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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

EUGENE DIVISION

AMERICAN MEDICAL ASSOCIATION; OREGON MEDICAL ASSOCIATION; PLANNED PARENTHOOD FEDERATION OF AMERICA, INC.; PLANNED PARENTHOOD OF SOUTHWESTERN OREGON; PLANNED PARENTHOOD COLUMBIA WILLAMETTE; THOMAS N. EWING, M.D.; MICHELE P. MEGREGIAN, C.N.M.,

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; DIANE FOLEY, M.D., in her official capacity as the Deputy Assistant Secretary, Office of Population Affairs; OFFICE OF POPULATION AFFAIRS,

Defendants.

Case No. 6:19-cv-318

COMPLAINT

TABLE OF CONTENTS

INTRODUCTION

1. Plaintiffs bring this action to set aside and enjoin the final rule titled *Compliance with Statutory Program Integrity Requirements* (the "Final Rule"), 84 Fed. Reg. 7,714, issued by the Department of Health and Human Services ("HHS") on March 4, 2019 (attached as Exhibit A). The Final Rule's effective date is May 3, 2019.

2. The Final Rule would radically alter and decimate the family-planning-assistance program established by Title X of the Public Health Service Act, 42 U.S.C. §§ 300 et seq.—with severe and irreparable public health consequences across the United States.

3. The Final Rule, moreover, will politicize the practice of medicine and the delivery of health care. It will cause patients to lose faith in their providers and the health care system as a whole. It will mandate that the speech of physicians and other health care professionals be tailored according to what the government may favor, rather than according to the interests of the patient, best medical practices, or accepted medical ethics. If allowed to stand, the Final Rule will reinforce a dangerous idea—that physicians and others in the medical profession are to place the interests of government above the interests of their patients.

4. Congress created the Title X program nearly 50 years ago to ensure that all people, and especially low-income women, have access to family planning care.

5. Plaintiffs are leading local and national health care organizations and individual health care professionals. They have participated, themselves or through their members or affiliates, in the Title X program for decades, and they play essential roles in the delivery of health care to millions of people across the country each year.

6. Title X has been extraordinarily successful. Under regulations that have been largely unchanged for decades, a large network of family-planning centers has flourished with enormous benefits to patients, their families, and public health.

7. For example, in 2015 (the most recent year for which data are available), the contraceptive care delivered by Title X-supported providers helped women avoid more than 800,000 unintended pregnancies. Without this care, experts have concluded, there would have been hundreds of thousands more unintended pregnancies and abortions in the United States.

8. Title X programs have also yielded vast benefits for sexual and reproductive health, contributing to the prevention, early detection, and treatment of sexually transmitted infections and the prevention and early detection of cervical cancer.

9. Crucial to the success of the program is the fact that services delivered under Title X must be "nondirective," "voluntary," and "comprehensive." These congressional mandates are critical for proper medical care and fundamental to full and frank communications and trust between a Title X patient and her or his health care provider.

10. Accordingly, with one brief exception that faced extensive opposition and that was never fully implemented, Title X regulations have long required that—if requested by their pregnant patients—practitioners in the Title X program must provide them nondirective counseling on all of their options, including counseling on and referral for abortion. Moreover, since its inception, Title X care has been delivered by health care providers who—outside the Title X program and with non-Title X funds—also provide abortion services.

11. Notwithstanding all of this, in June 2018, HHS proposed a radical change of course. That proposal faced vigorous and massive opposition in public comments—including by virtually every leading health organization in the United States—setting forth the legal and ethical flaws, drastic costs, and public health consequences of the proposed rule.

12. Nonetheless, as relevant here, HHS largely adopted the proposed rule without material change in the Final Rule, with one important exception that adds yet another legal flaw. At

its core, the Final Rule threatens the very purpose of Title X—representing an all-out assault on Title X patients' critical need for high-quality family planning care.

13. To that unlawful end, the Final Rule would impose radical requirements on Title X providers, principally by means of two central and integrated provisions.

14. *First*, the Final Rule imposes a gag on the medical profession that would have practitioners in the Title X program *direct* pregnant women toward continuing a pregnancy to term—regardless of what a patient actually wants (the "Gag Requirement").

15. The Final Rule implements this requirement in numerous ways. First and foremost, it bans abortion referrals while mandating prenatal referrals. In other words, Title X providers must *not* tell pregnant patients how and where they can access abortion safely and legally, but they *must* provide that information as to prenatal care—again, regardless of what a patient actually wants, or what is in the patient's best medical interest.

16. Moreover, under the Final Rule, HHS blesses biased and incomplete pregnancy counseling where the interests of the patient are no longer paramount. HHS further compels speech from those who would provide nondirective counseling on abortion. And HHS dramatically limits—without explanation—those who can provide such abortion counseling. Thus, the Final Rule authorizes and encourages Title X providers to tell pregnant patients about only *some* of their options and exclude any information about abortion. And even when a patient says she is only interested in information and counseling on abortion, the Final Rule would have practitioners disregard that patient decision, compel them to speak about other options she does not want, and, in all instances, tell her about the "risks and side effects to [her] unborn child." 84 Fed. Reg. at 7,747. What is more, only "physicians or advanced practice providers" can even provide such nondirective counseling on abortion (as HHS would define it), *id.* at 7,789 (to be codified at 42 C.F.R. § 59.14(b)(1)(i))—excluding vast numbers of medical professionals, including registered nurses and

health care assistants, who regularly work alongside physicians and advanced practice providers and effectively provide this counseling.

17. Finally, concerning the exception noted above (¶ 12), the Final Rule sets forth an unexplained and inexplicable additional ban on medical speech going beyond counseling on abortion—a speaker-based restriction on who can provide "pregnancy" counseling. 84 Fed. Reg. at 7,789 (to be codified at 42 C.F.R. § 59.14(b)(1)(i)). This ban was nowhere hinted at in the proposal, would cause disruption and delays in care, and is irrational.

18. *Second*, the Final Rule imposes onerous and vague "physical and financial" separation requirements that punish Title X providers for talking about or providing abortions with *non*-Title X funds and coerce them into abandoning that constitutionally protected activity (the "Separation Requirement").

19. Through the Separation Requirement, HHS has targeted so-called "prohibited activities"—defined so broadly as having virtually anything to do with abortion, from the provision of abortion with non-Title X funds to abortion referrals and even including abortion-related "brochures … sitting on a table." 84 Fed. Reg. at 7,790 (to be codified at 42 C.F.R. §§ 59.13-16). Title X providers who engage in these "prohibited activities" must now comply with new and sweeping requirements—including separate facilities, separate personnel and workstations, and separate health care records—that would harm patient care and result in immense and unnecessary costs, if compliance is even possible. Moreover, as HHS all but admits, the Separation Requirement is a solution in search of a problem. The Final Rule cited *no* evidence of misuse of Title X funds over the past *half-century*, instead relying on meritless notions of "potential" misuse and "confusion." *Id.* at 7,765.

20. Plaintiffs bring this suit under the Administrative Procedure Act ("APA") to vindicate Congress's intent in enacting Title X and to enforce their rights and the rights of their

patients. The Final Rule violates the APA in many respects: it is contrary to federal statutes and the First and Fifth Amendments to the United States Constitution, is arbitrary and capricious, and was promulgated without procedure required by law. It should be set aside and enjoined in its entirety, preliminarily and permanently.

21. If not enjoined, the Final Rule will irreparably harm Title X providers, their patients, and the public health of the nation.

22. The Gag Requirement alone would be devastating—and it goes into effect in 59 days. This requirement threatens the core of family-planning health care. Not only does it interfere with communications about patients' health care options, but it further *requires* Title X practitioners to *direct* women toward continuing a pregnancy to term. The Supreme Court recently warned against this very thing—"government[] … 'manipulat[ion]'" of the "'content of doctor-patient discourse'"—emphasizing that this tactic has been used "[t]hroughout history" to "increase state power and suppress minorities." *National Institute of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2374 (2018) ("*NIFLA*"). The Gag Requirement is fundamentally at odds with constitutional rights and the ethical and professional obligations of health care professionals—as Plaintiff American Medical Association forcefully made clear in comments on the proposed rule—giving vast swaths of providers no choice but to withdraw from Title X entirely. The resulting exodus would cause major gaps in access to care, harm public health, and produce significant, unnecessary cost.

