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

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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

(Caption continued on inside cover)

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

JOINT APPENDIX VOLUME II OF X

Of Counsel:

ROBERT P. CHARROW
General Counsel

SEAN R. KEVENEY
Deputy General Counsel
U.S. Department of Health & Human Services

JOSEPH H. HUNT
Assistant Attorney General

MICHAEL S. RAAB
LOWELL V. STURGILL JR.
SARAH CARROLL
LEIF OVERVOLD
Attorneys, Appellate Staff
Civil Division, Room 7226
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 532-4631
Counsel for Defendants-Appellants and Consolidated-Defendants-Appellants

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

Consolidated-Plaintiffs-Appellees,

v.

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

Defendants-Appellants,

DR. REGINA FROST AND CHRISTIAN MEDICAL AND DENTAL ASSOCIATIONS,

Intervenors-Defendants-Appellants,

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

Consolidated-Defendants-Appellants.

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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION; and PUBLIC HEALTH SOLUTIONS, INC., 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. **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

INTRODUCTION

1. Plaintiff National Family Planning & Reproductive Health Association ("NFPRHA") is a non-profit, membership organization comprised of hundreds of health care providers serving millions of low-income uninsured and underinsured patients each year in all fifty states and the District of Columbia. Among its members is Plaintiff Public Health Solutions, Inc. ("PHS"), a non-profit

health care services organization that serves more than 105,000 uninsured and underinsured clients each year in New York.[1]

2. Plaintiffs challenge a final rule promulgated by the United States Department of Health and Human Services ("HHS" or "Department") that, if allowed to take effect, will directly threaten Plaintiffs' ability to provide—and their patients' ability to access—essential, potentially life-saving medical care. Further, the challenged rule will only exacerbate health disparities in communities that already struggle to access basic services by imposing crippling costs on medical providers, such as Plaintiffs, that rely on federal funds to serve low-income patients.

3. The rule, entitled Protecting Statutory Conscience Rights in Health Care, 84 Fed. Reg. 23,170 (May 21, 2019) (to be codified at 45 C.F.R. pt. 88) ("Final Rule" or "Rule"), is scheduled to take effect on July 22, 2019 and is attached as Exhibit A.

4. The Final Rule encourages and authorizes discrimination by unlawfully granting a wide swath of institutions and individuals broad new rights to refuse to provide health care services and information. For example, to justify the Rule, HHS cited the case of Tamesha Means, who sought legal redress when she was turned away from a hospital three times in the midst of a miscarriage of a

[1] Unless otherwise specified, this Complaint refers to Plaintiff NFPRHA's members and Plaintiff PHS collectively as "Plaintiffs."

non-viable fetus, developing a life-threatening infection as a result, because the hospital's religious policies prohibited providing her the emergency abortion care she needed.[2] *See id.* at 23,176 n.27. HHS also cited the case of Rebecca Chamorro, who is seeking legal redress for being forced to undergo the additional stress, health risks, and cost of two surgical procedures, rather than a single one, because a hospital prohibited her willing doctor from performing a standard postpartum tubal ligation because it was considered sterilization.[3] *Id.* In addition, HHS cited the case of Evan Minton, who is seeking legal redress because his scheduled hysterectomy was canceled on the eve of that procedure, despite his doctor's willingness to proceed with that routine operation, because the hospital became aware he was transgender.[4] *Id.*

5. Tellingly, HHS cited each of these cases *not* because it was concerned with the physical, emotional, and dignitary harms these patients suffered when they were illegally prevented from obtaining the care they needed, but because HHS wants the Rule to be used to create more Tamesha Means, Rebecca Chamorros, and Evan Mintons.

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[2] American Civil Liberties Union, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "ACLU Comment") (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71138.

[3] *Id.*

[4] *Id.*

6. The Final Rule will also have a devastating effect on the Title X program—the nation's only federally-funded family planning program—by forcing Title X providers, including Plaintiffs, to hire and employ individuals who will withhold and obstruct access to complete, accurate, and unbiased information about abortion from their patients, and forcing Title X grantees to sub-grant these critical Title X funds to entities that will similarly withhold and obstruct access to this care.

7. Although the Rule primarily purports to interpret and implement three federal statutes, which HHS describes as "conscience-based protections," these statutes are far more limited in scope than the Rule acknowledges. Indeed, for decades Congress and HHS have balanced these statutes, which provide limited exemptions to certain institutions and individuals receiving certain federal funds, with patient safeguards and in harmony with other federal laws, such as the Title X statute. Yet despite Congress's and HHS's longstanding intention and understanding that statutes protecting religious refusals to provide health care operate as a shield, not a sword, the Rule categorically privileges providers' religiously motivated objections over the well-being of patients.

8. As set forth below, HHS lacks legal authority to promulgate the Rule. Moreover, the Rule's provisions radically expand these underlying statutes, contrary to their clear text and purpose, and in conflict with numerous other federal

statutes and the First and Fifth Amendments of the U.S. Constitution. And, in promulgating the Rule, HHS also failed to satisfy multiple requirements of the APA.

9. Each of these faults independently renders the Rule unlawful. Taken together, they demonstrate the fundamental unlawfulness and unworkability of HHS's actions.

10. Plaintiffs seek a judgment declaring the Rule in excess of statutory authority; not in accordance with law, including the U.S. Constitution; arbitrary, capricious, and an abuse of discretion; and without observance of procedure required by law. In addition, because the Rule will immediately threaten irreparable harm to Plaintiffs and their patients, Plaintiffs seek a preliminary injunction enjoining the Rule from taking effect, as scheduled, on July 22, 2019. Finally, Plaintiffs also seek an order permanently enjoining the Rule and remanding it to HHS for such further administrative proceedings as may be appropriate.

JURISDICTION AND VENUE

11. The Court has jurisdiction over the claims alleged in this Complaint pursuant to 5 U.S.C. §§ 701–706 (Administrative Procedure Act), 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 2201 (declaratory relief), and 28 U.S.C. § 2202 (injunctive relief).

12. HHS's promulgation of the Final Rule on May 21, 2019, constitutes a final agency action within the meaning of the APA, 5 U.S.C. §§ 702, 704, and therefore the Rule is judicially reviewable. Each Plaintiff is a "person" within the meaning of the APA, 5 U.S.C. § 551(2), and is authorized to bring suit under that statute. 5 U.S.C. § 702.

13. Venue in this judicial district is proper under 28 U.S.C. § 1391(e) because Plaintiff PHS resides in this district.

PARTIES

14. Plaintiff NFPRHA is a national, nonprofit membership organization established to ensure access to voluntary, comprehensive, and culturally sensitive family planning and sexual health care services, and to ensure reproductive freedom for all. NFPRHA represents more than 850 health care organizations and individuals, primarily health care professionals or practitioners, in all fifty states, the District of Columbia, and the territories. NFPRHA's organizational members include state, county, and local health departments; private, nonprofit family planning organizations; family planning councils; hospital-based clinics; and Federally Qualified Health Centers.

15. The vast majority of NFPRHA's organizational members, and their network of health centers, receive funds through HHS and are therefore subject to the Rule. For example, among other members, NFPRHA represents 67 of 90

recipients of grants under Title X of the Public Health Service Act ("PHSA"), which authorizes grants for family planning projects that benefit low-income, uninsured, underinsured, and other women, men, and adolescents. NFPRHA's Title X-grantee members operate or fund a network of more than 3,500 health centers that provide high-quality family planning and other preventive health services to more than 3.7 million low-income, uninsured, or underinsured individuals each year—roughly 94 percent of all patients served in Title X-funded health centers nationwide.

16. NFPRHA members reasonably fear that compliance with the Rule will prevent them from continuing to provide the same high-quality, voluntary, and informed reproductive health care they currently provide to their patients. At the same time, failure to comply with the Rule could subject NFPRHA members to the loss of hundreds of millions of dollars of federal funding without which they cannot operate. NFPRHA members also reasonably fear that the Rule will threaten the health of the patients they serve by impeding access to comprehensive reproductive health services, other health services (*e.g.*, LGBT-related care), and emergency care.

17. NFPRHA sues on behalf of all current and future members that receive federal funds that subject them to the Rule, and on behalf of those

members' sub-recipients, employees, staff, volunteers, servants, officers, agents, and patients.

18. Plaintiff PHS is a not-for-profit corporation organized under the laws of New York and a NFPRHA member, with its headquarters located at 40 Worth Street in New York City. PHS is dedicated to developing, implementing, and advocating for dynamic solutions to prevent disease and improve community health and serves 105,000 individuals and families through its direct services programs each year. Together with its two sexual and reproductive health centers and those of its delegates, PHS provides prenatal and family planning services to over 40,000 at-risk patients each year through a network of licensed health centers in New York City. The organization serves primarily low-income patients; 70% are below the federal poverty level ("FPL"), and over three-quarters are below 200% of the FPL.[5] PHS serves a diverse patient group, including adolescents and adults, LGBT individuals, immigrants, and people of different races and ethnic groups.

19. PHS receives a $4.6 million Title X grant, more than 60% of which ($2.8 million) is dispersed to five other organizational sub-recipients (also

[5] In 2019, the FPL for a single person is $12,490, and is $25,750 for a family of four in the 48 contiguous states and District of Columbia. Annual Update of the HHS Poverty Guidelines, 84 Fed. Reg. 1167 (Feb. 1, 2019). In 2019, 200% of the FPL for a single person in the 48 contiguous states and District of Columbia is $24,980 per year, and is $51,500 for a family of four.

sometimes referred to as delegate agencies or delegates) to provide family planning services to low-income and uninsured New Yorkers. PHS's patients are dependent on publicly subsidized health facilities to receive essential medical care. These services include the provision of contraceptives, reproductive health education, gynecological exams, prenatal care, STD and HIV testing and treatment, and mental health services, as well as pregnancy testing, options counseling, and referrals upon request.

20. In total, PHS receives $182 million in funds that originate from the federal government—$138 million of which originates from HHS, with PHS receiving $31.4 million of those funds directly from HHS—all of which could be at risk if PHS or any of its delegates are found to be out of compliance with the Final Rule. Without this publicly funded care, PHS's clients and its sub-recipients' clients would likely lack access to this critical, preventive care altogether.

21. PHS reasonably fears that compliance with the Rule will prevent them (including their delegates) from continuing to provide the same high-quality, voluntary, and informed health care to their patients. Failure to comply with the Rule, however, could subject PHS to the loss of millions of dollars in federal funding, which funds almost all of the family planning services the organization provides. PHS also reasonably fears that the Rule will threaten the health of its patients by impeding access to comprehensive care and emergency services.

22. PHS sues on its own behalf as well as its employees, staff, volunteers, servants, officers, agents, and patients.

23. Defendant the Department of Health and Human Services is a cabinet agency within the executive branch of the United States government and is an agency within the meaning of 5 U.S.C. § 552(f). HHS promulgated the Final Rule and is responsible for its enforcement.

24. Defendant Alex M. Azar II is the Secretary of Health and Human Services and is sued in his official capacity, as are his successors.

25. Defendant Office for Civil Rights ("OCR") is the office within HHS to which HHS has delegated its claimed responsibility for enforcing the Final Rule. OCR thus claims authority to initiate compliance reviews, conduct investigations, supervise and coordinate compliance by HHS and its components, and use other enforcement tools to address alleged violations and resolve complaints.

26. Defendant Roger Severino is the Director of the Office for Civil Rights at HHS. Defendant Severino is sued in his official capacity, as are his successors.

RELEVANT FEDERAL STATUTORY BACKGROUND

27. To understand the impact of the Final Rule on Plaintiffs and their patients, it is necessary to understand the numerous federal laws that govern the provision of health care, including health care programs funded by HHS.

Title X of the Public Health Services Act

28. The Title X program has been an essential piece of the U.S. health care system since 1970. Pub. L. No. 91-572, 84 Stat. 1504 (1970).

29. As noted above, Plaintiff NFPRHA's members, including Plaintiff PHS, serve 94% of patients obtaining Title X services nationwide.

30. Title X grants support family planning projects that offer "a broad range of acceptable and effective family planning methods and services" to patients on a voluntary basis, 42 U.S.C. § 300(a), creating a nationwide network of Title X health care providers.

31. Title X gives those with incomes below or near the federal poverty level free or low-cost access to clinical professionals, contraceptive methods and devices, and testing and counseling services related to reproductive health, including pregnancy testing and counseling.

32. The Title X program served more than four million patients in 2017.

33. Congress has expressly recognized that, in this area of individuals' reproductive decision-making, 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).

34. Accordingly, Congress has repeatedly and explicitly forbidden HHS from limiting Title X patients' access to medical information; from using Title X funds for involuntary care or directive, non-neutral counseling when a patient is pregnant; or from creating any other unreasonable barriers to patients' ability to make their own informed decisions about, and gain timely access to, the medical care they seek.

35. Indeed, every year from 1996 to the present, in making appropriations for Title X, Congress has reiterated that it must fund only *voluntary* family planning projects. This echoes two sections of the original Title X enactment. *See* 42 U.S.C. §§ 300, 300a-5. In addition, every year from 1996 to the present, Congress has mandated that within the Title X program, "all pregnancy counseling shall be nondirective." *See* HHS Appropriations Act, 2019, Pub. L. No. 115-245, 132 Stat. 2981, 3070-71 (2018).

36. Moreover, Title X providers are obligated to provide referrals upon request, particularly in the context of pregnancy testing and counseling. While Title X projects do "[n]ot provide abortion as a method of family planning," a project must:

(i) Offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:
(A) Prenatal care and delivery;
(B) Infant care, foster care, or adoption; and
(C) Pregnancy termination.

(ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.

42 C.F.R. § 59.5(a)(5).

Sections 1554 and 1557 of the Affordable Care Act

37. In the Patient Protection and Affordable Care Act ("PPACA"), which became law in 2010, Congress specifically identified rulemaking that is off limits for HHS, including in the agency's administration of Title X.

38. Section 1554 of the PPACA prohibits the Secretary of HHS from "promulgat[ing] any regulation" that "creates any unreasonable barriers" or "impedes timely access to health care services"; interferes with medical providers' communications with patients "regarding a full range of treatment options"; restricts "the full disclosure of all relevant information to patients"; or violates "the ethical standards of health care professionals." 42 U.S.C. § 18114.

39. Section 1557 is the non-discrimination provision of the PPACA. Section 1557 prohibits any health program or activity, any part of which receives

funding from HHS, or any health program or activity that HHS itself administers, from discriminating on the basis of race, color, national origin, sex, age, or disability. *See id.* § 18116(a).

Title VII of the Civil Rights Act of 1964

40. For decades, Title VII of the Civil Rights Act of 1964 ("Title VII") has required employers, including health care providers, to make reasonable accommodations for current and prospective employees' religious beliefs so long as doing so does not pose an "undue hardship" to the employer. 42 U.S.C. §§ 2000e(j), 2000e-2(a).

41. An "undue hardship" occurs under Title VII when the accommodation poses a "more than *de minimis* cost" or burden on the employer's business. *Trans World Airlines, Inc. v. Hardison*, 432 U.S. 63, 84 (1977); EEOC Guidelines, 29 C.F.R. § 1605.2(e)(1).

The Emergency Medical Treatment and Active Labor Act ("EMTALA")

42. EMTALA states, *inter alia,* that any hospital that receives Medicare funds and operates an emergency department must stabilize any individual determined to have an emergency medical condition. 42 U.S.C. § 1395dd(b). EMTALA defines "to stabilize" to mean "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[.]" *Id.* § 1395dd(e)(3)(A).

Federal Refusal Statutes

43. The Rule's purported purpose is to "implement[]" and "enforce[]" a collection of statutory provisions. *See* 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.1). Primary among those are the three federal laws relevant to the underlying action: the Church Amendments, 42 U.S.C. § 300a-7; the Coats-Snowe Amendment, *id.* § 238n; and the Weldon Amendment, Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, § 507(d), 131 Stat. 135, 562 (collectively, "the federal refusal statutes").

The Church Amendments

44. Originally sponsored by Senator Frank Church of Idaho, the Church Amendments refer to a series of laws passed in the 1970s.

45. Subsections (b) and (c)(1) were enacted in 1973 following a district court decision that enjoined a Catholic hospital from preventing a physician from performing a voluntary sterilization procedure on the grounds that the hospital's receipt of certain federal funds meant it was acting under the color of state law. *See* H.R. Rep. No. 93-227, at 1473 (1973) (citing *Taylor v. St. Vincent's Hospital*, 369 F. Supp. 948, 950 (D. Mont. 1973)).

46. In response to this and similar instances, Congress passed a law to make clear that the receipt of certain federal funds does not, in itself, obligate individuals or entities to provide abortion or sterilization services. *See, e.g.*, 119 Cong. Rec. S9599-601 (daily ed. Mar. 27, 1973) (statement of Sen. Church).

47. Church Subsection (b) thus provides that the receipt of federal funds under the PHSA[6] does not authorize a court or other "public official" to require an individual "to perform or assist in the performance of any sterilization procedure or abortion" if it would be "contrary to his religious beliefs or moral convictions," or an entity "to make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions" or "provide any personnel for the performance or assistance in the performance of any sterilization procedure or abortion if the performance or assistance in the performance of such procedures or abortion by such personnel would be contrary to the religious beliefs or moral convictions of such personnel." 42 U.S.C. § 300a-7(b).

[6] As the Final Rule acknowledges, although subsections (b), (c), and (e) of the Church Amendments also apply to recipients of funds under the Community Mental Health Centers Act, and subsections (b) and (c) to recipients of the Developmental Disabilities Services and Facilities Construction Act, those statutes have since been repealed. Thus, the Final Rule only purports to implement Church subsections (b) and (c)(1) with respect to recipients of PHSA funding. *See* 84 Fed. Reg. 23,171 n.3.

48. Subsection (c)(1) of the Church Amendment, also enacted in 1973, prohibits recipients of PHSA funds from "discriminat[ing] in the employment, promotion, or termination of employment" or "in the extension of staff or other privileges" to "any physician or other health care personnel" because the individual performed a sterilization or abortion or refused to perform such a procedure on the grounds it "would be contrary to his religious beliefs or moral convictions," or because of the individual's "religious beliefs or moral convictions respecting sterilization procedures or abortions." *Id.* § 300a-7(c)(1).

49. During debate over these provisions, Senator Church made clear it was not his intent to permit "a nurse or attendant somewhere in the hospital who objected" to an abortion or sterilization to "*veto the rights of a physician and the rights of patients* to have a procedure which the Supreme Court has upheld," nor was the "intention . . . 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. S9597 (daily ed. Mar. 27, 1973) (emphasis added).

50. Senator Church also clarified that "this amendment would not in any way affect sterilizations or abortions in publicly owned hospitals," *id.* at S9600, and that "[i]n an emergency situation—life or death type—no hospital, religious or not, would deny such services," *id.* at S9601.

51. Congress subsequently passed subsections (c)(2) and (d) of the Church Amendment in 1974. At that time, the Senate was considering a law, the National Research Act, which addressed funding for biomedical and behavioral research and sought to ensure that such research projects involving human subjects were conducted ethically. *See* 119 Cong. Rec. S29,213-32 (daily ed. Sept. 11, 1973).

52. To that end, subsection (c)(2) prohibits any recipient of "a grant or contract for biomedical or behavioral research under any program administered by [HHS]" from engaging in the same forms of discrimination as prohibited by (c)(1) because of a refusal

> to perform or assist in the performance of any such service or activity on the grounds that his performance or assistance in the performance of such service or activity would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting any such service or activity.

42 U.S.C. § 300a-7(c)(2).

53. Subsection (d), which was also adopted as part of the National Research Act, 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).

54. Subsection (e), enacted in 1979, prohibits recipients of "any grant, contract, loan, loan guarantee, or interest subsidy" under the PHSA or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 from discriminating against applicants to training programs due to reluctance or willingness to participate in abortions or sterilizations "contrary to or consistent with the applicant's religious beliefs or moral convictions." *Id.* § 300a-7(e).

The Coats-Snowe Amendment

55. In 1996, Congress adopted the Coats-Snowe Amendment to establish a narrow right to refuse to participate in medical training for abortion.

56. Congress was motivated to act in response to a decision by the Accrediting Council for Graduate Medical Education to require OB/GYN residency programs to provide opt-out abortion training beginning January 1, 1996.

57. The Coats-Snowe Amendment specifically prohibits the federal government or "any State or local government that receives Federal financial assistance" from discriminating against "any health care entity"—defined to include "an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions"—that refuses to perform abortions, undergo training in how to perform abortions, provide referrals for abortions or such training, or "make arrangements" for such activities, or that

attended a postgraduate training program that did not include abortion training. *Id.* § 238n(a), (c)(2).

58. The Amendment also requires federal, state, and local governments to accredit training programs that would otherwise be accredited but for their refusal to provide or refer for abortions, but allows accrediting agencies to "establish[] standards of medical competency applicable only to those individuals who have voluntarily elected to perform abortions." *Id.* § 238n(b).

59. Senator Coats clarified that the Amendment was not intended to interfere with training for, and therefore the provision of, emergency abortion care. *See* 142 Cong. Rec. 5165 (daily ed. Mar. 19, 1996) (statement of Senator Coats) ("[A] resident needs not to have performed an abortion on a live, unborn child, to have mastered the procedure to protect the health of the mother if necessary."); *id.* at 5166 (statement of Senator Coats) ("[T]he similarities between the procedure which [residents] are trained for, which is a D&C procedure, and the procedures for performing an abortion are essentially the same and, therefore, [residents] have the expertise necessary, as learned in those training procedures, should the occasion occur and an emergency occur to perform that abortion.").

The Weldon Amendment

60. The Weldon Amendment has been added to each appropriations act for the Departments of Labor, HHS, and Education since Fiscal Year 2005.

61. The Weldon Amendment prohibits appropriated funds from being made available to any "Federal agency or program, or to a State or local government," if it "subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions." Pub. L. 115-31, Div. H, § 507(d)(1).

62. The 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." *Id.* § 507(d)(2).

63. Representative Weldon directly addressed concerns about whether the Amendment applies to emergencies or whether it overrides EMTALA. He said:

> Hyde-Weldon does nothing [to deny women "access to an abortion needed to save the life of the mother"]. It ensures that in situations where a mother's life is in danger a health care provider must act to protect the mother's life.
>
> In fact, Congress passed the Federal Emergency Medical Treatment and Active Labor Act (EMTALA) forbidding critical-care health facilities to abandon patients in medical emergencies, and requires them to provide treatment to stabilize the medical condition of such patients - particularly pregnant women.

151 Cong. Rec. H177 (daily ed. Jan. 25, 2005); *see also* 150 Cong. Rec. H6817 (daily ed. Sept. 8, 2004) (statement of Representative Weldon) ("The policy simply states that health care entities should not be forced to provide elective abortion.").

* * *

64. No provision of the Church, Coats-Snowe, or Weldon Amendments, nor of any other statute, authorizes HHS to promulgate force-of-law regulations to interpret the federal refusal statutes.

2008 RULEMAKING UNDER THE FEDERAL REFUSAL STATUTES

65. The substance of the Church, Coats-Snowe, and Weldon Amendments has remained unchanged for years. HHS did not attempt to issue guidance or promulgate regulations interpreting or implementing these laws until 2008.

66. In August 2008, HHS published a proposed rule purporting to implement the federal refusal statutes. *See* Ensuring that Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 50,274 (Aug. 26, 2008). An earlier, leaked draft of the proposed rule contained a definition of abortion that seemed to cover many common forms of hormonal birth control. This re-definition of abortion sparked immediate controversy and was not included in the rule HHS ultimately proposed in 2008.

67. Even without the re-definition of abortion, the 2008 proposed rule engendered widespread condemnation. Leading medical associations, U.S. Senators, members of Congress, state attorneys general, and thousands of others counted among the 200,000 commenters who weighed in during an abbreviated

30-day comment period, overwhelmingly raising substantial issues with the proposal and urging HHS not to finalize the rule.

68. On December 19, 2008, HHS published a final regulation, which was virtually identical to its proposal. *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) (codified at 45 C.F.R. pt. 88) ("2008 Rule").

69. The 2008 Rule was immediately subject to litigation by advocacy groups (including Plaintiff NFPRHA) and multiple states raising, *inter alia*, HHS's lack of rulemaking authority under the federal refusal statutes; the rule's unreasonable definitions, interpretations, and attempted expansion of the Church, Coats-Snowe, and Weldon Amendments; its fundamental conflicts with the U.S. Constitution and other federal laws; and the rule's multiple APA violations, including HHS's failure to address significant public comments. *See, e.g.*, *Nat'l Family Planning & Reprod. Health Ass'n v. Leavitt*, No. 09-cv-00055 (D. Conn. Jan. 15, 2009); *State of Conn. v. United States*, No. 09-cv-00054 (D. Conn. Jan. 15, 2009); *Planned Parenthood Fed'n of Am. v. Leavitt*, No. 09-cv-00057 (D. Conn. Jan. 15, 2009).

70. In March 2009, prior to the resolution of the lawsuits, HHS proposed to rescind the 2008 Rule in its entirety. 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). The lawsuits were stayed pending the outcome of rulemaking. *See State of Conn. v. United States*, No. 09-cv-00054.

71. In 2011, HHS promulgated a final rule rescinding the 2008 Rule, though not in its entirety. *See* Regulation for the Enforcement of Federal Health Care Provider Conscience Protector Laws, 76 Fed. Reg. 9968, 9976-77 (Feb. 23, 2011) (codified at 45 C.F.R. pt. 88) ("2011 Rule").

72. HHS stated it was important to rescind the majority of the 2008 Rule because, in "attempting to clarify the Federal health care provider conscience statutes," HHS had "instead led to greater confusion," *id.* at 9969, and could "negatively affect the ability of patients to access care," *id.* at 9974. In particular, HHS explained that it was rescinding the 2008 Rule to "clarify [the] mistaken belief that [it had] altered the scope of information that must be provided to a patient by their provider in order to fulfill informed consent requirements." *Id.* at 9973. HHS also stated that the protections in the 2008 Rule should not "allow providers to refuse to provide medical care to an individual because the individual engaged in behavior the health care provider found objectionable." *Id.* at 9973–74.

73. On the other hand, the 2011 Rule stated that "the Department supports clear and strong conscience protections for health care providers," *id.* at 9969, and

that it would therefore retain the provision of the 2008 Rule designating OCR to receive and coordinate the handling of complaints based on the federal refusal statutes, *id.* at 9976–77. However, HHS deleted all references to the Church, Coats-Snowe, and Weldon Amendments as sources of rulemaking authority for this provision, stating that "none of these statutory provisions require promulgation of regulations for their interpretation or implementation." *Id.* at 9975.

2018 RULEMAKING AND THE FINAL RULE

2018 Notice of Proposed Rulemaking

74. Between 2008 and January 2018, OCR received fewer than fifty complaints alleging discrimination against health care providers in violation of federal refusal statutes, the large majority of which were filed since the November 2016 election. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3886 (Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88). To place that figure into context, OCR in total received over 30,000 complaints of discrimination against *patients* in fiscal year 2017 alone.[7]

75. There is no evidence OCR in any way mishandled or failed to take seriously the limited number of complaints alleging violations of the federal refusal statutes; similarly, there is no evidence that the federal refusal statutes have failed

[7] *Putting America's Health First: FY 2019 Budget*, Dep't of Health & Human Services, 124 (Feb. 19, 2018), https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf.

to adequately protect those who have a religious or moral objection to providing certain health care.[8]

76. Despite the lack of evidence of a problem, on January 18, 2018, HHS announced the creation of a new "Conscience and Religious Freedom Division" within HHS charged with protecting health care providers who refuse to provide health care.[9]

77. The next day, on January 19, 2019, the Office of Information and Regulatory Affairs ("OIRA") released the proposed version of the Final Rule ("Proposed Rule") to the public.

78. On January 26, 2018, HHS published its Notice of Proposed Rulemaking in the Federal Register, triggering a 60-day public comment period. 83 Fed. Reg. 3880.

79. As in 2008, by providing expansive definitions of key statutory terms, the Proposed Rule transformed the very limited exemptions for specified health care providers and entities under the federal refusal statutes into a sweeping right for virtually any entity in receipt of certain government funding, or individual

[8] *See, e.g.*, Letter from Linda Colon, Regional Manager, HHS, to Matthew Bowman & David Reich, M.D. (Feb. 1, 2013), http://www.adfmedia.org/files/Cenzon-DeCarloHHSfindings.pdf.

[9] Office for Civil Rights, *HHS Announces New Conscience and Religious Freedom Division*, Dep't Health & Human Services (Jan. 18, 2018), https://www.hhs.gov/about/news/2018/01/18/hhs-ocr-announces-new-conscience-and-religious-freedom-division.html.

employed by that entity, to refuse to provide a broad range of procedures, services, and information, including in cases of medical emergency.

80. The Proposed Rule also created and assigned to OCR broad and coercive enforcement powers that would allow HHS to cut off or claw back potentially billions of dollars of federal health care funds for alleged failure to comply with the rule.[10]

81. In one notable change from the 2008 proposed rule, the new Proposed Rule did not purport to extend the federal refusal statutes dealing with abortion to permit refusals to provide, assist in the performance of, or provide referrals for contraceptives.

82. HHS justified the Proposed Rule by citing as the "problem" cases in which patients sought remedies after being denied health care—to the detriment of their health and often for discriminatory reasons. *See* 83 Fed. Reg. at 3888-89, n.36. It is plain that HHS sought to make these types of refusals *more* commonplace under the Rule.

83. HHS received more than 72,000 comments at the conclusion of the 60-day public comment period on the Proposed Rule, a substantial majority of them negative.

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[10] *See generally* ACLU Comment; National Family Planning & Reproductive Health Association, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "NFPRHA Comment") (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70260.

84. Comments opposing the Proposed Rule were submitted by numerous organizations and individuals, including:

- Medical professional associations, such as the American Academy of Family Physicians, American Academy of Pediatrics, American Academy of Pharmacists, American College of Obstetricians and Gynecologists, American Hospital Association, American Medical Association[11];
- States and cities, as well as state public health and insurance departments[12];

[11] *E.g.*, American Academy of Family Physicians, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "American Academy of Family Physicians Comment") (Mar. 29. 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-34646; American Academy of Pediatrics, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "American Academy of Pediatrics Comment") (Mar. 29, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71048; American Academy of Pharmacists, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "American Academy of Pharmacists Comment") (Mar. 29. 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-65085; American College of Obstetricians and Gynecologists, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "American College of Obstetricians and Gynecologists Comment") (Mar. 29. 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70647; American Hospital Association, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "American Hospital Association Comment") (Mar. 29. 2018) https://www.regulations.gov/document?D=HHS-OCR-2018-0002-65761; American Medical Association, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "American Medical Association Comment") (Mar. 29. 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70564.

[12] *E.g.*, City of New York, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "City of New York Comment") (Mar. 29, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71028; City of Miami Beach, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care

- State officials, including at least 20 State Attorneys General; associations of state health officials such as the National Association of County and City Health Officials and the National Alliance of State & Territorial AIDS Directors[13];
- Former EEOC officials[14]; and
- Federal officials, including more than 100 members of the House of Representatives.[15]

(hereinafter "City of Miami Beach Comment") (Mar. 29, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-32207; State of Washington Department of Health, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "State of Washington Comment") (Mar. 29, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-65558; Dave Jones, State of California Insurance Commissioner, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "Jones Comment") (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70956.

[13] State Attorneys General, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "State Attorneys General Comment") (Mar. 29, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70188; National Association of County and City Health Officials, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "National Association of County and City Health Officials Comment") (Mar. 29, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70228; HIV Medical Association, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "HIV Medical Association Comment") (Mar. 29, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-69268.

[14] [14] Former EEOC Officials, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "Former EEOC Officials Comment") (Mar. 29, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71178.

[15] Members of U.S. House of Representatives, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "House of Representatives' Comment") (Mar. 29, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70254.

85. These comments identified myriad ways in which the Proposed Rule would improperly expand the reach of the federal refusal statutes and wreak havoc for patients and providers across the country. In particular, numerous comments identified the conflict between the Proposed Rule and the Title X program, as well as numerous other federal laws.

86. Prior to the promulgation of the Final Rule, on May 1, 2019, OCR revised its website to include a new mission statement. Whereas OCR's longstanding mission had been to "improve the health and well-being of people across the nation" and "to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination,"[16] the revised statement declared OCR's intention to operate as a "law enforcement agency," prioritizing the enforcement of federal refusal statutes.[17]

The Final Rule

87. On May 21, 2019, HHS published the Final Rule.

[16] Rachel Bergman, *HHS Office for Civil Rights Overhauled Its Mission and Vision Sstatements on Its Website*, Sunlight Foundation (May 1, 2019), https://sunlightfoundation.com/2019/05/01/hhs-office-for-civil-rights-overhauled-its-mission-and-vision-statements-on-its-website/.

[17] Dep't of Health & Human Servs., *OCR Mission and Vision*, https://www.hhs.gov/ocr/about-us/leadership/index.html (last accessed May 6, 2019) (listing as one of three OCR priorities "Ensuring that HHS, state and local governments, health care providers, health plans, and others comply with federal laws that guarantee the protection of conscience and free exercise of religion and prohibit coercion and religious discrimination in HHS-conducted or funded programs.").

88. The Final Rule sets forth various requirements and prohibitions purporting to interpret and implement the federal refusal statutes. *See* 84 Fed. Reg. 23,170 at 23,264–69

89. As set forth in the examples below, the Final Rule provides broad and unprecedented definitions of key statutory terms that have the effect of expanding the scope of the federal refusal statutes beyond their plain meaning and Congressional intent. *See id.* at 23,264–69.

90. The Rule also purports to grant broad enforcement authority to OCR, *see id.*, including the authority to strip Plaintiffs of millions of dollars in federal funding, *id.* at 23,269–72.

91. As in the Proposed Rule, the Final Rule cited cases where individuals had sought legal redress after being denied essential, even emergency, care as a justification for the Rule. *See id*. at 23,176.

The Final Rule's Definitions

"Discriminate" or "Discrimination"

92. The Rule provides a broad and unfounded definition of the terms "discriminate" and "discrimination" for purposes of Church Subsection (c) and the Coats-Snowe and Weldon Amendments, set forth *supra* in ¶¶ 48–52, 55–63, which

goes well beyond the common understanding of those terms and Congressional intent.[18]

93. **First**, the Final Rule expressly rejects Title VII's longstanding framework for balancing religiously motivated refusals to provide care with patient safety. *See id.* at 23,191 (explaining that the Rule "will differ from Title VII . . . by not incorporating the additional concept of an 'undue hardship' exception for reasonable accommodations").

94. Instead, the Rule's new definition of "discriminate" or "discrimination" eliminates any notion of a "reasonable accommodation" and instead imposes a virtually absolute obligation to accommodate employee objections, regardless of impact, giving employees carte blanch to refuse to do core aspects of their job and yet stay in their role. For example, the Final Rule:

- prohibits covered entities from asking job applicants whether they are willing to perform any aspect, even essential elements, of the position, *id.* at 23,263 (to be codified at 45 C.F.R. § 88.2);
- prohibits covered entities from asking existing employees if they object to performing a given job function more than once per calendar year without "persuasive justification" (undefined), *id.*; and

[18] *See* ACLU Comment at 9, 11; NFPRHA Comment at 8–10.

- prohibits covered entities from taking any steps to protect patient access to medical services and information, even in emergencies, unless those steps are "voluntarily accept[ed]" by the objecting employee, do not require any "additional action" from the objecting employee, or do not otherwise constitute an "adverse action" (undefined) against the objecting employee, *id.*

95. This dramatic revision of the legal obligations of covered entities, such as Plaintiffs, will make it difficult, if not impossible, for health care providers to ensure patients continue to receive the care they need and to which they are legally entitled.

96. For example, even though Congress has repeatedly affirmed that providing Title X patients with comprehensive and unbiased information about their pregnancy options is a core aspect of the program, *see supra* ¶¶ 30–36, the new definition of "discriminate" would make it impossible for Plaintiffs to require their employees to perform this essential job function, or even ask job applicants whether they would be willing to do so. *See* 84 Fed. Reg. at 23,265 (to be codified at 45 C.F.R. § 88.3(a)(2)(iv)).

97. Likewise, under the Rule, a hospital could not prevent its employees from withholding or otherwise obstructing transgender patients from obtaining gender-affirming surgeries, or even information about those surgeries, because

those surgeries can be considered "sterilizing" procedures. *See id.* Nor could hospitals even inquire of job applicants whether they would withhold or otherwise obstruct patients from obtaining such lawful care. *See id.*

98. The definition's categorical accommodation requirement was not included in the proposed rule. *See* 83 Fed. Reg. at 3923–24 (proposed definition of discrimination). Accordingly, HHS provided no notice of and solicited no comments on this unprecedented expansion of the meaning of the terms "discriminate" or "discrimination."

99. **Second**, the Final Rule explains that the definition is intended to prohibit state and local governments that receive federal funds from enforcing "neutral laws of general applicability" even though they are not by their "text, history, motive, or operation targeted at the protected activity of religious exercise." 84 Fed. Reg. at 23,189–90.

100. For example, even though Congress has repeatedly affirmed that providing Title X patients with comprehensive and unbiased information about their pregnancy options is a core aspect of the program, *see supra* ¶¶ 30–36, under the Rule a state or local governmental Title X grantee could no longer require sub-recipients to comply with Title X's statutory requirements. *See* 84 Fed. Reg. at 23,265 (to be codified at 45 C.F.R. § 88.3(b), (c)).

101. Similarly, even though Congress never intended the federal refusal statutes to apply in emergencies, *see supra* ¶¶ 49, 59, 63, under the Rule, a state or local government that receives federal funds—and even the federal government itself—could not enforce EMTALA (or similar state laws) against hospitals that refuse to provide emergency abortions. *See id.* at 23,265 (to be codified at 45 C.F.R. § 88.3(b), 88.3(c)).

"Assist in the Performance"

102. The Rule's broad and unfounded definition of "assist in the performance" for purposes of the Church Amendments, as set forth in *supra* ¶¶ 47–53, includes 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." *Id.* at 23,263.

103. In direct contravention of Congress's intent in passing the Church Amendments, *see supra* ¶¶ 49–50, and the plain meaning of the term, this new definition is so broad that it means an individual could refuse to, *e.g.*, schedule an appointment, admit a patient to a health care facility, update information in a patient's chart, transport a patient from one part of the facility to another, or even

take a patient's temperature as any of those activities has a "specific, reasonable, and articulable connection" to "furthering" the service. *Id.* at 23,263.[19]

104. Moreover, despite the fact that Congress has repeatedly affirmed that providing Title X patients with comprehensive and unbiased information about their pregnancy options is a core aspect of the program, the definition of "assist in the performance" would allow an individual to withhold information about abortion from a patient, even in an emergency. Even monitoring or otherwise ensuring that a Title X sub-recipient is complying with the legal requirement to provide nondirective pregnancy options counseling, including abortion referral, could be considered having a "specific, reasonable, and articulable connection" to "furthering" abortion. This only further impedes the ability of Title X providers to ensure they provide the full scope of services mandated by law and of Title X grantees to ensure that their sub-recipients comply with the legal requirements of the Title X program, and ensure that their patients are provided proper care.

105. In addition, Church subsections (c)(2) and (d) are not limited to PHSA funds and apply beyond abortion and sterilization to "any lawful health service [activity]" or "any part of a health service program." *Id.* at 23,265. As such, the Rule's definition of "assist in the performance" could embolden individuals to refuse to provide a broad range of other health care services and information,

[19] *See* ACLU Comment at 7–8, 14–16, 18; NFPRHA Comment at 4–5, 8.

including about contraceptives or LGBT-related care, even though Sections 1554 and 1557 of the PPACA prevent HHS from imposing barriers and sanctioning discrimination in health care access.

