comprehensive reproductive health care services; require Plaintiffs to deviate from their standards of patient care; and increase administrative and personnel costs by requiring Plaintiffs to hire additional employees, accommodate objecting employees, and ensure compliance with the Rule. *See* Chasen Decl ¶¶ 4–5; Coleman Decl. ¶¶ 53–83; Custer Decl. ¶¶ 39–49, 50–53, 62–67; David Decl. ¶¶ 25–49; Gallagher Decl. ¶¶ 30–40, 49–50, 54–59. But if Plaintiffs do not comply, the loss of federal funding could force the discontinuation of essential services, lead to a reduction in hours, and even closure of some health centers, jeopardizing care for thousands of high-risk patients. *See* Coleman Decl. ¶¶ 74–79, 83; Custer Decl. ¶¶ 7, 68; David Decl. ¶¶ 26, 52–54; Gallagher Decl. ¶¶ 40, 60–62. These harms will be disproportionately borne by Plaintiffs’ patients who already face significant barriers to health care—particularly women, people of color, rural patients, LGBTQ individuals, low-income individuals, immigrants, and people living with disabilities. Loss of Plaintiffs’ services could have life-threatening consequences.

ARGUMENT

A preliminary injunction is warranted where, as here, plaintiffs are likely to succeed on their claims, where they will suffer irreparable harm absent injunctive relief, and where the balance

of harms and the public interest weigh strongly in favor of granting the injunction. *See Metro. Taxicab Bd. of Trade v. City of New York*, 615 F.3d 152, 156 (2d Cir. 2010). Plaintiffs “need not show that success is an absolute certainty. They need only make a showing that the probability of their prevailing is better than fifty percent.” *Airbnb, Inc. v. City of New York*, No. 18-cv-7712-PAE, 2019 WL 91990, at *8 (S.D.N.Y. Jan. 3, 2019), *appeal docketed*, No. 19-288 (2d Cir. Jan. 31, 2019).

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS

A. The Rule Exceeds HHS’s Statutory Authority in Violation of the APA.

“It is well settled that an agency may only act within the authority granted to it by statute.” *Nat. Res. Def. Council v. Nat’l Highway Traffic Safety Admin.*, 894 F.3d 95, 108 (2d Cir. 2018) (“*NRDC*”) (citation omitted). Put another way, “an agency literally has no power to act unless and until Congress confers power upon it.” *Id.* at 112 (quotation omitted). The Rule must be “[held] unlawful and set aside,” 5 U.S.C. § 706(2)(C), because in the Church, Coats-Snowe, and Weldon Amendments Congress did not delegate rulemaking authority to HHS or the broad enforcement authority HHS claims for itself in the Rule.

1. Congress Did Not Delegate Authority to HHS to Promulgate this Rule.

In determining whether Congress has delegated rulemaking authority to an agency, the natural “starting point” is the text, because some “statute[s] give[] an agency broad power to enforce all [of its] provisions.” *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006); *see, e.g.*, 42 U.S.C. § 18116(c) (providing that “the Secretary [of HHS] may promulgate regulations to implement” Section 1557 of the Affordable Care Act). Not so here. *None* of the three federal refusal statutes include express language delegating to HHS (or any agency) the broad interpretive and enforcement authority that HHS assumes. Nor are the statutes contained within a statutory scheme that elsewhere delegates across-the-board authority to HHS. *Cf., e.g.*, 42 U.S.C. § 2000d-1

(expressly directing all relevant federal agencies to issue “rules, regulations, or orders of general applicability” to achieve the objectives of Title VI).

Recognizing the lack of an express delegation in the three federal refusal statutes, HHS appeals to its general housekeeping authority under 5 U.S.C. § 301. *See* 84 Fed. Reg. at 23,183, 23,209. But that statute is “simply a grant of authority to the agency to regulate its own affairs,” permitting “what the APA terms ‘rules of agency organization[,] procedure or practice’ as opposed to ‘substantive rules.’” *See Chrysler Corp. v. Brown*, 441 U.S. 281, 309–10 (1979). It does not grant agencies authority to issue regulations that have the force and effect of law or that otherwise exceed their substantive statutory authority.⁸

Nor are there any indications of an implicit delegation. *See Gonzales*, 546 U.S. at 267. To the contrary, the presumption against an implicit delegation is strong where, as here, the Rule raises significant federalism concerns by encroaching on states’ authority to regulate the practice of medicine. *Id.* at 274–75. Numerous state laws require medical providers to comport with professional standards of care, require the provision of emergency and medically necessary care, prohibit health care providers from abandoning a patient in need, protect patients’ right to informed consent, and protect and expand patient access to health services, including laws requiring pharmacies to dispense validly prescribed medication and laws requiring insurance plans to cover abortion. *See* Compl. for Declaratory & Injunctive Relief (“PPFA Compl.”) ¶¶ 117–18, Dkt. No. 1 (citing state laws); Compl. for Declaratory & Inj. Relief (“NFPRHA Compl.”) ¶¶ 99–101, 141,

⁸ The Rule also invokes “the various statutes and regulations governing HHS grants, contracts, and other programs discussed.” 84 Fed. Reg. at 23,221; *see id.* at 23,183–86. The many *regulatory* authorities cited are beside the point, as there is no delegation by *Congress* to HHS. As for statutes, the cross-referenced portions of the Rule have nothing applicable. The Federal Property and Administrative Services Act of 1949 is cited, but as relevant here, it simply authorizes agencies to “issue orders and directives that the agency head considers necessary to carry out” other specified regulations, 40 U.S.C. § 121(c), and does not authorize the Rule.

Nat'l Family Planning & Reproductive Health Ass'n v. Azar, No. 1:19-cv-5435 (S.D.N.Y. June 11, 2019), Dkt. No. 1 (same).⁹ In this context, “the background principles of our federal system . . . belie the notion that Congress would use such an obscure grant of authority to regulate areas traditionally supervised by the States’ police power.” *Gonzales*, 546 U.S. at 274; *see id.* at 275 (statute did not “delegate to a single executive officer the power to effect a radical shift of authority from the States to the Federal Government to define general standards of medical practice in every locality”). Where, as here, a regulation results in a “far-reaching” alteration of the “federal-state balance,” it cannot be assumed that Congress implicitly intended this result. *Id.* HHS simply “is not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law.” *Id.* at 258.

HHS’s claim of authority to interpret the Weldon Amendment is particularly unfounded. Weldon “is a spending measure and thus gives [health care providers] no enforceable rights,” *California ex rel. Lockyer v. United States*, 450 F.3d 436, 443 (9th Cir. 2006). In prior litigation concerning the Weldon Amendment, HHS *itself* conceded that “it is not clear that the Weldon Amendment can be said to delegate regulatory authority to the Executive Branch at all.” Br. of Defs. at 35, *NFPRHA v. Gonzales*, No. 1:04-cv-02148 (D.D.C. Dec. 24, 2004), ECF No. 9.¹⁰

⁹ It is likely that some will improperly attempt to invoke the Rule to avoid state laws that require insurance coverage of contraception (including Vermont’s, *see* Vt. Stat. Ann. tit. 8, § 4099c, and New York’s, *see* N.Y. Ins. Law. § 3221(1)(16) (eff. Jan. 1, 2020)) or laws that require emergency rooms to dispense emergency contraception to survivors of sexual assault (including New York’s, *see* N.Y. Pub. Health Law § 2805-p), even though contraception is not abortion and thus not covered by provisions in the Rule referring to abortion. *See, e.g., Real Alternatives, Inc. v. Sec’y Dep’t of Health & Human Servs.*, 867 F.3d 338, 353–54 & n.15 (3d Cir. 2017).

¹⁰ HHS looks for support in its regulations implementing the Hyde Amendment, 84 Fed. Reg. at 23,207, but Congress expressly delegated rulemaking power over Hyde to HHS. *See* 43 Fed. Reg. 4,570 (Feb. 2, 1978), <https://www.govinfo.gov/content/pkg/FR-1978-02-02/pdf/FR-1978-02-02.pdf#page=1> (citing Pub. L. 95–205 (HJRes 662)), 91 Stat 1460 (Dec. 9, 1977) (“The Secretary shall promptly issue regulations and establish procedures to ensure that the provisions of this section are rigorously enforced.”)).

Finally, as in *Gonzales v. Oregon*, where the Supreme Court rejected an agency rule prohibiting physician-assisted suicide protected by state law, the Rule is the subject of such “earnest and profound debate across the country” that “the oblique form of the claimed delegation [is] all the more suspect.” 546 U.S. at 267–68 (quotation omitted). The Rule will hinder access to an array of health services, including abortion, sterilization, contraception, end-of-life care, as well as many others. *See infra* Part I.B. The Rule prioritizes the right to refuse care above state and federal laws that protect patients, and ignores such laws that, for decades, have simultaneously protected the religious objections of health care workers while safeguarding patients’ access to care. *See infra* Part I.D. Courts “expect Congress to speak clearly if it wishes to assign to an agency decisions of vast economic and political significance.” *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014) (internal quotation marks and citations omitted); *accord King v. Burwell*, 135 S. Ct. 2480, 2488–89 (2015). “When an agency claims to discover in a long-extant statute an unheralded power to regulate a significant portion of the American economy,” courts “typically greet its announcement with a measure of skepticism.” *Util. Air Regulatory Grp.*, 573 U.S. at 324 (internal quotation marks and citations omitted). By HHS’s own estimate, it will cost over \$1 billion to implement the Rule, *excluding* foreseeable public health costs. *See* 84 Fed. Reg. at 23,227 (tbl. 1); *id.* at 23,240 (tbl. 6). Having intruded upon a matter of “vast economic and political significance” without any express statutory delegation, the Rule cannot stand.

2. HHS Was Not Delegated the Sweeping Enforcement Authority It Claims.

The Rule is particularly brazen in claiming expansive enforcement powers that Congress has not authorized. *See* 84 Fed. Reg. at 23,269–72 (to be codified at 45 C.F.R. §§ 88.4–88.7). The Rule asserts that HHS has “authority to enforce the Federal conscience and anti-discrimination laws,” *id.* at 23,220, as the basis for claiming sweeping law enforcement powers, *see id.* at 23,271–72. The Rule further asserts that “OCR has been delegated the authority to facilitate and coordinate

[HHS's] enforcement” of the refusal statutes. *Id.* at 23,271. But the Rule does not cite statutory provisions where Congress delegated such broad authority to *HHS* in the first place, and thus HHS “literally has no power” to exercise it. *NRDC*, 894 F.3d at 112.