23. Moreover, precious resources would be diverted to comply with the onerous and vague Separation Requirement, driving even more providers out of the program. And for those who remain in the program, money siphoned for compliance will mean less money for patients. For Title X programs across the country, that would result in fewer services and shorter hours, staff layoffs, and health center closures, particularly in the most underserved areas.

24. Ultimately, unless it is enjoined, the impact of the Final Rule will be a national public health crisis in short order. As commenters on the rule detailed, pregnancies that are unintended, and thus riskier, will increase. The number of abortions will also increase. And there will be fewer tests for sexually transmitted infections and cancer screens—putting patients and their partners at great health risk.

PARTIES

25. Plaintiff American Medical Association ("AMA") is the largest professional association of physicians, residents, and medical students in the United States. The AMA is an Illinois not-for-profit corporation headquartered in Chicago, Illinois. All of the state medical associations and most of the major specialty medical societies are represented in the AMA House of Delegates, with the AMA serving as the overall umbrella and voice of organized medicine in the United States.

26. The AMA represents virtually all United States physicians, residents, and medical students through its policymaking process. AMA members practice and reside in all States, including Oregon. AMA members practice in all areas of medical specialization, and AMA members counsel pregnant women about family planning, including the availability of abortion services, as part of Title X projects.

27. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health. Since its founding in 1847, the AMA has played a crucial role in the development of medicine in the United States.

28. Plaintiff Oregon Medical Association ("OMA") is a professional association of physicians organized for the purpose of serving and supporting physicians in their efforts to improve the health of Oregonians. The OMA represents physicians, residents, medical students,

and physician assistants who reside in the State. The OMA is an Oregon not-for-profit organization headquartered in Portland, Oregon.

29. The AMA and OMA file this lawsuit on behalf of themselves and their members and members' patients, including those members who counsel pregnant women as part of Title X projects, and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each State plus the District of Columbia. Its purpose is to represent the viewpoint of organized medicine in the courts.

30. The AMA and OMA have standing on behalf of their members who provide services to patients as part of Title X projects, including those members who counsel (or may in the future counsel) pregnant women as part of Title X programs, in that (1) their members would otherwise have standing to sue in their own right; (2) the interests the AMA and OMA seek to protect are germane to the purposes of the AMA and OMA; and (3) neither the claims asserted, nor the relief requested, requires the participation in this lawsuit of each individual AMA and OMA member.

31. Plaintiff Planned Parenthood Federation of America, Inc. ("PPFA") is a not-for-profit corporation organized under the laws of the State of New York. PPFA is the leading national organization dedicated to public education and advocacy in the field of reproductive health care. PPFA's core mission is to ensure the provision of comprehensive reproductive health care services, to provide educational programs relating to reproductive and sexual health, and to advocate for public policies to ensure access to health services—including and especially for individuals who are low-income or from underserved communities. PPFA also engages in public education about, and advocacy in favor of, the right of women to access safe and legal abortions.

32. PPFA is a membership organization composed of 54 affiliate organizations, with a Board of Directors. The member affiliates are responsible for setting the long-range goals and priorities of PPFA and for electing 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, and affiliate dues contribute to PPFA's financial support.

33. PPFA brings this action on behalf of itself and all of its member affiliates and their patients.

34. PPFA has standing on behalf of its member affiliates providing services to patients as part of Title X projects, in that (1) its member affiliates would otherwise have standing to sue in their own right; (2) the interests PPFA seeks to protect are germane to its purposes; and (3) neither the claims asserted, nor the relief requested, requires the participation in this lawsuit of each individual PPFA member affiliate.

35. Each of PPFA's member affiliates provides health care and educational services directly to the public in a distinct geographic area. Together, PPFA's affiliates operate more than 600 health centers in 48 States and the District of Columbia, serving patients across the country.

36. Plaintiff Planned Parenthood of Southwestern Oregon ("PPSO") is a not-for-profit corporation organized under the laws of the State of Oregon. Its principal office is in Eugene, Oregon. PPSO operates six health centers in Lane, Josephine, and Jackson Counties, and is the principal provider of reproductive health services in the southwestern Oregon region, including Benton, Coos, Curry, Douglas, Jackson, Josephine, Lane, and Linn Counties. All six of PPSO's health centers participate in the Title X program.

37. Although PPSO is an independent organization, it is an affiliate of PPFA and has the right to use the Planned Parenthood name and service mark. PPSO's affiliation with PPFA is

essential to PPSO's ability to provide the high-quality health care that it delivers to patients. Under the PPFA bylaws, PPSO is required to pay membership dues to PPFA.

38. PPSO brings this action on behalf of itself and its staff and patients.

39. Plaintiff Planned Parenthood Columbia Willamette ("PPCW") is a not-for-profit corporation organized under the laws of the State of Oregon. Its principal office is in Portland, Oregon. PPCW operates seven health centers in Oregon and Southwest Washington. All seven of PPCW's health centers participate in the Title X program.

40. Although PPCW is an independent organization, it is an affiliate of PPFA and has the right to use the Planned Parenthood name and service mark. PPCW's affiliation with PPFA is essential to PPCW's ability to provide the high-quality health care that it delivers to patients. Under the PPFA bylaws, PPCW is required to pay membership dues to PPFA.

41. PPCW brings this action on behalf of itself and its staff and patients.

42. PPFA, PPSO, PPCW, and all of PPFA's other affiliates are collectively referred to here as "Planned Parenthood."

43. Plaintiff Thomas N. Ewing is a board-certified family medicine doctor in Eugene, Oregon. He received his medical degree from Washington University School of Medicine in St. Louis, in 1983, and has been practicing medicine for more than 30 years. Dr. Ewing currently serves as the Vice President of Medical Services and Medical Director for PPSO. In his practice, Dr. Ewing sees Title X patients and, among other things, provides options counseling to pregnant women, including counseling on and referral for abortion. In addition, under his direction at PPSO, registered nurses and health care assistants provide options counseling for pregnant women, including counseling on and referral for abortion. Dr. Ewing is a member of the AMA, OMA, and American Academy of Family Physicians, among other associations.

44. Dr. Ewing brings this action on behalf of himself and his patients.

45. Plaintiff Michele P. Megregian is a certified nurse-midwife, specializing in midwifery care and general obstetric-gynecology care. She received both her B.S. in Nursing and graduate degree in Midwifery from Columbia University School of Nursing, in 1996 and 1997 respectively, and has practiced midwifery in a variety of settings, including public health clinics, community health centers, and hospital-based practices. Ms. Megregian previously served as a family planning clinician at PPCW and currently serves as a family planning clinician at PPSO. In her practice, Ms. Megregian sees Title X patients and, among other things, provides options counseling to pregnant women, including counseling on and referral for abortion. In addition, under her direction at PPSO, registered nurses and health care assistants provide options counseling for pregnant women.

46. Ms. Megregian brings this action on behalf of herself and her patients.

47. Plaintiffs have standing to assert the right of their patients or their members' or affiliates' patients because the Final Rule causes injury to Plaintiffs, there is a close relationship between Plaintiffs and their patients or members' or affiliates' patients, and patients face genuine obstacles to asserting their own rights, including because of privacy concerns.

48. Defendant United States Department of Health and Human Services ("HHS") is an agency of the United States government, located at 200 Independence Avenue, S.W., Washington, D.C. 20546. It is the federal agency responsible for, among other things, administering and regulating the family-planning program created by Title X of the Public Health Service Act.

49. Defendant Alex M. Azar II is the United States Secretary of Health and Human Services. He is sued in his official capacity.

50. Defendant Office of Population Affairs is the office within HHS that administers the Title X program.

51. Defendant Diane Foley, M.D., is the Deputy Assistant Secretary for the Office of Population Affairs. She is responsible for administering and implementing the Title X program. She is sued in her official capacity.