"Referral" and "Refer for"

106. The Rule's broad and unfounded definition of the terms "referral" and "refer for" for purposes of the Coats-Snowe and Weldon Amendments includes the provision of *any* "information in oral, written, or electronic form," if "the purpose or reasonably foreseeable outcome" of providing that information is "to assist a person in receiving funding or financing for, training in, obtaining, or performing" a health care service or procedure. *Id.* at 23,264. However, this understanding of "referral" or "refer for," where even telling a patient that abortion is an option becomes a referral under the Rule, contravenes the ordinary understanding of the term.[20]

107. As above, despite the fact that Congress has repeatedly affirmed that providing Title X patients with comprehensive and unbiased information about their pregnancy options is a core aspect of the program, this definition would allow an individual to withhold information about abortion from a patient, even in an emergency. Thus, as above, this new definition further impedes the ability of state and local governmental Title X providers to ensure they provide the full scope of

[20] *See* ACLU Comment at 7–9, 12, 14–18; NFPRHA Comment at 5, 8.

services mandated by law, and of Title X grantees to ensure that sub-recipients comply with the legal requirements of the Title X program.

The Final Rule's Compliance and Enforcement Requirements

108. Failure to comply with the Rule to HHS's satisfaction—or the failure of one of their sub-recipients to do so—could lead to the loss of Plaintiffs' federal funding and jeopardize Plaintiffs' ability to obtain federal funding in the future. This, in turn, could force Plaintiffs to reduce or discontinue providing critical health care services, if not force the outright closure of numerous health care facilities that provide essential care to underserved communities.[21]

109. For example, the Rule requires, with narrow exceptions, that "as a condition of the approval, renewal, or extension of any Federal financial assistance or Federal funds" from HHS, an entity must furnish both an assurance and certification of compliance with the Final Rule and the underlying federal refusal statutes. *Id.* at 23,269 (to be codified at 45 C.F.R. § 88.4(a)(1)–(2)) (emphasis added). Entities already in receipt of federal funds as of the effective date of the Final Rule shall submit the required assurance and certification "as a condition of any application or reapplication for funds" or "as a condition of an amendment or modification of the instrument that extends the term of such instrument or adds additional funds to it." *Id.* (to be codified at 45 C.F.R. § 88.4(b)). Failure to

[21] *See* ACLU Comment at 18–20; NFPRHA Comment at 1, 6–7.

comply with the assurance or certification requirements subjects covered entities to the enforcement mechanisms and penalties set forth *infra* at ¶¶ 113–116. *See id.* at 23,271–72 (to be codified at 45 C.F.R. § 88.7).

110. Such assurances will be difficult, if not impossible, to provide. For example, as discussed *supra* in ¶¶ 93–98, the Final Rule's vague and unworkable requirements do not provide sufficient guidance to Plaintiffs on how to structure their hiring and employment practices to both satisfy the terms of the Rule *and* continue to serve their patients' needs in a manner consistent with the standard of care. This precarious position is exacerbated by the Final Rule's many conflicts with other federal laws, including Title X, which leave covered entities to guess at how they can possibly comply with *all* their federal obligations—and then to blindly attest to the adequacy of their plan.

111. However, Plaintiffs' compliance obligations do not only come into being upon submission of the required assurances and certifications. The Rule requires covered entities at all times to maintain records "evidencing compliance." As one example, the Final Rule provides that OCR will consider an entity's "voluntary" posting of a notice, *e.g.*, on the entity's website as well as in "a prominent and conspicuous physical location . . . where notices to the public *and* notices to its workforce are customarily posted" informing employees of their right to refuse to participate in, refer for, or pay for health care services "that violate

your conscience, religious beliefs, or moral convictions" as "evidence" of an entity's compliance with the Rule. *Id.* at 23,270 (citing 45 C.F.R. § 88.5), 23,272 (to be codified at Appx. A to Part 88). By contrast, HHS has suggested that posting a notice designed to apprise patients of their right to health care information or the possibility that their services might be limited by the personal beliefs of their health care providers could *violate* the Rule. *See id.* at 23,192.

112. The Final Rule also purports to grant broad enforcement authority to OCR, including the authority to initiate compliance reviews and conduct investigations. *Id.* at 23,271–72 (to be codified at 45 C.F.R. § 88.7). HHS may commence a compliance review or investigation of any entity if HHS "suspect[s]," based on any source, noncompliance with the Final Rule or related statutes. *Id.* at 23,271. The Rule explicitly states that covered entities must provide HHS virtually unlimited access to its books, records, accounts, facilities, and information upon request, and without regard for privacy or confidentiality concerns. *Id.* at 23,270–71.

113. If HHS determines that there has been a "failure to comply" with any provision of the Final Rule or the statutes it purports to implement, the Rule authorizes HHS to temporarily or permanently withhold, deny, suspend, terminate, or claw back what may be billions of dollars in federal funds, including non-HHS-appropriated or administered funds. *Id.* at 23,271–72. Such authority even extends

to termination of funding during the pendency of good-faith, voluntary compliance efforts. *Id.*

114. As a general matter, the Rule does not require any nexus between the funding subject to termination and the alleged violation, nor does it specify procedures or factors for evaluating what sanction would be appropriate for a violation. *See id.* at 23,271–72. This would appear to authorize HHS upon a finding of violation of the subsection (c)(1) of the Church Amendment, which is limited to PHSA funds, to revoke an entity's funding disbursed under any or *all* federal programs.

115. Further, if HHS determines that an entity has failed to comply with any of these requirements, the entity must thereafter, in *any* application for new or renewed funding in the three years following, disclose that finding of noncompliance. *Id.* at 23,271.

116. The Final Rule also states that grantees may be held liable, and therefore subject to all the penalties set forth above, for any violations of the Rule or the underlying statutes by a sub-recipient. *Id.* at 23,270–71. This includes an obligation for entities to disclose noncompliance by sub-recipients in their own future funding applications. *Id.*

117. This affects Plaintiffs in two distinct ways. First, because some of Plaintiff NFPRHA's members (including Plaintiff PHS) delegate funds to sub-

recipients, under the Rule they are responsible not only for their own compliance but also for the compliance of their sub-recipients. Second, because some of Plaintiff NFPRHA's members are sub-recipients of grantees, if another sub-recipient in the network is found to be out of compliance with the Rule and the grantee is penalized for it, the other sub-recipient(s) could also lose their funding through no fault of their own.

The Final Rule's Failure to Comply with the APA

118. As set forth above, the Final Rule is in excess of HHS's rulemaking authority; impermissibly expands the underlying federal refusal statutes beyond their plain meaning and congressional intent; and directly conflicts with numerous other federal laws, such as Title X, EMTALA, and Section 1554 of the PPACA.

119. The Final Rule violates the APA in numerous other ways, as well.

120. For example, HHS failed to respond to significant comments and otherwise failed to account for the Rule's devastating impact on patients and public health. Despite numerous comments, including from leading medical organizations, describing the Rule's devastating impact on patients and public health, HHS refused to incorporate this critical information into its final analysis and decision to finalize the Rule.[22] *See, e.g.*, 84 Fed. Reg. at 23,252 (refusing to

[22] ACLU Comment at 4–6, 10–14; American Academy of Family Physicians Comment at 1; American Academy of Pharmacists Comment at 1–2; American Academy of Pediatrics Comment at 2–3; American College of Obstetricians and Gynecologists Comment at 1–2;

consider the Rule's impact on access to health care services because it could not quantify the expected impact). HHS likewise failed to adequately address the impact the Rule—which is expressly designed to allow health care providers to withhold information from patients—would have on informed consent or the standard of care.[23] Instead, HHS merely stated—without explanation or justification—that it did not believe informed consent would be impaired. *Id.* at 23,189.

121. In addition, HHS failed to justify its complete and sudden about-face from its position that the 2008 Rule—which purported to expand the meaning and scope of the federal refusal statutes in similar, if not identical, ways—undermined informed consent, *see* 76 Fed. Reg. at 9,973 (Feb. 23, 2011), reduced patient access to health care without a basis in the underlying statutes, *id*. at 9,974, and "created unnecessary additional financial and administrative burdens on health care entities," *id*.

American Hospital Association Comment at 3; American Medical Association Comment at 1–3, 6–7; City of New York Comment at 1–3; NFPRHA Comment at 5, 7–10; HIV Medical Association Comment at 1-2; National Association of County and City Health Officials Comment at 2; State Attorneys General Comment at 7–10, 18–20; State of Washington Comment at 2–3.

[23] American Academy of Pharmacists Comment at 2; American Academy of Pediatrics Comment at 2–3, 8–9; American College of Obstetricians and Gynecologists Comment at 1–2; American Medical Association Comment at 2; NFPRHA Comment at 5, 9–10; Wisconsin Medical Society Comment at 5; State Attorneys General Comment at 14–15; ACLU Comment at 8–9, 17–18.

122. By the same token, HHS failed to justify the sudden reversal of agency position that "the Federal health care provider conscience statutes . . . will continue to protect health care providers" without the need for HHS rulemaking interpreting those statutes and that the existing complaint process within OCR "provides a clear process to enforce those laws." *Id.*

123. To the contrary there is an utter lack of any evidence that the existing statutory framework, along with Title VII's requirement of reasonable accommodation of the religious and moral beliefs of all employees, are or ever have been insufficient to protect individuals in the health care context.

124. Finally, HHS's regulatory impact analysis, which is required under Executive Order 12,866 because the Rule is a "significant regulatory action," impermissibly disregarded evidence of significant indirect and direct costs imposed by the Rule. *See* Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993).

125. For example, the Rule utterly fails to account for the inevitable costs to already underserved patients (and their families) who are denied information about and/or access to health services, and the impact of the denial of such information and/or services, including in emergencies, on public health. The Rule also fails to account for the inevitable costs to health care providers, including Plaintiffs, to come into compliance with the Rule (*e.g.*, the significant time, expenses, and other resources required to revise employment practices, manuals,

and handbooks; re-train staff with supervisory responsibilities on hiring and accommodation requests; review all job descriptions, applications, and other employment recruitment materials; and obtain legal advice to determine how the Rule interacts with existing state and federal legal obligations); the costs of hiring additional personnel while maintaining staff who refuse to perform basic job functions; and the inevitable costs stemming from a loss of services, good will, and reputation when patients are refused care. For Plaintiff NFPRHA's members who are also Title X grantees, the Final Rule also fails to account for the significant time, expenses, and resources required for their sub-recipients to also come into compliance with the Final Rule. Lastly, the Rule fails to account for the damage to the public safety net if longstanding, proven providers of federally-funded care (such as Plaintiffs) lose their funding and are unable to continue serving the millions of patients they have served for decades.

THE HARMS CAUSED BY ENFORCEMENT OF THE FINAL RULE

126. If allowed to take effect, the Final Rule will inflict immediate, significant and irreparable harm on millions of individuals who rely on federally funded health care each year by limiting access to services and burdening health care providers across the United States, such as Plaintiffs, who provide this care.

127. The Rule will exacerbate existing systemic barriers by endangering Plaintiffs' members' ability to provide care to already underserved populations. For example:

- By requiring the absolute accommodation of an employee's refusal to provide certain information and services, the Final Rule could at any time force Plaintiffs to reduce the availability or scope of services they provide or even eliminate them entirely, particularly in small locations that may rely on a single staff member to perform multiple job functions.
- By prohibiting Plaintiffs from even asking job applicants whether they are willing to perform basic job requirements, and because the Final Rule does not require employees who intend to refuse to so notify their employers or their patients, neither Plaintiffs nor their patients may be aware when a staff member is denying a patient access to needed care or information;
- By prohibiting those of Plaintiff NFPRHA's members who are state and local governmental Title X grantees from requiring sub-recipients to comply with the statutory and regulatory requirements of Title X's abortion counseling and referral, the Final Rule will systematically undermine the integrity of the Title X program, further jeopardizing the

ability of Plaintiffs' patients to access necessary health care and make voluntary, informed decisions about their reproductive health.

128. For example, Plaintiff PHS is currently hiring for the position of a nurse in one of its home health programs, and typically fills multiple clinical and administrative positions each year. If the Rule takes effect, as planned, Plaintiff PHS will have no way to ensure it does not hire an applicant for its current open position or any future such positions, who will actively withhold and obstruct their patients' ability to obtain needed care and information, and refuse to perform essential aspects of their job.

129. In turn, the Rule's requirement that Plaintiffs hire and retain employees that withhold critical information from patients, even without patients' knowledge, will damage Plaintiffs' reputations as health care providers and cost them good will from patients, potential patients, and damage their ability to obtain funding from other sources.

130. Moreover, in view of the Final Rule's unprecedented grant of authority to OCR to investigate complaints and terminate federal funding based on vague and arbitrary criteria, and the requirement that Plaintiffs maintain and allow OCR access to "evidence" of compliance at all times, enforcement of the Rule will also put Plaintiffs at immediate risk of losing millions of dollars in federal funding,

further threatening the health of the millions of patients who rely on them for their health care.

131. The Rule will also inflict significant harm on Plaintiffs' patients by undermining the fundamental principles of informed consent. In order for patients to provide informed consent a provider must disclose relevant and medically accurate information about all treatment choices and alternatives in a nondirective fashion so that patients can make voluntary and informed decisions about their medical treatment.[24] The failure to provide this information not only deprives patients of the ability to make informed decisions, but also can effectively result in a denial of care because if the patient does not know the option exists, they cannot seek the care elsewhere. By permitting individual health care providers to withhold basic information about a patient's health care options, even in emergencies, the Final Rule contravenes these principles.

132. These harms will not just be limited to patients seeking abortion and sterilization. Though the underlying federal refusal statutes predominantly address abortion and/or sterilization, they are not exclusively limited to those services. For example, subsections (c)(2) and (d) of the Church Amendments permit employees of certain covered entities to refuse to perform or assist in the performance of "any

[24] ACLU Comment at 17–18; American Academy of Pediatrics Comment at 2–3; American College of Obstetricians and Gynecologists Comment at 2; American Medical Association Comment at 2; NFPRHA Comment at 9–10; State Attorneys General Comment at 14–15.

lawful health service" or "any part of a health service program." This could include, but certainly is not limited to, other health care services such as the provision of contraceptive and contraceptive counseling, transition-related health care, HIV testing and counseling, end-of-life care, assisted reproductive technology and fertility treatments, post-sexual assault care, and mental health care.

133. Moreover, even though the Final Rule does not purport to redefine abortion to include contraception, it is nonetheless foreseeable that individuals may attempt to invoke the protections of the underlying federal refusal statutes that deal with abortion to refuse to provide contraception based on their religious belief that certain forms of contraception are "abortifacients." Rather than prevent such further misuse of the federal refusal statutes, the Final Rule appears to encourage it. *See*, *e.g.*, 84 Fed. Reg. at 23,178 (citing approvingly to a lawsuit brought by a nurse alleging she was not hired because she refused to prescribe hormonal contraceptives, which she believed to be "abortifacients").

134. Individuals who already face severe challenges in accessing care, including women—particularly Black women and other women of color—LGBT patients, immigrants and people with limited English proficiency, patients in rural areas, and people with disabilities, stand to suffer the greatest harms from the Final Rule.

135. Title X projects, such as Plaintiff NFPRHA's members, serve racially and ethnically diverse populations, including a disproportionately high percentage of Black and Latina clients. According to 2017 data from the federal government, 22% of Title X patients self-identified as Black or African American and 33% as Hispanic or Latino/a, compared to 12% and 18% of the nation, respectively. Fourteen percent of 2017 users reported having limited English proficiency.[25]

136. This is certainly true of Plaintiff PHS: In 2017, 40% of PHS's Title X clients identified as Black or African American, compared to 26% of New York City's population; while 42% identified as Hispanic or Latino/a, compared to 29% of the City's population. A total of 15% of PHS's clients had limited English proficiency.

137. Women, particularly Black women and other women of color, historically have been subject to discrimination in health care and are still far more likely to face barriers to access, including discriminatory treatment by health care providers.[26] For example, research shows that, in many states, women of color disproportionately receive their care at Catholic hospitals, institutions which have a

[25] Office of Population Affairs, *Title X Family Planning Annual Report: 2017 National Summary*, U.S. Dep't of Health & Human Services (Aug. 2018), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2017-national-summary.pdf.

[26] *See, e.g.*, National Women's Law Center, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care at 10–11, (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71477.

history of denying emergency abortion care.[27] The Final Rule will only erect further barriers to care by empowering more hospitals and hospital employees to withhold information from pregnant patients, even in emergencies, and by impeding the ability of state and federal governments to enforce EMTALA and similar state laws.

138. LGBT patients also face substantial barriers to routine care and risk of discrimination. For example, nearly one in five LGBT people, including 31% of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away.[28] Yet the Final Rule's broad definitions of "discrimination" and "assist in the performance," for purposes of the Church Amendments, provide hospital employees with virtually limitless ability to refuse to take any action with an "articulable" connection to a sterilization procedure, which is how certain gender-affirming surgeries are categorized by certain health care providers. The Final Rule's other broad definitions could increase these barriers by inviting providers to refuse to provide care because of their gender identity or sexual orientation of a patient, in direct

[27] ACLU Comment, at 12; Alliance State Advocates for Women's Rights and Gender Equality, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care (hereinafter "Alliance Comment"), (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71601.

[28] National Coalition for LGBTQ Health, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care, at 2 (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71195.

contravention of other federal protections, such as Section 1557 of the Affordable Care Act. *See* 42 U.S.C. § 18116.

139. For patients in rural areas, the denial of care may likewise leave patients with no other options. Once again, these harms would fall most harshly on people of color in rural America, who are most likely to live in an areas designated as having a profound shortage of health professionals.[29] This problem is "particularly acute for immigrant, Latina women and their families who often face cultural and linguistic barriers to care, especially in rural areas."[30] These women "often lack access to transportation and may have to travel great distances to get the care they need."[31] If these women encounter the health care refusals sanctioned by the Final Rule they will often "have nowhere else to go."[32]

140. Moreover, because people with disabilities as a group are subject to higher unemployment and lower socio-economic status they may be more likely to rely on federally funded care.[33] Yet, under the Final Rule, the federally funded

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[29] *See, e.g.*, Alliance Comment, at 3.

[30] National Immigration Law Center Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care, at 4 (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71248.

[31] *Id.* at 4–5.

[32] *Id.* at 5.

[33] Disability Rights Education and Defense Fund, Comment Letter on Proposed Rule Protecting Statutory Conscience Rights in Health Care, at 2, (Mar 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-11375.

service providers upon whom people with disabilities rely to coordinate necessary services or to provide transportation or other key services through Medicaid or Medicare could invoke the Final Rule to refuse to, *e.g.*, set up an appointment for pregnancy options counseling or provide necessary services such as sign-language interpretation when an individual with disabilities is seeking emergency contraception.

141. To the extent the Rule impedes state and local governments' attempts to enforce laws protecting access to care and preventing discrimination against patients, these harms will only be magnified. For example, like many other states and the federal government, New York requires the provision of emergency and medically necessary care. *See* N.Y. Pub. Health Law § 2805-b. Like other states, New York also prohibits health care professionals from abandoning a patient in need, *see* 8 NYCRR § 29.2(a)(1), and protects patients' right to informed consent, *see* N.Y. Pub. Health L. § 2805-d.

142. For all these reasons, which are illustrative but by no means an exclusive accounting of the harms imposed by the Rule, the Final Rule will inflict immediate, significant, and irreparable injury on Plaintiffs and their patients for which there is no adequate remedy at law.

CAUSES OF ACTION

COUNT I
The Rule Exceeds Statutory Authority
(Administrative Procedure Act, 5 U.S.C. § 706(2)(C))

143. The allegations of paragraphs 1 through 142 are incorporated as though fully set forth herein.

144. The Final Rule is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," in violation of the APA, 5 U.S.C. § 706(2)(C), because, *inter alia*, the underlying laws—the Church, Coats-Snowe, and Weldon Amendments—do not delegate authority to HHS to promulgate force of law regulations interpreting those statutes.

145. Moreover, none of the statutory authorities upon which the Rule relies delegate or otherwise establish the broad enforcement authority that HHS creates and claims for itself in the Final Rule, including the authority to terminate federal financial assistance to entities found to be in violation of the Rule. *See* 84 Fed. Reg. at 23,221 (to be codified at 45 C.F.R. § 88.7(i)(3)(iv)).

COUNT II
The Rule Is Not in Accordance with Law
(Administrative Procedure Act, 5 U.S.C. § 706(2)(A))

146. The allegations of paragraphs 1 through 142 are incorporated as though fully set forth herein.

147. The Final Rule is contrary to law, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), for the following reasons, among others.

148. The Final Rule impermissibly and dramatically expands the set of individuals and entities who can claim protections and broadens what can be refused under the Church, Weldon, and Coats-Snowe Amendments by defining terms including but not limited to "discriminate" and "discrimination," "assist in the performance," and "referral" contrary to their plain meaning and Congressional intent. 84. Fed. Reg. 23,263–64 (to be codified at 45 C.F.R. § 88.2).

149. The Final Rule conflicts with and is not in accordance with the terms and purpose of Title X because it contravenes the statutory requirement that all pregnancy counseling provided in the Title X program be nondirective, *see* HHS Appropriations Act, 2019, Pub. L. No. 115-245, 132 Stat. 2981, 3070–71 (2018), by requiring Title X providers (including Plaintiffs) to permit their employees to withhold and obstruct access to information about abortion and requiring Title X grantees (including Plaintiffs) to permit their sub-recipients to do the same.

150. The Final Rule conflicts with and is not in accordance with the Coats-Snowe Amendment because it vastly expands the statute's scope beyond what Congress intended, which was to establish a limited right to refuse to participate in or provide abortion training. *See supra* ¶¶ 55– 59.

151. The Final Rule contains no emergency exception and therefore conflicts with and is not in accordance with EMTALA, which requires covered hospitals—including public, private, and religiously affiliated hospitals—to provide an appropriate medical screening to any patient requesting treatment, to determine whether an emergency medical condition exists, and either to stabilize the condition or to transfer the patient if medically indicated to another facility. 42 U.S.C. § 1395dd(a)–(c).

152. The Final Rule purports to authorize health care workers to restrict access to health services and withhold medical information and therefore conflicts with and is not in accordance with Section 1554 of the PPACA, 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." *Id.* § 18114.

COUNT III
The Rule is Contrary to Constitutional Right
(Administrative Procedure Act, 5 U.S.C. § 706(2)(B))

153. The allegations of paragraphs 1 through 142 are incorporated as though fully set forth herein.

154. The Final Rule conflicts with the First and Fifth Amendments of the U.S. Constitution in violation of APA, 5 U.S.C. § 706(2)(B), for the following reasons.

155. By imposing on Plaintiffs a categorical requirement to accommodate employees' religious objections to providing health care services—regardless of the impact on their business, other employees, or patients—the Rule violates the Establishment Clause of the First Amendment of the United States Constitution by impermissibly advancing religious beliefs at the expense of third parties and having the primary purpose and effect of promoting and endorsing religious beliefs.

156. By failing to provide adequate guidance about what conduct is prohibited and by encouraging arbitrary enforcement, the Final Rule is void for vagueness and violates Plaintiffs' rights to due process guaranteed by the Fifth Amendment of the United States Constitution.

157. By interfering with women's ability to obtain abortions necessary to preserve their health or life, the Final Rule violates Plaintiffs' patients' rights to

privacy and liberty guaranteed by the Fifth Amendment of the United States Constitution.

COUNT IV
The Rule is Arbitrary, Capricious, and an Abuse of Discretion
(Administrative Procedure Act, 5 U.S.C. § 706(2)(A))

158. The allegations of paragraphs 1 through 142 are incorporated as though fully set forth herein.

159. The Final Rule is arbitrary, capricious, and an abuse of discretion in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A) for the following reasons, among others.

160. HHS failed to adequately consider important aspects of the problem, including the Rule's harmful effects on patient health, informed consent, standards of care, the patient-provider relationship, and burdens on providers, as well as damage to the integrity of the Title X program. In addition to failing to adequately consider these harms, HHS failed to adequately consider the tremendous compliance-related burdens and costs the Final Rule will impose on Plaintiffs.

161. HHS failed to adequately address and resolve the Rule's conflicts and interactions with the U.S. Constitution and numerous federal laws, including Title X, EMTALA, and Sections 1554 and 1557 of the PPACA, and Title VII.

162. The Final Rule is a back-door attempt to undo HHS's own Title X regulations, which require abortion referrals to be provided to patients upon

request, *see* 65 Fed. Reg. 41,270, 41,279 (2000) (codified at 42 C.F.R. § 59.5(a)(5)), without specific notice and comment rulemaking.

163. HHS failed to clarify a number of vague terms and requirements the violation of which could cause covered entities to lose federal funding. These vague provisions include, *inter alia*: whether Plaintiffs are obligated to hire individuals who refuse to perform "the primary or substantial majority of the duties of the position," 84 Fed. Reg. at 23,192; what constitutes a "persuasive justification" for inquiring more than once per calendar year whether an employee intends to refuse to perform aspects of their job, *id.* at 23,263 (to be codified at 45 C.F.R. § 88.2); and when informing patients that certain staff refuse to provide certain information and services constitutes "retaliation," *id.* at 23,192.

164. HHS failed to provide a reasoned explanation for its reversal of longstanding policy concerning the scope of the federal refusal statutes, HHS's authority to implement regulations interpreting those statutes, and the reasoned conclusions set forth in the 2011 Rule.

165. HHS failed to demonstrate that existing legal protections—including the underlying federal refusal statutes, the existing administrative complaint mechanism within OCR, and Title VII—are insufficient to protect health care providers' religious and moral beliefs.

166. HHS failed to conduct an adequate regulatory impact analysis reflecting the considerable costs to patients and providers as evinced by the rulemaking record, pursuant to Executive Order 12,866, 58 Fed. Reg. 51,735, and instructions from both the Office of Management and Budget's Circular A-4 on Regulatory Analysis (2003) and HHS's own Guidelines for Regulatory Impact Analysis (2016), which detail best practices for assessing costs and benefits under regulatory impact analyses and require that agencies account for and quantify direct and indirect health costs to the fullest extent practicable.

167. HHS failed to respond to significant comments from leading medical associations, health care providers, and current and former government officials, regarding, *inter alia*, the Rule's: detrimental impact on health care access; exacerbation of existing health care inequities and barriers to access; burdens on health care providers like Plaintiffs; interference with the patient-provider relationship, including informed consent; and the vague, broad, and overly punitive enforcement authority assumed by HHS.

COUNT V
The Rule Was Promulgated Without Observance of Required Procedure (Administrative Procedure Act, 5 U.S.C. § 706(2)(D))

168. The allegations of paragraphs 1 through 142 are incorporated as though fully set forth herein.

169. HHS promulgated the Rule without fidelity to procedures required by

the Administrative Procedure Act, 5 U.S.C. § 706(2)(D), because, among other reasons, the Final Rule is not a "logical outgrowth" of the Proposed Rule as regards the definition of "discrimination." *See Nat'l Black Media Coal. v. FCC*, 791 F.2d 1016, 1022 (2d Cir. 1986).

170. Agencies must describe "with reasonable specificity" any proposed changes to a regulation because a "[g]eneral notice that a new standard will be adopted" violates the notice-and-comment requirements of the APA. *Time Warner Cable Inc. v. FCC*, 729 F.3d 137, 170 (2d Cir. 2013). Because of this procedural defect, commenters, including Plaintiffs, were deprived of the opportunity to weigh in on this definition.

PRAYER FOR RELIEF

Plaintiffs pray that this Court:

A. Issue preliminary and permanent injunctive relief, without bond, restraining Defendants, their agents, employees, appointees, and/or successors from enforcing, threatening to enforce, or otherwise applying the provisions of the Final Rule;

B. Enter judgment declaring the Final Rule is invalid;

C. Set aside and vacate the Final Rule;

D. Award Plaintiffs attorney's fees, costs, and expenses and any interest allowable by law under 28 U.S.C. § 2412; and

E. Grant such other and further relief that this Court deems just and appropriate.

Dated: June 11, 2019

/s/Alexa Kolbi-Molinas
Alexa Kolbi-Molinas
Lindsey Kaley*
Elizabeth Deutsch*
Brigitte Amiri
American Civil Liberties Union Foundation
125 Broad Street, 18th Floor
New York, NY 10004
Phone: (212) 549-2633
Fax: (212) 549-2652
akolbi-molinas@aclu.org
lkaley@aclu.org
edeutsch@aclu.org
bamiri@aclu.org

Elizabeth O. Gill**
American Civil Liberties Union Foundation of Northern California, Inc.
39 Drumm Street
San Francisco, CA 94111
Phone: (415) 621-2493
Fax: (415) 255-8437
egill@aclunc.org

Daniel Mach**
American Civil Liberties Union Foundation
915 15th Street NW
Washington, DC 20005
Phone: (202) 675-2330
Fax: (202) 546-0738
dmach@aclu.org

Christopher Dunn
Erin Beth Harrist
Donna Lieberman
New York Civil Liberties Union Foundation
125 Broad Street, 19th Floor
New York, NY 10004
Phone: (212) 607-2298
cdunn@nyclu.org
eharrist@nyclu.org
dlieberman@nyclu.org

Attorneys for Plaintiffs

* Application for admission forthcoming
***Pro hac vice* motion forthcoming

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

NOTICE OF MOTION

PLEASE TAKE NOTICE that, upon the accompanying memorandum of law, attached declarations, and the complaints in these actions, Plaintiffs, by their undersigned counsel, will move this Court, before the Honorable Paul A. Engelmayer, United States District Court Judge, at the Thurgood Marshall United States Courthouse, 40 Foley Square, Courtroom 1305, New York, New York, for an order pursuant to Rule 65(a) of the Federal Rules of Civil Procedure and 5 U.S.C. § 705 for a preliminary injunction barring Defendants from implementing and enforcing the regulation entitled 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), promulgated by Defendant the U.S. Department of Health and Human Services, and for such other and further relief as the Court deems just and proper.

Dated: June 17, 2019

Respectfully submitted,

/s/*Sarah Mac Dougall*

Sarah Mac Dougall
Cristina Alvarez*
Covington & Burling LLP
620 Eighth Avenue
New York, NY 10018-1405
Tel: (212) 841-1000
Fax: (212) 841-1010
smacdougall@cov.com
calvarez@cov.com

Kurt G. Calia*
Marina Dalia-Hunt*
Covington & Burling LLP
3000 El Camino Real, 5 Palo Alto Square
Palo Alto, CA 94306-2112
Tel: (650) 632-4717
Fax: (650) 632-4800
kcalia@cov.com
mdaliahunt@cov.com

Diana Salgado*
Planned Parenthood Federation of America, Inc.
1110 Vermont Ave., NW Ste. 300
Washington, D.C. 20005
Tel.: (202) 973-4800
Fax: (202) 296-3480
diana.salgado@ppfa.org

Hana Bajramovic
Planned Parenthood Federation of America, Inc.
123 William St., 9th Floor
New York, NY 10038
Tel.: (212) 541-7800
Fax: (212) 247-6811
hana.bajramovic@ppfa.org

Michelle Banker
Sunu Chandy*
National Women's Law Center
11 Dupont Circle, NW #800

Washington DC 20036
Tel: (202) 588-5180
Fax: (202) 588-5185
mbanker@nwlc.org
schandy@nwlc.org

Adam Grogg*
Robin F. Thurston*
Democracy Forward Foundation
P.O. Box 34553
Washington, DC 20043
Tel: (202) 448-9090
agrogg@democracyforward.org
rthurston@democracyforward.org

* *Pro hac vice* motion forthcoming

Attorneys for Plaintiffs PPFA and PPNNE

/s/*Alexa Kolbi-Molinas*
Alexa Kolbi-Molinas
Lindsey Kaley*
Elizabeth Deutsch*
Brigitte Amiri
American Civil Liberties Union Foundation
125 Broad Street, 18th Floor
New York, NY 10004
Phone: (212) 549-2633
Fax: (212) 549-2652
akolbi-molinas@aclu.org
lkaley@aclu.org
edeutsch@aclu.org
bamiri@aclu.org

Daniel Mach**
American Civil Liberties Union Foundation
915 15th Street NW
Washington, DC 20005
Phone: (202) 675-2330
Fax: (202) 546-0738
dmach@aclu.org

* Application for admission forthcoming
**Pro hac vice* motion forthcoming

Attorneys for Plaintiffs NFPRHA and PHS

Ryan Weinstein*
Paulina Slagter*
Covington & Burling LLP
1999 Avenue of the Stars
Los Angeles, CA 90067-4643
Tel: (424) 332-4800
Fax: (424) 332-4749
rweinstein@cov.com
pslagter@cov.com

* *Pro hac vice* motion forthcoming

Attorneys for Plaintiffs PPFA and PPNNE

Christopher Dunn
Erin Beth Harrist
Donna Lieberman
New York Civil Liberties Union Foundation
125 Broad Street, 19th Floor
New York, NY 10004
Phone: (212) 607-2298
cdunn@nyclu.org
eharrist@nyclu.org
dlieberman@nyclu.org

Elizabeth O. Gill**
American Civil Liberties Union Foundation of Northern California, Inc.
39 Drumm Street
San Francisco, CA 94111
Phone: (415) 621-2493
Fax: (415) 255-8437
egill@aclunc.org

* Application for admission forthcoming
**Pro hac vice* motion forthcoming

Attorneys for Plaintiffs NFPRHA and PHS

To:

Bradley Humphreys, counsel for Defendants, by email to bradley.humphreys@usdoj.gov.

Matthew Colangelo, lead counsel for plaintiffs in *New York v. U.S. Dept. of Health & Human Servs.*, No. 1:19-cv-4676 (S.D.N.Y.), by email to matthew.colangelo@ag.ny.gov.

UNITED STATES DISTRICT COURT
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)
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)

DECLARATION OF SARAH MAC DOUGALL

SARAH MAC DOUGALL declares pursuant to 28 U.S.C. § 1746 as follows:

1. I am an associate at Covington & Burling LLP, and counsel to Plaintiffs Planned Parenthood Federation of America, Inc. ("PPFA") and Planned Parenthood of

Northern New England, Inc. ("PPNNE") in *PPFA et al. v. Azar et al.*, No. 1:19-cv-5433 ("PPFA Action"). This Court has accepted the PPFA Action as related to *National Family Planning and Reproductive Health Services Association et al. v. Azar et al.*, No. 1:19-cv-5435 ("NFPRHA Action"), and, on June 14, 2019, granted permission for the plaintiffs in those cases to file a joint motion for preliminary injunctive relief. *See* PPFA Action Dkt. No. 17; NFPRHA Action Dkt. No. 23.

2. I make this declaration in support of Plaintiffs' Joint Motion for Preliminary Injunction and Memorandum in Support, and to place before the Court documents and information necessary for the determination of the Motion.

3. Attached as Exhibit A is a true and correct copy of select federal statutory provisions, attached for the Court's convenience.

4. Attached as Exhibit B is a true and correct copy of the declaration of Kimberly Custer, Executive Vice President, Health Care Division, PPFA, dated June 14, 2019.

5. Attached as Exhibit C is a true and correct copy of the declaration of Meagan Gallagher, President and CEO, PPNNE, dated June 13, 2019.

6. Attached as Exhibit D is a true and correct copy of the declaration of Clare M. Coleman, President and CEO, National Family Planning & Reproductive Health Association, dated June 17, 2019.

7. Attached as Exhibit E is a true and correct copy of the declaration of Lisa David, President and CEO, Public Health Solutions, dated June 17, 2019.

8. Attached as Exhibit F is a true and correct copy of the declaration of Stephen Todd Chasen, M.D., F.A.C.O.G., Professor of Clinical Obstetrics and Gynecology at Weill Cornell Medical College, Cornell University, and Attending Obstetrician and Gynecologist at New York Presbyterian Hospital, dated June 13, 2019.

I declare under penalty of perjury that the information above is true and correct.

Executed on June 17, 2019, in New York, New York.

/s/
Sarah Mac Dougall

EXHIBIT B

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, Secretary of the United States Department of Health and Human Services, in his official capacity, *et al.*, Defendants.	Civil Action No. 1:19–cv–05433 Hon. Paul A. Engelmayer

DECLARATION OF KIMBERLY CUSTER
IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

I, Kimberly Custer, declare and state as follows:

1. I am the Executive Vice President of the Health Care Division for Planned Parenthood Federation of America, Inc. ("PPFA").

2. This declaration is based on the knowledge and experience I have acquired in two decades of employment with PPFA and several PPFA member-affiliates, a review of PPFA business records, and information obtained through the course of my duties at PPFA. If called and sworn as a witness, I could and would testify competently thereto.

3. I submit this declaration in support of Plaintiffs' Motion for a Preliminary Injunction, which seeks to prevent the enforcement of the rule entitled "Protecting Statutory Conscience Rights in Health Care," 84 Fed. Reg. 23,170 (May 21, 2019) (to be codified at 45 C.F.R. pt. 88) (the "Refusal of Care Rule" or the "Rule"). I am familiar with the Refusal of Care Rule.

4. As I understand it, the Refusal of Care Rule could force PPFA and its member-affiliates to accommodate a broad group of individuals, including employees, interns, volunteers, trainees, and contractors, who—contrary to our mission—refuse to provide or assist with core reproductive services, such as abortion, sterilization, and potentially other health services, regardless of the burden that it would impose on our health centers and their patients. I also understand that the Rule broadly defines "assisting in the performance" of a procedure or service to include, among other activities, "counseling, referral, training, or otherwise making arrangements" for the procedure or service. The accommodation required by the Rule would threaten Planned Parenthood patients' access to comprehensive reproductive health care, and run counter to our medical standards requiring that patients be provided with information and health care in an objective and nonjudgmental manner. In many cases absolute accommodation would also be costly and time-consuming, and result in a disruption in services. In certain circumstances, it would be impossible.

5. The accommodation required by the Rule would also pose security and privacy risks to Planned Parenthood and our patients. It is already the case that anti-abortion individuals seek positions with our affiliates in order to obtain information about Planned Parenthood and our patients. The Rule will severely hamper the ability of our affiliates to screen for such individuals.

6. In addition, Planned Parenthood will have to spend significant staff time revising employment materials, conducting trainings with human resources personnel and supervisors, and retaining and paying outside legal counsel to advise on employment matters.

7. The Refusal of Care Rule puts Planned Parenthood affiliates at risk of losing hundreds of millions of dollars of federal funds. Many of PPFA's member-affiliates would be

forced to reduce their hours, cut their staff, and/or even close health centers if they lost all of their federal funding. This outcome would be devastating to Planned Parenthood and individuals who rely on us—especially people with low incomes, rural residents, and people of color who frequently have no other affordable option for high-quality and often life-saving reproductive care.

I. MY BACKGROUND

8. After receiving a B.A. from the University of Oregon, I held a series of management positions in the private sector. In 1997, I joined a Planned Parenthood affiliate as a Vice President for Community Affairs.

9. In 2004, I became the President and CEO for Planned Parenthood of North East Pennsylvania. For the next decade, I served as the chief executive of several Planned Parenthood affiliates.

10. In 2015, I accepted my current position as the Executive Vice President of the Health Care Division of PPFA. In this role, I oversee all health care programs for PPFA—including medical services, health education, health care operations, business analytics, accreditation, and evaluation for PPFA's affiliates—as well as affiliate governance and leadership. I also help develop short- and long-term strategies for affiliates to achieve their core mission of delivering high-quality reproductive health services.

II. PLANNED PARENTHOOD'S MISSION AND STRUCTURE

11. PPFA strives to ensure access to comprehensive reproductive health care services; advocates for public policies that support access to health care, especially for people who have low incomes or who are from underserved communities; and provides educational programs relating to reproductive and sexual health. PPFA also advocates for the right to access safe and legal abortion.

12. While PPFA is dedicated to ensuring access to comprehensive reproductive health care services, PPFA itself does not provide medical services. Medical services are provided by 53 Planned Parenthood affiliates in 48 States and the District of Columbia. These affiliates operate nearly 600 health centers across the nation, and they provide services to millions of patients from all 50 States and the District of Columbia each year.

13. PPFA is a not-for-profit corporation organized under the laws of New York and has its principal place of business in New York City (Manhattan). Our affiliates are members of PPFA, but each is a separately incorporated not-for-profit organization, with its own Chief Executive Officer and Board of Directors. Each affiliate provides medical and educational services in its community or communities.

14. In order to be certified as an affiliate and carry the Planned Parenthood name, each organization must satisfy the Standards of Affiliation laid out in PPFA's bylaws. Among other things, the Standards of Affiliation require that an affiliate publicly support the purposes and policies of PPFA and provide medical services that meet PPFA's Medical Standards and Guidelines ("MS&Gs"). For example, PPFA's MS&Gs and accreditation standards require that information that a patient needs to make an informed decision, including for abortion and sterilization, must be presented in an objective and nonjudgmental manner. Compliance with the MS&Gs is required to maintain affiliation with PPFA. Each affiliate is evaluated through PPFA's accreditation process at least every four years.