That HHS may have basic authority to “evaluate compliance” with the federal refusal statutes and take remedial actions on a case-by-case basis as provided for in the 2011 Rule, *see* 76 Fed. Reg. 9,976–77 (codified at 45 C.F.R. § 88.2); *Gonzales*, 546 U.S. at 264, does not mean that Congress has granted HHS the draconian enforcement power it claims for itself in this Rule, including the right to terminate, withhold, deny, suspend, or claw back *all* federal funds for violating any provision of the Rule or underlying statutes, even if the funds are unconnected to the alleged violation and if voluntary compliance efforts are pending, *see* 84 Fed. Reg. at 23,271–72 (to be codified at 45 C.F.R. § 88.7(i)).¹¹ Nor does it grant HHS the authority to impose the onerous assurance and certification, compliance, and record-keeping requirements in the Rule. *See* 84 Fed. Reg. at 23,269–71 (to be codified at 45 C.F.R. §§ 88.4, 88.6). Nothing in the underlying statutes grants HHS this power. *NRDC*, 894 F.3d at 108.

A comparison to other laws imposing conditions on federal funds proves the point. The enforcement provisions of Title VI, for example, are “carefully constructed . . . to ensure that . . . withholding of funds”—a drastic remedy—“is ordered only where appropriate.” *Guardians Ass’n v. Civil Serv. Comm’n of City of N.Y.*, 463 U.S. 582, 609–10 (1983) (Powell, J., concurring). In Title VI, Congress authorized termination of funding only by “an express finding on the record, after opportunity for hearing, of a failure to comply;” requires agencies to tailor their remedy “to

¹¹ Authority to evaluate compliance also does not permit HHS to promulgate substantive rules creating broad new rights and obligations. *Cf. Pharm. Res. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28 (D.D.C. 2014) (statutory delegation to enforce on a case-by-case basis does not “give[] HHS the broad rulemaking authority” to promulgate a “proactive, prophylactic” rule).

the particular program, or part thereof, in which such noncompliance has been so found;” and even requires congressional committee notification before the funding termination can take effect. 42 U.S.C. § 2000d-1. Other civil rights statutes delegate funding termination authority in similar ways, with comparable protections.¹² The “silen[ce]” of Church, Weldon, and Coats-Snowe “contrasts sharply with the[se] other enforcement provisions.” *Omni Capital Int’l, Ltd. v. Rudolf Wolff & Co.*, 484 U.S. 97, 106 (1987). “Congress knows how to authorize [enforcement by federal agencies] when it wants to provide for it. That Congress failed to do so here argues forcefully that such authorization was not its intention.” *Dynegy Midstream Servs., LP v. Trammochem*, 451 F.3d 89, 95 (2d Cir. 2006) (quoting *Omni*, 484 U.S. at 106).

B. The Rule Is Arbitrary and Capricious.

Even if HHS had the authority to promulgate the Rule (and it did not), the Rule is arbitrary and capricious and must be set aside. 5 U.S.C. § 706(2)(A). HHS has not “give[n] adequate reasons for its decisions,” *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016), but instead has “relied on factors which Congress has not intended it to consider, entirely failed to consider . . . important aspect[s] of the problem,” and has offered “explanation[s] for its decision[s] that run[] counter to the evidence before [it],” *Motor Vehicle Mfrs. Ass’n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

1. HHS Failed to Consider Important Aspects of the Problem.

“[A]n agency ‘may not entirely fai[l] to consider an important aspect of the problem’ when deciding whether regulation is appropriate.” *Michigan v. EPA*, 135 S. Ct. 2699, 2707, 2711 (2015)

¹² See, e.g., 20 U.S.C. § 1682 (Title IX) (very similar to Title VI); 42 U.S.C. § 6104 (Age Discrimination Act) (same); 29 U.S.C. § 794 (Rehabilitation Act of 1973) (incorporating “[t]he remedies, procedures, and rights set forth in title VI”); 42 U.S.C. § 18116(a) (Section 1557 of the ACA) (“enforcement mechanisms provided for and available under . . . title VI, title IX, section 794, or [the] Age Discrimination Act shall apply . . . [to] violations of this subsection.”).

(alteration in original) (quoting *State Farm*, 463 U.S. at 43). HHS failed to consider a number of important aspects of the problem, each of which renders the Rule arbitrary and capricious.

First, HHS failed to consider the Rule’s deleterious effects on patient health. HHS received overwhelming evidence through comments that the Rule threatens harm to patients. A broad coalition of the nation’s trusted medical organizations—the American Medical Association, the American Academy of Family Physicians, the American Nurses Association, the American College of Obstetricians and Gynecologists, the American College of Emergency Physicians, the American Academy of Pediatrics, the American Hospital Association, and the Association of American Medical Colleges, among others—submitted comments opposing the Rule, as did health care providers such as Plaintiffs, state and federal officials, religious groups, and advocates representing communities likely to be harmed by the Rule, among others. PPFA Compl. ¶¶ 9, 60, 108–16 (citing comments); NFPRHA Compl. ¶¶ 84–85, 131–40 (same). These comments explained that the Rule will reduce access to health care services and result in negative health outcomes, especially in already-underserved communities, impair patients’ informed consent, and violate medical standards of care. *See id.*

Despite the serious concerns raised by commenters, HHS summarily rejected that the Rule will harm patient health because, according to HHS, *commenters* did not identify “suitable data.” 84 Fed. Reg. at 23,251–52. But the responsibility lies squarely *with HHS* to set forth “a detailed description of the actual impact expected from the rule on access to care, health outcomes, and associated concerns.” *Id.* at 23,252. It is the agency that must establish “a rational connection between the facts found and the choice made,” including by “point[ing] to . . . data.” *Nat’l Treasury Emps. Union v. Horner*, 854 F.2d 490, 499 (D.C. Cir. 1988) (quoting *State Farm*, 463 U.S. at 43); *see, e.g., Tripoli Rocketry Ass’n, Inc. v. ATF*, 437 F.3d 75, 77 (D.C. Cir. 2006) (agency

action was arbitrary and capricious where there was a failure to “offer[] data specific to the” problem at issue). HHS plainly failed to do so here.

As a result, the Rule does not adequately account for the serious and wide-ranging negative effects on patients who are denied care, including financial, physical, and mental harms. These harms include adverse health outcomes for patients who are denied information about and/or access to care, as well as costs, including both time and expense, related to these patients having to find and obtain care from another source. They also include the harm of patients declining to seek health care because they fear refusal by a provider. These harms were “factually substantiated in the record,” *see* PPFA Compl. ¶¶ 9, 60, 108–16 (citing comments); NFPRHA Compl. ¶¶ 84–85, 131–40 (same). HHS’s failure to account for these harms renders the Rule arbitrary and capricious. *Humane Soc’y of U.S. v. Zinke*, 865 F.3d 585, 606 (D.C. Cir. 2017); *see, e.g., Stewart v. Azar*, 313 F. Supp. 3d 237, 263 (D.D.C. 2018) (vacating HHS’s regulations where “the Secretary never once *mention[ed]* the estimated 95,000 people who would lose coverage, which gives the Court little reason to think that he seriously grappled with the bottom-line impact on healthcare”); *California v. Azar*, No. 19-CV-01184-EMC, 2019 WL 1877392, at *38 (N.D. Cal. Apr. 26, 2019) (failure to consider “ample evidence” in comments of “substantial” costs to public health rendered Title X regulation arbitrary and capricious).

To the extent HHS mentions these harms, it arbitrarily dismisses them out-of-hand. For example, HHS asserts, without explanation, that informed consent will not be impaired. 84 Fed. Reg. at 23,189; *see also* 84 Fed. Reg. at 23,180–82 (dismissing “comments expressing concern about the impact of the rule on access to care in rural communities, underprivileged communities, or other communities that are primarily served by religious healthcare providers or facilities”). HHS’s “willful blindness in this regard fully deserves the label ‘arbitrary and capricious.’” *MCI*

Telecomms. Corp. v. FCC, 842 F.2d 1296, 1304 (D.C. Cir. 1988). Although HHS alleged it could not quantify the Rule’s expected impact on health, a purported inability to *quantify* does not justify a failure to *consider*. *California v. Azar*, 2019 WL 1877392, at *39 (“HHS cannot simply disregard costs that are uncertain or difficult to quantify.”). Indeed, the excuse is hardly credible, as HHS could not quantify the supposed benefit it touts of increased participation in the health care workforce, yet it relied heavily on that to support its decision. 84 Fed. Reg. at 23,247; *see id.* at 23,252. HHS cannot have it both ways. *Nat. Res. Def. Council v. U.S. Nuclear Regulatory Comm’n*, 879 F.3d 1202, 1214 (D.C. Cir. 2018) (“Of course, it would be arbitrary and capricious for the agency’s decision making to be ‘internally inconsistent.’” (quoting *Air Transp. Ass’n of Am. v. Dep’t of Transp.*, 119 F.3d 38, 43 (D.C. Cir. 1997))).

Second, in adopting a regulation that burdens Plaintiffs and their patients, HHS failed to consider the adequacy of accommodations that have long existed for employees based on their religious beliefs. For decades, Title VII has provided a framework that accommodates health care providers’ religious beliefs while simultaneously ensuring that patients receive the health care they need. This approach is readily at hand and long-tested, but HHS has failed to explain why this approach is inadequate. Under Title VII, employers (such as Plaintiffs) must provide reasonable accommodations of employees’ or applicants’ sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an “undue hardship” on an employer in performing business operations. *See* 42 U.S.C. § 2000e-2. Thus, when a health care worker requests such accommodation, the employer may consider the potential effect on patients, coworkers, public safety, and other legal obligations. *Id.*

Health care workers have relied on Title VII’s balancing test and would continue to do so without the Rule. *See, e.g., Noesen v. Med. Staffing Network, Inc.*, 232 Fed. App’x 581, 584 (7th

Cir. 2007) (holding that a pharmacy reasonably accommodated employee by allowing him to transfer to co-worker any prescriptions involving contraceptives). Title VII ensures the required accommodation is reasonable under the circumstances and poses no undue hardship to the employer. *Id.* at 584–85 (“[A]n accommodation that requires other employees to assume a disproportionate workload (or divert them from their regular work) is an undue hardship as a matter of law.”).