JURISDICTION AND VENUE

52. The Court has jurisdiction over this action under 28 U.S.C. § 1331. The Court is authorized to issue the relief sought here under the APA, 5 U.S.C. §§ 702, 704-706, the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, Rules 57 and 65 of the Federal Rules of Civil Procedure, and the inherent equitable powers of this Court.

53. Venue is proper in this district under 28 U.S.C. § 1391(e)(1) because defendants are officers or employees of the United States; the OMA, PPSO, PPCW, Dr. Ewing, and Ms. Megregian reside in this district; and no real property is involved in the action.

54. Divisional venue is proper under District of Oregon Local Rule 3-2(b) because a substantial part of the events or omissions giving rise to this action occurred in the Eugene Division. PPSO's principal office is in Eugene, Oregon, and Dr. Ewing and Ms. Megregian work at PPSO and reside in Eugene, and, for the reasons explained here, all would be injured by the Final Rule.

THE TITLE X PROGRAM

A. PURPOSE AND STRUCTURE

55. Enacted in 1970, the Family Planning Program established by Title X of the Public Health Service Act makes family-planning services available to low-income individuals for free or at low cost. *See* 42 U.S.C. §§ 300 et seq. It is the only domestic federal program devoted solely to family planning for uninsured, underinsured, and low-income people.

56. Title X funds a broad range of services, including contraceptive services, information, and education; education about natural family-planning methods; infertility services; services to adolescents; sexually transmitted infection ("STI") and HIV testing and referral;

preventive care such as well-woman visits and breast and cervical cancer screenings; pregnancy testing and counseling; and training for providers and clinic personnel.

57. The program arose from a growing recognition of the effects of unintended childbearing on poverty levels, educational attainment, and adverse maternal and child health outcomes—and of the fact that available contraceptive options like oral contraceptives (*i.e.*, "the pill"), which were newly available in the 1960s, were unaffordable for too many Americans.

58. When it passed with broad bipartisan support, Congress declared that Title X's purpose was "to assist in making comprehensive voluntary family planning services readily available to all persons desiring such services." Family Planning Services and Population Research Act of 1970, Pub. L. No. 91-572, § 2(1), 84 Stat. 1504 (1970).

59. Thus, the basic function of Title X is to fund family-planning services for people who are unable to pay for them. Title X accomplishes this by providing funding for grantees who offer direct services to low-income Americans, contract with sub-grantees to offer those services, or both. *See* 42 U.S.C. § 300(a).

60. Although Section 1008 of Title X provides that no Title X funds "shall be used in programs where abortion is a method of family planning," 42 U.S.C. § 300a-6, that provision does not seek to interfere with communications concerning abortion between a Title X provider and her or his patient—as Congress and HHS have repeatedly made clear.

61. In fact, Representative John Dingell, the sponsor of the amendment adding Section 1008, opposed "restrictions on [abortion] counseling and referral." *Statutory Prohibition on Use of Appropriated Funds in Programs Where Abortion is a Method of Family Planning; Standard of Compliance for Family Planning Services Projects*, 53 Fed. Reg. 2,922, 2,930 (Feb. 2, 1988). This amendment was added, instead, in recognition of the fact that the criminal laws of many States at the time prohibited

abortion, and thus that federal funds should not be used to perform procedures that would violate state criminal law.

62. Congress has repeatedly reaffirmed by statute the proposition that the government must not interfere with full and frank communications between Title X providers and their patients. Indeed, annually since 1996, Congress has mandated in Title X appropriations acts the requirement that all pregnancy counseling be "nondirective." *E.g.*, Department of Health and Human Services Appropriations Act, 2019, Pub. L. No. 115-245, 132 Stat. 2981, 3070-3071 (2018) (hereinafter, the "Nondirective Mandate"); Department of Health and Human Services Appropriations Act, 1996, Pub L. No. 104-134, 110 Stat. 1321-221 (1996).

63. Congress has reiterated the core principles underlying the Nondirective Mandate and has enacted additional provisions ensuring, among other things, that patients receive all medically appropriate information from their providers. Specifically, in 2010, as part of the Affordable Care Act, Congress mandated that HHS

> shall not promulgate any regulation that—(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

Pub. L. No. 111-148, § 1554, 124 Stat. 259 (codified at 42 U.S.C. § 18114).

64. Title X regulations have long conformed to these statutory directives. For nearly 50 years, with only one exception, HHS has interpreted Title X to reflect Congress's intent to provide nondirective, voluntary, and comprehensive family-planning services, including counseling on and referral for abortion if requested by the patient.

65. The exception was in 1988, when HHS briefly changed course, issuing a rule that prohibited Title X projects from "provid[ing] counseling concerning the use of," or "provid[ing] referral" for abortion. 53 Fed. Reg. at 2,945.

66. That 1988 rule faced vast opposition and was also the subject of extensive litigation. And although the Supreme Court upheld that rule against a facial challenge in *Rust v. Sullivan*, 500 U.S. 173 (1991), it was the subject of additional litigation, was never fully implemented, and was ultimately suspended and then revoked.

67. Specifically, in 1993, President Clinton issued a memorandum to the Secretary of Health and Human Services directing her to suspend the 1988 rule's prohibition on abortion counseling and referral because, among other reasons, it "endanger[ed] women's lives and health by preventing them from receiving complete and accurate medical information and interfere[d] with the doctor-patient relationship by prohibiting information that medical professionals are otherwise ethically and legally required to provide to their patients." *Memorandum for the Secretary of Health and Human Services*, 58 Fed. Reg. 7,455 (Feb. 5, 1993).

68. Then, in 2000, HHS issued a final rule that formally eliminated the 1988 rule's prohibition on Title X programs providing abortion counseling and referrals. *Standards of Compliance for Abortion-Related Services in Family Planning Services Projects*, 65 Fed. Reg. 41,270, 41,270 (July 3, 2000). Moreover, consistent with the longstanding interpretations of Section 1008 as well as Congress's repeated directives in annual appropriations acts, the 2000 rule requires—upon a patient's request—nondirective counseling for all pregnancy options. 42 C.F.R. § 59.5(a)(5). As the 2000 rule makes clear, the policies and interpretations set forth therein "have been used by the program for virtually its entire history; indeed, they have been in effect during the pendency of this rulemaking." 65 Fed. Reg. at 41,271.

69. Thus, as the 2000 rule reaffirmed, a Title X 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 with respect 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) (emphasis added).

70. This requirement accords squarely with Congress's mandates that Title X services be nondirective, voluntary, and comprehensive. It ensures that pregnant patients have the *opportunity* to receive nondirective, comprehensive counseling on their pregnancy options and, *if they so request*, actually receive that counseling.

71. In issuing the 2000 rule, HHS explained that Congress had repeatedly emphasized the importance of the nondirective counseling requirement, citing multiple appropriations bills requiring that pregnancy counseling in Title X projects be "nondirective." 65 Fed. Reg. at 41,273.

72. HHS further emphasized the importance of ensuring that any such counseling be governed by what a patient actually wants. "If projects were to counsel on an option even where a client indicated that she did not want to consider that option," HHS explained, "there would be a real question as to whether the counseling was truly nondirective or whether the client was being steered to choose a particular option." 65 Fed. Reg. at 41,273. Accordingly, "if the client indicates that she does not want information and counseling on any particular option, that decision must be respected." *Id.*

B. TITLE X PATIENTS, PROVIDERS, AND PUBLIC HEALTH BENEFITS

73. Over the course of its nearly 50-year history, the Title X program has been an enormous success for individuals, their communities, and the nation. Indeed, Title X's impact on

the public health of the nation—including, especially, people of limited means—cannot be overstated.

74. Every year, Title X providers serve more than 4,000,000 patients.

75. In 2017 alone, Title X projects provided more than 2,800,000 patients with contraceptive services. As studies show, in 2015 (the most recent year for which these numbers are available), the contraceptive care provided by Title X providers helped women avoid more than 800,000 unintended pregnancies. Without the services provided by Title X-funded clinics, as experts at the Guttmacher Institute have concluded, there would have been hundreds of thousands more unintended pregnancies and abortions in the United States. *See* 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.