15. The member-affiliates set the long-range goals and priorities of PPFA and elect the PPFA Board of Directors. Through their participation and voting, PPFA's member-affiliates control the mission and direction of PPFA. Under PPFA's bylaws, PPFA's member-affiliates are also required to contribute financially to PPFA.

16. Affiliation with PPFA is important to the success of an affiliate. PPFA affiliates pay membership dues for the support, leadership, and guidance that PPFA provides, as well as the right to use the Planned Parenthood name and mark. The Planned Parenthood name signals that an affiliate stands for certain values and provides nonjudgmental, high-quality health care and educational services.

III. HEALTH CARE SERVICES PROVIDED BY PLANNED PARENTHOOD AFFILIATES

17. Each Planned Parenthood affiliate offers a wide range of family planning services and reproductive health care. These services may include contraception, including highly effective long-acting reversible contraceptives ("LARCs"); contraceptive counseling; physical exams; clinical breast exams; screening for cervical cancer; testing and treatment for sexually transmitted infections ("STIs"); pregnancy testing and counseling; colposcopies (a type of cervical cancer test); gender affirming care, including hormone therapy for transgender patients; some sterilization services, including vasectomies; abortion; and health education services. Availability of some of these services, including contraception, contraceptive counseling, and abortion, is a core part of Planned Parenthood's beliefs as an organization. Accordingly, the MS&Gs by which Planned Parenthood affiliates must abide require provision of these services.

18. In 2018, Planned Parenthood affiliates provided more than 9,800,000 services to approximately 2,400,000 patients during the course of approximately 4,000,000 visits. They provided reversible contraceptives to more than 1,800,000 patients and administered more than 560,000 cancer screenings and preventive services, such as breast exams and cervical screens (Pap tests). An estimated one out of every three women nationally has received care from a PPFA affiliate at least once in her life.

19. In the past several years, the occurrence of gonorrhea, chlamydia, and syphilis has dramatically spiked in communities nationwide, particularly in the communities that Planned Parenthood serves. Accordingly, STI testing and treatment has become a larger portion of Planned Parenthood's service mix. In 2018, our affiliates administered more than 4,900,000 STI tests, as compared to approximately 4,700,000 STI tests in 2017 and approximately 4,400,000 STI tests in 2016.

20. In my experience, there are many reasons why patients choose to receive care from PPFA affiliates rather than other providers of reproductive health care (when such alternative providers are available at all). Some patients choose Planned Parenthood because our expertise and specialization in reproductive health care make us the top choice for high-quality medical care.

21. Others choose Planned Parenthood because of our reputation for providing nonjudgmental and culturally sensitive care; Planned Parenthood staff are trained to acknowledge and respect patients' customs regarding reproductive health. Indeed, many of our patients receive their other health care from other providers, but because of privacy concerns and fear of judgment, they retain Planned Parenthood as a separate provider for their reproductive health care.

22. Our patients also turn to us for nonjudgmental and high-quality abortion care. Planned Parenthood affiliates are often the only abortion providers available; very few practicing OB-GYNs perform abortions, particularly OB-GYNs in private practice and those located in the Midwest and South. Moreover, of the relatively small number of OB-GYNs who do provide abortions, such services are not generally available but are instead reserved for existing patients. Today, 95% of abortions in the United States are performed in freestanding clinics, like the

health centers of Planned Parenthood affiliates. For this reason, abortion is a critical component of Planned Parenthood's mission.

23. Planned Parenthood health centers also tend to be much more convenient for their patients than other reproductive healthcare providers. Planned Parenthood affiliates can often see patients quickly—in many cases on a walk-in basis—whereas other providers frequently have long wait times for appointments.

24. Most Planned Parenthood health centers offer extended hours, which are especially important to patients with low incomes, many of whom have inflexible schedules due to work or childcare responsibilities. More than 80% of Planned Parenthood health centers offer appointments after 5 p.m. at least one day per week, nearly 60% offer appointments past 6 p.m. at least one day per week, and 45% offer weekend appointments.

25. In recent years, many Planned Parenthood affiliates have served a critically important role providing care, including hormone therapy, to transgender individuals. Planned Parenthood health centers are often the only place that these patients can access care without judgment or discrimination. In 2018, twenty-nine affiliates reported at least one health center providing gender affirming care.

26. Planned Parenthood affiliates also play a particularly important role in providing reproductive and other health care to individuals with low incomes. Most of PPFA affiliates' patients are poor and/or uninsured; approximately 73% have incomes at or below 150% of the federal poverty level. Fifty-six percent of affiliate health centers are in Health Professional Shortage Areas ("HPSAs") and/or in rural or other Medically Underserved Areas ("MUAs"), as designated by the Health Resources and Services Administration, a subagency of the U.S. Department of Health and Human Services ("HHS").

27. Planned Parenthood health centers also play a critical role in serving communities of color and in many cases are the only health centers providing reproductive health care in such communities. Approximately 26% of Planned Parenthood's patients are Latinx, 18% are Black, and 11% are Native American, Asian, or Multiracial. Over the past five years, Planned Parenthood has served an increasing number of patients in these groups.

IV. FEDERAL FUNDING RECEIVED BY PLANNED PARENTHOOD AFFILIATES

28. Almost all of Planned Parenthood's 53 member-affiliates receive federal funding. While the amount of federal funds varies by affiliate, many affiliates receive a significant portion of their budget from federal funds, and collectively, our affiliates have hundreds of millions of dollars at stake under the Refusal of Care Rule.

29. More specifically, almost all PPFA affiliates participate in Title XIX of the Social Security Act, more commonly known as the Medicaid program. The Medicaid program is a cooperative federal-state program that provides medical assistance to individuals with low incomes. These affiliates provide Medicaid-funded health care services to patients with low incomes at health centers all across the country. In 2017, Planned Parenthood affiliates received more than $418 million in Medicaid funds for reimbursement of services provided to Medicaid patients.

30. Further, Planned Parenthood provided family planning care in 2017 to an estimated 1.6 million patients in the Title X program. Title X, the federal program that subsidizes the provision of family planning services to people with low incomes, enables Planned Parenthood affiliates to offer these services on a sliding-fee scale, depending on the patient's ability to pay. Under Title X, the Secretary of HHS "is authorized to make grants and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of

voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services." 42 U.S.C. § 300(a). These grantees may provide the program services themselves or contract with delegate agencies (or "subgrantees") to provide the services. Planned Parenthood affiliates serve as both direct grantees and subgrantees.

31. In 2017, Planned Parenthood affiliates received more than $67 million in Title X grants to support, for example, Pap tests, breast exams, and STI tests. Title X money is also used to support other critical needs that are not reimbursable under Medicaid or commercial insurance, like individual patient education, community-level outreach, and public education about family planning and related sexual health issues. Although Planned Parenthood affiliates only operate 13% of health centers in the Title X program, they serve 40% of the patients in the program.

32. PPFA affiliates also receive other HHS funds, including under the Social Services Block Grant ("Title XX" or "SSBG") program, which allocates funds to states to support social services for vulnerable children, adults, and families; the Maternal and Child Health Block Grant ("Title V") program, which supports the health of women, children, and their families; the Teen Pregnancy Prevention Intervention Grant ("TPPI") program, which funds organizations working to prevent teen pregnancy across the United States; the Ryan White AIDS program; and the National Breast and Cervical Cancer Early Detection Program ("NBCCEDP"). In 2017, Planned Parenthood affiliates received more than $3 million from SSBG, almost $2 million from Title V, more than $4 million from TPPI, more than $100,000 from the Ryan White AIDS program, and more than $350,000 from NBCCEDP.

33. It is my understanding that because of their receipt of these federal funds, PPFA affiliates will be required to sign a new certification that they are in compliance with the Refusal

of Care Rule and that failure to comply with the Refusal of Care Rule could lead to termination of all federal funding—which, as demonstrated above, amounts to hundreds of millions of dollars across the country.

V. BURDENS IMPOSED BY THE REFUSAL OF CARE RULE

34. Prior to the Refusal of Care Rule, whether Planned Parenthood affiliates were obligated to hire or accommodate individuals who expressed objections to performing job duties based on religious belief was governed by the standard for religious discrimination under Title VII of the Civil Rights Act, as well as by any obligations imposed by applicable state law. Under the Title VII standard, affiliates have no obligation to accommodate a religious objection if doing so would pose an undue hardship.

35. I understand that the Refusal of Care Rule, however, prohibits health care providers that receive certain federal funding, as our affiliates do, from "discriminating" against individuals who refuse to perform or assist in the performance of abortion, sterilization, and potentially other services, but makes clear that the Rule differs from Title VII by not incorporating the additional concept of an "undue hardship" exception for accommodations. I also understand that the Refusal of Care Rule prohibits Planned Parenthood affiliates from (1) asking *prospective* employees, interns, volunteers, and trainees whether they are willing to perform the essential functions of their job; (2) asking *existing* employees, interns, volunteers, and trainees if they object to the performance of any of their job functions more than once per calendar year absent an undefined "persuasive justification"—even in the event of an emergency; and (3) taking steps to protect patient access to the objected-to health services unless the objecting employee "voluntarily accepts" an undefined "effective accommodation" that does not amount to an "adverse action" or otherwise "exclude" the employee from a "field of practice." It

is my understanding that the Rule expressly declines to say whether a health care provider could disqualify a person with religious or moral objections to covered practices if such covered practices made up the primary or substantial majority of the duties of the person's position.

36. The Refusal of Care Rule's requirement that our affiliates accommodate the beliefs of employees, interns, trainees, and contractors at all costs, regardless of hardship to the affiliate, would mark a dramatic departure from our current practice. Planned Parenthood affiliates could be forced to hire and accommodate an unlimited number of individuals who refuse to provide or assist with abortion, sterilization, and potentially other core services we provide. This change in practice would jeopardize the ability of our patients to receive the nonjudgmental care and information they need, and in certain circumstances these accommodations would be impossible.

37. Accommodation would also impose significant security risks on Planned Parenthood affiliates, which may be forced to hire or accommodate individuals who are opposed to Planned Parenthood's mission and seek to sabotage our affiliates.

38. Finally, the Refusal of Care Rule grossly underestimates the costs Planned Parenthood affiliates would have to expend in order to revise employment practices and policies.

A. Burden on Staffing Practices and Effects on Service Offerings

39. Planned Parenthood affiliates employ thousands of individuals, and have a significant number of job vacancies at any given time. In 2018, PPFA affiliates had 8,857 full-time and 1,347 part-time employees, in addition to 31,544 volunteers.

40. Based on the number of employees replaced during the past several years, I estimate that Planned Parenthood affiliates make hiring decisions for approximately 2,000 employee vacancies per year.

41. Many of our affiliates have dealt with instances in which an employee, trainee, intern, volunteer, or applicant for a job has objected to providing or assisting with abortion care. Some have incurred costs—such as staffing changes or increased personnel—in accommodating these personal objections. Some affiliates have also experienced having an employee or applicant for a job object to providing gender affirming care to transgender individuals.

42. Accommodation issues like these often arise when an affiliate or health center expands or adds new services. For example, sometimes a health center that did not previously provide abortion services or gender affirming care adds these services, or an affiliate or health center expands its abortion services to later gestational ages. An individual sometimes indicates that he or she does not want to participate in the new services, including abortion and gender affirming care, and the affiliate must determine whether and how it is able to accommodate that individual.

43. Accommodating someone who objects to participating in the provision of a health care service offered by an affiliate can be very time-consuming and costly, especially for those affiliates with small health centers and/or those in remote locations. Many affiliates have very few individuals working at any particular health center at a time, and if one of those individuals is not willing to participate in providing a particular service, no other person may be available to take over his or her role. The impracticality of these objections is compounded by the fact that our affiliates cannot always predict which services will be provided on a given day or shift. In particular, patients seeking pregnancy testing or visiting us for another service in which a pregnancy diagnosis is possible need to have access to counseling about all of their options, including abortion. Some health centers also accept walk-in patients.

44. For many of our affiliates, if they were required to hire or accommodate someone who refused to provide or assist with abortion care, it would be difficult or prohibitively expensive to continue providing abortion services at one or more of their health centers. For example, I am aware that one affiliate currently has an employee who objects to abortion in a center with a small staff in a community with limited other options for abortion care, and it presents an ongoing challenge. Many of the affected health centers are located in areas without many other abortion providers, which would also negatively impact access throughout the region.

45. Similarly, for many affiliates, hiring or accommodating someone who refused to provide gender affirming care would make it difficult or prohibitively expensive to continue providing that care at one or more health centers.

46. While PPFA does not track precise figures, I know from my experience working with a wide range of affiliates and health centers that it is common for a health center to be staffed with a single licensed clinician. It is also common for a smaller health center to be staffed with only a very small number of total staff members. Accommodating all objections by employees, interns, trainees, and contractors would affect morale in some health centers.

47. Under the Refusal of Care Rule, affiliates must accommodate—or even hire and then accommodate—individuals in these jobs who refuse to participate in providing health care services that are central to the affiliates' mission to provide comprehensive, nonjudgmental reproductive health services. Such accommodation would be very expensive, time-consuming, and in certain instances, impossible.

48. The Refusal of Care Rule also increases affiliates' legal exposure for employment decisions it makes, even though Planned Parenthood has just cause to make those choices. For

example, a Planned Parenthood affiliate might choose not to hire an applicant because the applicant is unqualified—but if the applicant also happens to be opposed to providing abortion care, the affiliate will open itself up to risk of a complaint to HHS's Office for Civil Rights ("OCR"), which could lead to a loss of federal funding. The Refusal of Care Rule will force Planned Parenthood to substantially increase documentation related to hiring and other human resources decisions, adding further administrative burdens to each affiliate's practices.

49. If the Refusal of Care Rule is not enjoined, affiliates will be forced to hire some individuals they would not otherwise have hired under existing law. It will be very difficult, if not impossible, to unwind those hiring decisions after the fact. For example, some of our affiliates have staff who are members of collective bargaining units and whose employment is subject to the terms of those agreements.

B. Reputational Harms and Damage to Patient and Community Trust

50. If the Rule takes effect, it will also be detrimental to Planned Parenthood's reputation as a provider of compassionate and nonjudgmental care by sending a message to patients and communities that we cannot be relied on to provide that care consistently.

51. In particular, in many communities, we are already the last or among the last providers of abortion care, and patients seeking an abortion face severe community disapproval of their choice to have an abortion. They expect—and deserve—to come into one of our health centers and receive counseling about all of their options and, if they decide to terminate their pregnancy, to obtain abortion care without judgment by their providers. By condoning unlimited staff objections to provision of abortion care, the Rule would permit additional stigmatization of our patients seeking abortions, in turn damaging our reputation among patients.

52. In addition, to the extent that the Rule requires forced accommodation of staff who oppose emergency contraception, it will also harm our patients looking for readily available care to prevent an unintended pregnancy. These patients have five days or less to obtain contraception, and they come to us expecting that we will meet their needs, whatever those may be. If they are turned away by our providers, or told that they will have to obtain that care from someone else, our patients will get a message of disapproval—a message that is directly contrary to Planned Parenthood's standard of care and our longstanding reputation in communities we serve. The impact of these refusals will fall particularly hard on patients seeking emergency contraception after a sexual assault. We do not want to contribute further to the trauma these individuals have already experienced.

53. The reputational injury that PPFA and its affiliates will experience will be compounded by the fact that affiliates might not know if a staff member has refused to provide care or counseling for individuals on the basis of an objection. This lack of information will limit our ability to mitigate—as best we can under the circumstances—the impact of a provider's refusal on patient care by ensuring, if possible, that another staff member is able to care for that patient.

C. Increased Security Risks

54. I also have grave concerns that compliance with the Refusal of Care Rule could lead to security and privacy risks. Of course many individuals who might object to providing or assisting with our services pose no threat to our affiliates. However, it is critical that we be able to identify the subset of individuals who may seek positions with affiliates in order to infiltrate Planned Parenthood and use the information they gather or their access to our facilities to harm our staff, providers, and patients.

55. There is no limit to what people will do to infiltrate and sabotage Planned Parenthood. Individuals opposed to Planned Parenthood have filmed and harassed patients as they walked into health centers; recorded addresses of staff members and followed those staff members home; and contacted health centers under false pretenses—e.g., as a worker for a business providing services to an affiliate or as a staff member of a partner organization—in order to fish for information.

56. Many affiliates report that one or more individuals who they believed to be opposed to Planned Parenthood or the services Planned Parenthood provides have applied to work, intern, train, volunteer at, or contract with the affiliates. There have been instances in which abortion opponents filled out online applications for employment with us and in which an opposition member posted a job vacancy on her social media account and asked followers to apply.

57. Violence against abortion providers and abortion-providing facilities is not a new phenomenon.[1] However, it has spiked in recent years, following infiltration of Planned Parenthood in July 2015 by the anti-abortion Center for Medical Progress ("CMP"). CMP posed as a fake biomedical research company and filmed a series of undercover videos showing Planned Parenthood employees discussing fetal tissue donation. In July and August 2015, immediately following the release of the CMP videos, Planned Parenthood affiliates reported a sharp increase in threats, harassment, vandalism, and violence against them, their staff members, and their patients at health centers around the country—more than triple the number of incidents

[1] According to the National Abortion Federation, "there have been 11 murders, 26 attempted murders, 42 bombings, 185 arsons, and thousands of incidents of criminal activities directed at abortion providers" since 1977. National Abortion Federation, *2015 Violence and Disruption Statistics* 1 (2016), https://prochoice.org/wp-content/uploads/2015-NAF-Violence-Disruption-Stats.pdf [hereinafter "NAF Report"].

that affiliates reported in July and August of the previous year. Then, in November 2015, a man shot and killed three people and injured nine at a Planned Parenthood health center in Colorado Springs, Colorado, specifically noting that he was inspired by the anti-abortion rhetoric around fetal tissue donation.[2] The "2015 statistics reflect a dramatic increase in hate speech and internet harassment, death threats, attempted murder, and murder, which coincided with the release of heavily-edited, misleading, and inflammatory videos beginning in July."[3]

58. By preventing Planned Parenthood affiliates from identifying job applicants and other individuals seeking to work with us who oppose our mission, the Refusal of Care Rule would allow opponents to infiltrate our affiliates and obtain information or even film covert videos, which could lead to harassment, death threats, and murder, as it did in 2015.

59. The Refusal of Care Rule could further lead to harassment by allowing anti-abortion individuals to obtain employees' and patients' personal information. There are many websites where anti-abortion activists post photographs of staff members, along with photographs of their cars and homes, sometimes with addresses, license plate numbers, and private phone numbers. These posts expose our employees to harassment in their homes and neighborhoods. Anti-abortion activists often picket employees' homes, send graphic postcards to employees' home addresses, and even distribute pamphlets in employees' neighborhoods to "warn" neighbors that someone associated with abortion lives nearby. For this reason, many Planned Parenthood employees keep their affiliation with the organization private. Providing

[2] *See* Fred Barbash & Yanan Wang, *The Twisted 'Dream' of Accused Planned Parenthood Killer Robert Dear Jr.*, Wash. Post (Apr. 12, 2016), https://www.washingtonpost.com/news/morning-mix/wp/2016/04/12/the-twisted-remorselessness-of-accused-planned-parenthood-killer-robert-dear-jr/.

[3] *See* NAF Report at 1.

anti-abortion activists with additional access to Planned Parenthood affiliates and their staff would only exacerbate the harassment that our staff already face.

60. In addition, Planned Parenthood takes seriously its obligation to protect the privacy of patients who use its services, including services that may be stigmatized in the communities in which Planned Parenthood operates. By forcing Planned Parenthood to hire and accommodate individuals opposed to its mission, the Refusal of Care Rule could result in the release of private information—including names and addresses of patients—to individuals motivated to misuse it.

61. The release of information about patients and staff to individuals with ill will toward our organization could also result in an increase in abortion stigma in communities in which we provide services. As a result of stigma, individuals who provide or obtain abortion are labeled as different, stereotyped or associated with negative attributes, conceived of as an "other," and then subjected to status loss and discrimination. For providers and patients at Planned Parenthood affiliates, abortion stigma can lead to isolation, burnout, self-judgment, and physical and mental health consequences.

D. Review and Other Compliance Costs

62. The Refusal of Care Rule will also impose significant compliance costs on Planned Parenthood affiliates. I understand that HHS has estimated that family planning centers will spend (1) two hours on average familiarizing themselves with the Rule and its requirements, which represents a "one-time opportunity cost of staff time (a lawyer) to review the rule"; and (2) "an average of 4 hours [per year for the first five years] reviewing the assurance and certification language and the Federal conscience protection and associated anti-discrimination laws and the rule," which is "a function of a lawyer spending 3 hours reviewing the assurance

and certification and an executive spending one hour to review and sign." 84 Fed. Reg. at 23,240–41. I strongly disagree with these estimates.

63. As an initial matter, the time to review the Rule and associated laws is grossly underestimated. The Rule covers more than one hundred pages in the Federal Register, and the associated laws include not only the "Church, Weldon, and Coats-Snowe Amendments" but also "22 additional statutory provisions." 84 Fed. Reg. at 23,240. Affiliates would need to seek legal counsel to ensure that their policies and practices are in compliance with the Refusal of Care Rule. For counsel to thoughtfully review each of these documents would take several days—not several hours—of work. In addition, in states where there are potentially conflicting state laws, affiliates may need legal counsel to decipher whether those state laws have been preempted, or how the Rule and State laws operate in conjunction with each other.

64. In addition, because HHS requires additional protections under the Refusal of Care Rule than those that prevent religious discrimination under Title VII, Planned Parenthood affiliates will have to expend a significant amount of time and, in turn, money to revise their employment practices and policies in order to ensure compliance with the Rule.

65. In particular, I believe that nearly all affiliates would have to train any staff member with supervisory responsibilities on how to deal with hiring and accommodation requests in light of the Rule. PPFA affiliates have 1770 managers at nearly 600 locations across the country, and they may also need to train non-managerial staff who are involved in hiring.

66. In addition, affiliates will also have to review and revise employee manuals and handbooks to ensure that they are in compliance with the Refusal of Care Rule.

67. Similarly, all job descriptions, applications, and other employment recruitment materials will have to be reviewed line-by-line, and edited, where necessary. Again, each

affiliate's Human Resources Manager or Director will likely perform this task. I estimate that this will take at least 30 minutes for each job description and application, given the need to be detail-oriented when completing the task. As noted above, Planned Parenthood affiliates must make hiring decisions for approximately 2,000 employee vacancies per year.

E. Cost of Noncompliance

68. As high as the cost of compliance would be, the cost of noncompliance would be astronomical. Many of PPFA's affiliates would have to consider reducing their hours, their staff, or even closing health centers if they lost all of their federal funding. This would leave the vulnerable populations we serve without access to reproductive health care. As noted above, 73% of Planned Parenthood patients have incomes at or below 150% of the federal poverty level. Fifty-six percent of Planned Parenthood health centers are in HPSAs and/or MUAs. Planned Parenthood health centers also play a critical role in serving communities of color and in many cases are the only health centers providing reproductive health care in such communities. If Planned Parenthood affiliates lost all of their federal funding, the outcome would be devastating to the individuals who rely on us for their reproductive health care—especially patients with low incomes, rural patients, and patients of color who often have no other affordable option for reproductive care.

69. These draconian impacts on affiliates could occur based on noncompliance that is only tangentially related to us. It is my understanding that Planned Parenthood affiliates as well as their delegate agencies must comply with the Refusal of Care Rule, and that affiliates could lose their HHS funding if their delegate agencies or subcontractors were found not to be in compliance. In addition, where an affiliate is a subgrantee of a state agency, it could also lose all

of its federal funding if another subgrantee were to violate the Refusal of Care Rule—leaving the affiliate without federal funds even though it was in compliance with the Rule.

* * *

70. In sum, it is my belief that the Refusal of Care Rule will have a very large impact on the staffing practices of Planned Parenthood affiliates nationwide, the security of our providers and patients, and the nonjudgmental, compassionate patient care we are known for providing.

I declare under penalty of perjury of the laws of the United States that the foregoing is true and correct and that this declaration was executed on this 14th day of June 2019.

Kimberly Custer

EXHIBIT C

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, Secretary of the United States Department of Health and Human Services, in his official capacity, *et al.*, Defendants.	Civil Action No. 1:19-cv-05433 Hon. Paul A. Engelmayer

DECLARATION OF MEAGAN GALLAGHER
IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

I, Meagan Gallagher, declare and state as follows:

1. I am the President and Chief Executive Officer ("CEO") of Planned Parenthood of Northern New England, Inc. ("PPNNE"), a position I have held since 2013. As CEO of PPNNE, I lead the largest reproductive health care and sexuality education provider in northern New England. PPNNE's mission is to provide and protect access to reproductive health care and sexuality education so that all people can make informed, voluntary choices about their reproductive and sexual health. PPNNE operates 21 health centers across Vermont, New Hampshire, and Maine and serves more than 45,000 patients each year.

2. Before taking on my current role, I was the Senior Vice President of Business Operations at PPNNE. Prior to that I served as Chief Financial Officer, Chief Operating Officer, and Senior Vice President of Strategic Initiatives and Growth of the Planned Parenthood League of Massachusetts.

3. The facts I state here are based on my experience, my personal knowledge, my review of PPNNE business records, and information obtained through the course of my duties at PPNNE. If called and sworn as a witness, I could and would testify competently thereto.

4. I submit this declaration in support of Plaintiffs' Motion for a Preliminary Injunction, which seeks to enjoin the rule entitled "Protecting Statutory Conscience Rights in Health Care" (the "Rule"), 84 Fed. Reg. 23,170, issued by the U.S. Department of Health and Human Services ("HHS") on May 21, 2019. I am familiar with the Rule.

5. As explained below, the Rule presents a grave threat to PPNNE's mission and our ability to ensure that our patients have access to high-quality, comprehensive, and nonjudgmental care—regardless of the services our patients seek and regardless of their identity. The Rule will severely impair our operations, including our employment practices, and pose a threat to the security of our health centers. I am also deeply concerned about our ability to comply with the Rule's broad and vague requirements and understand that noncompliance could lead to loss of our federal funding. Loss of federal funding would do immense damage to PPNNE's ability to continue to provide quality, comprehensive family planning services to thousands of low-income individuals in northern New England.

BACKGROUND

A. PPNNE and Its Patients

6. Founded in 1965, PPNNE is a non-profit corporation incorporated in Vermont with headquarters in Colchester, Vermont. PPNNE is an affiliate of Plaintiff Planned Parenthood Federation of America ("PPFA"). Per PPFA's accreditation requirements, medical services at all Planned Parenthood affiliates must be provided in accordance with up-to-date, evidence-based standards of practice for family planning and reproductive health care. Affiliating with PPFA is critical to PPNNE's mission. It allows us to use the "Planned Parenthood" name, which patients

recognize as one attached to an organization that provides nonjudgmental, high-quality, and comprehensive reproductive health care.

7. Like other PPFA affiliates, PPNNE provides reproductive health care services as a "one stop shop." A patient can get an office visit, most relevant lab tests, and any needed drugs or supplies at one location without having to travel to a pharmacy or lab testing facility. This model is particularly important for the low-income patients served by PPNNE who often do not have the time, money, or resources to take time off work or school or to arrange alternative childcare necessary for these patients to make repeated medical visits. The "one stop shop" model increases the likelihood that patients will get their tests completed *and* take the medicines they are prescribed.

8. PPNNE offers education and counseling on reproductive health and provides comprehensive reproductive health care services. These services include birth control, such as emergency contraception and long-acting reversible contraceptives ("LARCs," the most effective form of birth control); testing and treatment for sexually transmitted infections ("STIs"); testing for HIV and the HPV virus; pregnancy testing; breast and cervical cancer screenings; and safe and legal abortion. PPNNE's abortion care includes medication abortions through 11 weeks after the first day of a patient's last menstrual period and surgical abortions through 19 weeks. In addition, all PPNNE health centers offer PEP and PReP for HIV prevention; gender affirming care, including hormone therapy for transgender patients; prenatal screenings and referrals; and referrals for sterilizations (e.g., vasectomies).

9. In 2018, PPNNE served more than 45,000 patients at more than 67,000 patient visits. These services included approximately 8,500 pregnancy tests; 6,300 LARC insertions; provision of 73,000 packs of birth control pills; 61,000 instances of screening and/or treating STIs,

including chlamydia, gonorrhea and syphilis; 10,000 HIV tests; 2,000 prescriptions for emergency contraception, including for individuals who were victims of sexual assault; and about 3,500 abortion procedures.

10. Most of PPNNE's patients have low incomes. In 2018, 47 percent of its patients in Vermont, 55 percent of its patients in New Hampshire, and 57 percent of its patients in Maine had incomes at or below 150 percent of the federal poverty level.

11. A large portion of our patients are on Medicaid: approximately 29 percent who visit a Vermont health center, 28 percent who visit a New Hampshire health center, and 14 percent who visit a Maine health center.

12. Many of our patients are uninsured or underinsured. In 2018, for example, 20 percent of our patients did not pay for services using some form of public or private insurance, a strong indicator of insufficient insurance access.

13. PPNNE serves a significant number of rural patients, as Vermont, Maine, and New Hampshire are all states with large rural areas.

14. Several of PPNNE's health centers serve areas that have been designated by the Health Resources and Services Administration ("HRSA"), an HHS subagency, as medically underserved in some manner or as experiencing a provider shortage. Those health centers include facilities in Sanford and Portland, Maine; Manchester, Claremont, and Keene, New Hampshire; and Burlington, St. Johnsbury, and Newport, Vermont.

15. PPNNE health centers are staffed with experienced practitioners. We employ physicians, advanced practice clinicians (physicians' assistants, nurse practitioners, certified nurse midwives), registered nurses, and medical assistants. Each operates within their particular, authorized scope of practice so that health care services are delivered as efficiently and cost-

effectively as possible. While not all of our practitioners have the skills and training to provide every service we offer, such as abortion services, we expect all of our practitioners to be able and willing to provide patients with accurate information about our services or refer them to a practitioner who can provide such information.

16. PPNNE currently employs about 240 individuals, including full-time staff, part-time staff, and contract workers. We also currently have interns, trainees, and contractors who help facilitate and provide patient care and fulfill our mission. While I would not consider all of these individuals PPNNE staff, throughout this declaration, I include within the term "staff" all such individuals, in addition to our employees, given the broad definitions in the Rule.

17. In 2018, we posted about 90 job openings and had 58 interns and approximately 1,000 volunteers. Currently, PPNNE has 26 job openings and 16 positions for interns and volunteers that we are actively seeking to fill, including positions at a number of our smaller health centers that are more leanly staffed.

B. PPNNE's Federally Funded Services

18. PPNNE receives a significant amount of federal funding; in 2018, those funds accounted for $6.7 million, or 28 percent, of PPNNE's total revenue. This total includes both federal grants and payments from Medicaid and Medicare.

19. The federal grant program from which PPNNE receives the most funding is the Title X program, which subsidizes the provision of family planning services to low-income people. Under Title X, HHS "is authorized to make grants and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services." 42 U.S.C. § 300(a). Title X grantees may provide the program services themselves or contract with delegate agencies (or "subgrantees") to provide the services. PPNNE receives a direct Title X grant

in New Hampshire and is a subgrantee in Vermont and Maine.

20. Services provided under the Title X program include contraceptive services and counseling, pelvic exams, pregnancy testing and counseling, testing for STIs and HIV, screening for breast and cervical cancer, and certain basic infertility services. With respect to contraception, the Title X guidelines say that Title X projects should "make available to clients all methods of contraception approved by the Federal Food and Drug Administration," including oral contraceptives, IUDs, and emergency contraception. In addition, each Title X project must "[o]ffer women the opportunity to be provided information and counseling regarding each of the following options: (A) [p]renatal care and delivery; (B) [i]nfant care, foster care, or adoption; and (C) [p]regnancy termination." 42 C.F.R. § 59.5. Title X permits entities that provide abortions to receive Title X funds for a family planning project, provided that those entities maintain programmatic and financial separation between the subsidized project and their abortion services and the project does not include "abortion as a method of family planning." 42 U.S.C. § 300a-6.

21. Under PPNNE's current Title X grant and subgrants, we receive $1.9 million a year to provide family planning services to low-income individuals throughout the region.

22. PPNNE also receives approximately $313,000 a year of federal funding from the state of Vermont under the Social Security Block Grant ("SSBG" or "Title XX") program, 42 U.S.C. § 1397 *et seq*., to provide family planning services. The SSBG program is administered by HHS to provide funds for each State to furnish social services best suited to meet the needs of its residents.

23. PPNNE receives approximately $400,000 a year in additional funding from other HHS programs as well.

24. In addition, all of our health centers provide care to patients who receive Medicaid benefits or who are insured via Medicare. The annual Medicaid and Medicare payments to PPNNE total approximately $2.7 million.

25. PPNNE is also partnering with a team of researchers from local universities and states to provide phlebotomy services for the Drug Injection Surveillance and Care Enhancement for Rural Northern New England study (DISCERNNE). This study is funded in part by the National Institute on Drug Abuse, within HHS's National Institutes of Health.

26. Therefore, PPNNE and its patients have a lot at stake under the Rule. If PPNNE were found to be out of compliance with the Rule, we could lose more than $6.7 million—or approximately 28 percent of our revenue. HHS provides Title X funding to Maine Family Planning, which provides subgrants to PPNNE and other entities; it is my understanding that a compliance action against one of those other subgrantees could place PPNNE's funding at risk.

THE RULE'S IMPACT ON PPNNE AND ITS PATIENTS

27. There are several aspects of the Rule that are deeply troubling. If PPNNE is forced to implement the Rule, it will interfere with and frustrate PPNNE's mission to champion and promote quality sexual and reproductive health, and will put patients at risk of being denied care and information about the services they seek.

28. First, I understand that under the Rule, any individual who works at PPNNE—including clinicians, volunteers, trainees, and contractors—has the right to refuse to provide or assist with abortion or sterilization services, and potentially other services we provide, if that individual claims a religious or moral objection. The Rule also broadly defines "assisting in the performance" of a particular service to sweep in a universe of activities that may be refused, including but not limited to "counseling, referral, training, or otherwise making arrangements" for the procedure or service. I also understand that the Rule does not incorporate the "undue hardship"

exception to religious accommodations from Title VII, and instead appears to require absolute accommodation of employees' objections—even as to core health services that our patients rely upon us to provide.

29. Second, I understand that the Rule includes a definition of "discrimination" that, among other things, would prohibit PPNNE from asking prospective employees, interns, volunteers, and contractors about whether they have an objection to performing or assisting in the performance of abortion or sterilization, and possibly other services, prior to finalizing the employment or work relationship. The Rule's restrictions on questions we can ask during pre-employment and other screening interviews increases the likelihood that we will have to accommodate individuals who refuse to provide certain care and for whom we would not currently be required to provide accommodation.

A. The Rule Threatens Patient Access to Care and Is Not Workable for Our Health Centers.

30. Currently, PPNNE has a policy of providing accommodations that allows us to balance our obligations to accommodate employees' religious beliefs and practices, including their refusal to participate in specific health care services, with the needs of the patients we serve. This Rule upends that careful balance and instead forces us to put our patients' needs second to those who wish to deny them care.

31. Accommodating a blanket refusal by one of our staff to perform or assist in the performance (as broadly as that is defined) of all abortions or another reproductive health care service that we provide, as the Rule appears to require, would be very burdensome for PPNNE given the manner in which we provide health care. On any given day we may see patients who are seeking STI treatment, abortion care, gender affirming care, or any of our other services. Our clinicians are expected to provide the services our patients require (within the limits of their

training) and to do so in a compassionate, nonjudgmental manner.

32. Moreover, we may not know in advance every service that will be provided on a given day or shift. We allow for walk-in patients, and even our scheduled patients may come in for one service but ultimately need or request other health care or information about different health services.

33. For example, a patient who comes in for pregnancy testing may discover she is pregnant. PPNNE provides ethical, non-directive pregnancy counseling in the following ways: Patients are asked about their feelings about their pregnancy. PPNNE health care providers use open-ended questions to best understand what options each patient may pursue, and make sure that, when the patient is unsure, she understands all options: parenting, adoption, and abortion. Patients are given resources according to the option(s) they express interest in, and for all options if they are undecided. This non-directive pregnancy counseling often requires referrals for particular pregnancy services, including abortion, on request of the patient. When making referrals, PPNNE providers are open and transparent with patients about which referral partners provide which services, consistent with medical and ethical standards. PPNNE providers only provide information about or refer patients for services that patients have indicated they are interested in receiving or learning more about.

34. Forcing PPNNE to accommodate individuals who refuse to provide care will be especially burdensome for our patients seeking abortion care. Abortion care is an extremely stigmatized health service that patients can only access at a very limited number of providers. Our society and culture already make people feel bad about the decision not to carry an unwanted pregnancy to term. Indeed, there are often protestors outside PPNNE's health centers who shame patients for their reproductive choices. But when people walk through our doors, they know our

health centers are a safe space for them to talk about *all* of their options without judgment. If our patients were to encounter someone at our health centers who would not provide them information about or provide the procedure itself, they would be further stigmatized. Most of our patients would have nowhere else to turn.

35. The forced accommodations required by the Rule will also be detrimental to our patients who seek access to emergency contraception, including our patients who are victims of sexual assault. Emergency contraception is birth control that an individual can use to prevent pregnancy up to five days after unprotected sex. Depending on a patient's circumstances, she may need a form of emergency contraception that requires a visit to a health care professional and a prescription. By the time some patients reach us to obtain emergency contraception, they may have only a short window remaining to utilize this form of care, and any further delay could result in unintended pregnancy. To the extent that the Rule could be interpreted to require accommodation of staff who object to the provision of emergency contraception, the Rule would imperil these patients' health.

36. Moreover, under the Rule, we might not know if one of our staff is refusing to provide information or services. As I understand it, under the Rule, an individual could decline even to tell the patient that the individual has withheld full information about the range of available and recommended medical options. This aspect of the Rule could have a devastating effect on a person's health and life. A clinician who declines to provide all relevant medical information and options to a patient and refuses to refer that patient to someone who will, or who privileges a personal view over the scientific consensus, could no longer be counted on to adequately serve our patients.

37. Even assuming we could withstand keeping on staff someone who refuses to provide or assist with the core reproductive services we are known for providing, we would have to radically revise our work schedules or send clinicians to different health centers (assuming that is legally permissible under the Rule, as I explain below) to account for the limitations in the services a clinician is willing to perform.

38. Accommodating individuals who have an objection to providing or assisting with a core health service would be nearly impossible at some of our health centers that employ only a few individuals. PPNNE has 18 health centers where there is only one licensed clinician at any given time, and that person is expected to provide a full range of reproductive health care, including contraception, emergency contraception, and medication abortion. We also have eight health centers that generally have only three individuals on staff at a given time: a clinician, a front-office staff member, and a healthcare assistant who, for example, takes patients' vital signs and medical histories.

39. A refusal by any one of the individuals at one of these small centers to perform or "assist in performing" an abortion, pregnancy testing, birth control counseling, or other reproductive health care services would make it very difficult and costly, if not impossible, for those health centers to continue providing the full scope of reproductive health care currently offered. For example, if the front-desk staff person had an objection to scheduling or checking in patients who seek abortion services, there would be no way to accomodate this person because there may be no other staff member working who has the knowledge and training to play that role. The same would be true for the one clinician who is responsible for caring for all the patients seen on that clinician's shift, and for the person in the back of the health center who is responsible for taking vital signs, medical history, etc. for all patients. There may be no one else who can step in

to do these individuals' jobs if they refuse to care for a patient.

40. Accordingly, depending on the scope of the objection, the responsibilities of the staff person, and the nature of the health center's capacity, an objecting individual could force us to cut services and turn away patients, potentially resulting in reduced hours, elimination of staff positions, and closure of health centers.

B. The Rule Will Harm PPNNE's Reputation and Reduce Patient and Community Trust in PPNNE.

41. The Rule will also injure PPNNE's reputation in communities we serve and damage patient goodwill and trust. We are trusted by patients and the communities we serve to provide nonjudgmental, science-based counseling on reproductive health and sexuality. Indeed, in many areas that our health centers are located, we are the only health care provider that provides such counseling and care.