The Rule, by contrast, eliminates any balancing of the needs of employers and employees. Not only does the Rule fail to acknowledge or appreciate the burden on employers from accommodating expanded refusals under the Rule, it explicitly rejects an “undue hardship” limitation on the absolute accommodations it requires. *See* 84 Fed. Reg. at 23,191. By failing to explain why Title VII’s framework is inadequate, or even to acknowledge or appreciate the burden on employers from accommodating expanded refusals that the Rule will enable, HHS unlawfully ignores an important aspect of the problem. *State Farm*, 463 U.S. at 43.

2. HHS Failed to Reasonably Explain Its Reversal of Policy.

HHS fails even to acknowledge its abrupt policy reversal, let alone provide the requisite detailed justification. A “change [to] existing policies,” requires “a reasoned explanation for the change.” *Encino Motorcars*, 136 S. Ct. at 2125. At minimum, an agency must “‘display awareness that it is changing position’ and ‘show that there are good reasons for the new policy.’” *Id.* at 2126 (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). Where, as here, an agency’s “new policy rests upon factual findings that contradict those which underlay its prior policy” or “its prior policy has engendered serious reliance interests,” a “detailed justification” for the new position is required. *Fox*, 556 U.S. at 515.

The Rule is not only a direct reversal of HHS policy; it is also a return to—and expansion—of a policy that HHS previously determined is dangerous to patient welfare. HHS’s regulatory history on this subject evidences the arbitrariness of its decision making:

- As explained above, *see supra* Part II, in 2008, HHS promulgated a regulation very similar to the Rule, also purporting to implement the Church, Coats-Snowe, and Weldon Amendments through expansive definitions of their terms. 73 Fed. Reg. at 78,072.
- Shortly thereafter, HHS proposed repealing the 2008 Rule in its entirety because the 2008 Rule failed sufficiently to address the commenters’ concerns, including that the expanded definitions would (1) negatively affect patients’ ability to give informed consent, (2) impede patients’ ability to receive the medical care they needed, and (3) encourage providers to refuse care on discriminatory and illegal bases. 74 Fed. Reg. at 10,207.
- HHS ultimately rescinded the 2008 Rule nearly in full. In so doing, HHS stated the 2008 Rule caused confusion about the scope of statutory protections, 76 Fed. Reg. at 9,974; could “*negatively affect the ability of patients to access care* if interpreted broadly;” *id.*; caused confusion regarding informed consent requirements, *id.* at 9,973; and improperly suggested providers could “refuse to treat entire groups of people based on religious or moral beliefs,” *id.* HHS also found the 2008 certification requirements unnecessary because the process it retained to receive and handle complaints sufficed to protect those alleging violations of the refusal statutes. *Id.* at 9,974.

Yet even though commenters explicitly pointed out the factual findings and concerns animating the rescission of the 2008 Rule, HHS *does not even mention* them, let alone provide a “detailed justification” or even a “reasoned explanation” for rejecting them.¹³ HHS’s complete disregard for its drastic change in policy renders the Rule arbitrary and capricious. *See Fox*, 556 U.S. at 515. Its 2011 position has been settled policy for nearly a decade. In that time, it has “engendered serious reliance interests.” *See id.*

¹³ PPFA Comments at 20–21; Comment Letter from Inst. of Pub. Integrity (“Institute of Public Integrity Comments”) at 1 (Mar. 27, 2018), <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72071>.

HHS tries to justify the Rule by pointing to complaints alleging violations of federal refusal laws. 84 Fed. Reg. at 23,175–76. But OCR received *fewer than fifty complaints alleging violations of federal refusal laws between 2008 and January 2018*, 83 Fed. Reg. at 3,886, compared to the tens of thousands of complaints for violations of civil rights laws and HIPAA that OCR receives annually.¹⁴ Equally important, HHS points to *no evidence* that HHS lacked the necessary tools to investigate and remedy any violations of the federal refusal laws in response to those complaints. While HHS claims an uptick in complaints since November 2016, 84 Fed. Reg. at 23,175, it provides no information on the validity of those complaints or whether the complainants were able to obtain relief from existing legal protections. Indeed, HHS has refused to respond to FOIA requests seeking records of those purported complaints.¹⁵ Given existing, long-standing legal protections for health care providers’ religious and moral beliefs, reference to alleged, unsubstantiated claims that a problem exists is not reasoned decision-making. *See Ass’n of Private Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 448 (D.C. Cir. 2012) (finding agency’s reference to “isolated examples” supporting policy insufficient); *Nat’l Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831, 839, 841 (D.C. Cir. 2006) (agency action premised on “a claimed record of abuse” is arbitrary where the agency “provided no evidence of a real problem”).

HHS also relies on stale survey data and conjecture to argue the Rule is needed to prevent practitioners from leaving medicine, but this fares no better. *See* 84 Fed. Reg. at 23,175, 23,252–53 (citing polling of health care providers who self-selected into particular religiously-affiliated medical associations from 2009 and 2011). An agency’s “predictive judgments” about a rule’s

¹⁴ *See* HHS, “FY 2019 Budget in Brief” at 124 (Feb. 19, 2018), <https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf> (“[i]n FY 2017, OCR received approximately 30,166 complaints.”).

¹⁵ *See, e.g., Compl., Ctr. for Reproductive Rights & Nat’l Women’s Law Ctr. v. Dep’t of Health & Human Servs.*, No. 1:18-cv-1688 (D.D.C. July 19, 2018), ECF No. 1.

likely effects are subject to deference only if they are “based on some logic and evidence, not sheer speculation.” *California v. Azar*, 2019 WL 1877392, at *30 (quoting *Sorenson Commc’ns Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014)). And in any event, HHS prediction “runs counter to the evidence before the agency,” *State Farm*, 463 U.S. at 43: commenters who opposed rescinding the 2008 Rule relied on the same data to argue that rescission would lead to a shortage of physicians, *see* 84 Fed. Reg. at 23,175–23,176. But HHS provides no data to support that the rescission of the 2008 Rule actually resulted in a shortage of physicians, nor does it appear HHS made any effort to collect actual data on this question. *See also* PPFA Compl. ¶ 97 (citing to news article showing that since the 2011 rescission, physicians’ offices have added 400,000 jobs). HHS’s lack of credible explanation for its position change condemns the Rule.

3. HHS Failed to Conduct an Adequate Regulatory Impact Analysis.

“[R]easonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions.” *Michigan v. EPA*, 135 S. Ct. at 2707. “As a general rule, the costs of an agency’s action are a relevant factor that the agency must consider before deciding whether to act,” and “consideration of costs is an essential component of reasoned decisionmaking under the [APA].” *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 732–33 (D.C. Cir. 2016).

The Rule was classified as a “significant regulatory action,” requiring HHS to conduct a regulatory impact analysis under Executive Order 12,866. A cost-benefit analysis should account for direct and *indirect* costs associated with a rulemaking. *See Michigan v. EPA*, 135 S. Ct. at 2707. “[A] serious flaw undermining that analysis can render the rule unreasonable.” *California v. Azar*, 2019 WL 1877392, at *37 (quoting *Nat’l Ass’n of Home Builders v. EPA*, 682 F.3d 1032, 1039–40 (D.C. Cir. 2012)) (reviewing a cost-benefit analysis under the arbitrary-and-capricious standard). Agencies are required to account for direct and indirect health costs to the fullest extent practicable, including “outcomes that cannot be quantified but may have important implications

for decision-making.” HHS, *Guidelines for Regulatory Impact Analysis* at 47 (2016), https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.

HHS’s consideration of the Rule’s costs fails basic requirements for rationality. As discussed previously, *supra* Part I.B.1, HHS expressly refused to account for the negative effects on patient health and welfare, notwithstanding that these are indirect costs that HHS must consider. *Michigan v. EPA*, 135 S. Ct. at 2707; *California v. Azar*, 2019 WL 1877392, at *38–40. Moreover, though HHS acknowledges that the Rule will impose compliance costs on regulated entities, it severely underestimates these costs and dismisses many of them as non-quantifiable (which HHS effectively treats as no cost). 84 Fed. Reg. at 23,227 tbl.1; *id.* at 23,240 tbl.6. In particular, the Rule minimizes the significant labor and legal costs that entities required to comply with the Rule (like Plaintiffs) would incur to review and alter their current employment policies, provide training for staff, and otherwise implement changes to their operations to ensure compliance with the Rule. *See* Coleman Decl. ¶¶ 71–80; Custer Decl. ¶¶ 38, 62–67; David Decl. ¶¶ 44–49; Gallagher Decl. ¶¶ 55–56.¹⁶ These fundamental flaws in HHS’s cost-benefit analysis undermine its conclusions and further render the Rule arbitrary and capricious. *See Nat’l Ass’n of Home Builders*, 682 F.3d at 1039–40.

C. HHS’s Definition of “Discrimination” in the Final Rule Is Not a Logical Outgrowth of the Proposed Rule.

HHS did not give the public fair notice of the definition of “discrimination” that the agency adopted in the final Rule. The APA requires an agency to provide the public with notice and opportunity to comment before promulgating a rule. 5 U.S.C. § 553(b)(3). “While a final rule need not be an exact replica of the [proposed] rule . . . , the final rule must be a ‘logical outgrowth’ of

¹⁶ Institute of Public Integrity Comments at 4–9.

the rule proposed” such that “affected parties [have] notice and an opportunity to respond.” *Nat’l Black Media Coal. v. FCC*, 791 F.2d 1016, 1022 (2d Cir. 1986) (quoting *AFL-CIO v. Donovan*, 757 F.2d 330, 338 (D.C. Cir. 1985)). A final rule is a logical outgrowth of a proposed rule if the agency “expressly ask[s] for comments on a particular issue or otherwise ma[kes] clear that the agency [is] contemplating a particular change.” *CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1081 (D.C. Cir. 2009).