76. In 2017, Title X funds also helped provide more than 6,400,000 STI tests (including nearly 1,200,000 HIV tests), nearly 700,000 Pap tests, and nearly 900,000 clinical breast exams.

77. Sixty-seven percent of people receiving preventive care through the Title X program live in poverty, and 90% have incomes that are at or below 250% of the federal poverty level.

78. Title X providers provide significantly better access to contraceptive care than non-Title X public and private providers. A recent study published by HHS administrators showed that Title X providers do a better job overall than non-Title X centers in providing safety-net reproductive health care that is consistent with current, evidence-based clinical guidelines. Marion W. Carter et al., *Four aspects of the scope and quality of family planning services in US publicly funded health centers: Results from a survey of health center administrators*, 94 J. Contraception 340 (2016), http://dx.doi.org/10.1016/j.contraception.2016.04.009.

79. As just one example, Title X providers are more likely to offer intrauterine devices ("IUDs") and contraceptive implants onsite. *See, e.g.*, Heike Theil de Bocanegra et al., *Onsite Provision*

of Specialized Contraceptive Services: Does Title X Funding Enhance Access?, 23 J. Women's Health 1, 4 (May 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4011460/. Those contraceptive methods, often grouped under the umbrella term "LARCs" (long-acting reversible contraceptives), are by far the most effective contraceptive methods.

80. Title X's impact on broader public health is also significant. Title X providers are critical in the effort to identify and treat STIs. For example, Title X providers screen for chlamydia and treat it early to prevent infertility. Title X providers are more likely than public non-Title X providers and private providers to follow chlamydia screening guidelines for testing those most at risk for chlamydia. Joan M. Chow et al., *Comparison of Adherence to Chlamydia Screening Guidelines Among Title X Providers and Non-Title X Providers in the California Family Planning, Access, Care, and Treatment Program*, 21 (8) J. Women's Health 837, 837 (Aug. 2012), https://www.ncbi.nlm.nih.gov/pubmed/22694761.

81. Title X plays other critically important public-health roles as well. For example, Title X has made possible innovative public health work in response to the opioid crisis, integrating reproductive health services into substance use disorder treatments. *See, e.g.*, Mishka Terplan, *Reproductive Health Is Grounded in Human Rights*, Baltimore Sun (Nov. 22, 2018), https://www.baltimoresun.com/news/opinion/oped/bs-ed-op-1123-gag-rule-20181119-story.html. Moreover, because Title X health centers are often the *only* places where many individuals receive *any* health care services, these clinics are "important sites for substance use assessment, and, as such, they enable early intervention to prevent the development of opioid misuse and addiction." *Id.*

82. The Title X program's impact is particularly significant for communities of color and in rural areas. Of the more than 4,000,000 patients served across the nation by Title X health centers in 2017, 22% identified as black or African American and 33% identified as Hispanic or

Latinx. And in rural areas, Title X health centers are often the *only* provider of reproductive health services for low-income individuals.

83. Plaintiffs and their members and affiliates are deeply committed to Title X's mission of providing comprehensive family planning services, regardless of means. The experiences of Plaintiffs—and in particular, Planned Parenthood—bear out the importance of the Title X program.

84. Founded more than a century ago, Planned Parenthood is at the forefront of providing high-quality reproductive health care to individuals and communities facing serious barriers to obtaining such care—especially low-income individuals, individuals in rural and other medically underserved areas, and communities of color.

85. Planned Parenthood health centers offer a full range of reproductive health care services: preventive care visits, breast exams, Pap tests, general health assessments, a wide range of contraception methods, pregnancy testing, urinary tract infection treatment, and cervical and testicular cancer screening.

86. As a safety-net provider, Planned Parenthood serves as a critical entry point into the health care system for those in need.

87. Planned Parenthood's 54 member-affiliates operate more than 600 health centers across the nation and serve approximately 2,400,000 patients each year.

88. In 2017, Planned Parenthood affiliates provided health care services to approximately 40% of *all* the patients who received care in the Title X program—approximately 1,600,000 patients.

89. In 2017 alone, Planned Parenthood health centers provided an estimated 183,000 Pap tests, 2,720,000 STI tests, and 196,000 breast exams through the Title X program.

C. THE TITLE X PATIENT-PROVIDER RELATIONSHIP

90. The relationship between Title X patients and their health care professionals is essential to patient health, and full and frank communication is sacrosanct.

91. As experts have explained, "[f]or many low-income Americans, especially women, access to th[e] set of services [under Title X] represents the most trusted entry point to all medical care—many patients are not aware of other services that may be offered in the community, and a Title X program is truly a gateway to all other health care." Claire Brindis, *Comment Letter on Proposed Rule for Compliance with Statutory Program Integrity Requirements*, at 3 (July 31, 2018), https://www.regulations.gov/document?D=HHS-OS-2018-0008-204364. "Indeed, for many low-income women, visits to a family planning provider are their *only* interaction with the health care system at all." *Id.* (emphasis added).

92. Title X's role is especially important because many women seek out specialist providers for their family-planning care. Studies have shown that, even where women have primary-care options available, they prefer to get reproductive health and family-planning care from clinicians who specialize in those areas. Indeed, as one study explained, "[l]arge majorities of women … said that they chose the family planning clinic because the staff is knowledgeable about—or easy to talk to about—sexual and reproductive issues or because the clinic makes it easy for them to get the contraceptive method they want, and to do so directly, without having to make a separate trip to a pharmacy to have a prescription filled." Jennifer J. Frost et al., *Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Women's Health Care Needs*, 22 Women's Health Issues 519, 523 (2012), https://doi.org/10.1016/j.whi.2012.09.002.

93. Because healthy women of child-bearing age tend to seek out such specialized care, Title X health centers facilitate a crucial "touch," and the potential for referrals, with medical personnel that otherwise might not have happened.

94. To Title X patients, as Plaintiffs can attest from experience, they are simply seeing their doctor, nurse, or other medical professional and expect comprehensive medical care and counseling.

95. Especially in this context—which for many patients provides their *only* interaction with a medical professional—there must be full and frank communications between that medical professional and patient.

96. As the AMA made clear in its comments on the proposal leading to the Final Rule, "frank and confidential communications with … patients has always been a fundamental tenet of high quality medical care." AMA, *Comment Letter on Proposed Rule for Compliance with Statutory Program Integrity Requirements*, at 1 (July 31, 2018) ("AMA Comment Letter"), https://www.regulations.gov/document?D=HHS-OS-2018-0008-179739. "A physician must always have the ability to freely communicate with his or her patient, providing information to patients about their health and safety, without fear of intrusion by government and/or other third parties." *Id.* at 2. Thus, "[r]egulations that restrict the ability of physicians to explain all options to their patients and refer them, whatever their health care needs, compromise this relationship and force physicians and other health care providers to withhold information that their patients need to make decisions about their care." *Id.*

97. This fundamental medical tenet is also embodied in core ethical requirements, which provide, among other things, that patients have the right "'to receive information from their physicians and to have the opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives.'" AMA Comment Letter, *supra*, at 3 (quoting AMA's Code of Medical Ethics Opinion E-1.1.3).

98. Far from disputing these points, HHS acknowledged in the Final Rule the critical importance of "open communication" between a patient and her or his health care professional. 84

Fed. Reg. at 7,783. And HHS further acknowledged that "medical ethics obligations require the medical professional to share *full and accurate information* with the patient, in response to her specific medical condition and circumstance." *Id.* at 7,724 (emphasis added).

99. But in the very next breath, as described below, HHS injected the government into the patient-provider relationship and imposed a gag on medical speech fundamentally at odds with the very ethical obligations that HHS acknowledged. HHS did so even while claiming to be "[p]rotect[ing] the patient/healthcare provider relationship." HHS, *Fact Sheet: Final Title X Rule Detailing Family Planning Grant Program* (Feb. 22, 2019), https://www.hhs.gov/about/news/2019/02/22/fact-sheet-final-title-x-rule-detailing-family-planning-grant-program.html.