42. We have had patients tell us that they seek care at our health centers because they know we provide nonjudgmental care and will provide patients with information about all of their options. This is especially true for our patients who come in with or suspect that they have an unintended pregnancy and who are looking for information about abortion.

43. It is critical to our mission and reputation that the counseling services we provide be accurate, science-based, and balanced. If patients are not receiving complete, science-based information about their reproductive health options, it will undermine patients' trust in PPNNE, and result in a loss of goodwill in the community. Similarly, if patients encounter staff at our health centers who refuse to care for them or provide them with the information they are seeking, they are likely to feel stigmatized and lose trust in Planned Parenthood.

C. The Rule Poses a Security Threat to PPNNE and Its Staff and Patients.

44. Planned Parenthood's mission is to provide comprehensive reproductive and

complementary health care services and information in settings that preserve and protect the essential privacy and rights of each individual. For this reason, PPNNE has developed a screening process for employees and other staff members to ensure we work with qualified individuals who are committed to providing nonjudgmental care to all patients—regardless of the services they seek and their identity. A key aspect of the screening process is determining whether prospective employees, interns, trainees, and contractors are actually willing to provide or assist with the health services that we offer to our patients.

45. We also view our screening process as essential to maintaining the safety and security of PPNNE, its staff, and its patients. PPNNE has developed procedures to screen out applicants who may pose a security threat. Although certainly not all individuals opposed to providing or assisting with services we provide have bad intentions, it is a sad reality that there are individuals who strongly oppose Planned Parenthood because we provide abortion services and they will take extreme action to obstruct the delivery of abortion services and even hurt those providing abortion services. Several of our health centers have been targeted by anti-abortion protestors, and anti-abortion advocates have posted the name of PPNNE's medical director on a website that encourages people to harass anyone associated with abortion. Other affiliates and PPFA, our national office, have also been the subject of large-scale operations to sabotage Planned Parenthood by individuals whose mission is to destroy the organization. Abortion providers have been harassed and even killed. Thus, we take the security of our staff, their families, our patients, and organization very seriously.

46. We have had individuals in the past apply for a job with PPNNE who we believed to be opposed to Planned Parenthood or the services Planned Parenthood provides, but through our screening processes were able to detect their true motives and prevent them from being hired.

47. It is my understanding that the Rule prohibits us from asking applicants basic questions about whether they have objections to providing or assisting with any service. As a result, the Rule will fundamentally alter the screening processes I described above, which depend on our ability to ask these questions of applicants.

48. The required changes to our screening process will impair our mission, forcing us to bring on board a potentially unlimited number of staff who are unwilling to perform core aspects of their jobs and our services. The Rule will also pose a security threat by limiting the tools at our disposal to root out applicants with malicious intentions; these individuals, if hired, may have access to our staff and patients, including our patients' most private health information. I also fear that under the Rule even more such individuals will apply for jobs at PPNNE because they will know that we cannot affirmatively ask them in the screening process whether they object to providing or assisting with our services.

D. The Rule Permits Conduct Inconsistent with Our Providers' Professional Obligations.

49. Planned Parenthood's Medical Standards & Guidelines clarify that health care providers must inform their patients about *all* relevant options for treatment—regardless of whether the provider finds any of those options morally objectionable—in order to abide by the principles of informed consent. If physicians have religious or moral objections to providing a particular procedure, their ethical obligation is to refer patients to another provider who will treat them. In emergency situations in which a referral is not possible, they must provide the care the patient requires.

50. By allowing health care workers to refuse to provide patients with care or information about their options, even in emergencies, the Rule would facilitate a violation of these foundational principles of ethics—elevating health care workers' personal beliefs above their

patients' health. For example, a health care worker may refuse to provide gender affirming care to a transgender patient on religious or moral grounds, leaving that individual without necessary care in the short term, and discouraged from accessing other health care in the long term. And if a health care worker at one of our leanly staffed, rural health centers refused to provide a pregnant patient with information about all of her options, including abortion, the patient could be prevented from accessing abortion until later in pregnancy, when risks of complication are higher. The pregnant patient may even be delayed past the point in pregnancy when abortion is available in her state. In all these instances, the health care workers would be putting their personal beliefs above a patient's health, or even life.

E. The Rule Will Impede Our Patients' Access to Care That Depends on Other Entities.

51. In addition to threatening patient care offered directly by PPNNE, the Rule, once effective, would impair our patients' access to care that depends on other providers. For example, while abortion is a very safe medical procedure, some of PPNNE's abortion patients who experience complications need to seek care at hospitals. Other patients are not experiencing a complication, but are concerned about signs or symptoms and will seek care at hospitals or with other providers. I am worried that if the Rule takes effect, these patients may be denied care by a practitioner who refuses to treat them because they are seeking care related to an abortion.

52. In addition, a patient who chooses to continue her pregnancy to term may either spontaneously abort (this is commonly called miscarriage), or develop a medical complication so serious that it is medically advisable to terminate the pregnancy. These patients need to have their pregnancies ended or their abortions completed and a denial of care could threaten their lives, health, or future fertility.

53. The substantial percentage of PPNNE's patients who rely on health insurance may also face impediments to care erected by insurance companies and permitted by the Rule. For example, Vermont has a law that requires group health insurance plans sold in the state to provide coverage for contraceptive drugs and devices if the plan provides prescription drug coverage. I am concerned that some insurance companies may refuse to provide contraception for reasons they deem permitted by the Rule, frustrating patient access to care. If an insurance company does not reimburse for contraception, our health centers would bill the patient on a sliding-fee schedule, potentially at increased cost to the patients.

F. The Rule Will Force PPNNE to Expend Substantial Resources for Compliance.

54. I understand that, under the Rule, PPNNE will have to certify compliance with the Rule, even though there are many aspects of compliance that we simply do not understand.

55. If the Rule takes effect, we will have to review and revise our interviewing processes and our guidelines for supervisors, and revise and reprint our employee personnel manual—all of which will take a significant amount of staff time. We will also need to organize and conduct new trainings for human resources staff and supervisors who handle personnel matters at all of our health centers about our obligations under the Rule. Any such significant policy changes require legal review, and we will likely need to obtain outside employment counsel.

56. In addition, we will most certainly have to seek legal advice to help us navigate all the questions the Rule raises but does not address. For example, the Rule raises serious questions about our training regime. Currently, all of our clinicians are trained in the basics of abortion care and contraceptive care. In addition, we provide ongoing training to our clinicians, including by having a site manager or assistant site manager observe a clinician to assess his or her competency in counseling patients.

57. The Rule also raises questions about whether Planned Parenthood must keep on staff individuals who refuse to perform primary job functions, whether patients can be denied care or information even in emergency or life-threatening situations, and what is a "persuasive" enough justification for inquiring about employee objections more than once per year. It also does not address what would happen if an employee developed an objection after having already told the employer that he or she has no objections.

58. The Rule also does not clarify how far an employer must go to accommodate an objector to avoid unlawful discrimination. For example, must an employer take religious objections into account when making scheduling decisions, or would that instead be considered discrimination? Is an employer allowed to require employees to tell someone when they have refused to provide care to a patient? Similarly, the Rule says that "an entity subject to any prohibition in this part shall not be regarded as having engaged in discrimination against a protected entity where the entity offers and the protected entity [e.g., an employee or volunteer] voluntarily accepts an effective accommodation for the exercise of such protected entity's protected conduct, religious beliefs, or moral convictions." 84 Fed. Reg. at 23,263. But it is unclear what providers should do when an employee does not "voluntarily accept[]" an offered accommodation and instead demands an accommodation that would put patients at risk or otherwise compromise patient care.

59. In addition, I understand that the Rule states: "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." This simply does not provide any guidance and instead suggests that were we to post such notice we could be found to have engaged in discrimination and risk that an enforcement action be taken against PPNNE.

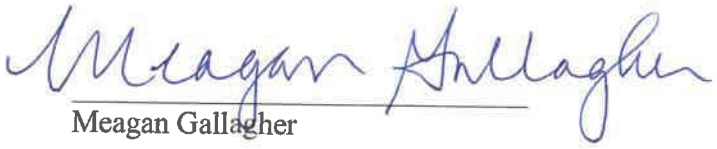
THE IMPACT OF A LOSS OF FEDERAL FUNDING ON PPNNE

60. Given the breadth of the Rule and the numerous unanswered questions about how we must comply with the Rule, I am very concerned that we may run afoul of the Rule's onerous and vague requirements. If PPNNE lost federal funding, we would not be able to continue our operations as they exist today. Our health care centers are already operating at a budget deficit. While we currently are able to cover these gaps through temporary measures and fundraising, we would not be able to make up for the loss of all or a significant portion of our federal funding.

61. A complete loss of federal funding would likely result in a significant decrease in our size and ability to provide health care services to our patients. We estimate that it would require the closure of between 8 and 11 health centers, which would likely impact between 11,000 and 19,000 patient visits. We would likely have to eliminate staff positions in those health centers as well as reduce our administrative and centralized support staffing. In addition to these closures, we would have to consider reducing our hours and staffing at the remaining health care centers, and/or increasing what we charge for our services.

62. If PPNNE had to close health centers, reduce hours, reduce staffing, or increase its fees, these changes would significantly undermine (and at a minimum, delay) low-income individuals' access to the critical reproductive health services we provide. There are not enough other health care providers in the region to take care of our patients if we are forced to cut back. In particular, other providers in our communities do not have the capacity to take our Medicaid patients, nor do I believe they would want to do so given Medicaid reimbursement rates.

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



Meagan Gallagher

EXHIBIT D

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

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. 19-cv-05435 (rel:19-cv-04676-PAE; 19-cv-05433-PAE)

DECLARATION OF CLARE M. COLEMAN

I, Clare M. Coleman, declare and state the following:

1. I am the President and CEO of the National Family Planning & Reproductive Health Association ("NFPRHA"), a Plaintiff in this action. I submit this declaration in support of Plaintiffs' motion for a preliminary injunction barring enforcement of the Department of Health and Human Services ("HHS") regulation entitled: Protecting Statutory Conscience Rights in Health Care, 84 Fed. Reg.

23,170 (May 21, 2019) (to be codified at 45 C.F.R. pt. 88) (the "Health Care Refusal Rule" or the "Rule"). A preliminary injunction would preserve the *status quo* during the pendency of this case and allow NFPRHA's members to continue to provide quality family planning and other critical health care services to low-income patients as they have for decades, and prevent the Health Care Refusal Rule from disrupting and undermining the provision of this critical health care.

2. I submit this declaration to provide information about NFPRHA's membership, on whose behalf it sues, and the Title X program. I also set forth facts showing the irreparable harms that will ensue if the Health Care Refusal Rule is allowed to take effect. These harms will affect not only Plaintiffs—including their clinicians and their patients—but also the general public health across the country.

MY BACKGROUND AND EXPERTISE

3. I have led NFPRHA for nearly ten years. Prior to assuming NFPRHA's leadership, I was President and CEO of Planned Parenthood Mid-Hudson Valley, a Title X provider with, at that time, 11 health centers in a four-county area. At Planned Parenthood Mid-Hudson Valley, I directed a 110-person staff, the majority of whom were dedicated to providing clinical services, and I oversaw the organization's $9 million operating budget.

4. My work experience also includes significant time as a senior staff

person on Capitol Hill, with an emphasis on health care and appropriations-related efforts, and as a legislative representative for Planned Parenthood Federation of America.

5. As discussed below, from 2010 to 2014, the Centers for Disease Control and Prevention ("CDC") and HHS's Office of Population Affairs ("OPA") (the HHS office responsible for Title X family planning) developed a joint publication on how to provide quality family planning services. That document, "Providing Quality Family Planning Services," is now referred to in the field as "the QFP."[1] In developing these new national clinical standards for family planning care, CDC and OPA worked with various panels of outside experts.

6. The Acting Director of OPA appointed me to serve as a member of the Expert Working Group that advised the CDC and OPA throughout their development of the QFP. The Expert Working Group advised on the structure and content of the QFP recommendations and helped make those recommendations as feasible and relevant to the needs of the field as possible.

7. Through my professional experience, my interactions with NFPRHA members and with OPA and other federal agencies, my related work with Congress, and my review of literature and historical material, I am well-versed in

[1] Centers for Disease Control and Prevention & Office of Population Affairs, *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs* (Apr. 2014), https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf (hereinafter "QFP").

the history of Title X, all aspects of Title X programs (including best practices for providing family planning services and ensuring compliance with federal funding restrictions), and the process of Title X grant-making, and am regarded as an expert in the field.

8. This declaration is based upon my personal knowledge, experience, and expertise.

NFPRHA AND ITS MEMBERSHIP

9. NFPRHA is a national, non-profit membership association that advances and elevates the importance of family planning in the nation's health care system and promotes and supports the work of family planning providers and administrators, especially those in the safety net (i.e., those providing publicly funded care). The interests that NFPRHA seeks to vindicate in this suit are central to its mission. NFPRHA is the lead national advocacy organization for the Title X family planning program, and it works to maintain Title X as a critical part of the public health safety net. NFPRHA envisions a nation where all people can access high-quality, client-centered, affordable, and comprehensive family planning and sexual and reproductive health care from providers of their choice.

10. In addition to its Title X advocacy, NFPRHA provides education, expert resources, and technical assistance to Title X grantees and sub-recipients, and concretely supports the work of those entities on an ongoing basis as they

implement Title X. In addition to its direct membership assistance, NFPRHA's meetings and conferences enable members to share expertise and experiences. If necessary, NFPRHA engages in litigation to ensure that Title X operates lawfully. Among other efforts, NFPRHA also advocates for and supports maintaining access to abortion services and works to advance health equity by eliminating barriers that contribute to disparities in health care access.

11. NFPRHA represents more than 850 health care organizations in all 50 states, the District of Columbia, and the U.S. territories, and also includes in its membership individual professionals with ties to family planning care. NFPRHA's organizational members include state, county, and local health departments; private non-profit family planning organizations (including Planned Parenthood affiliates and many others); family planning councils; hospital-based health practices; and federally qualified health centers ("FQHCs"). One of NFPRHA's members is Plaintiff Public Health Solutions.

12. NFPRHA currently has more than 65 Title X grantee members and almost 700 Title X sub-recipient members. 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.

13. The majority of these patients live on income levels at or below the

poverty line and are uninsured or underinsured. In 2017, 90% of Title X users had family incomes that qualified them for either subsidized or no-charge services. Forty-two percent of Title X users were uninsured, which is more than triple the national rate for adults (13%).[2] If they were not able to obtain care at the health centers associated with NFPRHA members, many of these patients would have no other access to family planning services.

14. The services NFPRHA members provide include contraceptive education and counseling; a wide range of contraceptive services, including provision of birth control pills, emergency contraception, and intrauterine contraceptives (commonly called IUDs); breast and pelvic exams and cervical cancer screening; education on health promotion and disease prevention; pregnancy testing and non-directive pregnancy options counseling and referrals; screening for, and treatment of, sexually transmitted infections; and HIV testing and counseling. In addition to providing family planning services, some NFPRHA members also provide a range of other reproductive and primary health care services including prenatal care and abortion services.

15. In addition to Title X funding, many of NFPRHA's organizational members and their network of health centers accept Medicaid. Medicaid, Title

[2] Office of Population Affairs, *Title X Family Planning Annual Report: 2017 National Summary* (Aug. 2018), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2017-national-summary.pdf (hereinafter "2017 FPAR").

XIX of the Social Security Act, 42 U.S.C. § 1396, is a joint federal-state program that provides reimbursement to health care providers for the provision of health care services, including family planning services, to low-income individuals. In 2017, Medicaid paid for $495 million worth of services provided by entities that receive Title X funding.

16. Additional federal funding sources administered by HHS help finance services provided by many NFPRHA members, including the Title V Maternal and Child Health Block Grant (a federal-state partnership to supplement health care for mothers, children and their families); Title XX Social Services Block Grant (grants to enable states to fund a range of social and health services); Temporary Assistance to Needy Families (grants to states to provide cash assistance, education and direct services, including family planning, for needy families); the Ryan White HIV/AIDS Program (the largest federally funded program for low-income, uninsured, and under-insured people living with HIV/AIDS); CDC's STD program funds (grants to all states and certain cities with high STD prevalence rates); State Children's Health Insurance Program (federal matching funds to states to expand health care coverage for uninsured children); and grants under Section 330 of the Public Health Services Act to provide primary health care services to underserved populations.

17. NFPRHA members also receive federal funding administered by

agencies other than HHS, which would nonetheless be at risk under the Rule. This includes, for example, the Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC"), which is administered by the Department of Agriculture.

HISTORY AND STRUCTURE OF THE TITLE X PROGRAM

18. Title X is the only dedicated source of federal funding for family planning services in this country. Title X became law as part of the "Family Planning Services and Population Research Act of 1970." Pub. L. No. 91-572, 84 Stat. 1504 (1970).

19. Title X was enacted with overwhelming bipartisan support. In 1969, President Richard M. Nixon called on Congress to "establish as a national goal the provision of adequate family planning services … to all those who want them but cannot afford them," stressing that "no American woman should be denied access to family planning assistance because of her economic condition." President Richard M. Nixon, Special Message to the Congress on Problems of Population Growth (July 18, 1969).

20. However, Congress also recognized that, in this area of individuals' reproductive decision-making, there must be "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). Thus, through Title X, Congress sought to provide low-income patients with biomedical contraceptives, with equal access to high-quality family planning medical care, and with the true freedom to make their own decisions about whether and when to have children. Those purposes remain the Title X program's central focus.

21. Indeed, every year from 1996 to the present, in making appropriations for Title X, Congress has reiterated that it must fund only *voluntary* family planning projects. This echoes two sections of the original Title X enactment. 42 U.S.C. §§ 300, 300a-5. In addition, every year from 1996 to the present, Congress has mandated that within the Title X program, "all pregnancy counseling shall be nondirective." *See* HHS Appropriations Act, 2019, Pub. L. No. 115-245, 132 Stat. 2981, 3070-71 (2018).

22. Section 1001 of the statute provides for the funding of competitive grants to public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects, *see* 42 U.S.C. § 300, and those projects are Title X's means of service provision to individuals.

23. In every fiscal year from 2015 to 2019, Congress has appropriated $286,479,000 annually for Title X purposes. Of that, HHS distributes approximately $260 million annually in grants under Section 1001 to fund Title X family planning services.

24. HHS awards grants to fund Title X care in geographic service areas throughout the country and in the U.S. territories. Within each project funded by Title X, there are typically three levels: the grantee, sub-recipients, and individual service sites.

25. Title X coverage across the nation, whether urban, rural, or suburban, is wide. In 2010, the Guttmacher Institute reported that 72% of U.S. counties had at least one health center supported by Title X.[3]

26. In some states and territories, the state or territorial health department is the sole grantee operating the single Title X project for the state or territory; other states or territories have a non-profit organization as the sole grantee; and in other states or territories there may be multiple Title X grantees with multiple projects. Roughly half of Title X grantees are governmental entities and half are non-profit institutions. Some grantees handle only overall program direction, funding, administration, and oversight, while their sub-recipients provide all clinical care at their service sites. In other instances, the grantee itself operates direct service sites and may or may not also have sub-recipients who operate additional sites.

27. In 2017, Title X-funded health centers served 4,004,246 clients.

[3] Special tabulations of data from Jennifer J. Frost, Mia R. Zolna & Lori Fohwirth, *Contraceptive Needs and Services, 2010*, Guttmacher Institute (July 2013), https://www.guttmacher.org/sites/default/files/report_pdf/ contraceptive-needs-2010.pdf.

Women made up 88% of those served, men 12%. Title X programs serve patients without regard to age or marital status. In 2017, approximately 91% of program users were adults; 9% were 18 or 19 years of age, 47% were between 20 and 29, 36% were 30 or older. Title X programs serve a racially and ethnically diverse population, including a disproportionately high percentage of black and Latina clients. According to the 2017 FPAR, 54% of program users identified as white, 22% as black or African-American, 33% identified as Hispanic or Latinx, 4% as Asian, and 1% as either Native Hawaiian or Other Pacific Islander or American Indian or Alaska Native. 2017 FPAR at 10-12. 25. Fourteen percent of 2017 users reported having limited English proficiency. *Id.* at ES-2.

28. Consistent with Title X's purpose, providers in a Title X project must give priority in the provision of services to persons with limited incomes and in fact, Title X clients are overwhelmingly poor or low-income. In 2017, 90% of clients had incomes at or below 250% of the federal poverty level ("FPL"); 67% had incomes at or below poverty the poverty level and 23% had incomes between 101-250% of the FPL. *Id.* at 21. In 2017, the FPL for a single person was $12,060 and $24,600 for a family of four in the 48 contiguous states and District of Columbia.[4] As required by Title X regulation, clients with incomes below the federal poverty line do not pay anything for the services or supplies they receive

[4] Office of the Secretary, U.S. Dep't of Health & Human Services, *Annual Update of the HHS Poverty Guidelines*, 82 Fed. Reg. 8831 (Jan. 31, 2017).

from a Title X provider. For clients with incomes not below the federal poverty line but not more than 250% of that level, Title X providers charge using a schedule of discounts to the reasonable cost of providing services or supplies.

TITLE X CLINICAL STANDARDS AND PROGRAM REQUIREMENTS

29. Each Title X project supplements its federal funding with service reimbursement payments, such as from Medicaid or private insurance, patient-paid fees (from those with incomes between 101 and 250% of the FPL as well as from patients paying full fee for their care), and/or state, local or private sources. These sources, together with Title X funds, comprise the project's overall budget. But the Title X grants are the essential backbone of this national program. That is because the Title X grant requires the critical feature of free care for low-income patients, supports staff and infrastructure expenses that are not reimbursable under insurance, arises out of merit-based selection of grantees, and requires providers to comply with all of the Title X program's comprehensive requirements.

30. All care within any Title X project, even though the Title X grant is only a part of the project's budget, is bound by the federal law, regulations, and clinical and administrative standards of the Title X program.

31. The central OPA office within HHS, which was created by the same legislation that established Title X, administers the overall program. As OPA's current Program Requirements for Title X summarize:

> All Title X-funded projects are required to offer a broad range of acceptable and effective medically (U.S. Food and Drug Administration (FDA)) approved contraceptive methods and related services on a voluntary and confidential basis. Title X services include the delivery of related preventive health services, including patient education and counseling; cervical and breast cancer screening; sexually transmitted disease (STD) and human immunodeficiency virus (HIV) prevention education, testing, and referral; and pregnancy diagnosis and counseling.[5]

The Program Requirements also specify that Title X services are to comply with the national standards of clinical care set forth in the QFP, discussed further below.

32. When a patient comes to a Title X-funded health center, she or he sees and experiences it as a place to gain access to clinical care by medical professionals—just like any other health center or doctor's office.

33. Likewise, the clinical care expected by patients and offered under the terms of Title X is the same type of care that is offered in a private-practice medical office, not second-class care. The confidential, trusting clinician-patient relationship, for example, is at least as important to Title X patients as it is to any other patient populations.

34. In fact, in my experience and based upon my knowledge of the field, 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.

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[5] Office of Population Affairs, *Program Requirements for Title X Funded Family Planning Projects*, at 5 (Apr. 2014), https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf.

That is because Title X patients often have had a previous negative experience in attempting to navigate the health care system as low-income persons and have fewer personal connections to health care professionals that they can draw upon. They often have no or limited other options for care. Patients often face multiple challenges in receiving appropriate and complete clinical care, such as language barriers, cultural differences, a history of trauma or abuse, and/or other vulnerabilities. And 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 to allow the communication that is essential for quality clinical care and education.

35. For all these reasons, Title X patients especially need to be able to count on the professionalism, thoroughness, and sensitivity to patients' concerns from the medical providers they encounter within Title X health centers.

The QFP Clinical Standards

36. Because Title X aims to best advance equal and effective access to family planning methods and services, OPA has periodically adopted and revised clinical standards and other program guidance. These have governed grant applicants and grantees to help ensure that Title X programs are providing evidence-based clinical care consistent with current nationally recognized standards, and are consistently and effectively accomplishing Title X' s purpose.

37. In 2014, the OPA and the Centers for Disease Control issued a joint publication on clinical standards for providing quality family planning services. The QFP describes national clinical guidance for any family planning provider, whether funded by Title X or not.

38. The QFP set new national clinical standards for family planning services, after a lengthy process involving dozens of technical experts and the Expert Working Group of which I was a part. It drew on the CDC's "long-standing history of developing evidence-based recommendations for clinical care" and the fact that "OPA's Title X Family Planning Program has served as the national leader in direct family planning service delivery" since 1970. QFP at 2.

39. The QFP's recommendations "outline how to provide quality family planning services, which include contraceptive services, pregnancy testing and counseling, helping clients achieve pregnancy, basic infertility services, preconception health services, and sexually transmitted disease services." *Id.* at 1. These recommendations, for example, are used by medical directors, including those who oversee Title X projects, "to write clinical protocols that describe how care should be provided." *Id.* at 3.

40. As described in the QFP, chief among the essential attributes of quality care (discussed immediately after safety and effectiveness) is a "[c]lient-centered" approach. *Id.* at 2. Client-centered care means starting from the client's

own reason for seeking family planning information or services. *Id.* at 2, 4. It is also essential that care "is respectful of, and responsive to, individual client preferences, needs, and values" and that individual "client values guide all clinical decisions." *Id.* at 4. Thus, under the QFP standards, providers' own preferences do not determine patient care. Instead, providers are trained and work hard to provide patients in a culturally sensitive and individualized way, with the information and assistance each patient needs to make informed decisions consistent with the patient's own priorities and beliefs—not those of an individual provider.

41. Similarly, QFP appendices that address quality family planning counseling and best practices for providing information to clients stress the fundamental principle that "[e]stablishing and maintaining rapport with a client is vital to" family planning counseling. *Id.* at 45; *see id.* at 48.

42. Further, "[c]lients need information that is medically accurate, balanced, and nonjudgmental to make informed decisions," and the provider "must present information in a manner that can be readily understood and retained by the client." *Id.* at 46. The QFP discusses strategies for making information accessible and clear to clients, to help ensure that each one can understand the options and make informed choices.

43. The QFP specifically instructs, 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." *Id.*at 14. "Options counseling should be provided in accordance with the recommendations from professional medical associations, such as ACOG [(the American College of Obstetricians and Gynecologists)] and AAP [(the American Academy of Pediatrics)]." *Id.* at 14. 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.*

44. Similarly, at the National Clinical Training Center for Family Planning, funded by OPA to support Title X-funded providers, one of the 14 designated "core competencies" for family planning care is the ability to "[p]rovide pregnancy testing and counseling and appropriate referrals (to prenatal care, adoption services, and abortion), as needed."[6] The core competency emphasizes that this counseling should be nondirective and include medically accurate discussion about options.

45. The QFP also endorses an approach to contraceptive counseling that emphasizes sharing with patients information about effectiveness of contraceptive choices. It "support[s] offering a full range of Food and Drug Administration (FDA)-approved contraceptive methods," as long as each is safe for the particular

[6] National Clinical Training Center for Family Planning, *Core Competencies for Contraceptive and Other Related Family Planning Services in the Context of Zika*, http://nctcfp.org/Competencies/Core%20Competencies%20in%20English.pdf

patient, "as well as counseling that highlights the effectiveness of contraceptive methods" so that "clients can make a selection based on their individual needs and preferences." QFP at 2, 8. For clients "who have completed childbearing or do not plan to have children," the QFP instructs that "permanent sterilization (female or male) is an option that may be discussed. Women and men should be counseled that these procedures are not intended to be reversible and that other highly effective, reversible methods of contraception (e.g., implants or IUDs) might be an alternative if they are unsure about future childbearing." *Id.* at 9.

46. The QFP standard is to provide equitable, evidence-based care consistent with current professional knowledge, so that family planning does not vary in quality because of the personal characteristics of clients or the personal preferences of providers. *Id.* at 4.

PRIOR FEDERAL HEALTH CARE REFUSAL REGULATION AND LITIGATION

47. In the decades-long history of the federal health care refusal statutes, none of which delegate rulemaking authority to HHS, regulations purporting to clarify and interpret these laws have been promulgated only one other time, in late 2008.

48. At that time, HHS promulgated a notice of proposed rulemaking purporting to interpret and enforce the federal health care refusal statutes claiming "concern . . . that there is a lack of knowledge on the part of States, local

governments, and the health care industry" of the refusal rights contained within these statutes. Proposed Rule, Ensuring that Department of Health and Human Services Funds Do Not Support Coercive of Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 50,274, 50,278 (Aug. 26, 2008)) (hereinafter "2008 NPRM"). Despite allowing only a 30-day comment period, HHS received more than 200,000 comments in response to the proposed rule—the vast majority of which opposed the rule as unnecessary, unauthorized, and overbroad. Notably, HHS conceded in the final rule published December 19, 2008, it received "no Comments indicating that there were any [federal] funding recipients not currently compliant with [the underlying statutes]." Ensuring that Department of Health and Human Services Funds Do Not Support Coercive of Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 78,072, 78,095 (Dec. 19, 2008) (hereinafter "2008 Refusal Rule").

49. The 2008 Refusal Rule would have permitted institutions and individuals employed at federally funded health care entities to refuse to provide a variety of basic health care services, including information, counseling and referrals, while completely ignoring the needs and rights of patients. *Id.* at 78,074. The 2008 Refusal Rule was scheduled to become effective on January 20, 2009—Inauguration Day.

50. On January 15, 2009, NFPRHA filed suit in the U.S. District Court for

the District of Connecticut seeking to enjoin the rule from taking effect (*National Family Planning & Reproductive Health Association, Inc. v. Leavitt*, No. 09-cv-55). The case was consolidated in the same court with similar challenges brought by then-Connecticut Attorney General Richard Blumenthal (on behalf of himself and the Attorneys General of California, Illinois, Massachusetts, New Jersey, New York, Oregon and Rhode Island) and the Planned Parenthood Federation of America and Planned Parenthood of Connecticut.

51. A new notice of proposed rulemaking proposing to rescind the 2008 Refusal Rule was published in the Federal Register on March 10, 2009, with a 30-day comment period. Proposed Rescission of the Regulation Entitled "Ensuring that Department of Health and Human Services Funds Do Not Support Coercive of Discriminatory Policies or Practices in Violation of Federal Law," 74 Fed. Reg. 10,207 (Mar. 10, 2009) (hereinafter "2009 NPRM"). Because rescission had been proposed, the federal lawsuit was put on hold.

52. In 2011, HHS rescinded those aspects of the 2008 Refusal Rule that were "unclear and potentially overbroad in scope," but maintained those parts of the rule establishing an enforcement process for the federal health care refusal statutes and began an "initiative designed to increase the awareness of health care providers about the protections provided by the health care provider conscience statutes, and the resources available to providers who believe their rights have been

violated." Regulation for the Enforcement of Federal Health Care Provider Conscience Protections, 76 Fed. Reg. 9968, 9969 (Feb. 23, 2011) (hereinafter "2011 Rule"). This rule remains in effect.

THE 2019 HEALTH CARE REFUSAL RULE CONFLICTS WITH TITLE X'S COMMITMENT TO CLIENT-CENTERED CARE AND WILL HARM TITLE X PATIENTS

The Health Care Refusal Rule Will Authorize Employees With Religious or Moral Objections to Categorically Refuse to Provide Required Title X Services Despite the Harm It Would Cause to Patients or the Employer

53. As I understand it, the Health Care Refusal Rule includes expansive definitions that dramatically expand the scope, meaning, and impact of the underlying statutory refusal provisions, permitting numerous individuals—in Title X-funded settings and despite Title X requirements or client needs and wishes—to refuse to perform or take any "action that has a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program" administered by HHS (like Title X).

54. The Rule's expansive definitions of "assist in the performance" and "referral" and "refer for" would permit employees of Title X-funded health centers and other federally funded entities to refuse to provide certain reproductive health information and referrals, despite patient needs and in clear violation of the fundamental tenets of informed consent, ethics, and the Title X program requirements, including those found in the regulations, the statute, and the QFP.

55. As I understand it, the Rule also makes dramatic changes to the existing statutory understanding of "discriminate" or "discrimination," requiring an absolute accommodation by employers of their employees' religious and/or moral objections to performing or assisting in the performance of sterilization or abortion (including counseling and referral) and rejecting the longstanding balancing approach of Title VII of the Civil Rights Act that provided employers with the ability to manage religious accommodations for employees in a manner that balances the religious beliefs of the employee with the business operation needs of the employer.

56. The Rule also prohibits employers from asking job applicants whether they have any such objections to performing these aspects of the job. In fact, HHS explicitly refused to address in the Rule whether an employer under the Rule would be allowed to disqualify a person with religious or moral objections to covered practices even if such covered practices made up the primary or substantial majority of the duties of the position. However, HHS also stated in the Rule's preamble that it is "not an acceptable practice under Federal conscience and anti-discrimination laws for covered entities to deem persons with religious or moral objections to covered practices, such as abortion, to be disqualified for certain job positions on that basis." 84 Fed. Reg. at 23,191. As such, the rule puts Title X-funded health centers in the position of being forced to hire people who

intend to refuse to perform essential elements of a position.

57. Thus, "discrimination" under the Rule would seem to prohibit a Title X-funded entity from even asking a person applying for a job as a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests whether the individual would refuse to provide non-directive options counseling, let alone not hire the applicant because of such objections. And, once hired, the Title X-funded entity would be required to accommodate that objection without regard to the burden placed on the employer or the impact on patients.

58. Indeed, the Rule provides no meaningful guidance on how an employer is supposed to ensure patients continue to receive care in the face of an employee's objection to performing a core job function and still comply with the Rule. 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." 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 provide cold comfort to the employer trying to determine how to balance patient health and safety and comply with Title X's requirements and ensure that patients are receiving the care to which they are entitled by law, on a limited budget, without

risking the loss of critical federal funding.

59. This difficulty will be especially acute in Title X-funded settings without many employees, located in sparsely populated or rural areas, and in the 649 counties where a Title X-funded health center is the only publicly funded family planning provider.[7] For example, one Title X grantee in a rural state has only three nurse practitioners for its more than 10 health centers; these clinicians travel from health center to health center, meaning that only one would be at any one service site only a few days per month. If one (or more) of those clinicians objected to providing certain services, it would make it incredibly difficult for the health center or grantee to ensure that its patients continue to receive that care.

60. Title X-funded family planning organizations typically have deep expertise in the care they provide, and are trusted in their communities to provide high-quality, confidential, voluntary care to their clients. However, to the extent the Rule forces Title X providers to hire and employ individuals who actively withhold information and services from clients, the Rule will harm the providers' reputations and the provider-patient relationship of trust.

[7] Jennifer J. Frost et al., *Publicly Funded Contraceptive Services at U.S. Clinics, 2015,* Guttmacher Institute, (Apr. 2017), https://www.guttmacher.org/report/publicly-funded-contraceptive-services-us-clinics-2015.

The Health Care Refusal Rule Will Also Harm Title X Patients By Allowing into the Title X Network Employees and Entities That Refuse to Provide Required and Critical Title X Health Care Services

61. In many respects, the Health Care Refusal Rule is an attempt by HHS to achieve by a back door what courts have already blocked: remaking Title X's network of providers in order to replace high-quality, trusted providers with new participants who object to core Title X care and use their religious beliefs to limit patients' access to complete and accurate reproductive health information, displacing the primacy of a patient's own beliefs or needs.

62. In the arena of health care, and particularly family planning and sexual health, HHS-funded programs cannot achieve their fundamental, statutory objectives if grantees, providers, and contractors have a categorical right to refuse to provide essential services, such as non-directive pregnancy options counseling.

63. As I understand it, for state and local health departments (NFPRHA represents 80% of health department Title X grantees) the Rule's definitional expansion of discrimination would also put health department grantees and sub-recipients in the untenable position of being forced 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.

64. As such, the Health Care Refusal 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 that adhere to the law and provide full and accurate information and services to patients. 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. Diverting funds away from providers offering the full range of family planning and sexual health services would not only seriously undermine public health, especially for the low-income, uninsured, and under-insured, but would also be contrary to congressional intent and explicit statutory requirements of the Title X family planning program.

65. The Health Care Refusal Rule is HHS's third attempt to drastically change the Title X network in the last two years and reshape it contrary to the program's intent.

66. Traditionally, Title X grant competitions are run each year, and over a three-year period, all the grants are newly competed and awarded. The 2018 Funding Opportunity Announcement ("FOA"), which was unprecedented in that all jurisdictions were competed in a single year, drastically altered the criteria for evaluating grant applications. In particular, these changes deemphasized and devalued the provision of core Title X services—including nondirective pregnancy options counseling and abortion referrals—so that providers with objections to

performing those core services could still compete in the program. Fortunately, even with the relaxed criteria, HHS did not receive sufficient, adequate applications from those opposed to abortion counseling and referrals to fundamentally alter the network in the way it intended.

67. However, when that attempt to remake the network through the grant-making process failed, on June 1, 2018, HHS published a notice of proposed rulemaking for the Title X family planning program ("2018 Title X NPRM"). The 2018 Title X NPRM not only reintroduced the majority of a Reagan-era Title X rule known as the "domestic gag" rule, but it expanded those provisions and introduced numerous new and harmful requirements and restrictions.

68. The final rule was published on March 4, 2019. *See* Compliance with Statutory Program Integrity Requirements, 84 Fed. Reg. 7714 (Mar. 4, 2019) (hereinafter "2019 Title X Rule"). Among other provisions, the 2019 Title X Rule violated various federal laws by restricting the ability of *all* Title X providers to provide abortion referrals and allowing providers to exclude the option of abortion from pregnancy counseling, even when the patient specifically seeks information about abortion.

69. NFPRHA filed a challenge, along with three co-plaintiffs and in conjunction with a related case filed by the Attorney General of Washington, to the 2019 Title X Rule, seeking to enjoin and set aside the unlawful rulemaking before

the rule's effective date of May 3, 2019. On April 25, the U.S. District Court for the Eastern District of Washington issued a preliminary injunction enjoining HHS from implementing or enforcing any part of the 2019 Title X Rule. *See Washington v. Azar*, 376 F. Supp. 3d 1119 (E.D. Wash. 2019).

70. In effect, the Health Care Refusal Rule is an attempt to accomplish via the back door—the dismantling of these core elements of the Title X program—what HHS has been unable to and prevented from directly accomplishing by other means.

The Refusal Rule's Compliance and Enforcement Mechanisms Are Ripe For Abuse, Will Create Significant Compliance Burdens, and Will Jeopardize The Future of the Title X Program

71. In addition to the harms I describe above, I am very concerned that the Rule's new compliance and enforcement mechanisms will threaten the critical funding our members rely on to provide essential health care services.

72. For example, the Rule would allow the Office for Civil Rights to investigate any Title X-funded entity whenever any information—even a third-party complaint or a news report—"indicates a threatened, potential, or actual failure to comply with Federal conscience and anti-discrimination laws" or the Rule.

73. The Rule also requires covered entities to at all times maintain records "evidencing compliance" and explicitly states that covered entities must provide

the Department virtually unlimited access to its books, records, accounts, facilities, and information upon request, and without regard for privacy or confidentiality concerns.

74. If HHS determines that an entity—or one of its sub-recipients—is out of compliance with the Rule, HHS can withhold, deny, suspend, terminate, or clawback billions of dollars in federal funds, including non-HHS appropriated or administered funds. HHS can even terminate federal funding during the pendency of good-faith voluntary compliance efforts.

75. Moreover, given the Rule's permitting broad investigations based on potentially biased, agenda-driven complaints and the significant penalties under the Rule—including the requirement to report violations for a three-year period in any future grant applications—entities that receive HHS funds (including NFPRHA members) face significant concern about how collected information is intended to be used and whether it and/or any violations will unfairly prejudice consideration of applicants for federal funds or penalize currently funded entities in ways that could be extremely harmful.

76. Any loss of Title X funds would have a direct impact on NFPRHA members' functions: cuts in health centers' hours; staff layoffs; and, in some cases, health center closures. This would mean fewer patients would receive much-needed contraceptive and preventive services, as NFPRHA members are often low-

income patients' only option.