The final Rule includes three key subsections within the definition of “discrimination” that were not contained in the Proposed Rule, for which no comments were solicited, and which were not reasonably foreseeable. New subsection (4) explains that an employer may offer an employee an “effective accommodation” so long as the employee “voluntarily accepts” and that OCR will “take into account the degree to which an entity had implemented policies to provide effective accommodations.” 84 Fed. Reg. at 23,263. New subsection (5) provides that employees may only be asked if they are willing to perform an essential job function to which they might morally object *after* being hired, and only once per calendar year, absent a “persuasive justification.” *Id.* And in new subsection (6), the Rule states that the use of alternate staff or methods to provide or further any objected-to conduct would not “by itself” constitute discrimination only if it “does not require any additional action by, or does not take any adverse action against” the objecting employee and does not exclude the employee from their “field[] of practice.” *Id.* Subsection (6) further states it may be considered “adverse or retaliatory action” if an employer informs the public of alternate staff or methods to provide the objected-to conduct.

These new subsections are not a “‘logical outgrowth’ of the rule proposed.” *Nat’l Black Media Coal.*, 791 F.2d at 1022 (quoting *AFL-CIO*, 757 F.2d at 338). The Proposed Rule was silent as to Title VII, and made no mention of any accommodation framework, let alone one as

unworkable as the one in the final Rule. Indeed, HHS noted in the final Rule that its definition of “discrimination . . . does not function in the same way as the approach set forth in Title VII, specifically regarding parts of the reasonable accommodation of religion standard.” *Id.*

The Rule “pull[s] a surprise switcheroo” on Plaintiffs. *Riverkeeper, Inc. v. EPA*, 475 F.3d 83, 116 (2d Cir. 2007) (quoting *Envtl. Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005)). Plaintiffs did not have “fair notice” of HHS’s intent to add these new subsections into the definition of “discrimination,” and had no reasonable opportunity to comment on them. *See Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007); *Nat’l Black Media Coal.*, 791 F.2d at 1022, 1023 (“notice was insufficient when a final rule differed significantly from the proposed rule”); *see also Time Warner Cable Inc. v. FCC*, 729 F.3d 137, 170 (2d Cir. 2013) (“[A]n unexpressed intention cannot convert a final rule into a logical outgrowth that the public should have anticipated.” (quoting *Council Tree Commc’ns, Inc. v. FCC*, 619 F.3d 235, 254 (3d Cir. 2010))). Plaintiffs’ comments to the Proposed Rule urged HHS to make clear that the Rule does not deviate from Title VII, but Plaintiffs had no way of knowing that HHS intended to create an entirely new accommodation framework, nor could they have known what that framework would be. Had Plaintiffs known HHS was considering defining “discrimination” in this manner, they would have made clear that these subsections are onerous, vague, and unworkable in the health care setting and constrain the ability of Plaintiffs, providers of comprehensive reproductive health services, to ensure that their patients receive necessary care.

D. The Rule Is Contrary to Law in Violation of the APA.

Even assuming that HHS had authority to issue this Rule (which it did not) and that the Rule is procedurally sound (which it is not), HHS still deserves no deference because the Rule is contrary to the “unambiguously expressed intent of Congress” in the underlying refusal statutes,

as well as other federal laws. *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 842–43 (1984). It is thus also “not in accordance with law” and must be set aside. 5 U.S.C. § 706(2)(A).

1. The Rule Impermissibly Expands the Narrow Underlying Statutes.

The Rule both expands and directly contradicts the underlying federal refusal statutes by broadly defining the terms “discrimination,” “assist in the performance,” “referral” or “refer for,” and “health care entity,” in a manner contrary to the statutes’ plain meaning and the drafters’ legislative intent.

First, as described further above, Subsections (4), (5), and (6) of HHS’s definition of “**discrimination**” require Plaintiffs to hire and provide absolute accommodation to individuals who refuse to provide care to their patients. But this definition would violate the Establishment Clause. *See infra* Part I.D.5; *see also Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 709 (1985) (finding statute “impos[ing] on employers and employees an absolute duty to conform their business practices to the particular religious practices of the employee” violated Establishment Clause). Because courts must construe statutes to avoid an interpretation that violates the Constitution, this Court should conclude that Congress did not intend the constitutionally infirm definition of “discrimination” adopted in the Rule. *See Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA*, 846 F.3d 492, 517–18 (2d Cir. 2017).

Second, HHS’s definition of “**assist in the performance**” sweeps much more broadly than Congress intended. In the Church Amendments, Congress provided that a health care professional is not required to “perform” or “assist in the performance” of “any sterilization procedure or abortion.” 42 U.S.C. § 300a-7(b)(1); *see id.* § 300a-7(d) (same for individuals who “assist in the performance of” an HHS-funded “health service program or research activity”). To “assist” is “to

give support or aid,” and a “performance” is “the execution of an action.”¹⁷ Congress made clear that this “support or aid” must be closely related to the “action”: the sponsor of the Church Amendments explained that “[t]here is no intention here to permit a frivolous objection from someone unconnected with the procedure to be the basis for a refusal to perform what would otherwise be a legal operation.” 119 Cong. Rec. 9597 (Mar. 23, 1973) (statement of Sen. Church).

The Rule, by contrast, defines “assist in the performance” to include any action that has a “specific, reasonable, and articulable connection” to “furthering” a procedure otherwise performed by someone else, including but not limited to “counseling, referral, training, or otherwise making arrangements” for the procedure or service, “depending on whether aid is provided by such actions.” 84 Fed. Reg. at 23,263–64 (all definitions to be codified at 45 C.F.R. § 88.2). This new definition is so broad that it means, for example, that simply scheduling an appointment, admitting a patient to a health care facility, transporting a patient from one part of the facility to another, providing referrals, or even filing a patient’s chart could conceivably be considered “assist[ing] in the performance” of a health care service, as any of those activities could have a “connection” to “furthering” the service. Under this definition, virtually any employee, trainee, or volunteer could “veto” a patient’s access to care by refusing to perform those functions. HHS itself notes that it explicitly intended for this definition to include decidedly non-medical tasks such as “[s]cheduling” an abortion. 84 Fed. Reg. at 23,186.

Third, because “**referral**” is included in the definition of “assist in the performance,” the Rule would allow any of the extremely broad range of individuals ostensibly covered by the Rule to refuse not only to participate in services to which they object directly, but also to withhold

¹⁷ See Merriam-Webster’s Dictionary, “Assist,” <https://www.merriam-webster.com/dictionary/assist> (last visited June 12, 2019); Merriam-Webster’s Dictionary, “Performance,” <https://www.merriam-webster.com/dictionary/performance> (last visited June 12, 2019).

information from patients without the patients' knowledge. "Referral" or "refer for" is defined to include 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." 84 Fed. Reg. at 23,264. This includes information that could provide "*any assistance*" to a person "obtaining, assisting, training in, funding, financing, or performing" the health care service as long as the referrer "sincerely understands" that this is a "possible outcome" of the referral. *Id.* at 23,199.

This definition of "referral" or "refer for," which would include even confirming to a patient that abortion is an option, contravenes the ordinary understanding of the term. For example, if a patient at a Title X-funded clinic learns she is pregnant and asks a nurse or counselor whether abortion is legal in her state, the nurse or counselor could invoke the Rule and refuse to answer the question on the grounds that doing so constitutes a "referral" for abortion. The use of this term in a manner that upends medical ethics and the requirements of informed consent bends the plain meaning of the term "referral" in the health care setting so far as to break it. Moreover, these expansive definitions defy the plain meaning of the terms and contravene Congress' intent that no one be denied services as a result of the Church Amendments. *See* 119 Cong. Rec. 9596 (Mar. 27, 1973) (statement of Sen. Stevenson) ("No individuals will be denied an abortion or sterilization consistent with their own religious or moral convictions . . .").

Fourth, and finally, HHS likewise substantively amends the Weldon and Coats-Snowe Amendments by altering—and expanding—the definition of "**health care entity.**" The Coats-Snowe Amendment, which was entirely concerned with abortion training, defines "health care

entity” to include “an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions.” 42 U.S.C. § 238n(c)(2); *see also* 142 Cong. Rec. 5158 (March 19, 1996) (statement of Sen. Coats) (“What I was trying to do with [the Coats] [A]mendment was simply address the question of training for induced abortions.”); 142 Cong. Rec. 4296 (March 14, 1996) (statement of Senator Coats) (“We are simply saying that if [ACGME] did not accredit because a hospital . . . decided not to mandate the requirements of teaching their residents abortion procedures, that they will not be in a position of losing their funds.”). And the Weldon Amendment defines “health care entity” to include “an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.” 132 Stat. at 3118(b). The sponsor of the Weldon Amendment made clear that it was meant to apply to a limited group of *health care professionals* and *health care institutions*:

This provision is intended to protect the decisions of ***physicians, nurses, clinics, hospitals, medical centers, and even health insurance providers*** from being forced by the government to provide, refer, or pay for abortions.

150 Cong. Rec. H10,090 (Nov. 20, 2004) (statement of Rep. Weldon) (emphasis added). Thus, it is clear that there as no intention for the provision to apply more widely.

The Rule, however, expands the term for both Amendments to permit refusals not intended nor sanctioned by Congress. For example, the inclusion of a “***plan sponsor***” (84 Fed. Reg. at 23,264) extends the reach of the Weldon Amendment to employers with no connection to health care other than the provision of employee benefits, which may allow employers to invoke the Rule to deny abortion coverage to their employees; and inclusion of a “***third-party administrator***” (*id.*) would extend the Weldon Amendment to allow entities whose only function is to process benefits

claims to rely on the Weldon Amendment to deny insurance claims based solely on objections to abortion. Moreover, the inclusion of “*pharmacists*” (*id.*) to the Coats-Snowe Amendment extends that statute well beyond the abortion-training context. In each of these ways, the Rule defies Congressional intent.