ABORTION SERVICES OUTSIDE THE TITLE X PROGRAM

100. Consistent with—and indeed critical to—its mission of promoting access to comprehensive reproductive health care for all, Planned Parenthood advocates for access to safe and legal abortion for individuals. Planned Parenthood affiliates also provide abortion services, outside the Title X program with non-Title X funds.

101. Approximately one in four women in this country will have an abortion by age 45. Women decide to end a pregnancy for a variety of reasons, including familial, medical, financial, and personal reasons. Some women need an abortion to avoid endangering their life or health; others seek to terminate pregnancies arising from rape or incest; still others may seek an abortion because they cannot afford or do not feel prepared to care for a child. As studies have shown, many women who seek abortions are mothers who have decided that they cannot parent another child at this time, and many plan to have children or add to their families at a later stage.

102. In many communities, Planned Parenthood is the only abortion provider. For example, PPSO has four health centers in southwestern Oregon that offer abortion services. If PPSO's health centers did not offer abortion services, many women in southwestern Oregon who

needed or sought access to abortion would not have access to any other abortion provider because the only other abortion providers in the area have no or limited additional capacity.

103. As noted above, Section 1008 of Title X has always prohibited the use of Title X funds for abortions, and Planned Parenthood complies with that directive.

104. Moreover, HHS regulations and Title X grants already require that a Title X program's federal funds be used *solely* for Title X purposes, and not any others. *See, e.g.*, 42 C.F.R. § 59.9; *Provision of Abortion-Related Services in Family Planning Services Projects*, 65 Fed. Reg. 41,281, 41,281-41,282 (July 3, 2000). And as HHS has long made clear, Title X providers already must ensure that "[n]on-Title X abortion activities must be separate and distinct from Title X projects." 65 Fed. Reg. at 41,282. They do so through, for example, "counseling and service protocols, intake and referral procedures, material review procedures, and other administrative procedures." *Id.*

105. Under longstanding Title X regulations, however, separate facilities, staff, and record systems are *not* required. To the contrary, HHS has expressly authorized the use of "shared facilities," "common staff," and "single file system[s]." 65 Fed. Reg. at 41,282; *see* 65 Fed. Reg. at 41,270.

THE SWEEPING PURPOSE AND EFFECT OF THE 2019 FINAL RULE

106. The Final Rule would radically alter and decimate the Title X program, with severe and irreparable public health consequences across the United States. Moreover, these consequences would be disproportionately felt by low income patients, the very patients that Title X was meant to help.

A. PROPOSED RULE AND EXTENSIVE OPPOSITION

107. The Final Rule arose out of a proposed rule, issued by HHS on June 1, 2018. *See Compliance with Statutory Program Integrity Requirements*, 83 Fed. Reg. 25,502. That proposal was opposed by virtually every leading health organization in the United States, among many others.

108. Touting the proposed rule at a major antiabortion organization's gala, President Trump underscored one of its obvious purposes—an attack on safe and legal abortion. "For decades," he claimed, "American taxpayers have been wrongfully forced to subsidize the abortion industry through Title 10 federal funding." *Remarks by President Trump at the Susan B. Anthony List 11th Annual Campaign for Life Gala*, White House.gov (May 22, 2018), https://www.whitehouse.gov/briefings-statements/remarks-president-trump-susan-b-anthony-list-11th-annual-campaign-life-gala/. "So today," he continued, "we have kept another promise. My administration has proposed a new rule to prohibit Title 10 funding from going to any clinic that performs abortions." *Id.*

109. Targeting not only abortion but also the Title X program as a whole, HHS's proposal set forth a series of dramatic and devastating changes to the program. Among other things, it sought to impose a gag on the medical profession (the Gag Requirement); onerous and vague "physical and financial" separation requirements (the Separation Requirement); and a series of additional requirements that would work a fundamental shift in the Title X program away from its emphasis on methods of family planning that are effective and acceptable to low-income patients and toward instead policy preferences with no grounding in the law or public health.

110. Among many others, the following leading health organizations in the United States submitted comment letters strongly condemning the proposal: the AMA, Planned Parenthood, the American College of Obstetricians and Gynecologists, the American College of Physicians, the American Academy of Family Physicians, the American Academy of Nursing, and the American Academy of Pediatrics.

111. In a nearly 100-page comment letter, for example, Planned Parenthood urged HHS to withdraw the proposed rule in its entirety, challenging virtually all of its provisions and arguing that the proposal was legally flawed and would harm patient care. *See generally* PPFA, *Comment Letter on Proposed Rule for Compliance with Statutory Program Integrity Requirements* (July 31, 2018), https://www.

regulations.gov/document?D=HHS-OS-2018-0008-198841. Planned Parenthood warned that the Gag Requirement alone would result in a mass exodus of providers from the Title X program—including all Planned Parenthood affiliates and numerous States—leading to reduced patient care on a vast scale. *Id.* at 15-16. Planned Parenthood also explained that the Separation Requirement was extremely onerous and vague, and effectively disqualified it from the Title X program because of its speech and conduct outside of the Title X program. *See id.* at 26-40.

112. The AMA also voiced its strong opposition to the proposed rule. *See* AMA Comment Letter, *supra*, at 1-5. Its letter similarly urged HHS to abandon its attack on family-planning services, explaining that it would undermine patients' access to high-quality medical care and information, dangerously interfere with the patient-physician relationship and conflict with physicians' ethical obligations, exclude qualified providers, and jeopardize public health. *See id.*

B. FINAL RULE

113. On March 4, 2019, HHS issued the Final Rule. As relevant here, HHS largely adopted the proposed rule without change in the Final Rule—with one important exception (discussed below at ¶¶ 131-135) that adds yet another legal flaw.

114. HHS ignored or otherwise failed to meaningfully respond to the numerous fundamental flaws with and consequences of the proposal described by Plaintiffs and many others. Moreover, it issued the Final Rule after an "unconventional and nontransparent" regulatory review process marked by "troubling irregularities." Congressman Elijah E. Cummings et al. Letter to Director Mick Mulvaney and Administrator Neomi Rao, at 1-2 (Feb. 14, 2019), https://www.help.senate.gov/imo/media/doc/2019-02-14.EEC%20Murray%20Hassan%20Harris%20to%20Mulvaney-OMB%20Rao-OIRA%20re%20Title%20X%20FINAL.pdf. Among other things, these irregularities included ramming the Final Rule through the last stage of the regulatory review

process (review by the Office of Information and Regulatory Affairs) in less than two weeks, despite numerous requests for stakeholder meetings and the fact that the average review period is 45 days.

115. This inflexible, unresponsive, and truncated approach—in the face of vast opposition to the proposed rule—is unsurprising and in fact underscores that the Final Rule is the result of Defendants' prejudgment and "unalterably closed mind," *Alaska Factory Trawler Ass'n v. Baldridge*, 831 F.2d 1456, 1467 (9th Cir. 1987).

116. As with the proposal, the Final Rule consists of two central, integrated provisions—the Gag Requirement and the Separation Requirement—as well as a series of additional, related requirements.

1. Gag Requirement

117. The Final Rule injects the government between a medical provider and patient, imposing a gag on medical speech. Put simply, it imposes a content-based and viewpoint-based unconstitutional proscription on medical professionals concerning abortion-related speech that would have practitioners in the Title X program *direct* women toward continuing a pregnancy to term.

118. The Final Rule implements this directive Gag Requirement in several ways.

119. *First*, HHS affirmatively *prohibits* referrals for abortion while *mandating* referrals for prenatal care—regardless of what a patient actually wants.

120. Specifically, the Final Rule imposes an express "[p]rohibition on referral for abortion." 84 Fed. Reg. at 7,788 (to be codified at 42 C.F.R. § 59.14(a)); *see id.* (Each project "must … [n]ot provide, promote, refer for, or support abortion as a method of family planning." (to be codified at 42 C.F.R. § 59.5(a)(5))).