77. Indeed, six in ten Title X patients reported that the Title X-funded health center constituted their only source of health care over the past year.[8] Fourteen percent of all women and 25% of all poor women who obtained contraceptive services did so at a Title X-funded health center.[9] Ten percent of women who received a Pap test or pelvic exam, 18% of women who received testing, treatment, or counseling for a sexually transmitted infection (STI), and 14% of women tested for HIV during that time period received that care at a Title X-funded health center.[10]

78. Thus, loss of Title X-funded care—whether through reduced hours, staff layoffs, or closures—or directly through the provider refusals permitted by the Health Care Refusal Rule—will cause NFPRHA members' patients to suffer not only diminished access to family planning care, but also a range of other preventative care. The Health Care Refusal Rule would force NFPRHA members' patients to lose access to standard, ethical pregnancy counseling and referrals for abortion care, and would leave NFPRHA's members with few, if any, options to "use alternate staff or methods to provide or further any objected-to conduct"

[8] Megan L. Kavanaugh, Mia R. Zolna & Kristen Burke, *Use of Health Insurance Among Clients Seeking Contraceptive Services at Title X-Funded Facilities in 2016*, 50 Perspectives on Sexual & Reproductive Health 101 (Sept. 2018) https://www.guttmacher.org/journals/psrh/2018/06/use-health-insurance-among-clients-seeking-contraceptive-services-title-x.

[9] *Id.*

[10] *Id.*

without risking it being considered "adverse treatment" against the objecting employee or sub-recipient.

79. If HHS succeeds in bringing religious objectors into the Title X network, patients will also encounter more sites with other limitations, including only one or a few contraception options and no information about a broader range of methods, further undermining the program. All of these impacts will expose patients to greater health risks and more unintended pregnancies. The Health Care Refusal Rule will harm the central purpose of Title X and sacrifice low-income patients' care to these new mandates.

80. Given the consequences are so severe, the cost-burdens associated with complying with the Rule—including obtaining legal advice to assess and advise on compliance, including the Rule's interaction with existing state and federal legal obligations; reviewing and potentially revising job descriptions, hiring practices, and employee recruitment materials; revising policies and procedures, manuals, and handbooks; re-training staff with supervisory responsibilities on hiring and accommodation requests; and, of course, the cost of providing accommodations under the Rule and providing, if possible, alternate means for patients to receive the objected-to care—are significant.

81. Yet HHS grossly underestimates what compliance will entail. For example, the Rule estimates that covered entities will spend: (1) two hours on

average familiarizing themselves with the rule and its requirements, which represents the "one-time opportunity cost of staff time (a lawyer) to review the rule"; and (2) "an average of 4 hours [per year for the first five years] reviewing the assurance and certification language and the Federal conscience protection and associated anti-discrimination laws and the rule," which is "a function of a lawyer spending 3 hours reviewing the assurance and certification and an executive spending one hour to review and sign." 84 Fed. Reg. at 23,240-41.

82. Based on my knowledge and expertise of how seriously our members take their legal and ethical obligations, and based on my own review of the Rule (which runs over 100 pages) and the underlying laws, I believe this estimate totally misjudges the costs simply attempting to come into compliance with the Rule will impose on our members. For example, when the QFP standards were put in place in 2014, it took many grantees a year or more to update all policies and protocols, revise materials and have those materials reviewed by outreach and education committees (a process required under Title X guidelines), and sufficiently train staff at all service sites on the new clinical standards.

* * *

83. In conclusion, based on my knowledge and experience, it is my firm belief that if this Rule takes effect it will have a devastating impact on our members, the patients they serve, and the Title X program as a whole.

I declare under penalty of perjury that the foregoing is true and correct. This declaration was executed on June 13, 2019, in Washington, D.C.

Clare M. Coleman

EXHIBIT E

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

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-05435 (rel: 1:19-cv-04676-PAE; 1:19-cv-05433-PAE)

DECLARATION OF LISA DAVID

Lisa David declares and states as follows:

1. I am the President and Chief Executive Officer at Public Health Solutions ("PHS"). PHS is a not-for-profit corporation organized under the laws of New York, headquartered at 40 Worth St, New York, NY 10013. I have been the President and Chief Executive Officer of PHS since 2015.

2. I have more than three decades experience working in the health services field, including in the areas of hospital administration and direct services management. At PHS and throughout my career, I have been responsible for managing nonprofit public health care institutions' budgets, compliance and quality management, recruitment, and general operations.

I work closely with PHS's Program Directors to track, assess, and strategize ways to improve the performance of our programing, as well as managing our finances.

3. PHS was first established in 1957 and is currently the largest public health nonprofit serving New York City. PHS was originally created as part of the New York City Department of Health and Mental Hygiene ("DOHMH"), and though we are no longer part of a city agency, we continue to have a robust, long-standing partnership with the New York City and State governments. Our work reaches clients in all five boroughs, as well as in Nassau, Suffolk, Putnam, Westchester, and Rockland Counties. Notably, our sexual and reproductive health centers have been providing comprehensive, community-based family planning services (and related health care) to Brooklyn for over 50 years, resulting in a stable and trusted presence in their communities.

4. As an organization, PHS is dedicated to developing, implementing, and advocating for dynamic solutions to prevent disease and improve community health. PHS has been a leader in addressing crucial public health issues, including food and nutrition, health insurance access, maternal and child health, reproductive health, tobacco control, and HIV/AIDS prevention. Our programs have a strong focus on health disparities to ensure New York City families have the basics for a healthier life. As a Title X grantee, we are also a proud member of Plaintiff National Family Planning and Reproductive Health Association.

5. PHS employs approximately 415 individuals, including full-time staff, part-time staff, and contract workers. In addition, interns, volunteers, and contractors support us in caring for our clients and their communities.

6. I have read the Department of Health and Human Services' ("HHS") final rule (the "Rule") at issue in this case and understand that, unless it is blocked by a court, it will take

effect on July 22, 2019. Because I believe the Rule will immediately impede our efforts to achieve our goals, jeopardize the health and well-being of our patients, and will harm PHS's longstanding reputation in the community as a trusted provider of patient-centered, compassionate, high-quality health care, I submit this declaration in support of Plaintiffs' Motion for a Preliminary Injunction.

PHS'S FEDERAL FUNDS AT RISK BY THE RULE

7. Federal funds account for almost all of the money that PHS uses to provide family planning services either directly or through agencies with which it contracts.

8. PHS is New York City's largest grantee for the Title X[1] program—the federal government's only funding stream dedicated exclusively to family planning services—and has successfully competed for Title X grant funds for 36 years. PHS was most recently awarded a $4.6 million Title X grant, approximately 86% of which ($3.9 million) is dispersed to five delegate agencies (known as "sub-recipients"), as well as PHS's own two sexual and reproductive health centers, to provide family planning services to low-income and uninsured New Yorkers. PHS is also a sub-recipient of the New York State Department of Health's ("DOH") Title X grant, through which it receives additional Title X funding for its two health centers.

9. PHS and its sub-recipients rely on Title X funding to deliver family planning services. Title X funding constitutes approximately two-thirds of PHS's total family planning program revenue. This funding supports the provision of comprehensive sexual and reproductive health services, including clinical and support staff salaries and maintaining the health centers, as well as the procurement of contraceptives to increase same-day access to

[1] Title X refers to Title X of the Public Health Services Act ("PHSA"). 42 U.S.C. § 300(a).

methods that are more expensive for health centers to routinely stock, such as long-acting reversible contraceptives.

10. PHS and its sub-recipients are also reimbursed through the federal Medicaid program for services provided to eligible patients, including for family planning services and prenatal care. Medicaid reimbursement comprises 99% of PHS's non-grant patient service revenue.

11. PHS is the lead agency for the Healthy Start Program, an HHS project funded under the PHSA, which is a partnership through which pregnant people and children up to age two are referred for services to strengthen family resilience.

12. PHS receives over $25 million in grant funding from HHS for the Hospital Preparedness Program and Public Health Emergency Preparedness Cooperative Agreements. Through these programs, PHS supports hospitals and community-based organizations in developing and maintaining disaster plans for public health emergencies.

13. As a longstanding partner with the New York City government, PHS is also the administrator for a substantial amount of federal grant funding that the City receives, meaning PHS is responsible for re-granting that funding to other organizations. PHS administers the NYC DOHMH's $140 million grant from the Centers for Disease Control and Prevention to do HIV prevention work, as well as to train people to do that work. PHS is also the administrator for $125 million in grant funding from the Ryan White HIV/AIDS Program administered by HHS, which PHS re-grants on behalf of the NYC DOHMH as well as Rockland, Putnam, and Westchester Counties. Administering these grants strengthens PHS's already deep roots in the community through its work with over 200 local community organizations that receive the funding.

14. In total, PHS receives $182 million in funds that originate from the federal government—$138 million of which originates from HHS, with PHS receiving $31.4 million of those funds directly from HHS—all of which could be at risk if PHS is found to be out of compliance with the Rule.

15. As President and Chief Executive Officer, I am responsible for ensuring that our clinical locations and sub-recipients provide their clients with the full range of services required by the federal law governing these funding streams. For example, the Title X program requires PHS and its sub-recipients to provide clients with a broad range of effective, medically-approved family planning methods and services (such as comprehensive reproductive health exams, STD and HIV testing and treatment, and pregnancy testing); to provide services while respecting our clients dignity, and without subjecting them to any coercion; and to offer non-directive options counseling to pregnant people, including regarding prenatal care and delivery, infant care, adoption, and abortion. All PHS and sub-recipient facilities offer a broad range of medically approved family planning methods either on site or by referral.

16. Additionally, I am responsible for ensuring, along with PHS's Program Directors, that our services are meeting all applicable standards of care, including ensuring that patients provide informed consent. The AMA's Code of Medical Ethics explains that patients have a right to make voluntary, well-considered decisions about their care, and so health care providers must inform their patients about all relevant options for treatment in order to abide by the principles of informed consent.

17. To ensure compliance with state and federal standards and guidelines, PHS puts its sub-recipients through a rigorous application process. In addition, PHS employs an extensive quality-monitoring program for both its own sites and its sub-recipients. PHS conducts a

comprehensive monthly review of its own health centers' quality data, and reviews reports from sub-recipients on a quarterly basis, in addition to regular monitoring visits, internal reviews of policies and procedures, and interviews of staff and clients. We also closely monitor, investigate, and respond to all clients' complaints.

PHS'S HEALTH SERVICES

18. PHS addresses critical public health issues through a client-centered approach, which is at the core of our mission. In 2018, PHS served 105,000 individuals and families across New York City through our various direct services programs.

19. The services offered by our centers include: affordable, comprehensive, and confidential reproductive healthcare for adults and adolescents; services to support pregnant and parenting families, including one-on-one health care and education in the home as well as group support during pregnancy and early childhood; health insurance enrollment; and food benefits assistance, among other innovative public health programs and initiatives. Part of PHS's strength is our demonstrated ability to cross-refer clients to other PHS programs for a continuum of critical services, and to that end, some of the programs are even located together. For example, our sexual and reproductive health centers have on-site health insurance enrollment services, and frequently refer patients to our home-visit health care programs. Our Neighborhood Women Infants and Children ("WIC") program centers regularly refer clients to our programs for health insurance enrollment and food benefits assistance, both of which are located at the same site.

20. With respect to reproductive health care, PHS and its sub-recipients provide prenatal and family planning services to over 40,000 at-risk patients annually throughout New York City. As noted above, in addition to the provision of most available birth control methods

on-site (including long-acting reversible contraceptives and emergency contraception), Title X-funded services at our two health centers include free walk-in pregnancy testing; gynecological exams; men's sexual healthcare; teens' sexual healthcare; STD and HIV testing, treatment, and counseling; mental health services; and health education. We also provide additional services at our health centers, such as prenatal care and HIV prevention through HIV Pre-Exposure Prophylaxis, with non-Title X funds.

21. At all of our health centers, patients with a positive pregnancy test who receive counseling are offered neutral, nondirective counseling on all pregnancy options—including adoption, continuation of the pregnancy, and abortion—and referrals for medical care outside of the program are made as requested. This is not only required by federal law, but fundamental principles of medical ethics and informed consent. All counseling is provided in a patient-centered approach and is guided by the specific needs, values, and requests of the patients.

22. Our client population for family planning services is diverse: We see people of all races and ethnic groups. In 2017, 40% of PHS's Title X clients identified as Black or African American, compared to 26% of New York City's population, while 42% identified as Hispanic or Latino/a, compared to 29% of the City's population. We serve teenagers and adults; people who have children, or plan for children, or do not want to be parents. Our patients are married and unmarried; lesbian, gay, bisexual, transgender, and queer ("LGBTQ") individuals; and a significant portion are immigrants. A total of 15% of the clients had limited English proficiency.

23. We serve predominantly low-income, high-risk patients who are dependent on publicly subsidized health facilities to obtain basic—but critical—medical care. Approximately 70% of PHS patients are 100% below the poverty level, 76% are 200% below the poverty level,

and 26% lack health insurance.[2] Nearly all of our patients rely on Medicaid. The overwhelming majority of our family planning patients reside in medically underserved areas where reproductive health services are not easily accessed. Without publicly funded health care, our patients would likely receive no preventative care at all.

24. I know from my experience in the family planning field that the availability of pregnancy counseling, including information and referrals for abortion, is essential to the ability of our patients and their families to take control of their lives and do the best they can to create the futures they want for themselves and their children. Some of our clients tell us that they are doing everything possible to provide for their children and know that they cannot afford to expand their families. Other clients share that they are working their way through college or have just secured employment and that early parenthood (or another child) would derail their plans for education or work. We care for clients who are in abusive relationships for whom pregnancy can put them at grave risk both because abuse often increases during pregnancy and because having a child makes it much more difficult for a person to eventually escape from an abusive relationship. For these patients, access to contraception and abortion can be a matter of survival. For our clients who have recently given birth, it is important for their own health and for healthy birth outcomes that they not become pregnant again until their bodies have recovered. Finally, some of our clients do not want children, but without birth control and referrals to abortion care, they are unable to exercise autonomy and self-determination. For all of these clients, and others, the family planning services we provide are critical.

[2] In 2019, the 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 FR 1167 (February 1, 2019). In 2019, 200% of the FPL for a single person in the 48 contiguous states and District of Columbia was $24,980 per year, and $51,500 for a family of four.

THE RULE WILL INFLICT IMMEDIATE AND IRREPARALE HARM ON PHS AND ITS PATIENTS

25. I am very concerned that if the Rule takes effect, it will immediately prevent us from ensuring that our patients continue to receive the services they need in a safe, timely fashion—or at all. In addition, I fear that because the Rule prevents us from guaranteeing that our patients continue to receive the services we are obligated by federal law to provide, we may be forced to reduce or discontinue these essential reproductive health services.

26. Moreover, while PHS has always, to the best of my knowledge, complied with *all* federal laws and guidelines, I am very concerned that, because the Rule is in places vague and in other places appears to be inconsistent with existing legal requirements, the Rule places PHS at serious risk of losing its $138 million in federal funds administered by HHS. And, as I explain further below, if PHS lost its federal funding it would be devastating; we would have to close the doors on our two sexual and reproductive health centers instantly, leaving our patients to try to find other health care providers that provide free or low-cost high quality care. At a minimum, the health centers' 38 employees would be laid off. Additionally, losing our funding stream would impact our sub-recipients, putting their programing, employees, and clients at risk as well.

The Rule's Impact on PHS's Healthcare Delivery Model

27. It is critical to PHS's philosophy of care that we deliver all of our services in a compassionate and nonjudgmental way. For this reason, we work hard to recruit and hire people who are qualified and willing to provide the full range of services to all of our clients. During the hiring process, we inform all applicants of the nature of PHS's work, making sure to describe all of our programs and scope of services, including that we provide emergency contraception as well as counseling and referral for abortion care. We explain that we offer the same, comprehensive, high quality care to all patients, including to LGBTQ individuals, clients who

are sexually active outside of marriage, and to other members of our diverse client base.

28. No matter what specific position applicants have applied for within our health services programs, we ask whether they are willing and able to participate in providing all of our services to all of our clients. We do that because our employees of necessity work as a team, performing work beyond the specifics of their more individualized position titles. Experience teaches that clients rarely compartmentalize their lives to match our different program areas, but rather have a variety of interconnected needs. For example, a client who comes to our maternal and child health programs might reveal that she is pregnant and wants an abortion. Or an adolescent seeking sexual health education might reveal that he is in a same-sex relationship and wants testing and preventative treatment for HIV.

29. Over the years we have identified numerous job applicants who, once they learned more about PHS, have said that they would not be able to provide all of our services in a non-judgmental manner as required by the job, or would not be able to care for one or more of the populations we serve. PHS does not make decisions about job applicants based on their personal beliefs or presume that applicants of any given religious background would be less qualified or unwilling to perform a job at PHS. Rather, PHS relies on the applicants' self-identified limitations in their ability and willingness to perform all required aspects of the job.

30. However, the Rule completely eliminates our ability to strike the appropriate balance between individual staff member's objections and our patients' needs. For example, as I understand it, the Rule prohibits us from even asking job applicants whether they are willing to provide information about and referrals for abortion to patients who request it, or take any other action that has a "specific, reasonable, and articulable connection" to "furthering" an abortion. Yet PHS fills several positions each year for health care providers who conduct home visits, and

about six sexual and reproductive health providers (including doctors, nurses, social workers, and health educators). This does not even include hiring for other administrative staff positions that do not directly provide medical care or counseling, but who work with clinical staff to assist the provision of medical care and counseling.

31. Given that, under the Rule, the requirement to accommodate existing employees' refusals to provide certain care appears absolute, PHS would want to be even more careful about whom it hires when replacing existing positions—particularly nurses and social workers—but the Rule expressly forbids this. For example, there is a current opening for a nurse in one of our home health programs. PHS staff are currently reviewing applications for the position, and at this stage in the process, are assessing whether applicants are comfortable with providing all services required as part of our home-visiting model. If the Rule goes into effect, we will need to make changes to our hiring procedures in the middle of the process, resulting in delays in filling the position and uncertainty as to whether the candidates will provide the broad range of care required by the program. What if a patient reveals to this nurse during a home visit that she had unprotected sex and wants a pregnancy test and to discuss her options? When clients trust their PHS provider enough to reveal these confidences, we know that we are doing our job. Therefore, all of our employees must be able to connect clients to the services they need, whether by providing them with emergency contraception or pregnancy options counseling, or referring them for testing for STDs or for abortion care. It would turn our healthcare delivery model on its head if, following the client's disclosure, the PHS nurse refused to provide the care, information, counseling, or referrals the client needed. Not only would we not be providing the client with what they require, we would be passing judgment on them, thereby shutting down future communication between the client and our staff—if that client returns to us for care at all. Thus,

if the Rule takes effect, I am extremely concerned that PHS will now have no way of knowing if we have hired a candidate who would not help a client needing non-directive pregnancy options counseling or reproductive family planning, even though that is a key component of our service to those clients.

32. Of course, when objections to participating or assisting in the participation of any health care service do arise we have always strived to accommodate our staff members' objections. But our success in doing so has turned on having the flexibility to balance the needs of our patients with the individual beliefs of our staff. Where possible we have transferred duties, re-assigned staff, or otherwise accommodated the staff member's objection.

33. But under the Rule, we can only ask an employee if they object to performing one of their core job functions *after* we have hired them—and even then we can only ask once a year, unless there is persuasive justification to do so more often, but the Rule does not explain what meets that threshold. The employee, however, is under no obligation to inform us of any objections at any time. It could be weeks or months, if at all, before we ever find out that one of our employees is withholding care from our patients. From PHS's point of view, any amount of time where patients are not receiving complete counseling and evidence-based care is too long; when questions about abortion or other treatment do arise, it is at the very heart of our mission to provide comprehensive and accurate information in a non-judgmental manner. Our reputation depends on our non-judgmental approach and we believe it's why our clients stay with us for years and years and refer their friends and family to us as well.

34. Moreover, assuming we are aware of any such objections, the Rule appears to impose on PHS a categorical obligation to accommodate any employee's objection to, for instance, providing information or referrals relating to abortion or sterilization, even in an

emergency, regardless of the impact on patient and public health. In particular, I understand the Rule would eliminate any flexibility we once had to transfer duties or reassign staff. Our only option under the Rule would be to offer the objecting employee a "voluntarily acceptable" accommodation, whatever that may be.

35. I know for a fact that the total lack of flexibility under the Rule could be a problem at some of our clinical locations. For example, it is my understanding that before I started at PHS, our health centers were providing medication abortion for a period of time, and some of the nurses objected to being involved in the service. However, PHS staff were able to have conversations with those nurses about their concerns, conduct trainings to educate staff about medication abortion, and limit the provision of medication abortion to clinicians who did not object to medication abortion. Under the Rule, it is unclear whether it would be permissible for us to take any or all of these actions. Would the discussions and training with staff be considered "retaliation" or an "adverse action"? We have no way of knowing, and yet the consequences of being found to be out of compliance with the Rule could be devastating.

36. Currently, we employ only five medical providers (one doctor, three nurse practitioners, and one certified nurse midwife), three licensed practical nurses, and two social workers who are expected to cycle through our two clinical health centers in Brooklyn. The center in the Eastern Parkway neighborhood of Brooklyn has, at times, only one medical provider on hand to treat patients. Thus, if the medical providers, nurses, or social workers at any of these sites refused to provide non-directive options counseling, including information about abortion, we could not continue to provide these services.

37. This is so for several reasons. First, we do not have the funding to hire any additional staff at these sites. Each of our grant programs is very restrictive in how the funding

can be used, so the funds are not fungible across programs (and that assumes there would be a surplus that could be used to subsidize another program, when in fact our grant funding already does not cover the full cost of providing services). Second, we do not have another program that employs doctors, so we could not simply reassign them (putting aside whether that would constitute discrimination under the Rule). Third, we are required by both state and federal law to provide options counseling and referrals for abortion to all our patients, so, based on our funding and staffing limitations, there is no role at the health centers that would allow a clinician to avoid mention of abortion entirely. We practice non-judgmental and non-coercive counseling to satisfy our ethical obligations and good medical practices as health care providers. Such counseling should be based on the requests and situation of the patient, otherwise it risks imposing the provider's values on patients and undermining provider-patient relationships.

38. Nor could we transfer a client from staff person to staff person in the middle of a counseling session. For example, if a staff person were willing to discuss two but not all three pregnancy options with a client—that is, if a counselor were willing to discuss with a pregnant client her option to carry the pregnancy to term and raise a child and her option to carry the pregnancy to term and place the baby for adoption, but were not willing to discuss the abortion option—we could not simply transfer that client to another staff member to learn about abortion after she heard the first two options. In a program such as the Healthy Start Program that would be completely unworkable, because providers are visiting patients in their home, so there is no one else available to continue counseling. And assigning the client to a new provider would undermine the efficacy of the program, which is intended to create continuity in health care providers for patients who otherwise endure multiple clinical transitions from their pregnancies, to giving birth, to postpartum and pediatric care. As an administrative matter, in a health center

setting, this would interfere with client flow, inconvenience other clients, and lengthen office visits for clients who already have limited time. Further, our health centers accept walk-in clients, so it would be impossible to predict in advance what services will be needed on a given shift—and even when patients have scheduled appointments, they may ultimately request other treatment, counseling, or referrals about different services.

39. But more importantly, transferring clients to a different staff person sends a not-so-subtle message to the client that the PHS counselor is making a judgment about the abortion option and cannot even discuss it. This is contrary to our non-judgmental approach and unacceptable. Participation in our programs is voluntary, and disruption in the patient-provider relationship through the denial of a counseling request could not only disrupt the candor in the relationship, but could end the patient's participation in the program, leading to negative health outcomes for them and their families. I have no doubt that an interaction during a nurse's home-visit appointment that leaves the patient without access to the abortion she needs, and with a feeling that her PHS provider judged her for wanting an abortion, will be the end of that client relationship. And many of our clients learn about us through word-of-mouth—we do minimal marketing or advertising—so if trust in PHS is compromised, needy clients will simply not come to PHS for any of their other health and social services needs, and ultimately, they will not get the care they (and their young children) need, which would have broader public health consequences as well, including an increase in sexual transmitted infections, undetected cancers, and unwanted pregnancies, among other effects.

40. Additionally, arranging to transfer patients assumes that we will know about the staff person's objection and could plan accordingly, but the Rule does not ensure that we are aware of what services our staff will refuse to provide. As described above, I am gravely

concerned that, under the Rule, we may not even know if one of our staff members are withholding information or services from their patients, putting us at risk of violating our legal and ethical obligations, and risking our patients access to the critical, often life-altering, care they need and to which they are entitled.

41. This concern is not limited to counseling regarding abortion services, but extends to other PHS health services and counseling. Many of our health care providers work with patients to develop their long-term reproductive life plan, which sometimes includes counseling, referring for, and coordinating access to permanent forms of contraception through sterilization. Moreover, PHS is ahead of the curve in targeting high-risk populations, to ensure that those living with HIV/AIDS are connected with high-quality care, including LGBTQ individuals. However, given the Rule's broad definitions and confusing requirements, it is foreseeable that some providers will invoke the Rule to refuse basic care to patients simply because of their gender identity or sexual orientation.

42. Our sub-recipients' facilities will face the same challenges. Although we have a rigorous application and screening process, sub-recipients that already receive qualifying federal funds would be subject to the same restrictions we are under the Rule, and would be unable to confirm whether staff will request an accommodation and then refuse to provide the services. Likewise, once a sub-recipient is accepted to our grant programs, they are subject to the same accommodations requirements, potentially preventing us from fulfilling our grant obligations to the detriment of our patients.

43. The ramifications of violating the Rule are particularly expansive, because my understanding is that PHS can be held liable for violating the Rule if one of our sub-recipients violates the Rule. That means that all of PHS's federal funding could be put in jeopardy due to

the actions of a sub-recipient. And because PHS is a Title X sub-recipient for New York, should PHS violate the Rule, that would put all of the state of New York's federal funding at risk as well—thereby endangering all of their other sub-recipients' funding.

The Administrative Costs of the Rule

44. In addition to the costs to our patients and the public health, the Rule imposes significant and immediate costs on PHS.

45. I am aware that HHS estimates that the Rule will impose only minimal costs on each organization subject to its requirements. This is totally untrue. If the Rule is not blocked from taking effect, PHS would have to retain outside counsel to advise us and our Board of Directors. We would need to, with the assistance of legal counsel, review and revise our hiring and employment practices, policies, and forms, and our employee handbooks accordingly. This could be extraordinarily complicated not only because of the Rule itself, but also because many of our employees are covered by a union contract and the interaction between the union contract and the Rule will require additional time and resources to fully understand.

46. Once our new policies and practices are in place, we would have to hold trainings for our staff and our sub-recipients to educate them about our new policies and procedures, to the best of our understanding. Compliance with the Rule will necessitate redesigning of clinical protocols, patient flow, and the responsibilities and time management of staff across organizations and service sites, as well as determining how to document and monitor that new workflows are in compliance. Undergoing such organization-wide changes and re-trainings will require that, in the interim, services will be delayed or curtailed, leaving some patients to go without care.

47. In particular, we would also need to devote additional resources to observing

staff, as the Rule does not require an employee who refuses to provide certain services to notify a supervisor in advance, and we would be limited in our ability to ask employees. Unless we know what our employees are doing in the counseling or exam room, we will be unable to ensure the quality of our services. PHS already works with its network of sub-recipients to conduct compliance reviews using continuous quality monitoring and improvement practices as a core component of project management, to ensure the delivery of high quality family planning and related preventive health services. We also devote substantial time and energy to educating staff on the standards for non-judgmental, comprehensive reproductive health care, with the assumption that they will comply. Unless the Rule is blocked, PHS's Program Directors and other staff will need to spend even more time observing new hires and supervisors may need to do more frequent observations of employees and volunteers as they interact with clients in order to assure continued high quality of care. We would also need to review and revise our current grievance procedures for clients, and spend more time monitoring such grievances. However, it would be impossible to observe every client interaction, so there will be inevitable gaps in services for clients if staff can refuse care without notifying PHS.

48. I may also need outside legal counsel to determine how to provide services under some of the Rule's requirements that appear to conflict with mandates of other federal laws, as well as New York laws, that we are also obligated to follow. Under New York law, for instance, health professionals are prohibited from "abandoning or neglecting a patient or client under and in need of immediate professional care, without making reasonable arrangements for the continuation of such care."[3] New York law also specifically mandates informed consent for

[3] 8 NYCRR § 29.2; *see also* N.Y. Educ. Law § 6530 (defining professional misconduct as the same).

patients.[4] Under our Title X grant, we must likewise provide non-directive options counseling and a broad range of contraceptives. I would need guidance to navigate complying with the Rule's proscriptions, while still meeting our legal and contractual obligations.

49. We will also be required to devote significant staff resources to a job that does not exist today: tracking and maintaining the data necessary to demonstrate that PHS and its sub-recipients are in compliance with the Rule.

The Rule's Impact on PHS's Ability to Compete for Title X Funds

50. PHS is not only concerned about losing Title X funding should it violate the Rule. Even if PHS complies, the Rule would allow other organizations to compete with PHS for Title X funds, even when those institutions refuse to provide non-directive options counseling to their patients—a fundamental requirement of Title X—because to reject them would be an adverse action, prohibited by the Rule. Through the Rule, HHS is significantly lowering the barrier for entry into the Title X program, and it is the patients who will suffer. If PHS loses Title X grant funding to other organizations that object to providing the full range of reproductive health care, counseling, and referrals required under Title X, then PHS will have to cut Title X programming and services, and our former patients will not be able to access the services they need.

51. PHS will also be forced to reconsider whether it will participate in the Title X program at all. While PHS has a longstanding history of successfully competing for Title X funds and administering the program, the Rule's new requirements would be costly and perhaps impossible to implement. It is deeply concerning that violating the Rule, which PHS is subject to in part because of its participation in the Title X program, could put in jeopardy all of PHS's federal funding, implicating all of our programming beyond the reproductive health areas. As a

[4] N.Y. Pub. Health L. § 2805-d.

result, PHS may not be able to participate in the Title X program if bound by the Rule.

52. The loss of federal HHS dollars would be devastating to PHS and to the tens of thousands of clients we serve, particularly those living deepest in poverty. Even if they are able to access other health care providers, there are few other options for reproductive health care so patients will have to wait longer for appointments, and not all providers prioritize continuity of care, cultural sensitivity, and patient dignity as we do. By contrast, we have provided health care in these communities for decades, and worked hard to build up trust among those who may otherwise be reluctant to seek care through a variety of strategies, including recruiting linguistically and culturally competent staff. In some cases, PHS has been serving clients for an entire generation. Additionally, low-income clients often have the least flexibility in their schedules due to their job schedules, lack of adequate childcare options, or other reasons. For these reasons, at PHS we offer a variety of options for clients, including visits to our health centers, home visits, and after hours care. But we could not do this if we lost our federal funding. If this happened, we would have to cut back on services and close our own health centers—not to mention the impact on our sub-recipients and the sites that they run. Cuts in services to patients will cause them irreparable harm, as well as degrading public health.

53. If PHS were no longer able to provide family planning services, it would have an immediate and irreparable impact on vulnerable communities in particular. For example, PHS and its sub-recipients all provide services designed for teens and young adults, and in 2017, adolescents 19 or younger comprised 16% of all PHS' Title X Family Planning Program clients. But if adolescents seeking respectful, confidential care feel stigmatized due to a denial of treatment, counseling, or a referral, they are unlikely to return for additional services, cutting off what is, in some cases, their only source of sexual health education and care. We also serve a

significant portion of undocumented immigrants, for whom we are often their only option to access health services. If we violate their trust by refusing services, then the consequences can be dire if they are unwilling to return to our health centers and cannot find assistance elsewhere. I note that this erosion of trust will exacerbate the widely reported decreased enrollment in Medicaid and use of health care (including family planning) and other services by eligible individuals due to fear of punishment arising from the publication of proposed changes to the public charge determination.

* * *

54. If the Rule is not blocked, PHS will immediately face a Hobson's choice: attempt to comply with the Rule (depriving untold numbers of our patients of the services to which they are legally and ethically entitled, damaging our longstanding reputation as health care providers, incurring tremendous compliance-related costs, and risking being found in violation of other state and federal laws governing patient care) *or* decline millions of dollars in federal funding (forcing the discontinuation of services and even closure of some health centers, and leaving the thousands of high-risk patients who depend on us with few, if any, options). Of course, even if we attempted to comply with the Rule, some of its requirements are so vague, that we could nevertheless be found out of compliance—and even if we are found out of compliance and attempt in good faith to come into compliance, the Rule still gives HHS the right to withhold any or all of our federal funds during that process.

55. For all these reasons, I ask the Court to prevent the serious harm the Rule would immediately inflict on both our patients and on PHS itself by stopping enforcement of the Rule.

I declare under penalty of perjury that the foregoing is true and correct. This declaration was executed on June 17, 2019, in New York, New York.

Lisa David

EXHIBIT F

UNITED STATES DISTRICT COURT
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 (rel. 1:19-cv-4676; 1:19-cv-5435)

DECLARATION OF STEPHEN TODD CHASEN

Stephen Todd Chasen, M.D., F.A.C.O.G., declares and states as follows:

1. I am board-certified in Obstetrics and Gynecology and Maternal Fetal Medicine, and I am licensed to practice in the state of New York. I am also a Fellow of the American Congress of Obstetricians and Gynecologists. I currently hold several professional positions: I am a Professor of Clinical Obstetrics and Gynecology at Weill Cornell Medical College, Cornell University, and I am an Attending Obstetrician and Gynecologist at New York Presbyterian Hospital. A more complete account of my professional qualifications and accomplishments is set forth on my Curriculum Vitae, attached hereto as Exhibit A.

2. I submit this declaration in support of Plaintiffs' Motion for a Preliminary Injunction, preventing the enforcement of a regulation promulgated by the U.S. Department of

Health and Human Services ("HHS") entitled "Protecting Statutory Conscience Rights in Health Care."

3. In my professional opinion, implementation of the Regulation could have devastating consequences for pregnant women who need emergency medical care because it appears to allow health care providers to refuse to provide medical care, even in emergencies.

Refusing to Provide Referrals or Information About Abortion is Unethical and Contrary to Informed Consent Principles

4. The American College of Obstetricians and Gynecologists ("ACOG") advises that upon a pregnancy diagnosis, a patient should be fully informed, in a balanced manner about all options, including carrying the pregnancy to term or having an abortion. American College of Obstetricians & Gynecologists ("ACOG"), *Guidelines for Women's Health Care: A Resource Manual* 719-20 (4th ed. 2014). Furthermore, the American Medical Association ("AMA") Code of Medical Ethics advises that withholding information without the patient's knowledge or consent is ethically unacceptable. American Medical Association ("AMA") Code of Medical Ethics § 2.1.3. The challenged rules would authorize health care providers to violate medical ethics and principles of informed consent by withholding information or referrals from a patient. Withholding information about or referral to an abortion provider in an emergency could be life-threatening.

5. ACOG also recognizes that health care providers may have religious or moral objections to providing certain health care, but those objections do not extend to providing information and referrals. ACOG, *The Limits of Conscientious Refusal in Reproductive Medicine*, No. 385 (Nov. 2007, reaffirmed 2016). Indeed, even when providers have an objection to the provision of a certain aspect of reproductive health care, "they must impart accurate and unbiased information so that patients can make informed decisions about their

health care." *Id*. at 5. Similarly, "[p]hysicians and other health care professionals have a duty to refer patients in a timely manner to other providers if they do not feel that they can in conscience provide the standard reproductive services that their patients requests." *Id*.

Medical Conditions That Require Emergency Abortions

6. While many women have relatively healthy and uncomplicated pregnancies, between 15 and 25% of pregnant women either spontaneously abort their pregnancies prior to 20 weeks gestation (this is sometimes called miscarriage), or develop serious medical complications that could pose a serious risk to the woman's life or health. Because of the frequency with which these situations arise, any health care provider who treats pregnant women will sometimes be faced with circumstances in which his or her patients seek prompt abortions to prevent harm to their health or life.

7. For some of these women, it would be medically inadvisable to postpone medical treatment to either end the pregnancy or to complete the abortion, if the abortion has begun spontaneously. Indeed, depending on the particular medical condition (some of which I discuss below), if there is any delay in ending a pregnancy because the hospital where she goes or is taken in an emergency refuses to provide this necessary care, the pregnant woman could suffer a variety of serious impairments, including: loss of future fertility, seizures, strokes, renal failure, and even death.

8. Even if the pregnant woman's condition does not seem like an absolute emergency when she first arrives at a hospital seeking care, delaying treatment may be dangerous, as some conditions can deteriorate quickly and dangerously: an infection that seems mild may quickly become severe; moderate hemorrhage may become uncontrollable without notice; an unruptured ectopic pregnancy can hemorrhage and/or rupture at any time, with very

serious, sometimes lethal, consequences. Because the course of a serious pregnancy complication cannot be predicted, if there is *any* meaningful risk to the woman's life from continuing the pregnancy, the standard of care requires that the woman not be turned away and that an abortion be performed or completed promptly.

9. In order to understand how dangerous the Regulation is for pregnant women in this country, I will describe some of the more common situations that can arise quickly (and often without notice) in pregnancy. In considering how the Regulation will affect emergency medical treatment of pregnant women, it is important to bear in mind that most women, especially low-income women, do not have the luxury of choosing what hospital to go to and will not know in advance if their hospital has a policy that prevents the medical treatment they may ultimately need, or whether hospital staff will refuse to provide the needed care. This is especially true for women in need of emergency care who typically arrive by ambulance or simply rush to the closest emergency room. Thus, women with symptoms of ectopic pregnancy or pregnancy loss may unexpectedly end up in the emergency room of a hospital without any way of knowing if they will be unable to obtain appropriate medical treatment to prevent serious health complications or even save their life.

Threatened, Inevitable, or Incomplete Abortion

10. Among the most common complications of pregnancy are "threatened abortion," "inevitable" abortion, and "incomplete" abortion. A patient experiencing these conditions typically presents with abdominal pain and vaginal bleeding. If she is bleeding, but the cervix is not dilated, the spontaneous abortion is "threatened," but not certain. If there is bleeding and cervical dilation, the spontaneous abortion is "inevitable." If there is bleeding, cervical dilation, and gestational tissue is in the vaginal canal or has passed from her body, the spontaneous

abortion has begun, but is incomplete. Even in the presence of heavy bleeding and cervical dilation ("inevitable" abortion), the embryo may have a visible heartbeat.

11. The indicated treatment for inevitable and incomplete abortion (with significant bleeding or pain), as well as threatened abortion with significant bleeding where the woman wants to terminate the pregnancy, is to induce or complete the abortion. Because an ultrasound performed when the woman presents with any one of these conditions often confirms the presence of cardiac activity, a health care provider who is opposed to abortion may refuse to complete an inevitable or incomplete abortion.

12. However, failure to induce or complete abortion promptly in a woman with inevitable or incomplete abortion and significant bleeding, pain or signs of infection places her at risk of worsening pain, hemorrhage and/or serious infection. While some women may not end up with serious complications if they are denied care, some inevitably will: severe hemorrhage can develop or infection can set in at any point. To prevent these life- and health-threatening occurrences, if the woman presents with serious bleeding, severe pain, or evidence of infection, it is advisable to evacuate the uterus without delay.

Preterm Rupture of the Membranes with Chorioamnionitis

13. Another risky situation that arises in pregnancy is called "preterm rupture of membranes," which describes the rupture -- prior to the 37th week of gestation -- of the membranes that surround a fetus and that contain amniotic fluid. Preterm rupture of membranes most often occurs spontaneously for reasons that are not well understood. It is an important cause of maternal morbidity and mortality and can lead to serious infection.

14. When a pregnant woman experiences a preterm rupture of membranes together with chorioamnionitis – an infection of the placental lining – it is typically necessary to terminate

her pregnancy. If the fetus has not yet reached the gestational age where it is viable, the accepted medical treatment is abortion.

15. Abortion is necessary because chorioamnionitis may cause severe infection of the reproductive tract and systemic sepsis – a serious infection that spreads throughout the body – if treatment is delayed. The infection can result in scarring of reproductive organs, sometimes necessitating their removal, and may be fatal if allowed to progress untreated.