2. The Rule Conflicts with EMTALA.

Because it contains no protections to ensure adequate patient access to necessary health care in emergencies, the Rule conflicts with EMTALA. *See* 42 U.S.C. § 1395dd. Under EMTALA, any hospital that receives Medicare funds and operates an emergency department must provide an examination or treatment to individuals that come into the emergency room; must stabilize¹⁸ any individual determined to have an emergency medical condition¹⁹; and must not transfer the individual to another medical facility unless the individual requests the transfer or a physician certifies that the benefits of a transfer outweigh the increased risks to the patient. *See id.* In contrast, the Rule purports to interpret the federal refusal statutes to allow certain individuals to refuse to perform, refer for, or otherwise take any action that has a “connection” with “furthering” an abortion, even when the abortion is necessary to stabilize a pregnant person experiencing an emergency medical condition. The Rule also purports to prevent state and federal governments from enforcing EMTALA or similar state laws against entities that refuse to provide, make

¹⁸ EMTALA defines “to stabilize” as “to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility.” 42 U.S.C. § 1395dd(e)(3)(A).

¹⁹ EMTALA defines an “emergency medical condition” as “a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in (i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, (ii) serious impairment to bodily functions, or (iii) serious dysfunction of any bodily organ or part.” 42 U.S.C. § 1395dd(e)(1)(A).

arrangements for, or refer for emergency abortions. Accordingly, the Rule conflicts with EMTALA and similar state laws and exceeds HHS's authority under the federal refusal statutes, which do not allow for the refusal of emergency abortion care.²⁰

Despite the fact that abortion is the standard of care for stabilizing patients, within the meaning of EMTALA, experiencing certain pregnancy complications,²¹ and despite the fact that EMTALA has been law for more than three decades, HHS treats such emergency medical care as proscribed "discrimination." In its Proposed Rule, HHS cited as "[e]vidence" of the "[d]iscrimination" the Rule was intended to prevent, an ethics opinion by the American College of Obstetricians and Gynecologists ("ACOG") stating that "[i]n an emergency in which referral is not possible or might negatively affect a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections." 83 Fed. Reg. at 3,887-88. Despite commenter requests that HHS clarify that the Rule would not apply in medical emergency situations,²² HHS refused to do so.

²⁰ HHS also points to the preamble to the 2008 Rule, *see* 84 Fed. Reg. at 23,183, but that preamble sidesteps the issue of conflict, noting instead that HHS is "not aware of any instance" where a hospital's "entire staff objected to the service" or of any hospital that has a policy to refuse emergency abortions. 73 Fed. Reg. at 78,087-88. This reference is misleading. HHS itself highlighted the case of Tamesha Means (84 Fed. Reg. at 23,247-48), who was turned away from the only hospital in her area three times when her water broke at 18 weeks of pregnancy, causing her to develop a life-threatening infection. Because of its religious affiliation, the hospital did not inform Ms. Means that terminating her pregnancy was the safest course for her condition, putting her health at risk. Commenters also pointed HHS to examples in which entire religiously affiliated hospitals prohibited their staff from providing patients abortion care or information. *See* Comment Letter from the ACLU ("ACLU Comments"), at 12 (Mar. 27, 2018), <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71138>; PPFA Comments at 2-3.

²¹ *See* Chasen Decl. ¶¶ 11, 14-15, 19-20, 35; PPFA Comments at 5.

²² *See, e.g.*, PPFA Comments; ACLU Comments; AMA Comments.

Rather, the Rule’s claimed compliance with EMTALA is illusory and unsupported. HHS claims that “where EMTALA might apply in a particular case, [HHS] would apply both EMTALA and the relevant law under this rule harmoniously *to the extent possible*.” 84 Fed. Reg. at 23,188 (emphasis added). Yet HHS explicitly refused to answer, for example, whether an emergency medical technician or paramedic would be required to transport a person with an ectopic pregnancy for an emergency abortion, claiming it “would depend on the facts and circumstances.”²³ 84 Fed. Reg. at 23,188. But conflict between EMTALA and the Rule is readily foreseeable. *See* Decl. of Stephen Todd Chasen (“Chasen Decl.”) ¶¶ 3, 6–9, attached as Ex. F to Mac Dougall Decl.; *cf. Shelton v. Univ. of Med. & Dentistry of N.J.*, 223 F.3d 220, 223 (3d Cir. 2000) (describing case of labor and delivery nurse who was offered lateral transfer to the newborn intensive care unit after she refused to participate in emergency abortions, including where a patient experiencing placenta previa was “standing in a pool of blood.”). And, more importantly, HHS cannot purport to allow individuals and entities to refuse emergency care on a “case-by-case” basis. The plain language of EMTALA allows for no such exceptions, and the federal refusal statutes were never intended to do so. *See, e.g., California v. United States*, No. C05-00328, 2008 WL 744840, at *4 (N.D. Cal. Mar. 18, 2008) (“There is no clear indication, either from the express language of the Weldon Amendment or from a federal official or agency, that enforcing . . . EMTALA to require medical treatment for emergency medical conditions would be considered ‘discrimination’ under the Weldon Amendment if the required medical treatment was abortion-related services.”).

²³ HHS’s existing regulations consider an individual en route to a hospital in an ambulance owned and operated by the hospital to be covered by EMTALA, and in certain circumstances, an individual who is en route to a hospital in an ambulance that is not owned and operated by the hospital. 84 Fed. Reg. at 23,188.

The Rule’s disregard of EMTALA also conflicts with the federal refusal statutes, which were not intended to reach emergency abortions. 151 Cong. Rec. H177 (Jan. 25, 2005) (statement of Rep. Weldon) (citing EMTALA and stating Weldon Amendment “ensures that in situations where a mother’s life is in danger a health care provider must act to protect the mother’s life”); 142 Cong. Rec. 5165–66 (Mar. 19, 1996) (statement of Sen. Coats) (clarifying that Coats-Snowe Amendment, which focuses on abortion training programs, would not interfere with training to perform emergency abortions); 119 Cong. Rec. 9601 (Mar. 27, 1973) (statement of Sen. Church) (Church Amendments were not intended to reach emergency situations: “in an emergency situation—life or death type—no hospital, religious or not, would deny such services.”).

3. *The Rule Conflicts with Title X.*

The Rule is also contrary to both Title X of the Public Health Service Act, 42 U.S.C. § 300 *et seq.*, and appropriations legislation governing the Title X program, *see, e.g.*, HHS Appropriations Act, 2019, Pub. L. No. 115-245, 132 Stat. 2981, 3070–71 (2018). HHS “has gone beyond what Congress has permitted it to do,” *City of Arlington v. FCC*, 569 U.S. 290, 298 (2013), by contravening these provisions. *See Chevron*, 467 U.S. at 842–43 (“If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”).

Congress passed Title X in 1970 to “mak[e] comprehensive *voluntary* family planning services available to all persons desiring” them. Family Planning Services and Population Research Act, 1970, Pub. L. No. 91-572 § 2(1), 84 Stat. 1504 (1970) (emphasis added). Since then, the Title X program has been an essential piece of the U.S. health care system, and it remains the nation’s sole federally-funded family planning program. *See Coleman Decl.* ¶¶ 18–28. Congress expressly recognized that Title X requires “explicit safeguards to insure that the acceptance of

family planning services and information relating thereto must be on a purely voluntary basis by the individuals involved.” S. Rep. No. 91-1004, at 12 (1970).

Accordingly, Congress has repeatedly and expressly forbidden HHS from limiting Title X patients’ access to medical information, using Title X funds for involuntary care or directive, non-neutral counseling when a patient is pregnant, or creating any other unreasonable barriers to patients’ ability to make informed decisions about and gain timely access to medical care. Indeed, in making appropriations for Title X in every year from 1996 to the present, Congress has reiterated that it must fund only the delivery of *voluntary* family planning services. *See Oregon v. Azar*, No. 6:19-CV-00317, 2019 WL 1897475, at *4 (D. Or. Apr. 29, 2019), *appeal pending*, No. 19-35386 (9th Cir. filed May 6, 2019). This echoes two sections of the original Title X enactment. 42 U.S.C. §§ 300, 300a-5. In addition, Congress has annually mandated that within the Title X program, “all pregnancy counseling shall be nondirective.” *See* HHS Appropriations Act, 2019, 132 Stat. at 3070–71. This mandate requires Title X providers to offer pregnant patients neutral information about *all* their options, including abortion. And, consistent with Title X’s terms and statutory purpose, long-standing program requirements further obligate providers to furnish referrals for any of those care options, including abortion, upon a patient’s request. *See* Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, 65 Fed. Reg. 41,270, 41,279 (2000) (codified at 42 C.F.R. § 59.5(a)(5)); *see also* Coleman Decl. ¶¶ 4–6, 37–46 (describing national clinical standards for Title X); Gallagher Decl. ¶ 20 (same).

The Rule directly conflicts with Title X’s plain statutory text and clear Congressional mandates by purporting to establish an absolute right for individuals and entities to refuse to provide any information about abortion to Title X patients, forcing Title X providers to hire and continue to employ individuals who refuse to perform these essential job functions, and making it

difficult, if not impossible, for Title X providers to ensure patients continue to receive this care. In so doing, the Rule flouts the Congressional purpose of the Title X program by subjecting Title X patients—who often lack financial and other means of accessing medical services—to second-rate care (*e.g.*, *directive* pregnancy counseling), contrary to medical ethics and national standards. *See* Chasen Decl. ¶¶ 4, 9; Coleman Decl. ¶¶ 18–22, 29–46, 57–60, 63–70; Custer Decl. ¶¶ 4, 36, 43; David Decl. ¶¶ 15–16, 20–23; Gallagher Decl. ¶¶ 49–50. The Rule further undermines the fundamental integrity of the Title X program by prohibiting (state and local governmental) grantees from requiring subrecipients to meet these core Title X requirements. *See* Coleman Decl. ¶¶ 63–64, 79.