121. In the proposed rule, HHS purported to justify this prohibition on the proposition that "[r]eferrals for abortion are, by definition, directive." 83 Fed. Reg. at 25,506. HHS abandoned

that purported justification in the Final Rule, nowhere reprising the point. Instead, HHS simply invoked in the Final Rule its "belie[fs]" that, "in most instances when a referral is provided for abortion, that referral necessarily treats abortion as a method of family planning," and that "both the referral for abortion as a method of family planning, and such abortion procedure itself, are so linked that such a referral makes the Title X project or clinic a program one where abortion is a method of family planning." 84 Fed. Reg. at 7,717. HHS provided no further explanation for these "belie[fs]."

122. While banning abortion referrals, the Final Rule affirmatively *mandates* prenatal referrals. Specifically, the Final Rule provides that a Title X provider "shall" provide referrals for "prenatal health care" "once a client … is medically verified as pregnant," 84 Fed. Reg. at 7,789 (to be codified at 42 C.F.R. § 59.14(b)(1))—yet again, regardless of whether that patient actually requests prenatal care, and even if she expressly says she does not want it.

123. The Final Rule touts that, notwithstanding the abortion-referral ban, it permits a Title X provider to provide a "list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) … , some, but not the majority, of which also provide abortion as part of their comprehensive health care services." 84 Fed. Reg. at 7,789 (to be codified at 42 C.F.R. § 59.14(c)(2)). The Final Rule further specifies: "Neither the list nor project staff may identify which providers on the list perform abortion." *Id.*; *accord id.* at 7,761 ("The final rule prohibits the list and project staff from identifying which, if any, providers on the list provide abortions."). Thus, "where a pregnant woman asks for an abortion or an abortion referral," *id.* at 7,761, HHS would have a Title X provider give her—at most—a "list" that *must* include providers who do not provide abortion; must *not* include abortion providers who do not also provide "comprehensive primary health care" (a term the Final Rule does not define or otherwise explain); and must *not* identify which of the providers actually provide abortion services, *id.* at 7,789 (to be

codified at 42 C.F.R. § 59.14(c)(2)). Moreover, in the face of an express patient request for an abortion referral, HHS authorizes Title X providers to provide such a patient a list with "*no* providers of abortion." *Id.* at 7,761 (emphasis added). The Final Rule provided no justification for this incomplete and misleading scavenger hunt form of a "list."

124. Furthermore, the Final Rule provides only a limited exception for abortion referrals in the case of "emergenc[ies]." The Final Rule purports to allow for "medically necessary" referrals. 84 Fed. Reg. at 7,788 (to be codified at 42 C.F.R. § 59.5(b)(1)). But such referrals must be "consistent with § 59.14(a)," *id.*—under which referrals for abortions are banned—and the Final Rule otherwise states that only an abortion referral for an "*emergency* medical situation" would fall outside the "restrictions concerning abortion as a method of family planning," *id.* at 7,762 (emphasis added); *see id.* at 7,730 ("may refer for abortion for documented *emergency* care reasons" (emphasis added)). And "in cases involving rape and/or incest," the Final Rule would prohibit Title X providers from referring a patient to a specialized abortion provider, instead permitting only a referral to a "qualified, comprehensive health service provider who *also* provides abortion." *Id.* at 7,747 n.76 (emphasis added). In sum, the Final Rule not only limits what medical professionals can and cannot say to patients, but also attempts to take the place of the physician by dictating, without ever examining a patient, what is and is not a medical emergency, medically necessary, or comprehensive medical care.

125. *Second*, HHS eliminated the prior settled regulatory requirement that Title X providers *must* offer pregnant patients the *opportunity* to receive nondirective, comprehensive counseling on their pregnancy options and, *if patients so request it*, actually provide that counseling. *E.g.*, 84 Fed. Reg. at 7,716. Instead, HHS authorizes and encourages biased and incomplete counseling where the interests of the patient are no longer paramount; compels speech from those

who would counsel on abortion; and restricts, without explanation, who can even provide such abortion counseling.

126. Before HHS issued the Final Rule, Title X providers were required to advise their patients about their health care options according to their patients' interests, best medical practices, and accepted standards of professional ethics. Under the Final Rule, however, Title X providers are no longer held to such standards. They may, if they choose, tell pregnant patients about only *some* of their options; they may exclude *any* information about abortion, regardless of what a patient wants, needs, or requests and regardless of accepted medical practices and professional standards. Indeed, even if a patient says she is only interested in information and counseling on abortion, the Final Rule would require practitioners to ignore that patient decision entirely and mandate additional information beyond the patient's desires or needs.

127. As HHS previously wisely cautioned in promulgating the 2000 regulations, "If projects were to counsel on an option even where a client indicated that she did not want to consider that option, there would be a real question as to whether the counseling was truly nondirective or whether the client was being steered to choose a particular option." 65 Fed. Reg. at 41,273.

128. Yet under the Final Rule, Title X providers can simply refuse to provide that information in the face of an express patient request; alternatively, for those providers willing to counsel on abortion, HHS now compels them to speak on other options that the patient does not want. 84 Fed. Reg. at 7,747 ("In nondirective counseling, abortion must not be the only option presented[.]"). What is more—in all instances, including when counseling on abortion—the Final Rule would compel practitioners to tell pregnant patients about the "risks and side effects to [her] unborn child." *Id.*

129. The Final Rule further dramatically limits *who* can provide nondirective counseling on abortion (as HHS would impermissibly define it)—authorizing only "physicians or advanced practice providers" to do so. 84 Fed. Reg. at 7,789 (to be codified at 42 C.F.R. § 59.14(b)(1)(i)); *accord id.* at 7,761. The Final Rule defines "advanced practice providers" (or APPs) as follows: "a medical professional who receives at least a graduate level degree in the relevant medical field and maintains a license to diagnose, treat, and counsel patients." *Id.* at 7,787 (to be codified at 42 C.F.R. § 59.2).

130. Thus, under the Final Rule, all medical professionals other than doctors or APPs—for example, registered nurses and health care assistants—cannot provide the nondirective counseling on abortion that the rule allows of doctors and APPs. The Final Rule provides no explanation for this speaker-based ban on medical speech, much less the specific distinction that it draws between health care professionals. Nor does it address *any* consequences of this ban—on Title X providers, patients, or public health more generally. As just one example, Title X providers are safety-net providers, typically running with limited means and offering as appropriate direct patient services through registered nurses and other medical professionals who do not fall within the definition of APPs. Thus, imposing burdensome and costly impediments to the provision of services—as this speaker-based ban clearly does—will substantially reduce the ability to provide those services. Yet the Final Rule nowhere explains why HHS imposed this ban, much less how it would affect Title X providers and their patients.

131. *Third*, the Final Rule imposes an additional speaker-based ban on medical speech—in particular, a ban on who can provide "nondirective *pregnancy*" counseling—that was nowhere hinted at in the proposed rule.

132. The Final Rule touts that it "permits" "[n]ondirective pregnancy counseling." 84 Fed. Reg. at 7,716.

133. Yet under the Final Rule, such "[n]ondirective pregnancy counseling" may *only* be provided by "physicians or advanced practice providers." 84 Fed. Reg. at 7,789 (to be codified at 42 C.F.R. § 59.14(b)(1)(i)); *accord id.* at 7,761 ("[O]nly physicians and APPs may provide any nondirective pregnancy counseling.").

134. Thus, going beyond counseling on abortion, all medical professionals other than doctors or APPs—for example, registered nurses and health care assistants—are banned from providing "nondirective *pregnancy*" counseling. 84 Fed. Reg. at 7,761 (emphasis added).

135. The Final Rule, again, provided no explanation for this new ban on medical speech. Nor did it address any of the consequences of this new ban.

2. Separation Requirement

136. The Final Rule imposes extremely onerous and vague "physical and financial" separation requirements on Title X providers that engage in so-called "prohibited activities"—defined so broadly as to include virtually anything having to do with abortion. 84 Fed. Reg. at 7,789 (to be codified at 42 C.F.R. § 59.15).