16. For a physician to refuse to treat a patient with preterm rupture of membranes with chorioamnionitis would violate the standard of care. If the chorioamnionitis is severe, continued pregnancy is life-threatening. Even if the chorioamnionitis is relatively mild when the woman first presents, delaying treatment exposes her to a significantly increased risk of serious and even life-threatening infection that can develop rapidly and may not be brought under control with antibiotics. The presence of a fetal heartbeat does not change the risk of severe morbidity or death to the mother, and does not alter the obligation of a physician to promptly terminate the pregnancy to preserve maternal health.

Preeclampsia

17. Another condition that occurs in pregnancy is called "preeclampsia." It tends to occur toward the end of pregnancy, but can occur in the second trimester, prior to fetal viability, as well. Preeclampsia is a form of pregnancy-induced hypertension characterized by high blood pressure and proteinuria (excessive urinary protein). Patients with preeclampsia can also experience "eclampsia," characterized by grand mal seizures.

18. A patient with inadequately treated preeclampsia is at significant risk for cerebral hemorrhage (i.e. stroke), as well as liver dysfunction or failure, kidney failure, temporary or permanent visual disturbances or vision loss, coma, and death.

19. The only cure for severe preeclampsia is termination of the pregnancy. If severe preeclampsia occurs before the fetus has reached viability, the medically accepted treatment is abortion. To minimize the risk of significant physical injury or even death, it can be critical to stabilize the patient and then begin the abortion process without delay.

Placental Abruption

20. Some pregnant women develop a serious condition called placental abruption in which the placenta separates from the inner wall of the uterus, either partially or completely. Placental abruption can cause the woman to bleed heavily. If the fetus has not reached viability and the patient presents with severe hemorrhage, ending the pregnancy immediately is required to stop the bleeding.

Ectopic Pregnancy

21. A common complication of pregnancy is called "ectopic pregnancy." An ectopic pregnancy occurs whenever a fertilized egg – called a "blastocyst" at this stage – implants anywhere other than in the endometrial lining of the uterus. The vast majority of ectopic pregnancies involve a fertilized egg implanting in one of the fallopian tubes. In some cases, the pregnancy may develop significantly and cardiac activity may be present.

22. According to the Centers for Disease Control and Prevention, ectopic pregnancy accounts for approximately 2% of all reported pregnancies. Ruptured ectopic pregnancy is a significant cause of pregnancy-related mortality and morbidity, accounting for approximately 3.0% of all pregnancy-related deaths. It is the leading cause of obstetric hemorrhage-related mortality. The prevalence of ectopic pregnancy among women presenting to an emergency department with first-trimester vaginal bleeding, or abdominal pain, or both, has been reported to be as high as 18%. [ACOG Practice Bulletin #193. "Tubal Ectopic Pregnancy". The American

College of Obstetricians and Gynecologists: Washington DC, 2018.]

23. A fertilized egg that implants in one of the fallopian tubes may subsequently extrude into the peritoneal cavity. Such a "tubal abortion" typically occurs spontaneously and can result in hemorrhage.

24. A fertilized egg implanted in a fallopian tube may also cause the tube to rupture, resulting in hemorrhage.

25. In addition to life- or health-threatening hemorrhage, a ruptured tubal pregnancy can cause scarring of the tube, which can then result in either compromised fertility, infertility, and future ectopic pregnancy. An ectopic pregnancy can also attach to various organs, including the ovaries, the liver, and the intestines. These organs can be permanently compromised by the pregnancy.

26. An ectopic pregnancy generally requires either surgical or medical intervention. If no rupture has occurred, the ectopic pregnancy may often be terminated safely and effectively using the drug methotrexate. This drug causes the rapidly dividing cells comprising the pregnancy to die and to be either reabsorbed or expelled.

27. If surgery is necessary, such as in the case of a ruptured fallopian tube or impending rupture, it involves removing the pregnancy from the fallopian tube, and in some cases removal of a portion or all of the fallopian tube is required. Rarely, the ovary may be involved, and removal of the ovary may be necessary. In some circumstances, the implantation site may be such that removal of the entire uterus becomes necessary to protect the patient's life. Surgical intervention is less complicated and carries substantially less risk for the patient when performed before the ectopic pregnancy ruptures the fallopian tube or other organs.

28. Delaying treatment in cases of un-ruptured ectopic pregnancies exposes patients

to the risk of substantial physical harm and possibly of death. This is because at any moment, the patient may suddenly experience a rupture, requiring emergency surgery and resulting in permanent injury to one of more of her organs, or death from uncontrollable hemorrhage. Even if the woman does not die of hemorrhage, she may need blood transfusions, which carry their own risks.

29. To prevent the grave harms posed by an ectopic pregnancy, the standard of care for treating a suspected ectopic pregnancy does not permit delay in intervention. Indeed, any delay might well make the difference between a situation that may be treated with medication or relatively minor and uncomplicated surgery and an emergency procedure that carries greater risk of permanent injury or death.

Women Seeking Abortions Sometimes Need Emergency Care

30. Abortion is a very safe procedure. The overall abortion-related mortality rate in the United States is approximately 0.6 per 100,000 procedures (compared to a mortality rate for childbirth of approximately 8 per 100,000 women). Complications short of death are also very low. There are, however, occasions when women having abortions will need emergency care.

31. The most common serious complications occurring during surgical abortion procedures are uterine injury and/or hemorrhage. These conditions usually require immediate transfer from the health care facility where the abortion is being performed to a hospital. Delay in treatment once the woman arrives at the hospital could be catastrophic, leading to infertility or worse.

32. Often second-trimester surgical abortions are performed as a two-step, two-day procedure in which dilators are inserted into the woman's cervix on day one and the uterine evacuation is performed on day two. Patients return home between the two procedures. In a

very small percentage of cases, however, women go into labor at home as a result of the cervical dilators. These women often go to a hospital emergency room where they present in a similar condition to women who are in the midst of a miscarriage. If they are experiencing significant bleeding or have evidence of infection, they face all the same risks I describe above for women experiencing threatened, inevitable, or incomplete abortions, and require the same care.

33. Women having first-trimester medication abortions may also need hospital care. While this procedure is also extremely safe, a small percentage of patients undergoing medication abortion will experience significant blood loss. If these women call their health care provider, they may be told to go to the emergency room; other women will simply go to an emergency room on their own. Some medication abortion patients who are bleeding heavily do not require transfusions, but are best treated by completing the abortion surgically to stop the bleeding. Any delay in evacuating the uterus increases the risk that transfusion will become necessary.

34. Finally, some women who have already had a first- or second-trimester surgical abortion will develop serious complications a few days after the procedure is completed. The most common post-abortion serious complication is infection, the signs and symptoms of which usually arise within 48-96 hours post-abortion. In some cases, infection may be due to retained gestational tissue. If the woman first becomes aware of the symptoms (pain and fever) during normal business hours, and she lives near the health facility where the abortion was performed, she will often go there for treatment. However, if the symptoms develop over the weekend, or at night, or if the woman lives far from the abortion provider, she will generally go to the emergency room. Because untreated infection can result in chronic pelvic pain, infertility, or systemic sepsis and death, a high index of suspicion and expedient treatment are warranted.

35. Women in these circumstances may need immediate care, and this could include surgically evacuating any retained gestational tissue as well as administration of antibiotics. I am afraid that because the care they need could be seen as completing their abortions, or cooperating in the provision of abortion services, health care providers and hospital staff could refuse to provide or assist with that care, thereby threatening the lives and health of these women.

Conclusion

36. Based on ACOG's *The Limits of Conscientious Refusal in Reproductive Medicine*, No. 385 (Nov. 2007, reaffirmed 2016), "[a]ny conscientious refusal that conflicts with a patient's well-being should be accommodated only if the primary duty to the patient can be fulfilled." In an emergency, in which referral is not possible, "providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections."

37. If the Regulation is enforced, and if health care providers are permitted to refuse to provide necessary medical care to pregnant women even in an emergency, some women in this country will be subjected to sub-standard medical care, and will result in meaningfully increased maternal injury and mortality.

EXECUTED: June 13, 2019

I declare under penalty of perjury that the foregoing is true and correct.

Stephen Todd Chasen, M.D., F.A.C.O.G.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

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

PLEASE TAKE NOTICE that pursuant to Federal Rule of Civil Procedure 65, Plaintiffs hereby move the Court for a preliminary injunction to enjoin Defendants from implementing, applying, or taking any action under the Final Rule entitled *Protecting Statutory Conscience Rights in Health Care: Delegations of Authority*, 84 Fed. Reg. 23,170 (May 21, 2019), in order to preserve the status quo until this case is decided on the merits and final judgment is entered.

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

In support of this motion, Plaintiffs rely on the accompanying Memorandum of Law, the Declaration of Matthew Colangelo, the exhibits attached to that Declaration, the pleadings and papers on file in this action, and any argument and evidence that is presented on the hearing of this motion.

DATED: June 14, 2019

Respectfully submitted,

LETITIA JAMES
Attorney General of the State of New York

By: */s/ Matthew Colangelo*
Matthew Colangelo
Chief Counsel for Federal Initiatives
Lisa Landau, *Chief, Health Care Bureau*
Justin Deabler, *Assistant Attorney General*
Brooke Tucker, *Assistant Attorney General*
Amanda Meyer, *Assistant Attorney General*
Office of the New York State Attorney General
28 Liberty Street
New York, NY 10005
Phone: (212) 416-6057
Matthew.Colangelo@ag.ny.gov

Attorneys for the State of New York

Steven C. Wu
Deputy Solicitor General
Ester Murdukhayeva
Assistant Solicitor General

Of Counsel

ZACHARY W. CARTER
Corporation Counsel of the City of New York

By: */s/ Tonya Jenerette*
Tonya Jenerette
Deputy Chief for Strategic Litigation
Cynthia Weaver, Senior Counsel
Otis Comorau, Assistant Corporation Counsel
100 Church Street, 20th Floor
New York, NY 10007
Phone: (212) 356-4055
tjeneret@law.nyc.gov
cweaver@law.nyc.gov
ocomorau@law.nyc.gov

Attorneys for the City of New York

PHILIP J. WEISER
Attorney General of the State of Colorado

By: */s/ Jennifer L. Weaver*
Eric R. Olson
Solicitor General
Jennifer L. Weaver
First Assistant Attorney General
W. Eric Kuhn
Senior Assistant Attorney General
1300 Broadway, 10th Floor
Denver, CO 80203
Phone: (720) 508-6548
eric.olson@coag.gov
jennifer.weaver@coag.gov
eric.kuhn@coag.gov

Attorneys for the State of Colorado

WILLIAM TONG
Attorney General of Connecticut

By: /s/ *Maura Murphy Osborne*
Maura Murphy Osborne
Assistant Attorney General
Office of the Attorney General
55 Elm Street
P.O. Box 120
Hartford, CT 06141-0120
Phone: (860) 808-5020
Maura.MurphyOsborne@ct.gov

Attorneys for the State of Connecticut

KATHLEEN JENNINGS
Attorney General of Delaware

AARON R. GOLDSTEIN
Chief Deputy Attorney General
ILONA KIRSHON
Deputy State Solicitor

By: /s/ *David J. Lyons*
David J. Lyons
Deputy Attorney General
Delaware Department of Justice
Phone: (302) 577-8413
Fax: (302) 577-6630
david.lyons@state.de.us

Attorneys for the State of Delaware

KARL A. RACINE
Attorney General
District of Columbia

Robyn R. Bender
Deputy Attorney General

By: /s/ *Valerie M. Nannery*
Valerie M. Nannery
Assistant Attorney General
Office of the Attorney General for
the District of Columbia
441 4th Street, N.W., Suite 630 South
Washington, DC 20001
Phone: (202) 442-9596
Fax: (202) 730-1465
robyn.bender@dc.gov
valerie.nannery@dc.gov

Attorneys for the District of Columbia

CLARE E. CONNORS
Attorney General of the State of Hawai‘i

By: /s/ *Diane K. Taira*
Diane K. Taira, Supervising Deputy Attorney
General, Health Division
Jill T. Nagamine, Deputy Attorney General
Andrea J. Armitage, Deputy Attorney General
Department of the Attorney General
State of Hawai‘i
425 Queen Street
Honolulu, Hawai‘i 96813
Phone: (808) 587-3050
Fax: (808) 587-3077
Diane.K.Taira@Hawaii.gov
Jill.T.Nagamine@Hawaii.gov
Andrea.J.Armitage@Hawaii.gov

Attorneys for the State of Hawai‘i

KWAME RAOUL
Attorney General of the State of Illinois

By: /s/ *Sarah Gallo*
Sarah Gallo, Assistant Attorney General
Lauren Barski, Assistant Attorney General
100 West Randolph Street, 12th Floor
Chicago, IL 60601
Phone: (312) 814-8309
sgallo@atg.state.il.us

Attorneys for the State of Illinois

BRIAN E. FROSH
Attorney General of Maryland

By: /s/ *Steve M. Sullivan*
Steve M. Sullivan
Solicitor General
Kimberly S. Cammarata
Jeffrey P. Dunlap
Assistant Attorneys General
200 St. Paul Place
Baltimore, MD 21202
Phone: (410) 576-6325
Fax: (410) 576-6955

Attorneys for the State of Maryland

MAURA HEALY
Attorney General of the Commonwealth of Massachusetts

By: /s/ *Abigail Taylor*
Abigail Taylor
Jon Burke
Assistant Attorneys General
Civil Rights Division
Massachusetts Attorney General's Office
One Ashburton Place
Boston, MA 02108
Phone: (617) 727-2200
Fax: (617) 727-5762
Abigail.Taylor@mass.gov
Jonathan.Burke@mass.gov

Attorney for the Commonwealth of Massachusetts

DANA NESSEL
Attorney General
State of Michigan

By: /s/ *Fadwa A. Hammoud*
Fadwa A. Hammoud (P74185)
Solicitor General
Toni L. Harris (P63111)
Assistant Attorney General
Michigan Department of Attorney General
P.O. Box 30758
Lansing, MI 48909
Phone: (517) 335-7603
HammoudF1@michigan.gov
Harrist19@michigan.gov

Attorneys for the State of Michigan

KEITH ELLISON
Attorney General
State of Minnesota

By: */s/ Scott H. Ikeda*
Scott H. Ikeda
Assistant Attorney General
Atty. Reg. No. 0386771
445 Minnesota Street, Suite 1100
St. Paul, Minnesota 55101-2128
Phone: (651) 757-1385
Fax: (651) 282-5832
scott.ikeda@ag.state.mn.us

Attorneys for the State of Minnesota

GURBIR S. GREWAL
Attorney General
State of New Jersey

By: */s/ Glenn Moramarco*
Glenn Moramarco
Assistant Attorney General
Melissa Medoway, *Deputy Attorney General*
Marie Soueid, *Deputy Attorney General*
Deputy Attorneys General
Richard J. Hughes Justice Complex
25 Market Street
Trenton, NJ 08625
Phone: (609) 376-3232
Glenn.Moramarco@law.njoag.gov
Melissa.Medoway@law.njoag.gov
Marie.Soueid@law.njoag.gov

Attorneys for the State of New Jersey

AARON D. FORD
Attorney General
State of Nevada

By: */s/ Heidi Parry Stern*
Heidi Parry Stern (Bar No. 8873)
Solicitor General
Craig A. Newby (Bar No. 8591)
Deputy Solicitor General
Office of the Nevada Attorney General
555 E. Washington Ave., Ste. 3900
Las Vegas, NV 89101
HStern@ag.nv.gov

Attorneys for the State of Nevada

HECTOR BALDERAS
Attorney General of New Mexico

By: */s/ Tania Maestas*
Tania Maestas
Chief Deputy Attorney General
P.O. Drawer 1508
Santa Fe, New Mexico 87504-1508
tmaestas@nmag.gov

Attorneys for the State of New Mexico, by and through Attorney General Hector Balderas

ELLEN F. ROSENBLUM
Attorney General of the State of Oregon

By: /s/ *Brian A. de Haan*
Brian A. de Haan (NY Bar #4565396)
Elleanor H. Chin (OR#061484)
Senior Assistant Attorneys General
Oregon Department of Justice
1162 Court Street NE
Salem Oregon 97301
Phone: (503) 947-4700
elleanor.chin@doj.state.or.us

Attorneys for the State of Oregon

JOSH SHAPIRO
Attorney General of the Commonwealth of Pennsylvania

By: /s/ *Aimee D. Thomson*
Aimee D. Thomson (NY Bar #5404348)
Deputy Attorney General, Impact Litigation Section
Nikole Brock
Deputy Attorney General, Health Care Section
Pennsylvania Office of Attorney General
1600 Arch St., Suite 300
Philadelphia, PA 19103
Phone: (267) 940-6696
athomson@attorneygeneral.gov

Attorneys for the Commonwealth of Pennsylvania

PETER F. NERONHA
Attorney General of the State of Rhode Island

By: /s/ *Michael W. Field*
Michael W. Field
Assistant Attorney General
150 South Main Street
Providence, Rhode Island 02903
Phone: (401) 274-4400, ext. 2380
mfield@riag.ri.gov

Attorneys for the State of Rhode Island

THOMAS J. DONOVAN, JR.
Attorney General of the State of Vermont

By: /s/ *Eleanor Spottswood*
Eleanor Spottswood
Assistant Attorney General
Office of the Attorney General
109 State Street
Montpelier, VT 05609-1001
Phone: (802) 828-3178
eleanor.spottswood@vermont.gov

Attorneys for the State of Vermont

MARK R. HERRING
Attorney General of the Commonwealth of Virginia

By: /s/ *Toby J. Heytens*
Toby J. Heytens
Solicitor General
Matthew R. McGuire
Principal Deputy Solicitor General
Michelle S. Kallen
Deputy Solicitor General
Brittany M. Jones
John Marshall Fellow
Office of the Attorney General
202 North Ninth Street
Richmond, Virginia 23219
Phone: (804) 786-7240
solicitorgeneral@oag.state.va.us

Attorneys for the Commonwealth of Virginia

JOSHUA L. KAUL
Attorney General
State of Wisconsin

By: /s/ *Maura FJ Whelan*
Maura FJ Whelan
Assistant Attorney General
Wisconsin Department of Justice
Post Office Box 7857
Madison, Wisconsin 53707-7857
Phone: (608) 266-3859
whelanmf@doj.state.wi.us

Attorneys for State of Wisconsin

MARK A. FLESSNER
Corporation Counsel of the City of Chicago

By: /s/ *Stephen Kane*
Stephen Kane, Acting Deputy
Rebecca Hirsch, Assistant Corporation Counsel
Affirmative Litigation Division
City of Chicago Department of Law
121 N. LaSalle Street, Room 600
Chicago, IL 60602
Phone: (312) 744-8143
Rebecca.hirsch2@cityofchicago.org

Attorneys for the City of Chicago

KIMBERLY M. FOXX
Cook County Illinois State's Attorney

By: /s/ *Kimberly M. Foxx*
Kimberly M. Foxx, Cook County State's Attorney
Amy Crawford, Assistant State's Attorney
Deputy Bureau Chief – Civil Actions Bureau
Jessica M. Scheller, Assistant State's Attorney
Division Chief; Advice, Business & Complex Litigation – Civil Actions Bureau
500 W. Richard J. Daley Center Place, Suite 500
Chicago, IL 60602
Phone: (312) 603-3116
Phone: (312) 603-6934
Amy.Crawford@cookcountyil.gov
Jessica.Scheller@cookcountyil.gov

Attorneys for Cook County, Illinois

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

DECLARATION OF MATTHEW COLANGELO

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

I am an attorney in the Office of the New York State Attorney General and counsel to Plaintiffs in this action. I submit this Declaration in support of Plaintiffs' motion for a preliminary injunction.

Attached to this Declaration are true and correct copies of the following numbered exhibits:

1. Declaration of Sarah Adelman, Deputy Commissioner, New Jersey Department of Human Services.

2. Declaration of Dr. Nicole Alexander-Scott, Director, Rhode Island Department of Health.

3. Declaration of Charles Alfero, Executive Director, Center for Health Innovation.

4. Declaration of Laura M. Alfredo, Senior Vice President of Legal, Regulatory, and Professional Affairs and General Counsel, Greater New York Hospital Association.

5. Declaration of Dr. Machelle Allen, Senior Vice President and System Chief Medical Officer, New York City Health + Hospitals.

6. Declaration of Dr. John Andazola, Program Director of Southern New Mexico Family Medicine Program, and President of the New Mexico Primary Care Training Consortium.

7. Declaration of Dr. Bruce S. Anderson, Director of Health, State of Hawai‘i Department of Health.

8. Declaration of Sharon C. Boyle, General Counsel, Massachusetts Executive Office of Health and Human Services.

9. Declaration of Janet Brancifort, Deputy Commissioner, Connecticut Department of Public Health.

10. Declaration of Deanna Charest, Reproductive Health Unit Manager, Division of Maternal and Infant Health, Michigan Department of Health and Human Services.

11. Declaration of Sarah Clark, Chief Financial Officer, Vermont Agency of Human Services.

12. Declaration of Lori A. Coyner, Medicaid Director, Oregon Health Authority.

13. Declaration of Thomas M. Daly, Chief Financial Officer, University Hospital (Newark, New Jersey).

14. Declaration of Rebecca S. Dineen, Assistant Commissioner, Bureau of Maternal and Child Health, Baltimore City Health Department.

15. Declaration of Dr. Shereef M. Elnahal, Commissioner, New Jersey Department of Health.

16. Declaration of Katharine Eshghi, Senior Vice President and General Counsel, UMass Memorial Health Care.

17. Declaration of Dr. Ngozi O. Ezike, Director, Illinois Department of Public Health.

18. Declaration of Dr. Terence R. Flotte, Dean, Provost and Executive Deputy Chancellor, University of Massachusetts Medical School.

19. Declaration of Anne Foley, Senior Policy Advisor to the Secretary and Acting Undersecretary of the Health and Human Services Policy and Planning Division, Connecticut Office of Policy and Management.

20. Declaration of Andrew C. Forsaith, Director of the Office of Policy Initiatives and Budget, Wisconsin Department of Health Services.

21. Declaration of Dr. Adena Greenbaum, Assistant Commissioner, Bureau of Clinical Services, Baltimore City Health Department.

22. Declaration of Dr. Jerris R. Hedges, Dean, University of Hawaii John A. Burns School of Medicine.

23. Declaration of Susan Herbst, President, University of Connecticut.

24. Declaration of Dr. Heather Hirata, Director of Medical Services, University of Hawai‘i at Hilo.

25. Declaration of Dr. John G. Hunter, Executive Vice President and Chief Executive Officer, Oregon Health & Science University.

26. Declaration of Kathyleen Kunkel, Secretary of the Department of Health, State of New Mexico.

27. Declaration of Linda A. Lacewell, Acting Superintendent, New York State Department of Financial Services.

28. Declaration of Dr. Rachel L. Levine, Secretary of Health for the Commonwealth of Pennsylvania, and Professor of Pediatrics and Psychiatry at the Penn State College of Medicine.

29. Declaration of Dr. Michael Lucchesi, Interim Dean of the College of Medicine and Chairman of Emergency Medicine, Downstate Medical Center of the State University of New York.

30. Declaration of Kathryn Macomber, Acting Administrative Deputy, Michigan Department of Health and Human Services.

31. Declaration of Dr. James L. Madara, Chief Executive Officer and Executive Vice President, American Medical Association.

32. Declaration of Dr. Sandra Martell, Public Health Administrator, Winnebago County (Illinois) Health Department.

33. Declaration of Teresa D. Miller, Secretary for the Pennsylvania Department of Human Services.

34. Declaration of Dr. Andrew W. Nichols, Director of University Health Services, University of Hawai‘i at Mānoa.

35. Declaration of Dr. M. Norman Oliver, State Health Commissioner, Virginia Department of Health.

36. Declaration of Dr. David Prezant, Chief Medical Officer, Fire Department of the City of New York.

37. Declaration of Dr. Karyl T. Rattay, Director of the Division of Public Health, Delaware Department of Health and Social Services.

38. Declaration of Dr. Linda Rosen, Chief Executive Officer, Hawaii Health Systems Corporation.

39. Declaration of Dr. John Jay Shannon, Chief Executive Officer, Cook County (Illinois) Health and Hospitals System.

40. Declaration of Lisa Sherych, Interim Administrator, Division of Public and Behavioral Health, Nevada Department of Health and Human Services.

41. Declaration of Dr. KyleeAnn Stevens, Executive Medical Director for Behavioral Health, Minnesota Department of Human Services.

42. Declaration of Kimberly Swartz, Director of Preventive Reproductive Health, Vermont Department of Health.

43. Declaration of Dr. Craig S. Thomas, President, Hawaii Emergency Physicians Associated, Inc.

44. Declaration of Wayne Turnage, Deputy Mayor for Health and Human Services, District of Columbia, and Executive Director, District of Columbia Department of Health Care Finance.

45. Declaration of Dr. Terry Vanden Hoek, Head of Emergency Medicine and Chief Medical Officer, University of Illinois Hospital & Health Sciences System, and Rhonda Perna, Senior Director for Risk Management, Patient Safety, & Physician Excellence, University of Illinois Hospital & Health Sciences System.

46. Declaration of Fikirte Wagaw, First Deputy Commissioner, Chicago Department of Public Health.

47. Declaration of Marie Zimmerman, Assistant Commissioner for Health Care and Medicaid Director, Minnesota Department of Human Services.

48. Declaration of Dr. Howard A. Zucker, Commissioner, New York State Department of Health.

Also attached to this Declaration are true and correct copies of the following numbered exhibits, each of which is part of the Administrative Record in this action:

49. American Academy of Pediatrics, Comment Letter on Proposed Rule (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71048.

50. American College of Obstetricians & Gynecologists, Comment Letter on Proposed Rule (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70647.

51. American Medical Association, Comment Letter on Proposed Rule (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70564.

52. American Nurses Association and American Academy of Nursing, Comment Letter on Proposed Rule (Mar. 23, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-55870.

53. Attorneys General of New York, *et al.*, Comment Letter on Proposed Rule (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70188.

54. BlueCross BlueShield Association, Comment Letter on Proposed Rule (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70912.

55. California Department of Insurance, Comment Letter on Proposed Rule (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70956.

56. California Department of Justice, Comment Letter on Proposed Rule (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70182.

57. Christian Medical Association, Summary of Online Survey of Faith-Based Medical Professionals conducted April, 2009 and May, 2011, https://docs.wixstatic.com/ugd/809e70_7ddb46110dde46cb961ef3a678d7e41c.pdf.

58. Institute for Policy Integrity at New York University School of Law, Comment Letter on Proposed Rule (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72071.

59. Lambda Legal Defense & Education Fund, Inc., Comment Letter on Proposed Rule (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72186.

60. Memorandum from the Attorney General for All Executive Departments and Agencies, *Federal Law Protections for Religious Liberty* (Oct. 6, 2017), https://www.justice.gov/opa/press-release/file/1001891/download.

61. National Council of Jewish Women, Comment Letter on Proposed Rule (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70865.

62. National Immigration Law Center, Comment Letter on Proposed Rule (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71248.

63. National Women's Law Center, Comment Letter on Proposed Rule (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71477.

64. New York City Commission on Human Rights, *et al.*, Comment Letter on Proposed Rule (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71028.

65. New York State Department of Financial Services, Comment Letter on Proposed Rule (Mar. 21, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-51681.

66. Planned Parenthood Federation of America, Comment Letter on Proposed Rule (Mar. 27, 2018), https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71810.

Dated: June 14, 2019

/s/ Matthew Colangelo
Matthew Colangelo
Office of the New York State Attorney General
28 Liberty Street
New York, NY 10005
Phone: (212) 416-6057
matthew.colangelo@ag.ny.gov

Attorney for the Plaintiffs

Exhibit 1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

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

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF SARAH ADELMAN

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

2. I submit this Declaration in support of the State of New Jersey's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and the United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through the New Jersey Department of Human Services' ("DHS") personnel who have assisted me in gathering this information from our institution, or on the basis of documents that I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon DHS.

1. I am the Deputy Commissioner at DHS located in New Jersey. I have been employed as Deputy Commissioner since February 2018. In my capacity as Deputy Commissioner, I oversee the Division of Medical Assistance and Health Services ("DMAHS"), New Jersey's Medicaid and Children's Health Insurance Program ("CHIP"), the Division of Developmental Disabilities ("DDD"), and the Division of Aging Services "(DoAS"). These programs each manage federal funds including funding from the U.S. Department of Health and Human Services.

Impacts of Funding Termination

3. DHS is the largest state agency in New Jersey, serving about 2.1 million New Jerseyans, or one of every five state residents. DHS serves seniors, individuals and families with low incomes; people with developmental disabilities, or late-onset disabilities; people who are blind, visually impaired, deaf, hard of hearing, or deaf-blind; parents needing child care services,

and child support and/or health care for their children. DHS and its divisions provide programs and services designed to give eligible individuals and families the help they need to find permanent solutions to a myriad of life challenges. This is made possible through DHS's work to make strategic use of state and federal resources, establish community supports, and promote accountability among staff.

4. In FY2018, DHS received a total of $10.7 billion in federal HHS funding to serve a variety of programs important for maintenance of the health and welfare of New Jersey residents.

5. From Medicaid alone, DHS received $7.3 billion dollars in federal HHS funding in FY2018. Required State matching, which ranges from 10 to 50 percent, depending on the group served, totaled about $4 billion. DHS also received over $456 million in CHIP funding in FY2018. The State matched 12 percent of the federal funds, or about $50 million. Collectively, Medicaid and CHIP programs in New Jersey are referred to as "NJ FamilyCare." Through these programs, DMAHS services over 1.7 million people in the State. Eligibility for NJ FamilyCare is based primarily on income level. The Affordable Care Act expanded Medicaid eligibility so that individuals and families with incomes up to 138% of the federal poverty level are eligible for the program.

6. DoAS received a total of $85.8 million in HHS funding in FY2018, including around $30.7 million under the Older Americans Act. New Jersey matches roughly 15 to 25 percent of the federal funds under the Older Americans Act. The funds allow older adults to live in the community as long as possible with independence, dignity, and choice. DoAS serves as the focal point for planning services for older adults through oversight of home and community-based programs. DoAS and DMAHS also provide funding to nursing facilities through Medicaid

and the Older Americans Act. Because such facilities would be required to accommodate the objections of any staff to certain procedures, and due to the unclear and broad scope of the Final Rule, DHS must be prepared to be held responsible for any breach of the rule by hundreds of facilities.

7. DDD received a total of $850.9 million in federal HHS funding in FY2018. DDD funds and supports more than 600 agencies all across New Jersey providing education and other services for nearly 25,000 adults with developmental disabilities. Around 8,000 adults with developmental disabilities reside in more than 1,800 group homes across the State, funded by DDD.

8. DHS's Division of Family Development received a total of $840 million in HHS funding in FY2018, including around $400 million for Temporary Assistance for Needy Families, known as WorkFirst NJ ("WFNJ"). Approximately 40,000 individuals received WFNJ benefits including cash assistance, emergency housing assistance, child care, and job training and education supports in FY2018.

9. Given the size of these programs, it is very unlikely that adequate State funding would be available to offset a significant loss of federal dollars. Any significant federal reduction would require changes to eligibility requirements or the number of services offered. The reduction or cut-off in federal funding would mean a significant decrease in the number of individuals with low-incomes receiving health insurance benefits. It would also reduce the availability of DHS-administered services to families with low incomes, such as child care, work training, and cash assistance, as well as reduce the number of services available to older residents and individuals with disabilities. The viability of the state earned income tax credit, which many families depend on, would also be at risk under the Final Rule. A decrease in

funding to DDD would adversely affect the ability to provide comprehensive services to individuals with developmental disabilities in the State.

Immediate Impact of the Final Rule

10. Because the Final Rule threatens cuts in funding to recipients for the non-compliance of their sub-recipients, DHS understands that it would be expected to ensure that all sub-recipients are in compliance. Ensuring such compliance would likely require expending significant DHS resources to ensure that sub-recipients have policies and plans in place that enforce the Final Rule and plan for any religious or moral objections that may arise.

11. I anticipate that DDD, for example, would have to make complicated arrangements to ensure compliance of every one of its more than 120 group home providers. Group home providers are often responsible for scheduling medical appointments and providing transportation to and from medical services. The Final Rule would allow for nearly any group home employee to object to assisting in the performance of any services covered under the rule. Group homes, many of which are already short-staffed, would have to account for the possible objections of any one of their employees. Given that employers are restricted under the Final Rule from asking employees about objections more than once per calendar year and not before they are hired, group homes would have a difficult time ensuring that sufficient staff are present to transport individuals to reproductive care appointments. Additionally, DDD would have to institute measures to ensure that group homes are complying with the Final Rule and accommodating staff who are only tangentially associated with reproductive care, such as drivers and administrative staff. Such administrative burdens on DDD would divert time and resources away from overseeing facilities' treatment and care of individuals with disabilities.

12. For individuals with disabilities, this diversion of resources can be particularly harmful. Individuals with disabilities face an increased risk of sexual abuse and assault as compared to the general population. The need for reproductive care and the ability to make choices about their reproductive health is important. Prioritizing the objections of non-medical staff, such as drivers or administrative staff, over individuals' health choices made with the benefit of their health care professional, and in some cases their family and/or guardian, would put individuals with disabilities at risk.

13. The Final Rule is very broad and permits many individuals and entities to object without notice. I anticipate that DMAHS would likely have to overhaul Medicaid billing and contracting procedures to account for potential objections. Currently, 95 percent of NJ FamilyCare is delivered through Managed Care Organizations ("MCOs"). MCOs provide case management services and handle Medicaid billing. MCOs are required to cover, through Medicaid funds, ectopic pregnancies, miscarriage, and natural loss of pregnancy. Under the Final Rule, MCOs could object to covering such life-saving procedures. I anticipate that DMAHS would need to account for this possibility in advance, likely by shifting Medicaid billing for procedures related to loss of pregnancy to a separate billing structure. This likely would require DHS staff to expend significant time and resources to reviewing MCO contracts and restructuring billing to account for objections.

14. Additionally, because of the expansive definitions of who may be assisting in the performance of a medical procedure, DMAHS likely would also have to account for potential objections by its own administrative employees providing billing and support for therapeutic abortions, which are paid through State Medicaid funds, as previously described. The large pool of individuals covered by the Final Rule will likely complicate Medicaid's coverage structure

and will likely require the expenditure of significant time and resources to ensure that coverage for health care is not compromised due to potential objections by various entities with widely varying levels of involvement in the actual health care services beneficiaries receive. This process could also delay the delivery of health services and unnecessarily involve patients in complicated billing procedures.

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

Executed on this 11 day of June, 2019

Sarah Adelman

Deputy Commissioner
New Jersey Department of Human Services

Exhibit 2

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

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

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF DR. NICOLE ALEXANDER-SCOTT

1. I, Dr. Nicole Alexander-Scott, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I submit this Declaration in support of Rhode Island's involvement as a Plaintiff in the above-captioned matter against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of HHS, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through state personnel who have assisted me in gathering this information from our institution, or on the basis of documents that were provided to me and that I reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the Rhode Island Department of Health ("RIDOH").

3. My educational background includes undergraduate work at Cornell University, where I majored in Human Development and Family Studies, followed by SUNY Upstate Medical University at Syracuse in 2001. After completing a combined internal medicine-pediatrics residency at SUNY Stony Brook University Hospital in 2005, I finished a four-year combined fellowship in adult and pediatric infectious diseases at the Warren Alpert Medical School of Brown University. I later obtained a Master's Degree in Public Health from the Brown University School of Public Health. I have served as the Director of RIDOH since 2015. As Director, I have established the following three leading priorities for RIDOH: (1) addressing the socioeconomic

and environmental determinants of health; (2) eliminating disparities of health and promoting health equity; and (3) ensuring access to quality health services for all Rhode Islanders, including the state's vulnerable populations.

4. I bring relevant and valuable experience to my role as Director from (a) my work as a specialist in infectious diseases for children and adults, and (b) time spent in academia as an associate professor of pediatrics, medicine, and public health. I am board-certified in Pediatrics, Internal Medicine, Pediatric Infectious Diseases, and Adult Infectious Diseases. In 2018, I was elected by my peers to be the President of the Association of State and Territorial Health Officials ("ASTHO"), the national organization for state health directors.

5. Each incoming ASTHO President selects a Challenge as a focus for the year that s/he leads the organization. I chose "Building Healthy and Resilient Communities" as my Challenge because I wanted to help create tangible vehicles to support research and initiatives addressing the socioeconomic and environmental determinants of health in communities, such as education, housing, transportation, and employment, given that these and other community-level factors affect health outcomes most significantly.

6. RIDOH aims to give every person, in every community in Rhode Island, an equal opportunity to be as healthy as possible. Under my leadership, RIDOH has re-committed to addressing the socioeconomic and environmental determinants of health so that a person's health does not depend on his or her ZIP code, race, ethnicity, sexual orientation, gender identity, level of education, or level of income. I have had the distinct honor of being recognized for this work by numerous local and national organizations, including Grow Smart Rhode Island, the Rhode Island Chapter of the American Academy of Pediatrics, and the Kresge Foundation.

7. Rhode Island received over $2.1 billion in federal health care funding from HHS in the 2018 federal fiscal year for entities identified as being at the state level in the Tracking Accountability in Government Grants ("TAGG") System.

8. RIDOH receives an annual amount of federal funding totaling approximately $7,118,423 for programs for arthritis, asthma, cancer registry, breast and cervical cancer, comprehensive cancer, colorectal cancer, diabetes, heart disease and stroke, and screening for heart disease.

9. RIDOH was awarded $2,725,000 in Title X funds for family planning program services for project period April 1, 2016 through August 31, 2018. The number of clients served by Title X service sites in 2018 was 29,098.

10. These funds are essential to the functioning of RIDOH and maintaining public health within Rhode Island.

11. It is RIDOH's understanding that the Final Rule expands definitions of terms in ways that may affect how we function, specifically, the terms "assist in the performance," "discriminate or discrimination," and "health care entity."

12. "Assist in the performance" now means "to take an action that has a specific, reasonable, and articulable connection to furthering a procedure," which "may include counseling, referral,…or otherwise making arrangements for the procedure…depending on whether aid is provided by such actions." 84 Fed. Reg. at 23,236 (to be codified at 45 C.F.R. § 88.2). Under this definition, simply scheduling a medical appointment would constitute "assistance." RIDOH would be required to guess which routine procedures or referrals "may" constitute "assistance" that requires additional steps to accommodate workers or protect patients.

13. The terms "discriminate or discrimination" are equally broad and vague, providing that employers will need a "persuasive justification" to ask an employee if they are willing to perform an essential job function to which they might morally object. Providers would not be able to use alternate staff to provide any objected-to medical services if those efforts exclude an objecting staff member from their "field [] of practice" or require "any" additional action by that person. We also understand that any accommodation offered to an objecting employee must depend on that employee's willingness to accept that accommodation to avoid discrimination, regardless of the reasonableness of such accommodation. 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2). This runs contrary to Rhode Island law and RIDOH regulation. For example, RIDOH regulation requires reasonable accommodation by a pharmacy owner for licensed pharmacists who notify the pharmacy owner in writing of their ethical/moral/religious objection to filling certain prescriptions.

14. RIDOH Regulation 216-RICR-40-15-1.15.2.

15. The term "health care entity" is expanded in such a way that would allow objections by human resources analysts, customer service representatives, data entry clerks, and numerous other who believe that analyzing benefits or answering a benefits-related question is inconsistent with their personal beliefs.

16. At the core of the Final Rule lies a detrimental lack of clarity as to the parameters of these terms and who may be subject to them, but RIDOH must prepare for compliance with the Final Rule or be at risk for losing, at a minimum, all federal health care funding.

17. As the State's health regulator, RIDOH is responsible for enforcing laws directly affected by the Final Rule. Such laws include: the requirement that every health care facility, including free-standing ERs, provide prompt treatment of patients (R. I. Gen. Laws § 23-17-26(a));

allowing license revocation for physicians who abandon patients (R. I. Gen. Laws §§ 5-37-4, 5-37-5.1, and 5-37-6.3); the requirement that a pharmacy owner create a reasonable accommodation, without creating undue hardship, for licensed pharmacists who notify the pharmacy owner in writing of ethical/moral/religious objections to filling certain prescriptions (RIDOH Regulation 216-RICR-40-15-1.15.2); the requirement that a physician or anyone working in a health care facility give written notice of objection to performing abortions or sterilization procedures (R. I. Gen. Laws § 23-17-11); and informed consent laws regarding abortion procedures (R. I. Gen. Laws § 23-4.7-2). The Final Rule interferes with our ability to enforce these laws.