Numerous courts have already recognized that withholding information about abortion from patients during the pregnancy options counseling process violates the appropriations mandate, among other laws, *see infra* Part I.D.3. *See Oregon v. Azar*, 2019 WL 1897475, at *7–*10; *California v. Azar*, 2019 WL 1877392, at *14–*18; *Washington v. Azar*, No. 19-cv-03040, 2019 WL 1868362, at *7 (E.D. Wash. Apr. 25, 2019); *Mayor & City Council of Balt. v. Azar*, No. RDB-19-1103, 2019 WL 2298808, at *9–*10 (D. Md. May 30, 2019). Prior to finalizing this Rule, HHS promulgated new Title X regulations that attempted to prohibit Title X providers from giving their patients abortion referrals upon request and to allow providers to withhold any other information about abortion during pregnancy counseling. *See* Compliance With Statutory Program Integrity Requirements, 84 Fed. Reg. 7,714–91 (Mar. 4, 2019). The new Title X regulations were challenged and subsequently preliminarily enjoined as contrary to the statutes governing the Title X program, as multiple courts recognized that refusing to provide patients with the information they seek or about all of their options is “the very definition of directive counseling.” *Oregon v. Azar*, 2019 WL 1897475, at *9; *see also California v. Azar*, 2019 WL 1877392, at *1

(“[P]rovid[ing] incomplete and misleading information to women seeking to terminate their pregnancies contrary to what patients want and need, delaying and potentially frustrating their attempts to obtain time-sensitive care, and thereby jeopardizing their health and welfare . . . likely violates Congressional directives.”). Given that the Rule also attempts an impermissible end-run around the commands of Congress, the Rule should likewise be enjoined by this Court.²⁴

4. *The Rule Conflicts with Section 1554 of the Affordable Care Act.*

The Rule also directly conflicts with Section 1554 of the Affordable Care Act, which prohibits HHS from promulgating 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. the necessary standard of care. Indeed, the Rule violates *each* of Section 1554’s prohibitions.

Taking these prohibitions one by one:

- (1) The Rule creates unreasonable barriers to care because, under its terms, it permits a broad variety of individuals and entities related to the health care industry to block patients’ access to care. In rural or other underserved communities, such a refusal could force patients to travel long distances or reschedule and spend precious time trying to get care, if they are turned away on their first attempt.

²⁴ HHS has also acted arbitrarily and capriciously and exceeded its authority because the Rule overrides HHS’s own preexisting regulations requiring Title X patients to be provided with abortion referrals, upon request. *See* 65 Fed. Reg. 41,270, 41,279 (2000) (codified at 42 C.F.R. § 59.5(a)(5)). An agency cannot “adopt[] a new position inconsistent with any of the Secretary’s existing regulations” without engaging in direct notice and comment rulemaking on those regulations. *See Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 100 (1995). As described above, HHS already attempted to repeal those regulations via new regulations, which have been blocked by the courts. HHS cannot evade the courts and the rulemaking process by using this Rule to effectively repeal regulations it has already been prohibited from repealing directly.

- (2) The Rule impedes timely access to care as it may require a patient to seek care multiple times before finding a willing provider and because it provides no exception for emergency care. The Rule ignores the fundamental medical fact that abortion is, in certain circumstances,
- (3), (4), (5) The Rule interferes with communications regarding a full range of treatment options between the patient and the provider, restricts the ability of health care organizations to ensure their patients receive full disclosure of all relevant information, and violates the principles of informed consent and the ethical standards of health care professionals because of its expansive definition of “referral,” which allows a health care provider to refuse to disclose information about certain treatment options to patients.
- (6) The Rule limits the availability of health care treatment for the full duration of patients’ medical needs because it would allow providers to turn patients away in the midst of a course of treatment, if, for example, the patient sought information to which the provider had an objection.

In sum, the Rule’s unwarranted extension of the underlying statutes conflicts with the plain meaning of Section 1554 of the Affordable Care Act. *See Nat’l Ass’n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 666 (2007); *see also Mayor & City Council of Balt. v. Azar*, 2019 WL 2298808, at *8 (holding that a rule “permit[ting] a Title X project to give a patient who specifically requests a referral for abortion a referral list that contains no abortion providers, requir[ing] that the compiled list contain a majority of providers that are not responsive to the patient’s request, and . . . not allow[ing] the Title X project to identify which providers are responsive to the patient’s request” violates the non-interference mandate of the ACA, § 18114(3)–(5)); *Oregon v. Azar*, 2019 WL 1897475, at *12 (“That Congress intended in [§] 18114 to limit HHS’s rulemaking authority appears clear. . . . At this stage, there is at least a strong argument to be made that the [challenged rule] creates unreasonable barriers to Title X clients obtaining appropriate medical care and impedes their timely access to such care [in violation of § 18114(1) and (2).]”). As such, the Rule is not in accordance with law.

5. *The Rule Violates the Establishment Clause.*

Because the Rule impermissibly advances religious beliefs in violation of the Establishment Clause it is also contrary to law, and thus violates the APA. *See Thornton*, 472 U.S. 703. The Supreme Court has long recognized that “[t]he First Amendment . . . gives no one the right to insist that in pursuit of their own interests others must conform their conduct to his own religious necessities.” *Thornton*, 472 U.S. at 710 (alteration in original) (quoting *Otten v. Balt. & O.R. Co.*, 205 F.2d 58, 61 (2d Cir. 1953)).

In *Thornton*, the Supreme Court struck down a Connecticut law that provided all employees with an unqualified right to refuse to work on their Sabbath. *See* 472 U.S. at 706 (“No person . . . may be required by his employer to work on [his Sabbath]. An employee’s refusal to work on his Sabbath shall not constitute grounds for his dismissal.” (quoting Conn. Gen. Stat. § 53–303e(b) (1985))). As the Court explained:

The State thus commands that Sabbath religious concerns automatically control over all secular interests at the workplace; the statute takes no account of the convenience or interests of the employer or those of other employees who do not observe a Sabbath. The employer and others must adjust their affairs to the command of the State whenever the statute is invoked by an employee.

Id. at 709. Accordingly, the Court held that the Connecticut law’s “unyielding weighting in favor of Sabbath observers over all other interests contravenes a fundamental principle of the Religion Clauses” and was therefore unconstitutional. *Id.* at 710.

The similarities to the Rule are striking. The Rule imposes on Plaintiffs an absolute obligation to, *inter alia*, accommodate any employee who not only refuses to perform a given medical procedure, but also who refuses to take any action that has a “specific, reasonable, and articulable connection” to “furthering” virtually any lawful medical procedure or service performed by someone else, notwithstanding that these actions may be “the primary or substantial majority of the duties of the position,” 84 Fed. Reg. at 23,192, and irrespective of the impact the

refusal has on Plaintiffs' ability to provide these services to their patients. *See* Coleman Decl. ¶¶ 55–60; Custer Decl. ¶ 36; David Decl. ¶¶ 30–43; Gallagher Decl. ¶¶ 30–40.

Indeed, the Rule expressly rejects Title VII's "undue hardship" standard that permits an employer to consider the potential effect such accommodation would have on patients, coworkers, public health and safety, and other legal obligations. 84 Fed. Reg. at 23,191; *see also* 42 U.S.C. § 2000e-2. Therefore, as in *Thornton*, the Rule allows no exception for "special circumstances," 472 U.S. at 709; no exception "when honoring the dictates of [employees' religious beliefs] would cause the employer substantial economic burdens," *id.* at 709–10; and no exception "when the employer's compliance would require the imposition of significant burdens on other employees required to work in [their] place," *id.* at 710. Moreover, as in *Thornton*, the Rule's bar on even asking a job applicant whether they are willing to perform such duties, *see* 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2), effectively forces Plaintiffs' members and entire health care systems to adopt a belief system "unilaterally designate[d]" by any employee, 472 U.S. at 709. In short, by its terms, the Rule "imposes on employers and employees an absolute duty to conform their business practices to the particular religious practices of the employee." *Id.*

Given that the Rule appears to preclude consideration of any interests other than those of the objecting employee, the burden the Rule imposes on *nonbeneficiaries* is significant. *See, e.g., Cutter v. Wilkinson*, 544 U.S. 709, 720 (2005) (holding that "courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries"); *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 739 (2014) (Kennedy, J. concurring) (recognizing religious accommodation must not "unduly restrict other persons, such as employees, in protecting their own interests"); *Barber v. Bryant*, 193 F. Supp. 3d 677, 721 (S.D. Miss. 2016) (holding a law

“violates the First Amendment” when “its broad religious exemption comes at the expense of other citizens”), *rev’d on standing grounds*, 860 F.3d 345 (5th Cir. 2017).

The Rule goes so far as to even suggest that actions taken by an employer to ensure that patients are aware of the fact that someone on staff has an objection to providing certain information or services to which the patient is legally and ethically entitled could (subject to undisclosed criteria left entirely to HHS discretion) constitute discrimination against the objecting employee. *See* 84 Fed. Reg. at 23,192.²⁵ Moreover, faced with an employee’s refusal to provide services, Plaintiffs may have no choice but to attempt to hire additional employees, re-train existing employees to take over those job functions, and/or require existing employees to cover extended shifts, hours or duties, *see* Coleman Decl. ¶¶ 55–60; Custer Decl. ¶¶ 36, 41, 43, 47; David Decl. ¶¶ 34–37; Gallagher Decl. ¶¶ 37, 55—presuming, of course, these measures are acceptable to the objecting employee and do not, in the employee’s or HHS’s view, constitute an “adverse action” or “retaliation.” *See* 84 Fed. Reg. at 23,189–93. For many of Plaintiffs’ members such measures, even if acceptable to the employee and HHS, will be financially and logistically impossible. *See* Coleman Decl. ¶¶ 55–60; Custer Decl. ¶¶ 44–45, 47; David Decl. ¶¶ 37–40; Gallagher Decl. ¶¶ 38–39. Thus, the high cost of accommodation could result in the reduction or even discontinuation of critical services. *See* Coleman Decl. ¶¶ 80–82; Custer Decl. ¶¶ 44–45; David Decl. ¶¶ 37–40; Gallagher Decl. ¶ 40. And in turn, Plaintiffs’ patients will suffer delays in obtaining services, or be unable to obtain services altogether, which could increase risk to their

²⁵ *See* 84 Fed. Reg. at 23,192 (“The employer *may* also inform the public of the availability of alternate staff or methods to provide or further the objected-to conduct, *if* doing so does not constitute retaliation or other adverse action against the objecting individual or health care entity. For example, an employer *may* post such a notice and a phone number in a reception area or at a point of sale, but may not list staff with conscientious objections by name *if* such singling out constitutes retaliation.” (emphasis added)).

health and lead to serious health complications. *See* Coleman Decl. ¶¶ 61–65, 76–79 ; David Decl. ¶¶ 37–40, 53; Gallagher Decl. ¶¶ 36–37, 40. The Rule thus contravenes the Establishment Clause by impermissibly accommodating religious beliefs to the enormous detriment of others.