137. As discussed, the current regulations have long required that Title X providers ensure that "[n]on-Title X abortion activities … be separate and distinct from Title X project activities," while authorizing shared facilities, health care records, and personnel. 65 Fed. Reg. at 41,282. Title X providers who also provide abortions with non-Title X funds have complied with those requirements for decades.

138. Citing *no* evidence of misuse of Title X funds over the past half century, the Final Rule would impose new, drastic, and vague "physical and financial" separation requirements—including separate facilities, separate personnel and workstations, and separate health care records—on Title X providers that engage in abortion-related activities.

139. Invoking a boundless standard of "objective integrity and independence," the Final Rule provides:

> [A] Title X project must have an objective integrity and independence from prohibited activities. … The Secretary will determine whether such objective integrity and independence exist based on a review of facts and circumstances. Factors relevant to this determination shall include: (a) The existence of separate, accurate accounting records; (b) The degree of separation from facilities (*e.g.*, treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites) in which prohibited activities occur and the extent of such prohibited activities; (c) The existence of separate personnel, electronic or paper-based health care records, and workstations; and (d) The extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent.

84 Fed. Reg. at 7,789 (to be codified at 42 C.F.R. § 59.15).

140. Expressly integrated with the Gag Requirement, the "prohibited activities" are defined by cross-reference to other sections of the rule: § 59.13 ("Standards of compliance with prohibition on abortion"), § 59.14 ("Requirements and limitations with respect to post-conception activities"), and § 59.16 ("Prohibition on activities that encourage, promote, or advocate for abortion"). 84 Fed. Reg. at 7,789 (to be codified at 42 C.F.R. § 59.15).

141. These "prohibited activities" include the provision of abortion with non-Title X funds. 84 Fed. Reg. at 7,788 (to be codified at 42 C.F.R. § 59.14(a)). They also include abortion referrals, *id.* at 7,789, or anything that otherwise "encourage[s], promote[s], or advocate[s]" for abortion, *id.* (to be codified at 42 C.F.R. § 59.16)—even including abortion-related "brochures … sitting on a table … within the same space where Title X services are provided," *id.* at 7,790 (to be codified at § 59.16(b)(1)).

142. In the Final Rule, HHS cited *no* evidence of misuse of Title X funds. The proposed rule had principally relied on purported misuse of funds under the *Medicaid* program—a separate federal program. 83 Fed. Reg. at 25,509. The Final Rule abandoned reliance even on that,

conceding that any "demonstrated abuses of Medicaid funds do not necessarily mean Title X grants are being abused." 84 Fed. Reg. at 7,725.

143. Instead of evidence, in support of the Separation Requirement, HHS relied on "risk[s]" of "appearance[s]" and "perception[s]." 84 Fed. Reg. at 7,764. HHS claimed that permitting Title X providers to use shared facilities for "Title X services… and non-Title X services involving abortion" "create[s] a risk of the intentional or unintentional use of Title X funds for impermissible purposes, the co-mingling of Title X funds, [and] the appearance and perception that Title X funds being used in a given program may also be supporting that program's abortion activities." *Id.*

3. Additional Provisions

144. The Final Rule includes a series of additional provisions which, while generally disguised by vague or otherwise bland terms, would shift the Title X program away from its emphasis on providing high-quality family-planning methods and services to low-income patients and toward instead policy preferences with no grounding in the law or public health.

145. Starting with the definitions section, for example, the Final Rule rewrites the definition of "low income family" to accomplish an unrelated political goal—trying to fix the problems that the Trump Administration has created by exempting employers with a "religious or moral" objection to the Affordable Care Act's requirement that health plans include coverage for contraception. Accordingly, "for contraceptive services only," the Final Rule would allow Title X providers to include within the definition of "low income" those women who "ha[ve] health insurance coverage through an employer that does not provide the contraceptive services sought by the woman because the employer has a sincerely held religious or moral objection to providing such coverage." 84 Fed. Reg. at 7,787 (to be codified at 42 C.F.R. § 59.2).

146. As another example, the Final Rule also alters the eligibility and selection criteria HHS uses to decide which Title X projects to fund in an evident attempt to shift funds away from established, effective Title X providers such as Planned Parenthood that have long served Title X's mission. To that end, for example, the Final Rule would emphasize an applicant's "ability to procure a broad range of diverse subrecipients." 84 Fed. Reg. at 7,788 (to be codified at 42 C.F.R. § 59.7(c)(2)). Congress, however, did not prioritize "broad" or "diverse" groups of Title X providers over maximizing the reproductive health care offered to Title X beneficiaries. And giving special priority to such providers is especially problematic because experienced Title X providers are likely to be those who have spent the most time and effort developing programs serving Title X's goals and requirements—some for 40 years or more.

147. As yet another example, the Final Rule imposes "infrastructure" restrictions on Title X providers, requiring that "[g]rantees must use the majority of grant funds to provide direct services to clients." 84 Fed. Reg. at 7,790 (to be codified at 42 C.F.R. § 59.18(a)). But, without explanation, the Final Rule defines "infrastructure" so broadly as to include "bulk purchasing of contraceptives or other clinic supplies" and what have long been core Title X services—including "clinical training for staff" and "community outreach and recruitment"—thereby further unnecessarily restricting access to care under Title X. *Id.* at 7,774.

148. Despite its radical changes to the Title X program, the Final Rule's "transition provisions" require that Title X providers comply with most of its provisions within 60 or 120 days of its issuance—that is, by May 3, 2019, or July 2, 2019, respectively. *See* 84 Fed. Reg. at 7,714, 7,774; *id.* at 7,791 (to be codified at 42 C.F.R. § 59.19). The Final Rule is inconsistent with respect to the Gag Requirement's transition dates. Part of it, § 59.5(a)(5), is governed by a 60-day compliance date, *id.* at 7,774, 7,775, while another part, § 59.14, is governed by a 120-day compliance date, *id.* at 7,791 (to be codified at 42 C.F.R. § 59.15(c)).

149. Otherwise, as relevant here, the only exception is for the "physical separation" requirement; under the Final Rule, Title X providers must comply with that requirement within one year—by March 4, 2020. 84 Fed. Reg. at 7,791 (to be codified at 42 C.F.R. § 59.19(a)).

150. The Final Rule contains a regulatory impact statement concluding that it is "significant, but not economically significant" under Executive Order No. 12,866. 84 Fed. Reg. at 7,776. HHS identified no quantified benefits of the Final Rule. *Id.* at 7,777. HHS estimated present value costs over the next five years of $110.4 million. *Id.*

151. The regulatory impact statement did not account for, or even acknowledge, the significant health-related costs the rule would cause, including an increase in the number of unintended pregnancies and STIs as detailed by numerous comments on the proposal. Nor did the Final Rule acknowledge, much less meaningfully address, the fact that the Final Rule would force vast numbers of providers out of the Title X program. Instead, ignoring those comments and without evidence of any kind, HHS asserted only its belief that "these final rules will contribute to more clients being served, gaps in service being closed, and improved client care." 84 Fed. Reg. at 7,723. Moreover, the Final Rule dramatically underestimated compliance costs.

C. THE DEVASTATING AND IRREPARABLE IMPACT ON PLAINTIFFS, THEIR PATIENTS, AND THE PUBLIC HEALTH OF THE NATION

152. The Final Rule, if not enjoined, will have devastating and irreparable effects on Plaintiffs and the patients and communities they serve.

153. The Gag Requirement alone threatens the core of family-planning health care. It would give vast swaths of providers no choice but to withdraw from Title X entirely—including all Planned Parenthood affiliates, which serve approximately 40% of all Title X patients. Not only does the Gag Requirement interfere with communications about patients' health care options, but it further requires Title X practitioners to *direct* pregnant women toward continuing a pregnancy to term—regardless of what they actually want. It is thus fundamentally at odds with Planned

Parenthood's mission and the medical and ethical responsibilities of its medical professionals, all of which emphasize the patient's best interest. It is also fundamentally at odds with AMA's and OMA's members' ethical and professional obligations to abide by the highest standard of care, to provide comprehensive information to their patients, and to refer a patient to another professional if her care falls outside the treating clinician's practice.