18. For our State's health systems that operate ambulance fleets or contribute to fleets that respond to emergency calls, the Final Rule presents a Hobson's choice for RIDOH, other state agencies, and provider agencies: train and require EMS practitioners to assist in all emergency circumstances and face possible sanction for non-compliance with the Final Rule; or permit real-time objections from those personnel who could refuse to drive or assist in an emergency situation, either without the opportunity to provide other, non-objecting personnel or with the burden of spending significant resources to ensure such non-objecting personnel is readily available. This will create chaos in accessing critical, quality health care in life-threatening circumstances.

19. The Final Rule's expansion of the universe of objectors for religious, moral, or ethical reasons, its limits on requiring advance notice of such objection(s), and vagueness of definitions (e.g., "assist in the performance"), means RIDOH will have to expend significantly more resources and time to determine veracity of objections made by employees.

20. Compliance with the Final Rule is onerous, puts an undue burden on provider sites, and runs contrary to RIDOH's mission of ensuring access to quality health services for all Rhode Islanders.

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

Executed on this 7th day of June, 2019.

Nicole Alexander-Scott, MD, MPH
Director of Health
Rhode Island Department of Health

Exhibit 3

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

sTATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF CHARLES ALFERO

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

2. I submit this Declaration in support of the State of New York's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge or on the basis of documents I have reviewed.

3. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the people of southwestern New Mexico.

4. I am the executive director of the Center for Health Innovation (CHI), located in Silver City, Grant County, New Mexico. My educational background includes a masters in psychology from Western New Mexico University.

5. I have been employed as director of CHI since 2010. I am also the founder of Hidalgo County Medical Services (HMS), a Community Health Center providing primary medical, dental, mental health, family support, community development, and health policy services in southwestern New Mexico. CHI is a research, development and policy division of HMS and is working in 23 states on a variety of rural health workforce, public health improvements, integrated services and community/university collaborations.

6. I have been director of rural outreach for the University of New Mexico (UNM) Health Sciences Center and director of the Community Health Services Division in the New Mexico Department of Health (DOH) and am currently also director of the New Mexico Primary Care Training Consortium.

7. I have more than 41 years of experience in rural health policy, systems, and program development.

8. In my capacity at CHI, I am responsible for employing staff that serves remote counties in Southern New Mexico and statewide.

9. According to the U.S. Census Bureau, Hidalgo County, New Mexico's southernmost county, has a population estimated in 2018 as 4240 persons, 21% of whom are over 65. The population density was just over one person per square mile in the year 2010.

10. Grant County, also covered by health policy staff at our CHI center, has an estimated population of just over 27,000, almost 27% of whom are over 65. The population density is approximately 7 persons per square mile.

11. Understanding the diverse health and medical needs of persons in such a remote area requires sensitivity to many religious and ethical demands, and our area hospitals and clinics that provide direct services already struggle to meet such demands. Adding to the complexity of compliance with rules is likely to detract rather than enhance the services they already provide.

12. This is especially so as our medical entities cope with an aging population that will necessarily be facing end-of-life decisions made more complex by expansion of the conscience rules.

13. The right to life and health should not be based on religious beliefs in any area of health care.

14. The Final Rule's expansion of universe of objectors, its limits on requiring advance notice of objection, and vagueness of definitions (e.g., "assist in the performance"), means that direct services providers in the frontier area of New Mexico will need to expend more resources

to determine veracity of objections made by employees, as well as resources to support any potential litigation pursuant to decisions impacting the health and well-being of patients.

15. I know that New Mexico's health policy demands are already complex and that our laws already require respect for religious diversity. Therefore, adding to the complexity of the task of providing rural health care does not serve the needs of our sparse population.

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

Executed on this 7th day of June, 2019

Charles Alfero
Executive Director
Center for Health Innovation (CHI)

Exhibit 4

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

DECLARATION OF
GREATER NEW YORK HOSPITAL ASSOCIATION

1. I, Laura M. Alfredo, declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the following is true and correct:

2. I am the Senior Vice President of Legal, Regulatory, and Professional Affairs and General Counsel at the Greater New York Hospital Association (GNYHA), where I have been employed since 2015. My responsibilities include policy development and technical assistance on a range of matters affecting the legal and compliance function of our member hospitals and health systems.

3. I am offering this declaration in support of the of the State of New York's litigation against the United States Department of Health and Human Services (HHS) regarding the recently

issued final rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (Final Rule).

4. Founded in 1904, GNYHA is a trade association representing more than 160 hospitals and health systems in New York, New Jersey, Connecticut, and Rhode Island. In New York, GNYHA represents approximately 139 hospitals. All our members are either not-for-profit or public institutions.

5. Among the services that GNYHA provides to its members is technical assistance with developing best practices for the delivery health care services in a culturally competent manner that is consistent with local, State, and Federal anti-discrimination laws. This encompasses respect for the right of both health care workers and patients not to be unlawfully discriminated against. For example, we have assisted our members with understanding and implementing compliance programs in connection with Section 1557 of the Affordable Care Act and other anti-discrimination laws, including New York City and State statutes prohibiting public accommodations, including hospitals, from discriminating against those who use their facilities on the basis of sex, race, religion, and sexual identity, among other protected classifications.

6. GNYHA and its members have serious concerns about the recent regulatory changes contained in the Final Rule. These changes will increase the likelihood of a conflict between workers' and patients' rights and inappropriately emphasize the rights of workers over patients. It ignores the fact that hospitals and providers must comply with a host of anti-discrimination laws and regulations, in addition to laws like the Emergency Medical Treatment and Labor Act (EMTALA) and professional conduct standards prohibiting patient abandonment. HHS failed to take heed of comments, including GNYHA's, urging it to align the Final Rule with the existing "reasonable accommodation" framework that for decades has enabled hospitals to

balance worker and patient rights. Finally, the changes include ambiguous and potentially draconian compliance and enforcement provisions that could damage safety net hospitals, including many in New York State.

7. One of the regulatory changes that GNYHA is concerned about is the definition of Discrimination in the Final Rule. The changes will ban pre-employment inquiries regarding an applicant's potential objection to assisting in certain health care activities. They will also prohibit exclusion or restriction on employment based on an employee's self-disclosure of religious or conscience objections.

8. These changes could deprive hospitals of effective mechanisms for avoiding conflicts between worker and patient rights and potentially place hospitals in the position of having to choose which laws to violate. Hospitals routinely ask job applicants whether they require any accommodations to complete the essential functions of the position. This question is often incorporated into the employment application and is intended to capture information about physical and other impediments to the performance of the job. Under the Final Rule, this question could be seen as discriminatory.

9. In addition, many hospitals maintain policies on conscience rights that advise workers of their right to proactively notify the hospital of any conscience or religious objections to assisting in certain procedures. This is consistent with New York State law, which provides for a process by which health care workers may provide a "prior written refusal" to assist in an abortion. NY CVR 79-i.

10. The purpose of these policies is to allow for appropriate planning to ensure that an objecting worker is not placed in an uncomfortable position while allowing the hospital to arrange for safe staffing. This may include the hospital's decision not to place the objecting employee in

certain settings in which the objected-to conduct is likely to arise or where the consequences of a conflict between the worker's and a patient's rights could be dire, even if such a conflict were not likely to happen frequently.

11. The most obvious example of such a scenario is hospital emergency services. Many hospitals operate ambulance fleets and employ emergency medical technicians (EMTs) and paramedics. Hospital first responders augment the emergency corps operated by localities and are part of hospitals' critical sector role. In New York City, for example, the New York City Fire Department (FDNY) Emergency Medical Services operates the City's 911 system and dispatches FDNY or hospital assets, based on location, need, and other factors intended to optimize speed, efficiency, and patient safety and care.

12. To the extent the Final Rule will prohibit hospitals from inquiring of prospective EMTs and paramedics whether they require reasonable accommodations to perform their duties, there will be a risk that an objecting worker, faced with the imperative to treat or transport a patient who requires care that such worker finds objectionable, could place the patient and other workers in jeopardy in the field. Ambulances are typically staffed with two workers, one who drives and one who tends to the patient. In most cases, it would be unsafe to transport a patient without an attendant. Therefore, the only option in the event that a worker objected to conducting the transport would be to dispatch another ambulance. Clearly, this is not optimal for patient care or the efficient use of resources. It is not clear that HHS would not penalize a hospital for taking action to discipline or even transfer such an employee who jeopardizes patient safety in that manner; indeed, from the text and tone of the Final Rule, it appears HHS would take the position that the hospital could take no action that could be perceived as "adverse" whatsoever, even where its employee jeopardized patient safety by failing to come forward with their objections in a timely manner.

13. This concern is only magnified when one considers the Final Rule's new definition of Assist in the Performance. In the preamble, HHS acknowledges that activities such as scheduling and preparing a room or instruments would fall within this definition. This represents a marked expansion of the pool of workers who could potentially object to certain procedures and activities. To illustrate, one health system peri-operative department inquires of certain direct care providers, mainly nurses and surgical technicians, whether they have any objection to assisting in an abortion. Workers who respond affirmatively are not placed on a call list that is used on nights and weekends, the purpose of which is to replace staff members who may object to assisting in an abortion procedure but who may not have previously self-disclosed their objection. While this process may not be at odds with the new provisions in the Final Rule, by virtue of the new definition of Assist in the Performance, the health system may now have to survey both direct and non-direct care workers, including schedulers, transporters, and those individuals who prepare the operating rooms. This would be an onerous process that would be difficult to operationalize and maintain.

14. GNYHA is also concerned about the Final Rule's new requirement for an assurance and certification that applicants for Federal financial assistance or funds will comply with the Final Rule. Our concern stems from the aforementioned challenges with operationalizing compliance with the Final Rule in the context of the other laws, regulations, and professional standards that hospitals must adhere to. It is difficult to give an assurance of or certify compliance where the regulations are vague and in opposition to other requirements.

15. New York State hospitals, like most hospitals, are reliant on Federal funding, in particular Medicare funding. New York State hospitals, in the aggregate, have one of the lowest operating margins in the United States. There are 26 voluntary (non-public) hospitals throughout

New York State on a Department of Health "Watch List" for being at high-risk of closure because they have less than 15 days' cash on hand, as well as other indicators of poor financial condition. These hospitals are receiving approximately $600 million in State operating subsidies to prevent unplanned closures, while the facilities transform into more sustainable operating models and transition to payment methodologies with payers that are value-based. Many of these hospitals are in rural and underserved urban communities, where they are both the essential safety-net healthcare provider and a major employer. These hospitals are particularly vulnerable to Federal funding cuts and reimbursement losses and are thus potentially at particular risk under the Final Rule.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: June 10, 2019

Exhibit 5

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF DR. MACHELLE ALLEN

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

2. I submit this Declaration in support of the City of New York's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and the United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, NYC Health + Hospitals (herein after "Health + Hospitals" or "the System") personnel who have assisted me in gathering this information from the System, or on the basis of documents that I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon Health + Hospitals.

3. I am a Senior Vice President and the System Chief Medical Officer ("CMO") at Health + Hospitals, located in New York City. I am a graduate of Cornell University and the University of California, San Francisco, School of Medicine, and completed a residency in Obstetrics and Gynecology at Health + Hospitals/Jacobi. I have been employed as the System's CMO since April 2017. Prior to that date, I was the System's Deputy CMO since October 2013.

Background on the NYC Health + Hospitals; Receipt and Use of HHS Funds

4. Health + Hospitals is New York City's municipal hospital system and the largest public health care system in the United States. Health + Hospitals protects and promotes the health and well-being of 8.5 million diverse New Yorkers across all five boroughs, serving as the City's public safety net and health care system.

5. Health + Hospitals operates an integrated health care system consisting of: eleven acute care hospitals; five post-acute/long-term care facilities; "Gotham Health," a network of health clinics across the five boroughs offering primary and preventive care services; and "NYC

Health + Hospitals/At Home," a certified home health agency offering expert services in Manhattan, Queens, Brooklyn, and the Bronx.

6. Health + Hospitals offers: "MetroPlus," a low to no-cost health insurance plan serving more than 500,000 New York residents; "OneCity Health," the largest Medicaid Performing Provider System in the City composed of hundreds of health care providers, community-based organizations, and health systems; and "Health + Hospitals/Correctional Health Services," one of the largest correctional health care systems in the nation, with over 43,000 annual admissions in jails across the City.

7. In addition to this range of facilities and programs, twenty-two Health + Hospitals facilities have been designated as "Leaders in LGBT Healthcare Equality" by the Human Rights Campaign Foundation. This designation is given to entities that train staff in the provision of LGBTQ health care, have LGBTQ-responsive policies, and make those policies available to the public and staff.

8. Health + Hospitals received approximately $3.4 billion in fiscal year 2018 from HHS. In particular, Health + Hospitals received: $5,933,864 for services covered by Child Health Plus; $1,153,400,144 for services covered by Medicaid; $29,459,286 in federal grants related to HIV/AIDS, Sexually Transmitted Disease Treatment and Prevention, Substance Abuse Treatment, Public Health and Prevention, Immunization, Biomedical and Behavioral Research; $112,799,439 in other grants; $978,233,262 in Medicaid supplemental payments; and $1,114,354,374 for services covered by Medicare.

9. These federal funds allow Health + Hospitals to serve around one million patients annually and are essential to the functioning of our System and maintaining public health within our jurisdiction.

Existing Health + Hospitals Policies Addressing Religious Objections

10. Health + Hospitals has robust anti-discrimination policies that are tailored to comply with the existing requirements of our state and local laws on religious accommodation. Foremost among these, Health + Hospitals has an Equal Employment Opportunity ("EEO") Program and a Religious Accommodation Policy. Attached hereto as Exhibit A are true and correct copies of Operating Procedure No. 20-32, Equal Employment Opportunity Program ("EEO Policy"). Attached hereto as Exhibit B are true and correct copies of Operating Procedure No. 20-18, Corporation Policy with Respect to Requests for Religious Accommodation ("Religious Accommodation Policy").

11. The EEO Policy emphasizes its commitment to providing equal employment opportunities to all employees and applicants for employment without regard to, among other bases, their actual or perceived religion or creed. *See generally*, EEO Policy.

12. In the context of religious accommodations, Health + Hospitals "grant[s] requests by employees and prospective employees for a reasonable accommodation of the employee or prospective employee's religious beliefs, practices or observance." Religious Accommodation Policy at 1; *see also* EEO Policy at 3 (prohibiting the denial of reasonable accommodations for "sincerely held religious beliefs, observances, and practices").

13. An accommodation would not be available if it would impose an "undue hardship" on the particular facility or department. *Id.* at 7; Religious Accommodation Policy at 3. A requested accommodation may cause an "undue hardship" if it would be significantly difficult or unduly costly to implement, may affect patient care, or would fundamentally change the nature or operation of Health + Hospitals. *Id.*

14. The Religious Accommodation Policy likewise explains that,

> A request for a religious accommodation will be denied only if, after exploring reasonable alternatives, the network/facility where the employee works or has applied to work determines that granting the request will cause an undue hardship to the operation of the applicable network/facility either because it would interfere significantly with the safe and efficient operation of the network/facility (including, without limitation, its ability to care for patients in a unit or division affected by the request) or would result in significant expense in relation to the size and operating costs of the network/facility.

Religious Accommodation Policy at 1–2.

15. Requests for religious accommodations should be made in writing to a Senior Manager and be made as far in advance as possible. Religious Accommodation Policy at 2.

16. In determining whether to grant a religious accommodation request, the Senior Manager will engage in an interactive dialogue with the employee's department to discuss the effects of the accommodation on the department, and when appropriate, alternative accommodations with the employee. EEO Policy at 7–8.

17. The Religious Accommodation Policy requires the Senior Manager to give written decisions on the religious accommodation requests. The Religious Accommodation Policy also provides higher levels of review that offer additional opportunities for exploring alternatives not yet considered. Religious Accommodation Policy at 3–4.

18. Absent plain reason to believe otherwise—such as inconsistency of practice—the Senior Manager accepts the employee's assertion of the sincerity of his or her religious belief. Religious Accommodation Policy at 4.

19. Health + Hospitals's policies are modeled on a reasonable accommodation and undue hardship framework in order to balance a variety of interests, at times competing, that surface in the workplace. The desire to balance these interests is motivated in part by Health + Hospitals's fundamental mission to provide care to all as well as the need to operate a financially

sustainable public hospital system. Health + Hospitals employs tens of thousands of employees in a variety of patient care environments who utilize complex and highly-specialized skill sets. They work together to deliver care to some of the most vulnerable and underserved patients. It is therefore imperative that the System maintain planned and adequate staffing levels so that care can be delivered in a predictable and safe manner. The current model of evaluating requests for reasonable accommodations, which accounts for the burden on Health + Hospitals, allows the System to guarantee that patient safety is not negatively affected.

Immediate Impact of the Final Rule Upon Health + Hospitals

20. It is Health + Hospital's understanding that the Final Rule expands definitions of terms in ways that affect how we function, specifically: "assist in the performance," "discriminate or discrimination," "health care entity," and "referral or refer for."

21. There is a lack of clarity as to who or what falls under these terms, yet Health + Hospitals must prepare for compliance with the Final Rule.

22. ***Staffing costs.*** Health + Hospitals must expend time, resources, and effort by: modifying hiring practices; double or triple-staffing emergency functions in light of limits the Final Rule places on requiring advance notice of objections; and training staff on what behavior is now permissible from objectors and how to work around objections not planned in advance.

23. For example, in the context of a hysterectomy at least twelve different employees are involved in delivering direct care to the patient. This includes nurses, operating room technicians, and others. If clerical staff and housekeepers are included in that figure, the number increases to at least fifteen different people. Many of those individuals are scheduled to perform services weeks or months in advance. It may be impossible to perform the procedure when even one of them—for example, a scrub nurse or certified registered nurse anesthetist—lodges a last minute objection to providing care. In such an instance, the procedure may not be able to be

rescheduled for weeks or months. This could result in harm to the patient or could discourage the patient from coming back to have the procedure performed.

24. Hiring additional staff to act as alternate providers is impracticable for Health + Hospitals. As shown below, in fiscal year 2018, Health + Hospitals directly employed the equivalent of 35,860 full-time and part-time staff; 8,433 affiliate and temporary staff persons; and 700 staff persons who provided hourly services. These salaries amounted to over $4 billion.

FY18	H+H (Full Time & Part Time Staff)	Affiliate	Allowances	Overtime	Temporary Staffing	FY18 Total
Full Time Equivalent (FTEs)	35,860	5,657	700	2,144	2,776	47,138
Health + Hospital Corp ($ in 000s)	$2,588,661	$1,208,964	$51,931	$155,881	$155,529	$4,160,966

25. Additional staffing would be costly. It is not clear Health + Hospitals can feasibly comply with the Rule without compromising patient care.

26. ***Emergency care.*** As a result of the Rule, and the risk that any employee may now refuse to provide patient care without advance notice to the hospital, Health + Hospitals must attempt to create contingency staffing plans to ensure that more than one of each necessary professional is available at all times in its emergency rooms.

27. Health + Hospitals operates under enormous budgetary constraints and does not have additional staff to perform essential functions required for a patient experiencing an emergency.

28. For example, a woman who arrives at a Health + Hospitals emergency room with a miscarriage or ectopic pregnancy will typically encounter at least fifteen staff members during her course of treatment.

29. These staffers include: Registration Clerks; Triage Nurses; Patient Care Associates; Laboratory Techs; ER Doctors; OR Technicians; Clerical Staff; Radiologists; Radiology Technicians; Staff Nurses; Housekeeping Staff; Scrub Nurses; Circulating Nurses; Anesthesiologists; and Certified Registered Nurse Anesthetists.

30. Just as hiring additional staff for non-emergency services would be cost prohibitive, hiring additional staff for emergency services is not realistic.

31. ***LGBTQ health care.*** In order to better meet the needs of the estimated 750,000 LGBTQ individuals living in the City of New York, Health + Hospitals began collecting sexual orientation and gender identity ("SOGI") demographic information at the System's facilities. This data—identifying when, where, and why LGBTQ individuals seek medical treatment—will help the System better allocate resources. This, in turn, creates an affirming experience for LGBTQ patients at Health + Hospitals, thus reducing barriers to equitable care and improving patient outcomes.

32. The Final Rule threatens our effort to improve patient care. It deters LGBTQ individuals from disclosing information for fear that a System employee may refuse them services. It may even cause LGTBQ individuals to delay or refuse to seek care altogether due to stigma and discrimination in the health care setting.

33. ***Contractual relationships.*** Health + Hospitals must review contractual relationships with subcontractor institutions that are used to deliver health services in order to

ensure that such institutions are in compliance with the Rule. In doing so, Health + Hospitals must devote substantial time and resources to this immense undertaking.

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

Executed on this 7th day of June, 2019

Machelle Allen, M.D.

Senior Vice President and Chief Medical Officer NYC Health + Hospitals

Exhibit 6

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

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

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION of JOHN ANDAZOLA, M.D.

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

2. I submit this Declaration in support of the State of New York's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge or on the basis of documents I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the people of southwestern New Mexico.

3. I am the program director of Southern New Mexico Family Medicine Program, the president of the New Mexico Primary Care Training Consortium, a board member of the New Mexico Academy of Family Physicians and a board member of the Southwest Center for Health Innovation.

4. I have taught medicine for 18 years and have aided in the training and placement of approximately 60 family physicians in southern New Mexico. Others have gone on to hospitals and clinics in numerous other states.

5. I have served in my current role as program director of the Southern New Mexico Family Medicine Program at the Memorial Medical Center in Las Cruces NM, a 199-bed acute care facility and level-four trauma center serving the State's Mesilla Valley, for the past 10 years.

6. I have thorough acquaintance with the Title VII mandates requiring excusal of medical students and medical residents based on religious objection. In a previous position, I experienced the consequences of existing civil rights protections when I was a provider in an environment where religious objections to abortion-related procedures led to a patient's being required to carry a nonviable pregnancy to term.

7. I understand the current law and believe its application to those who have religious objections to certain reproductive procedures and/or end-of-life decisions is adequate.

8. Adding to the number of persons whose objections can affect patient care gives me great concern. It seems likely that allowing clerical staff to object to making appointments for procedures with which they have conscience objections could inject chaos in an already complex system of care, especially in areas such as southern New Mexico where there are few doctors and access to any care can become a challenge.

9. Further, I am concerned about legal conflicts that could lead to sacrificing our much-needed emergency services in order to preserve federal funds: I fear that our training hospital could be forced to curtail Emergency Medical Treatment and Labor Act (EMTALA) emergency services instead of risking federal funds compliant with conscience protections provided in the Final Rule. The inherent conflict between EMTALA's mandate to provide care despite personal religious objections in life-threatening situations and the Final Rule's mandate, 84 Fed. Reg. at 23,272, to observe the conscience objections even in life-or-death circumstances could reasonably result in a decision to stop providing emergency services. I believe that our hospital's provision of emergency medical care is essential in geographic area where patients have few alternate medical sources, yet I could also understand why our hospital could elect to stop providing emergency care rather than sacrificing federal funds because of an application of the Final Rule.

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

Executed on this 10thth day of June, 2019

John Andazola, M.D.
Director, Southern New Mexico Family Medicine Program, Memorial Medical Center

Exhibit 7

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF BRUCE S. ANDERSON, PH.D.

1. I, Bruce S. Anderson, Ph.D., pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I submit this Declaration in support of the State of Hawai‘i’s litigation against the United States Department of Health and Human Services (“HHS”), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (“Final Rule”). I have compiled the information in the statements set forth below either through personal knowledge, through State of Hawai‘i Department of Health personnel who have assisted me in gathering this information from our agency, or on the basis of documents I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the Department of Health (“DOH”).

3. I am the Director of Health for the State of Hawai‘i Department of Health located in Honolulu, Hawai‘i.

4. The mission of the Department of Health is to protect and improve the health and environment for all people in Hawai‘i. DOH’s philosophy is that health, that optimal state of physical, mental, social, and environmental well-being, is a right and responsibility of all of Hawai‘i’s people. The goals of the department are to: 1) promote health and well-being; 2) prevent disease and injury; 3) promote healthy lifestyles and workplaces; and 4) promote the strength and integrity of families and communities.

5. During the fiscal year that ended June 30, 2018, the DOH expended a total of $83,713,419 of federal funding awards, and $34,124,619 of the total was passed through to subrecipients for health and human services programs.

6. These funds are essential to the functioning of the DOH and maintaining public health within Hawai‘i.

The implementation of Final Rule will have a devastating impact on the many, many services provided to Hawai‘i’s people by the Hawai‘i Department of Health.

7. If the Final Rule is allowed to become effective, the DOH will have to expend immense time, resources, and effort to implement it in many ways, including: modifying hiring practices; hiring double-staff for emergency functions in light of limits the Final Rule places on requiring advance notice of objections, a task that is especially difficult because Hawai‘i has a considerable healthcare provider shortage, especially on the Neighbor Islands; training staff on what behavior is now permissible from conscience objectors; and determining how to work around objections not planned for in advance.

The following paragraphs describe in particular the effect the Final Rule would have on DOH's provision of care for the citizens of Hawai‘i.

8. The Harm Reduction Services Branch of the DOH ("HRSB"), is deeply concerned about the potential negative impact of this Final Rule. HRSB provides safety-net services for the screening and treatment of sexually transmitted infections ("STIs"), including HIV, and HRSB works to enhance the capacity of community-based medical providers to provide STI and HIV services. To the extent that the Final Rule would result in any primary care providers refusing to provide STI screening, treatment, or prevention services, or medical care related to the prevention or treatment of HIV, or any medical providers refusing to provide any type of medical care to persons living with HIV, or to lesbian, gay, bisexual, or transgender persons, this could lead to increases in the rates of STIs, including HIV, and increased morbidity and mortality from delays in diagnosis and treatment. Moreover, even the perception among populations at increased risk of STIs/HIV that medical providers might refuse to treat them based on moral or religious beliefs would create a barrier to engaging and retaining some individuals in medical care. At this point in the HIV epidemic there are medications that are highly effective in preventing individuals from contracting HIV, and highly effective treatments that maintain the

health of individuals living with HIV and prevent them from transmitting HIV to others. The safety-net services that HRSB has implemented in Hawai‘i help to ensure that cost and lack of insurance are not significant barriers to treatment. In Hawai‘i, the biggest challenge to realizing the potential of these interventions to end the HIV epidemic is stigma. If implemented, the Final Rule risks individuals delaying or forgoing medical care due to the fear of discriminatory treatment by medical providers.

9. The Emergency Medical Services and Injury Prevention System Branch of the DOH ("EMSIPSB") provides a variety of services including Emergency Medical Services ("EMS"), Administration of the State Trauma System, bariatric transfer oversight, and the Hawai‘i Poison Center. Invocation of this rule would adversely affect these services for Hawai‘i's residents and visitors.

10. EMSIPSB contracts with agencies in the 4 counties to provide 911 emergency service: in Hawai‘i County: Hawai‘i County Fire/EMS; in Kauai County: American Medical Response ("AMR") Kauai; in Maui County: AMR Maui; and on Oahu: City and County of Honolulu EMS. 911 helicopter services are provided on Maui and Hawai‘i County. The Maui unit serves all of Maui County including Kalaupapa, the infamous Hansen's disease refuge on the island of Molokai. Given the emergent nature of the 911 response including life, limb, and death, implementation of this rule would have devastating consequences for both residents and visitors. EMSIPSB's resources are currently stressed to the limit and therefore, it does not have the ability to dispatch a second ambulance if the original unit was not at full capacity because of application of the Final Rule.

11. In addition, EMSIPSB contractually provides support to Kapiolani Community College. EMS students have clinical rotations. They learn by observing and participating in

providing care for all emergency medical situations. This rule would cause confusion and adversely impact patient care as well as the students' ability to obtain their degrees if they were able to object to participating in a patient's care with no advance notice.

12. EMSIPSB also manages the Coast Guard's support service for bariatric patient transfers statewide. EMSIPSB medical directors approve the transfer and then interface with Coast Guard flight surgeons for final approval. C130s are used as the "flying ambulance" and the patient is served by the federally supported Disaster Medical Assistance Team ("DMAT"). The DMAT has a limited number of volunteer personnel and could not easily substitute personnel if assigned personnel invoke the Rule without having given notice. Invocation of this rule could be catastrophic.

13. DOH, through EMSIPSB, administers the Trauma System. There are eight, soon to be nine, Trauma Center hospitals and eleven critical access hospitals receiving contractual support in the State. Several of the hospitals allocate portions of this funding to support salaries for physicians and nurses. Trauma care is time sensitive. Trauma response health care providers applying this rule would cause delays in treatment and care that would adversely affect trauma care for the State's residents and visitors.

14. The Hawai‘i Poison Center ("HPC") provides 24/7 poison emergency help from specially trained nurses, pharmacists, and physicians via tele-health. HPC personnel are not unlimited. Calls are received from the public and health care professionals. Approximately 70% of calls from the public can be managed through the call alone, thus saving hospital and EMS health care dollars. The HPC accomplishes this through its ability to make follow-up calls. Poisoning exposures, including suicide attempts, can be life threatening. Hospitals depend on

the HPC service to provide medical consultations for managing acutely poisoned patients. Invocation of this rule could adversely affect patient care for residents and visitors.

15. The Final Rule gives an emergency health care provider an opportunity to object for practically any reason. Here are some examples of the possible scenarios if the Final Rule is made effective that could have life threatening consequences: 1) EMS or hospital personnel refuse to treat and transport an opioid addict (or any person with a drug related condition); 2) EMS refuses to treat and transport a septic HIV patient; 3) EMS refuses to treat and transport a patient after an attempted self-induced abortion; 4) Trauma center personnel refuse to treat a terrorist post a terror event; 5) Trauma center refuses to treat a person arrested for using their car to run over pedestrians (vehicular homicide); 6) Hospital personnel refuse to treat an Ebola patient; or 7) Poison center personnel refuse to assist suicidal caller because suicide is against their beliefs.

16. Recently EMS was asked to transfer a bariatric (morbidly obese) patient with multiple medical conditions overwhelming a neighbor island hospital. The patient had recently been arrested for an alleged murder. The patient was transported safely, but his care could easily have been jeopardized by any healthcare provider invoking the Final Rule, along the way.

17. The Public Health Nursing Branch ("PHNB") immunization clinics are staffed based on the number of appointments and the number of vaccinations clients will be receiving. If staff are not willing to counsel or vaccinate children, this will impact PHNB staffing to support that clinic. They may not be able to locate additional staff, as many are in the field on other assignments. If this occurs, PHNB may need for staff to work overtime or double up on staffing. They may need to turn clients away if they cannot provide overtime, and clients may not return. This can impact vaccination rates and community safety. With regard to family planning and

abortions, PHNB provides information and counseling to clients on pre-conception care, options during pregnancy, and other family planning options. Due to the high risk nature of PHNB's clients, if someone asked about abortion and the nurse refused to provide information, the professional client-nurse relationship would be adversely impacted and so could patient care. PHNB will have nurses supporting the Department of Human Services' ("DHS") First to Work contract in fiscal year 2020. The contract's target population is pregnant women and those with children 0-5 years of age. These clients will need counseling for pre-conception care. If this rule goes into effect, DOH may need to amend its memorandum of agreement with DHS.

18. The DOH's Developmental Disabilities Division provides services for nearly 3,000 people with moderate to severe intellectual and developmental disabilities. Primary funding is through the Medicaid 1915 (c) Home and Community Based Services ("HCBS") Waiver. The State could not operate services for this population without considerable burden without Medicaid funding. Services are provided to help people to integrate into the community in lieu of institutional care. Many of the services are provided to ensure health and safety for an extremely vulnerable population, including people with complex medical needs and behavioral issues. Many in the population need nursing care, delegated nursing services, personal assistance to perform activities of daily living, behavioral supports, supervision, and services to ensure their health, safety and protection. If funding were affected or if a waiver provider had religious or moral objections to performing a required function or working with a certain type of client, that client's health and safety could be compromised. Especially in rural areas and with lack of adequate workforce in a number of areas, this would heavily impact the ability to provide services necessary to ensure the health and well-being of the population. It would also impact the ability to meet compliance with federal requirements for community integration for HCBS

programs, and the likelihood for reverting back to care in institutions for this population would increase.

19. The Adult Mental Health Division ("AMHD") has very strong concerns about the possible negative impacts of this Final Rule on the adults served by both State-operated Community Mental Health Centers and contracted community purchase-of-service providers. These consumers have severe mental illnesses and are therefore very fragile and vulnerable. Having a staff member refuse to provide services to them could have devastating consequences. Continuity of care is vital for this population. If AMHD cannot know at hiring, or at least when hired, that its staff have some objections to providing certain types of care or care to certain types of people, it would not be able to ensure that staff is available to serve its consumers. It also may not be able to prevent consumers from overhearing that a staff member does not want to provide a service to that person. Additionally, Hawai‘i has a severe shortage of mental health service providers, especially psychologists and psychiatrists, and this shortage is especially dire on the neighbor islands and in rural areas. If one provider has religious or moral objections to providing a certain service or to providing a service to a certain person, there may be no other options for that consumer.

20. For the consumers who AMHD serves, stigma is a significant barrier to receiving services. The Surgeon General of the United States identified stigma as "the most formidable obstacle to future progress in the arena of mental illness and health." The deleterious effects of labeling someone with mental illness are pervasive and widely acknowledged, and mental illness stigma has been associated with discrimination in multiple systems (e.g., education, housing, work-force, health, mental health, and judicial). Though mental illness stigma has been described as a contributor to social and sexual isolation, recent evidence suggests that it also may

increase sexual risk behaviors. Because the majority of people in psychiatric care worldwide are sexually active and people with mental illness have sharply elevated rates of HIV infection compared to the general population in most regions where they have been examined, studies of the ways in which mental illness stigma impinges on the sexuality and sexual behaviors of people with psychiatric illnesses have emerged. It is a significant health risk. The Final Rule increases the negative effects of stigma on this population; it does not "do no harm."

21. The AMHD is also required by law to provide services to persons ("defendants") who are involved in the criminal justice system who are found to be unfit to proceed to trial or to be not penally responsible for their charged crimes due to physical or mental disease, disorder, or defect (also known as "forensically encumbered"). AMHD is required by State law to provide services to these consumers including forensic examinations, fitness restoration services, therapy services, psycho-social rehabilitation services, medication management, case management, and other relevant mental health and substance abuse services. Many of these consumers have multiple mental and physical health issues, along with co-occurring substance abuse disorders. Their needs are complex, and the Final Rule would make the provision of services to this forensically encumbered population more complex than it already is. The mental health provider pool in our State is not sufficiently robust to accommodate providers who refuse to provide a service they were hired or contracted to provide, or who refuse to provide a service to all of the patients they were hired or contracted to serve. This is especially true if these providers are able to object without providing advance notice, and if AMHD has no ability to offer reasonable accommodations that the providers must accept. AMHD's consumers will be the ones suffering the harms caused by the Final Rule. Forensically encumbered consumers are part of the criminal justice system and they have constitutionally protected rights. The Final Rule will cause a risk of

overburdening Hawai‘i’s criminal justice system’s duty to provide timely forensic evaluations and fitness restoration services, due process, and other constitutional rights to defendants if it allows providers in the system to object to providing services. The Final Rule would hamper Hawai‘i’s ability to ensure that forensically encumbered defendants receive the timely and appropriate services they need from AMHD.

22. The Child and Adolescent Mental Health Division (“CAMHD”), is the carve-out Medicaid provider for all plans for the most severely affected youth and adolescents who have behavioral and mental health issues. CAMHD serves approximately 2,500 youth a year with a broad spectrum of system of care services ranging from outpatient evaluations, to intensive in-home therapy, to residential and hospital-based programming. Inherent in the etiology of many, if not the majority, of our clients are Adverse Childhood Events (ACEs) that have contributed to the behavioral manifestations and symptoms that these youth display. The familial and societal condemnation of these youth and adolescents often contributes to their eventual diagnosis. One of the most common situations for this condemnation arises when a child discovers that he or she is gay or gender non-conforming and as a result is rejected by family or society for religious reasons. Alienation from family or community can and often does result in low self-esteem, guilt, feelings of loneliness, despair, and depression, which in children is often manifested in behaviors like running away, self-mutilation, substance abuse, criminal behavior, and attempted and sometimes realized suicide. Suicide is the leading cause of death for Hawai‘i residents ages 10 to 19 years old; surpassing traffic crashes, cancers, drownings, and heart disease. The teenage suicide rate in Hawai‘i exceeds the national rate.

23. In our own experience here in Hawai‘i, up to 60% of those incarcerated at the Hawai‘i Youth Correctional Facility, (HYCF) had genuine mental health diagnoses. Fortunately,

in recent years, we have been hugely successful in diverting over 50% of that former inmate population into mental health treatment, with the thinking that emotional supports rather than incarceration, which often only reinforces societal rejection, is a better alternative for the lives of these youth. As mentioned in the section regarding AMHD above, mental health care providers are in very short supply in Hawai'i. The suggested rule change would further restrict access to care, but more importantly, it would reinforce the rejection these youth feel, thus making their problems and behaviors snowball. It is CAMHD's belief that acceptance, not rejection, can best help these youth to feel like they belong, enhance their self-esteem, and help them to better integrate as adults into society. To send them the message that they are unacceptable is both professionally unethical and counter-therapeutic.

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

Executed on this 12th day of June, 2019.

Bruce S. Anderson, Ph.D.
Director of Health
State of Hawai'i

Exhibit 8

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

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

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF SHARON C. BOYLE

I, Sharon C. Boyle, do hereby depose and state the following:

1. I am General Counsel at the Massachusetts Executive Office of Health and Human Services ("EOHHS").

2. Prior to being named General Counsel in 2018, beginning in 2003 I served in a variety of roles at the Executive Office of Health and Human Services including Deputy General Counsel, Chief MassHealth Counsel and First Deputy General Counsel.

3. I am familiar with the Final Rule entitled "Protecting Statutory Conscience Rights in Health Care; Delegation of Authority" ("Final Rule").

4. I have either personal knowledge of the matters set forth below or, with respect to those matters for which I do not have personal knowledge; I have reviewed information gathered for me in my capacity as General Counsel.

5. EOHHS is a cabinet-level department responsible for providing health and human services to eligible individuals in Massachusetts. It is comprised of twelve agencies and directly manages the Commonwealth's Medicaid program, called MassHealth.

6. The MassHealth program provides health care benefits to one in four Massachusetts residents, either through its fee for service programs or through its contracted managed care providers.

7. EOHHS also oversees public health programs—including infectious disease and substance abuse programs—that impact every community in the Commonwealth. EOHHS agencies are also responsible for licensing and regulating most health care professionals and facilities in Massachusetts.

8. EOHHS also manages a network of health care providers including a network of public hospitals. The four public hospitals operated by the Department of Public Health alone employ more than 1,500 staff members and provide acute and chronic medical care to thousands of residents across the Commonwealth each year.

9. Federal funding is essential to EOHHS's ability to continue to provide critical services and protect public health in Massachusetts.

10. In federal fiscal year 2018, the EOHHS received approximately $11B in federal funds from the Medicaid and CHIP programs. In fiscal year 2019, EOHHS agencies estimate receiving additional federal grants for approximately $208.1M in federal funds for public health and prevention, $124.7M for substance abuse prevention and treatment, $3.2M in biomedical and behavioral research, $2.2M for STD treatment & prevention and $6.75M for immunizations.

11. The Final Rule affects the terms and conditions for this funding. As a result, EOHHS must expend time and resources reviewing and determining how to comply with the Rule while also continuing to fulfill responsibilities and mandates under state law.

12. If the Final Rule goes into effect, it would interfere with EOHHS agencies' ability to carry out their regulatory functions and operate health care programs and facilities consistent with Massachusetts laws and regulations.

13. The Rule also impacts the operation of public health providers, including Department of Public Health (DPH) hospitals, which must continue to provide high-quality, non-discriminatory care and services to patients consistent with Massachusetts laws and regulations. Existing DPH policies and practices balance conscience protections for health care workers with other important factors including patient care and safety and the operational needs of its hospitals. The final rule does not provide similar balancing protections and adopts a different

approach to consciousness objections, including by limiting DPH's ability to make staffing decisions to ensure that employees can carry out critical job requirements, are not placed in circumstances that conflict with moral and religious beliefs, and do not jeopardize patient care.