II. IRREPARABLE HARM WILL ENSUE IF THE RULE IS NOT ENJOINED.

Absent an injunction, Plaintiffs and their patients face serious and irreparable harm. Irreparable harm is an “actual and imminent” injury that “cannot be remedied by an award of monetary damages.” *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 660 (2d Cir. 2015). Harm may be irreparable “where the loss is difficult to replace or measure, or where plaintiffs should not be expected to suffer the loss.” *WPIX, Inc. v. ivi, Inc.*, 691 F.3d 275, 285 (2d Cir. 2012) (citing *Salinger v. Colting*, 607 F.3d 68, 81 (2d Cir. 2010)). As explained below, enforcement of the Rule will inflict irreparable harm on Plaintiffs and their patients in at least four ways: (1) it will violate their constitutional rights; (2) it will harm Plaintiffs’ mission, operations, goodwill, and, ultimately, Plaintiffs’ ability to provide quality reproductive care to millions of mostly low-income and uninsured patients; (3) it will harm those patients’ access to reproductive services and information; and (4) it will harm the provider-patient relationship.

A. Harm from Violation of Constitutional Rights

As explained above, *supra* Part I.D.5, the Rule violates Plaintiffs’ constitutional rights by impermissibly advancing religious beliefs in violation of the Establishment Clause. Injury from an alleged violation of constitutional rights is “presumed irreparable,” *Conn. Dep’t of Envtl. Prot. v. O.S.H.A.*, 356 F.3d 226, 231 (2d Cir. 2004), and “no further showing of irreparable injury is necessary,” *Mitchell v. Cuomo*, 748 F.2d 804, 806 (2d Cir. 1984) (citation omitted); *see Jolly v. Coughlin*, 76 F.3d 468, 482 (2d Cir. 1996) (a court may properly rely on the “presumption of irreparable injury that flows from a violation of constitutional rights”).

B. Harm to Plaintiffs' Mission, Operations, and Goodwill

As explained above, the Rule's drastic departure from Title VII's balancing approach mandates that providers accommodate objecting individuals no matter the burden. *See* 84 Fed. Reg. at 23,191. As a consequence, Plaintiffs' compliance burdens are immense. Coleman Decl. ¶¶ 71–82; David Decl. ¶¶ 44–49; Gallagher Decl. ¶¶ 30–40. For example, the Rule prohibits Plaintiffs from asking job applicants whether they object to performing the required tasks for the position in question, *see* 84 Fed. Reg. at 23,263, to be codified at § 88.2(6)). Thus, Plaintiffs will be unable to avoid hiring workers who will refuse to perform services central to Plaintiffs' mission, and which they are legally and ethically obligated to provide. Coleman Decl. ¶ 53–60; David Decl. ¶¶ 30–41; Gallagher Decl. ¶¶ 44, 46–48. Plaintiffs hire for thousands of positions each year, and currently have open positions. Custer Decl. ¶¶ 39–40; David Decl. ¶¶ 29–31; Gallagher Decl. ¶ 17. As a result, if the Rule takes effect, Plaintiffs will have no way to ensure that they do not hire someone who would refuse to provide the unbiased and nondirective care, information, counseling, or referrals to which a patient is legally and ethically entitled.

Even more troublingly, the Rule would force Plaintiffs to open their doors to—and even *to compensate*—those who have a strong opposition to the services Plaintiffs provide, who, posing as job applicants, seek to sabotage Plaintiffs' operations. Should Plaintiffs attempt to thwart such saboteurs through reasonable screening questions during the interview process, the Rule would threaten to strip Plaintiffs of millions in federal funding. David Decl. ¶¶ 7–14; Gallagher Decl. ¶¶ 44–48. That someone would seek to infiltrate reproductive health facilities in this way is hardly hypothetical; it is already the case that anti-abortion activists apply for positions at Planned Parenthood affiliates in an attempt to destroy the organization from the inside. Custer Decl. ¶ 56; Gallagher Decl. ¶¶ 45–46. Plaintiffs and their patients are routinely subject to coordinated

harassment campaigns, and extreme violence against abortion providers is increasingly commonplace. Custer Decl. ¶ 57.

Even setting aside these threats, providing the unlimited accommodations that the Rule mandates would be cost-prohibitive for many of Plaintiffs' health centers. Many centers operate on tight budgets with small staffs that include just a single licensed medical provider. Custer Decl. ¶ 46 ; David Decl. ¶¶ 36–37; *see also* Coleman Decl. ¶¶ 58–60. Because grant programs can be very restrictive in how funding can be used, hiring additional staff is not an option in many instances. David Decl. ¶ 37. PPNNE, for example, has 18 clinic sites where there is only one licensed clinician at any given time, who is expected to provide a full range of reproductive health care, including contraception, emergency contraception, and medication abortion. Gallagher Decl. ¶ 38. Similarly, PHS employs only one doctor, three nurse practitioners, and one certified nurse midwife who are expected to cycle through their two clinical health centers in Brooklyn; the health center in the Eastern Parkway neighborhood in Brooklyn has, at times, only one medical provider on hand to treat patients. David Decl. ¶ 36. Therefore, even if the Rule allowed employers the flexibility to re-assign staff (which, as set forth *supra* Part I.C, it may not²⁶), these health centers cannot—as HHS naively suggests—simply rearrange or hire additional staff to ensure patients are not denied care; instead, such health centers will have little choice but to cut services and turn

²⁶ For example, the Rule states that “the voluntary acceptance of an effective accommodation of protected conduct, religious beliefs, or moral convictions, will not, by itself, constitute discrimination.” 84 Fed. Reg at 23,191. The rule further states that “staffing arrangements,” such as “non-retaliatory staff rotations,” *can* be “acceptable accommodations in certain circumstances.” *Id.* But these vague platitudes do not assist an employer trying to determine how to balance ensuring a patient receives medically necessary care and complying with Title X’s requirements, on a limited budget, without risking the loss of critical federal funding. *See* Coleman Decl. ¶¶ 55–60.

away patients. Coleman Decl. ¶¶ 71–82; Custer Decl. ¶¶ 44–45; David Decl. ¶¶ 36–42; Gallagher Decl. ¶ 40.

By the same token, the Rule will force NFPRHA’s members that are state and local governmental Title X grantees to subcontract with entities without knowing (or even being able to ask) whether an entity objects to providing essential aspects of the Title X project. Coleman Decl. ¶¶ 61–70. As such, the Rule seems designed to allow entities that refuse to provide people seeking Title X health care with the basic information, options counseling, and referrals required by law to compete on the same footing for federal money with family planning providers, such as Plaintiffs, that adhere to the law and provide full and accurate information and services to patients. Coleman Decl. ¶¶ 61–70; David Decl. ¶ 50. The Rule thus threatens to divert scarce family planning resources away from entities that provide comprehensive family planning services to organizations that refuse to provide these services. Coleman Decl. ¶¶ 61–70; David Decl. ¶ 50.

Plaintiffs will also need to divert substantial resources that would ordinarily fund patient care to provide the unqualified accommodations that the Rule demands. Moreover, due to the Rule’s contradictory, ambiguous, and onerous requirements, Plaintiffs will be forced to obtain legal counsel to determine whether and how policies must be altered; to revise employment manuals and training programs; to maintain the records the Rule requires; and to provide the mandated assurances and certifications. Custer Decl. ¶¶ 62–67; Gallagher Decl. ¶¶ 5, 54–59. These economic harms are “irreparable *per se*” because defendants have sovereign immunity against money damages. *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008); see *United States v. State of New York*, 708 F.2d 92, 93–94 (2d Cir. 1983) (finding irreparable injury where plaintiff was unable to recover damages in federal court due to the defendant’s invocation of the Eleventh Amendment).

Further, Plaintiffs have deep expertise in the care they provide and are trusted in their communities to provide high-quality and confidential care to their clients. Coleman Decl. ¶ 60; Custer Decl. ¶¶ 50–51; David Decl. ¶¶ 3, 6, 52; Gallagher Decl. ¶ 41. By limiting Plaintiffs’ ability to ensure that their employees and members continue to provide comprehensive reproductive care and information, the Rule also threatens to harm Plaintiffs’ hard-earned reputation and goodwill, Coleman Decl. ¶ 60; Custer Decl. ¶¶ 50–53; David Decl. ¶¶ 39, 52; Gallagher Decl. ¶¶ 41–43, while undermining Plaintiffs’ missions, David Decl. ¶¶ 6, 33; Gallagher Decl. ¶ 43. These harms, too, are irreparable. *See, e.g., Register.com, Inc. v. Verio, Inc.*, 356 F.3d 393, 404 (2d Cir. 2004) (irreparable harm where defendant’s “actions would cause [plaintiff] irreparable harm through loss of reputation” and “good will”); *Valle del Sol Inc. v. Whiting*, 732 F.3d 1006, 1029 (9th Cir. 2013) (irreparable harm where “organizational plaintiffs have shown ongoing harms to their organizational missions as a result of the statute”); *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016) (similar); *California v. Azar*, 2019 WL 1877392, at *8 (damaging “organizational mission to promote access to high-quality healthcare” is irreparable harm).