14. Additionally, MassHealth's regulations prohibit providers from engaging in any practice that constitutes unlawful discrimination under any state law or regulation on the basis of race, color national origin, sex (including pregnancy, gender identity and sex stereotyping) age or disability. 130 CMR 450.202 (B)

15. MassHealth's regulations also prohibit MCOs, Accountable Care Partnership Plans, Primary Care ACO's, PCC's, the behavioral health contractor, SCOs and ICOs (collectively, Managed Care Entities or MCEs) from unlawfully discriminating and using any policy or practice that has the effect of unlawfully discriminating on the basis of health status, need for health care services, race, color, national origin, sex, sexual orientation, gender identity, or disability. 130 CMR 450.202(C).

16. Violation of 130 CMR 450.202(B) and (C) may result in administrative action – including monetary sanctions or contract termination or referral to the state Commission Against Discrimination.

17. The Final Rule jeopardizes MassHealth's ability to enforce its regulations as set forth above.

PURSUANT TO 28 U.S.C. § 1746, I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT. _

Executed on this 12 day of June, 2019

Sharon C. Boyle
General Counsel
Executive Office of Health and Human Services

Exhibit 9

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF JANET BRANCIFORT

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

2. I submit this Declaration in support of the State of Connecticut's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule" or "Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through the Connecticut Department of Public Health ("DPH") personnel who have assisted me in gathering this information from our agency, or on the basis of documents that I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon DPH.

3. I serve as a Deputy Commissioner for DPH, the State of Connecticut's lead agency for public health policy and oversight. DPH provides coordination and access to federal initiatives, training and certification, technical assistance and oversight and specialty public health services that are not available at the local level.

4. I am a Registered Respiratory Therapist and have a Master of Public Health degree. I have 41 years of experience in health and human services, including clinical, research and management experience. I have 13 years of experience in public health administration at DPH. I served as a manager in the Maternal Child Health Section at DPH for seven years prior to being appointed as a Deputy Commissioner in 2014.

I. The Role of Connecticut DPH in Serving the Health and Wellness of Connecticut's Residents

5. DPH is a lead state agency in a comprehensive network of public health services in Connecticut. DPH works in partnership with local health departments to coordinate and access federal initiatives, training and certification, technical assistance and oversight, and specialty public health services. It maintains up-to-date Connecticut health information and analytics which are

used by the Governor of Connecticut, the Connecticut General Assembly, the federal government and local communities to monitor the health of Connecticut's residents, to set health policy priorities and evaluate the effectiveness of health policy. DPH focuses on assuring quality and safety in health care to achieve positive health outcomes. It also seeks to streamline the administrative burden on regulated personnel, facilities, and programs.

6. DPH's mission is to ensure equitable access to resources and high quality health services for all of Connecticut's residents, to address the unique health needs of vulnerable populations living in our State, and to do no harm. Connecticut General Statutes § 19a-4j establishes an Office of Health Equity within DPH to improve the health of all Connecticut residents by working to eliminate differences in disease, disability and death rates among people of different races, ethnicities, ages, genders, socioeconomic position, immigration status, sexual minority status, language, disability, homelessness, mental illness or geographic area of residence. DPH's health equity policy is focused on achieving improved health outcomes for these groups across the State.

7. The majority of Connecticut's public health programs and services are supported by federal funds. For fiscal year 2019, DPH administered a budget of approximately $306 million. Forty-three percent of DPH's 2019 budget, or $132 million, was federal grant funding from various agencies including: HHS, the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Department of Homeland Security (DHS), and the Social Security Administration (SSA). The remainder of DPH's budget is comprised of state allocations (39%) and private or other sources including state approved bonding (18%).

8. DPH received approximately $52,632,185 in funds from HHS in Fiscal Year 2018.

II. Connecticut's Department of Health Passes Through HHS Funds to Sub-Recipients to Support Programs that are Critical to Maintaining and Improving the Health and Wellness of Connecticut's Residents

9. DPH passes through substantial amounts of the HHS funds to third parties, such as private healthcare providers. In total, DPH has 135 contractual and inter-agency relationships with sub-recipients that DPH uses to deliver health services. A few of the critical programs DPH administers with HHS funds are described below.

10. DPH passes HHS funds to Planned Parenthood for the DPH Family Planning program that prevents unintended pregnancy and decreases the birth rate among girls age 15-17 and provides them with primary reproductive health care. This program provides preventive reproductive health care, pregnancy prevention and testing/treatment of sexually transmitted disease and Human Immunodeficiency Virus (HIV) testing at 12 Planned Parenthood centers across Connecticut, and at four subcontracting sites, primarily to low income men and women of reproductive age. The program also provides training and educational programs for professionals serving this group.

11. DPH passes HHS funds through to the Personal Responsibility Education Program (PREP). PREP is an evidence-based, teen pregnancy, HIV, STD prevention program for at-risk youth ages 13-19 and pregnant or parenting youth up to age 21 delivered in school and/or community-based settings. PREP's prevention strategies are tailored to youth with histories of abuse, neglect, and trauma. In particular, PREP serves youth in the child welfare or juvenile justice systems who are at a greater risk for unplanned pregnancies and Sexually Transmitted Infections (STIs).

12. DPH passes HHS funds through to the School Based Health Centers (SBHC) program. SBHC provides health services to students at or near schools. SBHC services are

focused on, but not limited to, students who do not have access to a family doctor, or whose families have little or no health insurance. The comprehensive health care provided by SBHC helps Connecticut's students remain in school, stay healthy and be ready to learn.

13. DPH passes HHS funds through to the Children & Youth with Special Health Care Needs (CYSHCN) program. CYSHCN provides services for children who have, or are at increased risk for, a chronic physical, developmental, behavioral or emotional condition. CYSHCN provides medical home care coordination networks, coordination of services, information and referrals, provider and family outreach and parent-to-parent support, and access to respite and extended services. All of these services are tailored to children who require more health and social services than the general population.

14. DPH passes HHS funds through to the Office of Injury Prevention Intentional Injury Prevention Program. This program is a collaborative effort between DPH and the Connecticut Suicide Advisory Board (CTSAB) and the Child Maltreatment Domestic Violence Collaborative. The program seeks to reduce violence-related deaths and injuries caused by homicides, assault, suicide and suicide attempts, domestic violence, child abuse, and sexual violence. DPH's partners in this program have developed specific initiatives related to suicide prevention, fall prevention, concussion and traumatic brain injury prevention, sexual violence prevention, and opioids and prescription drug overdose prevention.

15. DPH passes HHS funds through to the Connecticut Breast and Cervical Cancer Early Detection Program (CBCCEDP). CBCCEDP is a comprehensive screening program available throughout Connecticut for women who are medically underserved. The program seeks to significantly increase the number of women who receive breast and cervical cancer screening, diagnostic and treatment referral services. The program services, which are provided

free of charge through DPH's statewide health care provider network, include: office visits, screening and diagnostic mammograms, breast biopsies, breast ultrasounds, fine needle aspirations, pap tests, colposcopies and colposcopy-directed biopsies, loop electrosurgical excision procedure (LEEP), surgical consultations, and clinical breast exams.

16. DPH passes HHS funds through to the Newborn Hearing Screening Program. This program seeks to reduce the loss to follow-up/loss to documentation about infants who have not passed a physiologic newborn hearing screening examination prior to discharge from the newborn nursery by utilizing specific, targeted and measurable interventions. Infants who do not pass newborn hearing screening and do not consistently receive follow-up testing are at risk for speech, language, social, and other delays.

17. DPH passes HHS funds through to Family Wellness Healthy Start (FWHS). FWHS provides care coordination, health education, referral and follow-up services and support during pregnancy and for up to two years postpartum to low income women and their babies in Hartford and New Britain, Connecticut. FWHS seeks to improve access to women's wellness visits; promote quality services; strengthen family resilience; achieve collective impact; and increase accountability through quality improvement, performance monitoring and evaluation.

18. DPH passes HHS funds through to Perinatal Case Management (PCM). PCM serves very high risk pregnant and parenting teens, including those with a history of substance abuse, mental illness, child welfare involvement, low income, unstable housing/homeless, and those at-risk for school drop-out and domestic violence. PCM provides intensive case management, home visits, parenting support and education, referrals and follow-up to mental health providers, health care, shelters, and substance abuse treatment to this group.

19. DPH passes HHS funds through to providers for HIV testing in clinical and non-clinical health settings. These HHS funds enable effective behavioral interventions, syringe services, condom distribution, social marketing, pre-exposure prophylaxis (PrEP) navigation services, health insurance premium assistance, CT AIDS Drug Assistance Program, treatment adherence, medical case management, early intervention services, outpatient ambulatory services, substance abuse treatment, mental health treatment, nutritional therapy, medical transportation, housing, oral health services and emergency financial assistance.

20. DPH passes HHS funds through to hospitals and local health departments to provide comprehensive testing and treatment for infected clients and those exposed to any Sexually Transmitted Disease (STD). These STD program funds pay for referrals for other services that clinicians determine to be needed.

21. The programs described in these preceding paragraphs—which are just a sampling—are absolutely essential to maintaining and improving public health in Connecticut. The loss of funding for any of these programs would be extremely detrimental to the health and well-being of Connecticut's residents.

III. The Final Rule Poses a Very Real Financial and Programmatic Risk to DPH and Its Sub-Recipient Entities

22. My understanding of the Final Rule is that the risk of loss of funds for DPH is both real and very hard for DPH to predict or prevent. DPH is at risk of losing all HHS funds if one of the 135 sub-recipients fails to comply with the Rule; but DPH's ability to control the actions of a sub-recipient is limited.

23. Even if DPH expends the substantial resources that would be needed to educate sub-recipients about the Final Rule, DPH may not be able to ensure that steps have been taken by

the sub-recipients to comply with the Final Rule. I am not sure how DPH will be able to adequately monitor sub-recipients on an ongoing basis for compliance.

24. Moreover, if one or more employees of a sub-recipient declines to perform a job, without notice, DPH will not be able to adequately assess whether any potential sub-recipient can actually provide the services contemplated by an award of funds. If the Final Rule prevents DPH from even screening sub-recipients for their ability to perform the procedures contemplated by an award of funds, then residents of Connecticut may not receive necessary care. The risk posed by an employee's refusal to provide care is especially acute for small-scale providers who will find it more difficult to double-staff to provide required care. In the long term, this may result in fewer awards to small-scale providers by DPH and a decrease in the number of services available to Connecticut's residents.

25. If HHS strips Connecticut's DPH of all of its funding because of an action of a sub-recipient, I am reasonably certain DPH will not be able to fill the gap to continue many, or maybe any, of these critical programs.

IV. Existing State Regulations and Policies Protect Connecticut Employees' Rights to Refuse to Provide Non-Emergency Care Based Upon Religious, Moral or Ethical Objections

26. My understanding is that Connecticut health care providers are already given protection to refuse to provide care to which they have an ethical, moral or religious objection. In Connecticut, existing regulations permit a healthcare provider who has an ethical, philosophical, or religious objection to certain procedures to decline to treat a patient, but require that the provider must turn over care of the patient without delay to another provider.

27. For example, a healthcare provider is not required to implement a "do not resuscitate order," but must turn over care to another provider who will implement the order and,

pending the assumption of care by another provider, must honor the order. *See* Regs. Conn. State Agencies § 19a-580d-9(a).

28. Connecticut law also allows an individual to refuse to assist in a non-emergency abortion if doing so would violate his or her judgment, philosophical, moral, or religious beliefs. *See* Regs. Conn. State Agencies § 19-13-D54.

29. I am also aware that some healthcare providers that receive HHS funds through Connecticut also have internal policies that address religious objections. For example, the University of Connecticut Health Center has an existing policy that permits an individual to raise a religious objection to participating in a procedure. The individual must do so in writing, and there is a procedure for evaluation of the request in light of the needs of the patient.

V. If Healthcare Providers in DPH Funded Programs Are Empowered to Refuse Care Without Prior Notice, Connecticut Residents Will Be Harmed

30. My understanding of the Final Rule is that it expands definitions of terms in ways that affect how DPH will function in the future. In particular, the Final Rule's definition of "assist in the performance" increases the number of individuals who may raise religious objections to go beyond covering healthcare providers who directly participate in a medical procedure. Under the Rule, as I understand it, now clerical staff and others who only indirectly aid a patient by scheduling a procedure or referring a patient to a specific healthcare provider can refuse to perform those functions. I am also concerned about the expanded or uncertain scope of the terms "discrimination" and "health care entity."

31. The lack of clarity as to who or what services fall under the Rule's terms creates a situation where the State of Connecticut, through DPH and other state agencies, must prepare for compliance with the Rule without a clear understanding of who the Rule applies to or how tangential their behavior may be and still fall under the Rule.

32. DPH must expend time, resources, and effort to comply with the Rule. DPH may have to modify hiring and contracting practices, as well as double-staff programs and services and other functions where there is a higher likelihood of an objection.

33. If a healthcare provider refuses to provide care, this will result in poorer health outcomes for Connecticut residents. These poor health outcomes are very serious and include increased infant HIV mortality rate, increased neonatal abstinence syndrome, increased HIV, HCV, STD and overdose related morbidity and mortality rates for populations in Connecticut. The risk of poor health outcomes will be exacerbated if a provider does not even need to provide notice of a refusal prior to refusing to provide care.

VI. If Providers Are Empowered to Refuse Care, the Final Rule Could Have An Especially Negative Impact on the Most Vulnerable Residents of Connecticut

34. Many of DPH's programs described above in Section II provide life-saving services to populations most in need, such as infants, youth, LGBT persons, women and families with limited income, and individuals who are at higher risk for HIV, STD, and opioid related overdoses in Connecticut.

35. The STD Control Program is a good example of the serious risk posed by a provider's refusal to provide care, without notice, even once. The STD Control Program receives funding from HHS to prevent, monitor the prevalence of, and control three major STDs: chlamydia, gonorrhea and syphilis. Disease Intervention Specialists (DIS) who work in this program are specially trained epidemiologists who link individuals testing positive for syphilis with treatment and help to locate their partners. Their work prevents further spread of the disease. DPH must be able to ensure that providers in this area are willing to actually fulfill the duties of the program.

36. There has been a significant increase in STDs in recent years across Connecticut, especially in young adults and adolescents, pregnant women and men who have sex with men. These individuals are often co-infected with other STDs, which makes them more susceptible to HIV. The STD Control Program helps to get these individuals into care and treatment as early as possible to protect them and the public at large.

37. Though easily treatable, untreated STDs can have lasting and devastating impacts, such as neurological and ocular syphilis, infertility in women and congenital syphilis which can lead to poor pregnancy outcomes, including miscarriages, premature births, stillbirths, or death in newborns. Babies exposed in utero can have deformities and delays in development. Connecticut had two cases of congenital syphilis in 2018. Just these two cases will have significant effects and indicate that DPH needs to increase testing and treatment of pregnant women.

38. If a patient is denied care or treatment for these, and other diseases, even one time, or if funding for these programs is stripped, the health of Connecticut's residents will be harmed. As a result, the State will almost certainly incur increased health care costs from delayed or denied treatment.

VII. The Final Rule's Threatened Loss of Funds Will Especially Impact Connecticut's Most Vulnerable Residents

39. The loss of HHS funds to the State due to non-compliance by a sub-recipient would result in negative health outcomes to the citizens of Connecticut because it could substantially reduce the ability of the State to provide healthcare to its citizens. Connecticut is facing another budget crisis and it is uncertain whether the Connecticut legislature would be

willing and able to allocate sufficient funds to programs impacted by a loss of HHS funds by DPH.

40. If Connecticut is stripped of HHS funds then it will not be able to provide the same quality healthcare services like HIV-related services to the LGBT population. An adequately funded HIV workforce is necessary to continue to provide critical prevention education to youth, routine HIV testing, linkage to care, and treatment services. If funding for HIV programs is lost, these patients and clients will be further marginalized and have poorer health outcomes. Ultimately, the State of Connecticut will incur some or all of the cost for this failure to provide adequate care.

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

Executed on this 12th day of June, 2019

JANET BRANCIFORT
DEPUTY COMMISSIONER,
CONNECTICUT DEPARTMENT OF PUBLIC HEALTH

Exhibit 10

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF DEANNA CHAREST

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

2. I submit this Declaration in support of the State of Michigan's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through Michigan Department of Health and Human Services personnel who have assisted me in gathering this information from our institution, or on the basis of documents that I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the Michigan Department of Health and Human Services.

3. I am the Reproductive Health Unit Manager within the Division of Maternal and Infant Health, Bureau of Family Health Services at the Department of Health and Human Services located in Michigan. I have a Master's in Public Health and more than fifteen years' experience in family planning and reproductive health, of which thirteen years has been with the Michigan Family Planning Program.

4. The MDHHS Family Planning Program has serious concerns related to the United States Department of Health and Human Services Final Health Care Refusal Rule. The Final Rule would significantly expand the ability of health care providers to withhold treatment, counseling, or medical information based on their religious or moral beliefs.

5. As an HHS Title X funded program, the Rule could jeopardize the MDHHS Family Planning Program's ability to meet the requirements of the Title X program, including providing services without discrimination, assuring access to a broad range of contraceptive methods, and providing services to minors.

6. The Rule would allow providers to withhold information about FDA approved contraceptive methods, counseling and referrals to abortion services, emergency contraception information, and vaccinations such as HPV and sterilization services.

7. The Rule could also allow providers to deny services to entire Michigan populations, such as minors, unmarried clients, clients living with HIV/AIDS, and LGBTQ people.

8. Clients who are low-income, uninsured or under-insured, or who live in rural communities could be disproportionately affected as alternative health care providers are not readily accessible.

9. The Final Rule does not consider the needs of Michigan clients and could create confusion about the rights and responsibilities of health care providers, entities, and clients and jeopardize the trusted client-provider relationship.

10. Withholding information from clients could also impact their ability to give informed consent for some health care services.

11. The Final Rule will have impacts for Michiganders and MDHHS in other areas outside the scope of the Family Planning Program, such as end-of-life care, blood transfusions, vaccinations, substance use disorders, civil rights laws related to employers, and likely many more.

12. Given that health care institutions owned and operated by Michigan will have no notice if one of their staff objects to the provision of a particular service or activity, those institutions will have to dramatically increase the staff available to serve patients in order to ensure that care is delivered.

13. The cost of this parallel staff will be unduly burdensome to the State institutions and to Michigan itself.

14. This is especially true in areas in which there are few other health care providers, such as rural areas, and in areas in which other providers are more likely to be religious and have objections of their own to the provision of certain types of care.

Executed on this 6th day of June, 2019

Deanna Charest
Reproductive Health Unit Manager
Division of Maternal and Infant Health, Bureau of Family Health Services
Michigan Department of Health and Human Services

Exhibit 11

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

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

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF SARAH CLARK

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

2. I am the Chief Financial Officer for the Vermont Agency of Human Services ("AHS"). I oversee the Agency's budget of $2.6 billion, which includes $1.4 billion in federal funds. I am responsible for budget development, federal financial reporting, federal cost allocation plans and managing the receipt and reconciliation of federal funds. I have worked in a financial capacity for the State of Vermont for 15 years. I have been the CFO of AHS for 4.5 years. I have a Masters' Degree in Business Administration from the University of Maryland, and a Bachelor's degree from American University.

3. I submit this Declaration in support of the State of Vermont's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule").

4. I make the statements set forth below based on my personal knowledge, through information obtained from other AHS personnel who have assisted me in gathering this information from our institution, or on the basis of documents that have been provided to and/or reviewed by me.

5. Medicaid is the national medical insurance program for the poor, which is jointly financed by state and federal government. Vermont's Medicaid program operates pursuant to federal approval as a demonstration project under Section 1115 of the Social Security Act (SSA), 42 U.S.C. § 1315.

6. Since 2005, Vermont has operated its Medicaid program under a Section 1115 waiver, using a public managed care-like model for health care delivery. Vermont Medicaid contracts directly with providers to deliver care to Medicaid members. Provider contracts stipulate that providers must be in compliance with all applicable state and federal laws. There are 17,189 individual providers enrolled in Vermont Medicaid. Providers include health care professionals working in solo or small practices, pharmacies, hospitals, residential treatment facilities, and specialists in numerous areas including obstetrics, pediatrics, and behavioral health.

7. Vermont's Medicaid program covers a wide variety of procedures and services, all of which must be medically necessary to qualify for Medicaid coverage. Covered benefits include, but are not limited to, the following: inpatient and outpatient hospital services; family planning services; Federally Qualified Health Center services; Rural Health Clinic services; transportation to necessary medical care; and services related to birth and pregnancy.

8. In state fiscal year 2018, Vermont spent $1.06 billion in federal funds on services under its Medicaid program. This includes Administrative Costs and the State Children's Insurance Program. Vermont receives majority of federal funding for Medicaid from the Center for Medicare and Medicaid Services ("CMS") which is a program of HHS.

9. Medicaid recipients include numerous vulnerable populations: children, individuals with physical and cognitive disabilities, and individuals with complex, long term health conditions. Disruption of care and loss of established provider relationships for such individuals will greatly increase incidence of preventable illness and otherwise manageable symptoms of chronic illness, as well as increasing the risk of catastrophic health events and death.

10. To the extent that "health care entity" as that term is used in the Final Rule includes contracted providers (clinics, hospitals, practitioner groups), a single staff member or practitioner's

decisions with respect to "assist[ing] in the performance" of care will not only disrupt the care of individual patients dependent on that provider, but also the contractual relationship between the contracted provider and Vermont Medicaid.

11. If contracted provider(s) refuse care to Medicaid members, Medicaid must cover care from an alternate provider. In many communities in Vermont, the number of potential providers for both primary and specialty care is limited. Refusals to provide care and attempts to accommodate those refusals when the Final Rule goes into effect would abruptly change the provider and Medicaid relationships in unpredictable and disruptive ways.

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

Executed on this 13th day of June, 2019

Sarah Clark
Chief Financial Officer
Vermont Agency of Human Services

Exhibit 12

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF LORI A. COYNER

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

2. I am the Medicaid Director at the Oregon Health Authority ("OHA"), the state agency responsible for public health programs in the State of Oregon, including administration of Oregon's Medicaid program. My educational background includes a Master of Arts degree in Statistics and over two decades of research, publication, and teaching in biostatistics and public health topics. Since 2000 I have worked in public, private, and academic settings in the field of public health policy and health administration. I served as Director of Health Analytics for OHA from 2013 to 2015 and as Medicaid Director from December 2015 to July 2017 and from February 2019 to the present.

3. I have over 20 years of experience in budgeting and developing programs in health care policy, public health, and clinical research, including structuring and implementing Oregon's the Oregon Health Plan ("OHP"), Oregon's managed care Medicaid program that includes coordinated care organizations ("CCOs").

4. I submit this Declaration in support of the State of Oregon's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule").

5. I make the statements set forth below based on my personal knowledge, through information obtained from other OHA personnel who have assisted me in gathering this information

from our institution, or on the basis of documents that have been provided to and/or reviewed by me.

6. The Oregon Health Authority operates a number of research, education, public health monitoring, and outreach programs, but the Oregon Health Plan is the fiscally largest OHA program and directly affects the lives of over 970,000 Oregonians across all thirty-six counties in the State. OHP members include families (including 400,000 children), people with disabilities, and people with severe long term illnesses such as HIV and Hepatitis C.

7. Medicaid is the national medical insurance program for the poor, which is jointly financed by state and federal government. OHP operates pursuant to federal approval as a demonstration project under Section 1115 of the Social Security Act (SSA), 42 U.S.C. § 1315.

8. Oregon has operated its Medicaid program under a Section 1115 waiver since the 1990s, and since July 2012 has operated using the coordinated care model for health care delivery. OHA contracts with CCOs and makes a capitated per member per month payment to each CCO for that CCO's OHP members. CCOs contract with providers to deliver care to OHP members. Providers include physicians, pharmacies, hospitals, residential treatment facilities, and specialists in numerous areas including obstetrics, pediatrics, and behavioral health.

9. OHA receives a majority of the funding for OHP (between $4 billion and $5 billion annually) from the Centers for Medicare and Medicaid Services ("CMS") which is an agency within HHS.

10. As of May 2019 there are 15 CCOs operating in Oregon. In the majority of Oregon counties there is only one CCO enrolling OHP members. Those CCOs in turn have limited numbers of providers, particularly in rural counties, with whom they contract to care for OHP members.

11. CCOs enter into annual contracts, including the per member per month reimbursement rate, with OHA to cover care for OHP members. The contracts require the CCOs to comply with all applicable laws and regulations, including Medicaid regulations and Oregon insurance laws.

12. The rates themselves are set on a multi-year cycle using an actuarial process that takes into account the demographic and health characteristics of the covered population, and past cost and utilization data.

13. To the extent that "health care entity" as that term is used in the Final Rule includes contracted providers (clinics, hospitals, practitioner groups), a single staff member or practitioner's decisions with respect to "assist[ing] in the performance" of care will not only disrupt the care of individual patients dependent on that provider, but also the contractual relationship between the contracted provider and the CCO.

14. If contracted provider(s) refuse care to OHP members, the terms of the CCO contracts require CCOs to cover care from an alternate provider. In many communities in Oregon, the number of potential providers for both primary and specialty care is limited. Refusals to provide care and attempts to accommodate those refusals when the Final Rule goes into effect would abruptly change the financial structure underlying the provider and CCO relationships in unpredictable and disruptive ways, thus destabilizing the entire OHP coordinated care structure.

15. To the extent the CCOs themselves are "health care entities" under the Final Rule, CCOs may seek to opt out of covering procedures, treatment, or prescriptions. Such refusal may conflict with Oregon laws regarding the coverage of certain procedures or conditions, and will also

disrupt the rate setting process which depends on analysis of past costs and utilization combined with predicted costs and utilization across whole patient populations.

16. If any CCO declines to cover a procedure or course of treatment for an OHP member, that CCO may be in breach of Oregon law, the CCO/OHA contract, or both. Termination of a CCO agreement will result in all of that CCO's members losing coverage, and corresponding disruption of care, particularly in the majority of the state where there is no alternate CCO and few if any alternate providers.

17. OHP members include numerous vulnerable populations: children, individuals with physical and cognitive disabilities, and individuals with complex, long term health conditions. Disruption of care and loss of established provider relationships for such individuals will greatly increase incidence of preventable illness and otherwise manageable symptoms of chronic illness, as well as increasing the risk of catastrophic health events and death.

18. The OHA does not have a means to replace whole provider networks or coverage in entire counties. In some areas and for some populations, OHA could move to a fee-for-service coverage model, but that would not solve the provider shortage in some areas, nor would it be possible to convert to fee-for-service on a large scale immediately in response loss of whole portions of the coordinated care network.

19. Losing the cost benefits of a coordinated care model of health care coverage and delivery would result in increased health care costs, including both direct care and ancillary costs in ways that it is presently difficult to quantify.

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

Executed on this 10th day of June, 2019

LORI A. COYNER

Medicaid Director, Oregon Health Authority

Exhibit 13

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF THOMAS M. DALY

1. I, Thomas M. Daly, FHFMA, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I submit this Declaration in support of the State of New Jersey's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and the United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through University Hospital personnel who have assisted me in gathering this information from our institution, or on the basis of documents I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon University Hospital.

Background

3. I am the Chief Financial Officer ("CFO") at University Hospital located in Newark, New Jersey. I hold a BBA in Accounting and have been employed as CFO since July 21, 2008. I am also a Fellow of the Healthcare Financial Management Association ("FHFMA").

4. In my capacity as CFO, I oversee the hospital's Finance and Health Information Management departments. I am responsible for direct oversight of establishing and operating within budgetary constraints. Moreover, I regularly coordinate with University Hospital's Chief Human Resources Officer, who is responsible for the hospital's current conscience objection accommodation policy. I anticipate that the Final Rule, if it takes effect, would likely have immediate financial consequences impacting areas over which I have direct oversight and responsibility.

5. University Hospital is an academic medical center and one of three Level One Trauma Centers in New Jersey. The hospital has over 500 medical staff, 140 adjunct medical staff, and 603 residents. University Hospital is the principal teaching hospital for Rutgers Biomedical and Health

Sciences ("RBHS"). University Hospital educates a large number of students, including approximately 762 medical students and 420 dental students annually. In addition, University Hospital educates students from a number of other RBHS schools, such as the schools of Nursing, Pharmacy, and Health Professions.

6. University Hospital is the principal research partner for Rutgers New Jersey Medical School and is currently supporting over 100 open clinical trials, the vast majority of which are federally funded. These trials will likely have a material impact on future patient care in New Jersey and around the world.

7. University Hospital consists of numerous departments, including Emergency Medicine, Trauma, and Family Health Services. Among the services provided to patients are vaccinations, abortions, sterilizations, end-of-life care, gender affirmation surgeries, and counseling and referral. The hospital also supports 18 distinct clinical New Jersey Medical School departments functioning within University Hospital.

8. The hospital is a critical medical center for patients in New Jersey's largest city. Over 16,000 patients are admitted to the hospital each year. The hospital has another 172,000 outpatient visits and more than 90,000 emergency room visits each year.

9. University Hospital is New Jersey's only public hospital, operating as an instrumentality of the State, with an operating budget of over $700 million per year. Approximately $525 million of the hospital's budget consists of a combination of federal and state funding. The hospital received a total of $516 million in Medicare and Medicaid funding in FY2018, with a portion of Medicaid funding coming from state matching funds. Additionally, in FY2018, University Hospital received $439,000 in federal grant funding to improve New Jersey's ability to prepare for, respond to, and recover from an Ebola or other emerging infectious disease

event. University Hospital also received over $700,000 for emergency preparedness and for state-wide medical coordination among its public health, healthcare, and emergency management systems. The Medical Coordination Center program took the lead in coordinating the responses to the Flight 1549 landing in the Hudson River, Hurricane Earl, Hurricane Irene, and Hurricane Sandy. Concurrently, it played a significant role in the development of several major statewide and regional plans including the Port Security Plan, Rail Security Plan, Prudential Center Plan, Newark Liberty International Plan, National Disaster Medical System Plan for Newark Liberty International Airport, and the Tropical Storm/Hurricane Plan. In light of the volume of federal funding received by University Hospital for these activities, discontinuance of or significant reduction in federal funding would have great adverse effects on the operation of the hospital, the ability prepare for emergencies and outbreaks, and patient care.

10. University Hospital is the largest provider of uncompensated care in the State. The funds received through HHS are crucial to the financial health of the hospital and its ability to provide equitable care to all of New Jersey's residents. Any reduction in funding to University Hospital could prove disastrous to the care provided to vulnerable and low-income populations in New Jersey.

University Hospital's Current Objection Policy

11. University Hospital is committed to providing quality, considerate, respectful, and comprehensive care to all patients. To that end, the hospital has developed a carefully considered policy to accommodate the religious beliefs and cultural values of its staff in a way that does not compromise patient care. The policy requires employees with a religious or moral objection to notify their supervisor in advance in writing if such objection may impact performance of their job duties. Except in an emergency setting, an employee may be excused from participating in any

specific patient care based on his or her cultural values, ethics, or religious beliefs. Under University Hospital's policy, participation means that an employee has direct involvement in the procedure or attendance in the room at the time of the procedure, and it specifically does not include pre- and post-procedure care, room cleaning, or record keeping. Under no circumstances does an employee have the right to refuse to care for a patient without prior approval, and any such refusal to provide care results in disciplinary action. In the event that University Hospital cannot accommodate an employee's objection, the employee is advised to seek a transfer to a department where conflict of care issues are less likely to occur. Finally, under the policy, University Hospital reserves the right to re-evaluate, revise, or revoke any accommodation if the department head determines that the current situation requires that the employee participate in previously excused procedures in order to provide appropriate patient care. Such circumstances can arise due to, among other things, emergencies, changes in staffing availability, or other hospital conditions.

12. University Hospital requires prior written notice of employees' objections for a number of reasons. First, in order to be compliant with applicable regulations and guidelines promulgated at the state and federal level, University Hospital must be able to predict its staffing needs with a reasonable degree of certainty. Having advance notice permits University Hospital to make informed staffing decisions to ensure quality patient care. This is especially important in University Hospital's operating rooms, which are staffed on night shifts by three-person teams consisting of a doctor, a nurse, and a scrub technician. During night shifts, the hospital has only two teams running the operating rooms. If an employee on an operating room team were to raise an objection without prior notification, patient care would most likely be compromised. For example, an operation could be interrupted or delayed and a patient placed at risk while staff searched for a doctor, nurse, or scrub technician who did not object to the procedure. Staffing a

large medical center like University Hospital is very complex. Allowing objections without prior notice would upend University Hospital's staffing plans and is not operationally, functionally, or financially feasible. Second, by requiring advance notice of objections, University Hospital is able to comply with New Jersey law, which requires that there be an "appropriate, respectful and timely transfer of care" if a health care professional declines to participate in withdrawing or withholding life-sustaining measures. N.J. Stat. Ann. § 26:2H-62(b). Such transfer of care can only be ensured if University Hospital has advance notice of objections and, therefore, the ability to staff its departments accordingly.

13. Additionally, University Hospital reserves the right to re-evaluate or revoke any accommodation in order to ensure patient care. For example, in the case of an emergency, an employee who previously objected to a certain procedure may nonetheless be required to participate in that procedure if he or she is the only employee available and a patient would be placed at risk were he or she not to participate. That is, while University Hospital strives to accommodate employees' cultural values and religious beliefs, patient care is the number one priority.

Immediate Impact of the Final Rule on University Hospital

14. The Final Rule, if it takes effect, likely will have an immediate and negative impact on University Hospital. For example, University Hospital will have to determine whether the Final Rule allows the hospital to maintain a policy that requires notice for objections, or if a staff member may object without prior notice. Because the Final Rule seems to allow objections without notice, University Hospital will have to take precautions in line with the assumption that staff may object without prior notice. It is our understanding that University Hospital would then be required to accommodate that objection even if it were to potentially place a patient at risk (for example, in a

case where an objection were raised for the first time during an emergency). As a critical provider of trauma services for the northern half of New Jersey, a liver transplant center, and the referral center for specialized Ophthalmology, Otolaryngology, Neurosurgery, and Orthopedic Care, University Hospital provides care in numerous emergency situations; objections made without prior notice would have a profound and detrimental impact on emergency patient care in New Jersey.

15. The Final Rule also may prohibit University Hospital from doing the following: disciplining employees who refuse to provide care based on sincerely held religious or moral objections without prior approval; inquiring about conscience objections prior to hiring; advising employees to seek transfer to a department where conflict of care issues are less likely to occur; or re-evaluating, revoking, or revising accommodations if the department head determines that the current situation requires the participation of previously-excused employees in order to provide appropriate patient care. Additionally, the Final Rule expands both the areas in which an employee can assert an objection on religious or moral grounds, as well as the overall number of covered employees, by allowing employees to object to emergency care, pre- and post- procedure care, scheduling, room cleaning and preparation. Ultimately, I expect the Final Rule to adversely affect University Hospital's ability to provide care to patients and to cost the hospital funds that could better be spent on improving patient outcomes.

16. ***Financial Costs of the Final Rule*** – The Final Rule will likely require University Hospital to over-staff in order to avoid a situation where the only available employee refuses to participate in an aspect of patient care. For example, University Hospital would likely need to ensure that more nurses or employees are on call and ready to respond were an individual to, without notice, assert a conscience objection. Double-staffing might not be enough, for example,

where the back-up nurse also asserts a conscience objection. Moreover, because of the Final Rule's expansive definitions of staff who participate in providing care, University Hospital will likely need to double-staff not just operating room staff, but also employees involved in the scheduling of procedures, in the provision of pre- and post-procedure care, and in the cleaning and prepping of rooms. The extremely broad scope of the Final Rule seems to implicate all areas of patient interaction, from the front door, to registration, to the front desk, to patient experience, to transport, counseling, and the provision of medical services. Such over-staffing will likely be unduly expensive and largely unworkable for University Hospital, the largest provider of uncompensated care in the State. Moreover, such over-staffing may nonetheless fail to both satisfy the Final Rule and ensure quality patient care; the hospital cannot account for every possible objection in every department. The level of redundancy required by the Final Rule is simply untenable and may even be impossible to achieve due the lack of available staff in the market and the enormous financial burden it causes.

17. ***Effect on Patient Care*** – Even if University Hospital were to take all of these expensive staffing precautions, the Final Rule likely would still adversely impact patient care. For example, if an employee asserts a conscience objection without notice, a procedure could be halted, perhaps at a critical time, while the employer searches for an employee that would not object. That delay could have negative consequences for the patient. Additionally, patient care will likely be negatively impacted when large amounts of funding that could have gone toward improving patient outcomes is re-directed to over-staffing positions to ensure backup in the event of a conscience objection. The hospital's primary mission is the provision of patient care. Prioritizing staff objections could impair physicians' and medical providers' (and, by extension, the hospital's) ability to effectuate that duty.

18. ***Effect on Hiring*** – The Final Rule also constrains University Hospital's hiring practices by generally prohibiting questions regarding a potential employee's conscience objections prior to hiring. As a result, University Hospital may fill a critical position with an employee who cannot perform the position's core requirements (and the Final Rule also precludes University Hospital from then transferring this employee to another department). Consequently, University Hospital will likely need to hire additional people to ensure that it has employees available who are willing and able to provide comprehensive, quality health care to all patients. Again, patient care will likely be negatively impacted when funding for improving patient outcomes or improving a certain hospital department is diverted to over-staffing in order to accommodate the Final Rule's requirements.

19. ***Impact on LGBTQ Care*** – University Hospital is committed to ensuring that all patients, regardless of sexual expression or gender identity, have access to high quality, comprehensive care. Moreover, University Hospital is working toward becoming a center for excellence for gender-affirming surgery. University Hospital will likely need to over-staff in order to ensure that care for patients who identify as LGBTQ is not interrupted or negatively impacted by an employee who, without notice, objects to providing care on religious or moral grounds. Again, such over-staffing will likely be unduly expensive for University Hospital.

20. ***Impact on Enforcement of New Jersey Law*** – If the Final Rule goes into effect, University Hospital will face significant difficulties reconciling the Final Rule with New Jersey state law regarding pharmacies. The Final Rule allows health care entities, including pharmacists and pharmaceutical assistants, to object to assisting in the performance of a health service program. Conversely, New Jersey law requires pharmacy practice sites to "fill lawful prescriptions for prescription drugs or devices[,]" even if an employee of the practice objects to filling the

prescription based upon "sincerely held moral, philosophical, or religious beliefs." N.J. Stat. Ann. § 45:14-67.1(a). University Hospital operates a pharmacy on site for immediate patient care that dispenses contraceptives, emergency contraception, and prescriptions that can be used for end-of-life care and in connection with gender affirmation surgery. In order to ensure compliance with the Final Rule, University Hospital will likely need to double-staff pharmacist and pharmaceutical assistant positions in order to ensure that it "fill[s] lawful prescriptions," *id.*, even in the face of objecting staff. Such double-staffing is unduly expensive, generally unworkable for the hospital, and may not even be a satisfactory way to reconcile the Final Rule and New Jersey law.

21. ***Drafting a New University Policy on Objections*** – I anticipate that, if the Final Rule takes effect, University Hospital will need to update its policy on conscience objections to ensure that it comports with the Final Rule. The hospital intends to ensure its full compliance with state and federal law. To do so, it will need to re-write its existing objection policy. This requires a multi-disciplinary approach and the input of the hospital's entire leadership team, including the Chief Executive Officer, Chief Medical Officer, Chief Nursing Officer, Chief Financial Officer, Chief Legal Officer, Chief Human Resources Officer, and Chief Operating Officer. Indeed, it is not clear that a new policy can be drafted that comports both with the Final Rule and pre-existing state law requirements in this area. Significant resource re-allocation will also be necessary to determine the veracity of any conscience objections and whether they are sincerely held.

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

Executed on this 7th day of June, 2019

Thomas M. Daly
Chief Financial Officer
University Hospital

CERTIFICATE OF SERVICE

I hereby certify that on April 27, 2020, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Leif Overvold
Leif Overvold