C. Harm to Patients’ Access to Reproductive Services and Information

As high as the cost of compliance would be, the cost of noncompliance would be astronomical. Loss of all federal funding for many of PPFA’s affiliates and NFPRHA’s members could force the discontinuation of essential services, lead to a reduction in hours, and even closure of some health centers. Coleman Decl. ¶¶ 76–78; Custer Decl. ¶ 68; David Decl. ¶¶ 26, 52; Gallagher Decl. ¶ 40. Plaintiffs’ patients—the majority of whom are low income, without health insurance, and racially and ethnically diverse, including a disproportionately high percentage of Black and Latinx patients—will suffer acutely from the resulting reduction in access to reproductive care. Coleman Decl. ¶¶ 56–60, 71–80; Custer Decl. ¶¶ 7, 26–27, 68; David Decl. ¶¶ 22, 52–53; Gallagher Decl. ¶¶ 5, 10, 62. At minimum, patients will need to travel longer

distances or wait longer to obtain needed medical care. Coleman Decl. ¶¶ 76–80; David Decl. ¶ 52; Gallagher Decl. ¶ 62. Still other patients—especially those in sparsely populated areas—will “have nowhere else to turn” and will be forced to forgo treatment altogether. Custer Decl. ¶ 7; David Decl. ¶¶ 52–53; Gallagher Decl. ¶ 62; *see* Coleman Decl. ¶¶ 59–60. Indeed, six in ten women who receive care in a Title X–funded health center report that this was the only health care they received in that year. Coleman Decl. ¶ 77. A reduction in access to reproductive health care leads to an increase in the prevalence of sexual transmitted infections, undetected cancers, and unwanted pregnancies. Coleman Decl. ¶¶ 77–79; Custer Decl. ¶¶ 17–19; David Decl. ¶¶ 39, 52; Gallagher Decl. ¶¶ 7–9.

A loss of critical reproductive services constitutes irreparable harm. *See, e.g., Pro-Choice Network of W.N.Y. v. Schenck*, 67 F.3d 377, 384 (2d Cir. 1995) (affirming finding below of “irreparable harm, including increased medical risks and the denial of constitutionally protected rights”), *aff’d in part on relevant grounds, rev’d in part*, 519 U.S. 357 (1997); *accord Harris v. Bd. of Supervisors*, 366 F.3d 754, 766 (9th Cir. 2004) (irreparable harm from pain, complications, and other adverse effects due to delayed medical treatment); *Mayor & City Council of Balt. v. Azar*, 2019 WL 2298808, at *12 (“irreparable injury occurs when the public loses medical services.”); *Oregon v. Azar*, 2019 WL 1897475, at *15 (harm to “public health in the form of an increase in sexually transmitted disease and unexpected pregnancies” is irreparable).

The Rule will also irreparably harm patients who require emergency care from others to avoid serious illness, injury, or death. As explained above, *supra* Part I.D.2, the Rule’s failure to address whether its refusal protections apply in emergency situations will embolden some to refuse to participate in emergency procedures needed to save women’s lives. In this way, the Rule threatens women with the gravest form of irreparable harm. Chasen Decl. ¶ 7.

D. Harm to the Provider-Patient Relationship

Finally, the Rule will cause additional irreparable harm by eroding trust between Plaintiffs and their patients. By empowering refusals of care and information and elevating health care workers' personal beliefs above their patients' health, the Rule would facilitate breaches of foundational medical ethics and national standards of care. Chasen Decl. ¶¶ 4–5; Coleman Decl. ¶¶ 53–55; David Decl. ¶¶ 37–40; Gallagher Decl. ¶¶ 41–43, 50. The American Medical Association's *Code of Medical Ethics* directs physicians to “[u]phold standards of informed consent and inform the patient about all relevant options for treatment, including *options to which the physician morally objects*.”²⁷ Indeed, in 2014, the Office of Population Affairs (“OPA”) of HHS, which administers the Title X program, and the Centers for Disease Control and Prevention (“CDC”) issued a joint publication “outlin[ing] how how to provide quality family planning services.” Coleman Decl. ¶¶ 5–6, 37–46. Chief among the essential attributes of quality care is a “client-centered” approach that “is respectful of, and responsive to, individual client preferences, needs, and values” and ensuring that “*client values* guide all clinical decisions.” *Id.* HHS and the CDC specifically instruct in the publication, in a section entitled “Pregnancy Testing and Counseling,” that pregnancy “test results should be presented to the client, followed by a discussion of options and appropriate referrals. Options counseling should be provided in accordance with the recommendations from professional medical associations, such as ACOG and AAP.” *Id.* It states that “[r]eferral to appropriate providers of follow-up care should be made at the request of the client” and not delayed. *Id.*

²⁷ AMA Comments; Comment Letter from Ass'n of Am. Med. Colls. (Mar. 26, 2018), <https://www.regulations.gov/document?D=HHS-OCR-2018-0002-67592> (emphasis added)

Notwithstanding the above, the Rule would impose severe sanctions against providers, like Plaintiffs, for ensuring employees' compliance with informed-consent standards and even with the federal government's own guidelines for evidence-based care. This compelled breach of professional ethics, standing alone, constitutes irreparable harm. *See, e.g., State of New York v. Schweiker*, 557 F. Supp. 354, 360 (S.D.N.Y. 1983) (finding irreparable harm where physicians' "reputation for trust" among clientele "will be damaged severely, if not effaced" by HHS rule requiring breach of ethical duty); *Advocates for Children of N. Y., Inc. v. Blum*, 529 F. Supp. 422, 423 (S.D.N.Y. 1982) (finding irreparable harm because rule would cause "irrevocable" breaches of professional ethics); *Mayor & City Council of Balt. v. Azar*, 2019 WL 2298808, at *12 (finding that "forcing . . . doctors to engage in the unethical practice of medicine" constitutes irreparable harm). Because the Rule does not obligate objecting workers to forewarn employers or patients of their objections, workers may deny care or withhold information without Plaintiffs or their patients knowing about it. As a result, some of Plaintiffs' patients will never obtain the care they need and will never learn about its availability. Coleman Decl. ¶¶ 54, 61, 64; Custer Decl. ¶ 53; David Decl. ¶¶ 33, 40; Gallagher Decl. ¶¶ 36, 50. Negative medical outcomes (and, to the extent the deprivation of treatment option information later becomes known by patients), will erode patients' trust in their medical practitioners. *See, e.g.,* Coleman Decl. ¶¶ 33–34, 60–61; David Decl. ¶¶ 31, 39; Gallagher Decl. ¶¶ 41–43, 50.²⁸

²⁸ While trust is an integral component of any provider-patient relationship, Title X patients often have a heightened need to be able to trust, understand, and rely upon the medical professionals that provide them with this safety-net care. Coleman Decl. ¶¶ 33–34, 60–61. That is because Title X patients often have a previous negative experience in navigating the health care system, as persons with low incomes have fewer personal connections to available health care professionals, and no or limited alternative options for care. *Id.* ¶¶ 33–34. Title X care touches on the most intimate and sensitive areas of life, again requiring a high degree of trust between patient and health care provider. *Id.* Thus, Title X patients especially need to be able to count on the thoroughness and sensitivity from medical providers at Title X health centers. *Id.*

III. THE BALANCE OF EQUITIES AND THE PUBLIC INTEREST FAVOR ISSUING AN INJUNCTION.

When the government is a party to a case in which a preliminary injunction is sought, the balance-of-the-equities and public-interest factors merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). Because Plaintiffs have shown that their constitutional rights will be violated, they “have also established that both the public interest and the balance of the equities favor a preliminary injunction.” *J.S.R. v. Sessions*, 330 F. Supp. 3d 731, 743 (D. Conn. 2018) (citation omitted). In addition, Plaintiffs demonstrated that the Rule violates the APA and conflicts with numerous federal statutes, and “there is generally no public interest in the perpetuation of unlawful agency action.” *See New York v. U.S. Dep’t Commerce*, 351 F. Supp. 3d 502, 676 (S.D.N.Y. 2019) (quoting *Newby*, 838 F.3d at 12). Moreover, as explained *supra* Part I.B.1, the Rule would limit Plaintiffs’ patients’ access to reproductive health care, and therefore a preliminary injunction weighs heavily in the public interest. Defendants, by contrast, will not be harmed by the issuance of an injunction, which will “preserve the relative positions of the parties.” *N. Am. Soccer League, LLC v. U.S. Soccer Fed’n, Inc.*, 883 F.3d 32, 37–38 (2d Cir. 2018). That is so particularly given that existing statutory protections, like Title VII, will remain in place, and given the absence of evidence that such protections are in any way inadequate. There is no need, let alone an urgent need, to change the status quo.

IV. NATIONWIDE RELIEF IS APPROPRIATE UNDER THE CIRCUMSTANCES.

“[W]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed.” *Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989); *cf. Texas v. United States*, 809 F.3d 134, 187–88 (5th Cir. 2015) (affirming nationwide injunction because injunction limited to one or more of the plaintiff states was likely to be “ineffective”). The ordinary result is

warranted here: Defendants should be preliminarily enjoined from implementing and enforcing the Rule nationwide. Nationwide relief is the only functional way to maintain the status quo and it is well within this Court’s broad equitable powers to grant such relief. *See generally Brown v. Plata*, 563 U.S. 493, 538 (2011) (“Once invoked, the scope of a district court’s equitable powers . . . is broad, for breadth and flexibility are inherent in equitable remedies”) (internal citations and quotations omitted).

Nationwide relief is also necessary “to provide complete relief to the [Plaintiffs].” *Madsen v. Women’s Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (quoting *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979)). Plaintiffs members operate hundreds of health centers in all 50 states, the District of Columbia, and the U.S. territories. Coleman Decl. ¶ 11; Custer Decl. ¶ 12. Moreover, given the interdependent nature of the Title X network—where funds are distributed to grantees, sub-recipients, and individual service sites, *see* Coleman Decl. ¶¶ 9–17, 24–26, 80–82—absent nationwide relief, Defendants could effectively enforce the Rule against Plaintiffs’ members, despite an injunction, by invoking the Rule against non-party Title X providers. Indeed, when these same Plaintiffs recently challenged a different set of regulations implicating the provision of non-directive pregnancy options counseling and referrals in the Title X program, issued by the same Defendants, *see supra* Part I.D.3, courts issued nationwide preliminary injunctions restraining HHS from enforcing those regulations in order to maintain the status quo. *See Oregon v. Azar*, 2019 WL 1897475, at *16; *Washington v. Azar*, 2019 WL 1868362, at *9; *see also New York v. U.S. Dep’t of Commerce*, 351 F. Supp. 3d at 677–78 (“Were the Court to hold that its injunction should apply only to Plaintiffs (whatever that would even mean given that Plaintiffs include NGOs with members in all fifty states and the District of Columbia), the Court would be drawing a line

which the agency itself has never drawn.”) (citations and internal quotation marks omitted). These principles compel a similar result here.

CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court enjoin implementation and enforcement of the Final Rule.

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