154. Moreover, as further discussed below, the Gag Requirement would have especially harmful consequences for Title X patients—including, in particular, communities of color. Among other things, forcing Title X practitioners to conceal or distort health care options will inevitably lead to an erosion of patient trust in their providers and the health care system as a whole. The patient-provider relationship is founded on trust. Once that trust is gone, patients may withhold important information because they no longer feel comfortable sharing it, or simply forgo needed care altogether. And the Gag Requirement's scavenger-hunt form of "list," if anything, makes things worse. It is incomplete and misleading. The only apparent purpose and clear effect is to create a barrier to timely access of medical care—which is pernicious in all events, but especially so for patients of limited means.

155. The Separation Requirement would cause further harms. The extreme and unnecessary costs of compliance would exceed the amount of Title X funding that Planned Parenthood's affiliates receive, making compliance effectively impossible and forcing providers to withdraw from Title X.

156. For example, four of PPSO's health centers—Eugene-Springfield, Ashland, Medford, and Grants Pass—provide abortions to women who choose to terminate a pregnancy. As authorized under the longstanding HHS regulations discussed above, these four clinics currently "co-locate" Title X and abortion services under one roof. Physical separation is not possible based

on how these four centers are currently configured, and opening separate facilities for Title X activities would be prohibitively expensive.

157. Moreover, the additional requirements for separate "personnel," "health care records," and "workstations" would not only involve cost-prohibitive administrative and maintenance costs, but would also endanger patient safety. Non-integrated medical records systems are contrary to best medical practices and increase the risk of error. Multiple medical records systems can cause incomplete medical histories, missing data, lost medical tests or test results, missing or incorrect medication or dosage instructions, missing allergy warnings, and other miscommunications across patient records that affect patient health and well-being.

158. The loss of Title X funds will in turn result in service denials and cuts, layoffs, and the closures of health centers that are often the only option for low-income patients in need of reproductive health care. And many of the health centers that would have to close or cut services as a result of a loss of Title X funding could not be reopened without extensive additional investment in infrastructure. Thus, for example, even if the Final Rule were later held unlawful at the end of this lawsuit, Planned Parenthood will not be able to reopen centers, resume relationships with the patients they have lost, reconstitute the programs and services that were terminated, or recall the employees who were essential to serving those patients.

159. The harm to Planned Parenthood's affiliates as a result of the Final Rule also harms PPFA's mission, and PPFA will suffer substantial reputational and operational injury if the Final Rule is not enjoined. PPFA will also face its own financial harm. By impairing affiliates' financial positions, the Final Rule will in turn impair the ability of affiliates to support the mission of PPFA; moreover, PPFA will be forced to divert resources independent of litigation costs toward combatting the effects of the Final Rule and supporting its affiliates.

160. Finally, the Final Rule poses a serious, grave risk to the health of Plaintiffs' patients, who are low-income individuals already facing barriers to care, as well as to public health generally.

161. While Planned Parenthood would continue to try to provide affordable care to all who need it, without Title X funding, many patients would have to pay more for care. Some of these patients will choose to come to Planned Parenthood but will have to ration care, choosing less effective forms of birth control or skipping testing. Others may seek out another Title X provider, but other providers will be unable to provide high-quality reproductive health and family-planning care for the large numbers of new patients who will need that care.

162. Planned Parenthood serves many times more contraceptive patients than Federally Qualified Health Centers ("FQHCs") or health department clinics, and in Planned Parenthood's absence, according to one study, the caseloads on FQHCs in particular would at least double or triple in many places. Jennifer J. Frost & Mia R. Zolna, *Response to Inquiry Concerning the Availability of Publicly Funded Contraceptive Care to U.S. Women*, Guttmacher Institute (May 3, 2017), https://www.guttmacher.org/article/2017/05/guttmacher-murray-memo-2017. This is particularly problematic because FQHCs and health departments already have significantly longer average wait times than Planned Parenthood health centers for an initial contraceptive appointment. Planned Parenthood's average wait time for an initial contraceptive visit is 1.2 days, while the average wait time for such a visit is 2.5 days at FQHCs and 4.1 days for health department sites. If Planned Parenthood patients have to seek care elsewhere due to Planned Parenthood no longer participating in Title X, that will leave the remaining care providers badly unable to cope with the level of need in their areas.

163. With nowhere to turn for high-quality reproductive health and family-planning care, many patients will simply go without care. A report by the Congressional Budget Office demonstrates that when Planned Parenthood health centers close, patients lose access to critical reproductive health and family-planning services; they do not find those needs served elsewhere.

Cost Estimate of the American Health Care Act, Congressional Budget Office (Mar. 13, 2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/americanhealthcareact.pdf.

164. Underscoring the point, a study published in *The American Journal of Public Health* showed disastrous results in Texas after state legislation restricted participation in family-planning programs, excluding experienced, proven provider networks like Planned Parenthood. A quarter of all clinics statewide closed, and reproductive health specialists lost over half of their patients. The study's authors concluded that, "when specialized family planning providers are marginalized or systematically excluded from public programs … women will lose access to essential preventive services." Karl White et al., *The Impact of Reproductive Health Legislation on Family Planning Clinic Services in Texas*, 105 Am. J. Pub. Health 851, 858 (2015), http://sites.utexas.edu/txpep/files/2017/04/White-et-al-Impact-of-Reproductive-Health-Legislation-AJPH-pre-print-2015.pdf.

165. FQHCs and public health departments are not specialists in reproductive health care; they serve primary care needs for everyone from infants to the elderly, including oral and mental health, substance abuse treatment, long-term support services, and early childhood development. They are simply not built to work as specialized, safety-net providers of reproductive health care services.

166. Patients are especially likely to lose contraceptive care, including access to LARCs, the most effective form of contraception, if Plaintiffs and their members and affiliates lose access to Title X funding. Planned Parenthood's health centers are considerably more likely to offer patients a broad range of medically approved contraceptive methods, including LARCs, than sites operated by other providers. Indeed, nearly all Planned Parenthood centers offer the full range of reversible contraceptive methods approved by the Food and Drug Administration, compared with just half of FQHCs and two-thirds of state health departments. Unlike many FQHCs and state health departments, nearly all Planned Parenthood centers offer insertion of IUDs and implants on the

same day as a client's initial appointment. Because LARCs are expensive, lower-income patients will find it difficult or even impossible to obtain them unless they are provided through a Title X grantee with the ability to subsidize the cost.

167. Moreover, in many areas, Planned Parenthood is the *only* provider of family-planning and reproductive health care services for low-income individuals. Because Planned Parenthood health centers will be forced to close or cut services in those areas if the Final Rule is implemented, patients in those areas who depend on that health center, even if they rely on Medicaid or private insurance, will also lose access to care.

168. Unless the Final Rule is enjoined, those disastrous results will be replicated across the country. And the consequences of the Final Rule will be disproportionately felt by low-income patients and patients of color—those who already face serious barriers to obtaining comprehensive, high-quality family-planning care.

COUNT ONE

APA: THE FINAL RULE IS CONTRARY TO LAW

169. The allegations in paragraphs 1 through 168 above are incorporated as if fully set forth herein.

170. An agency rule or action that is contrary to law is not valid. 5 U.S.C. § 706(2). The Final Rule is contrary to Title X, the Nondirective Mandate, and 42 U.S.C. § 18114, including as follows.

171. **Gag Requirement.** The Gag Requirement violates Title X and the Nondirective Mandate. *See* Consolidated Appropriations Act of 2018, Pub. L. No. 115-141, 132 Stat. 348, 716-717 (2018); 42 U.S.C. §§ 300, 300a-5. Family-planning projects that provide counseling and referrals for *only* non-abortion services are necessarily *directive*—they direct patients toward those non-abortion services and away from abortion. Moreover, by directing Title X projects to refer pregnant patients for prenatal health care—even when the patient does not ask for or want such referrals—

the Final Rule would require the provision of directive care and violate the requirement that services and information under Title X be voluntary.

172. The Gag Requirement is also contrary to law because it contravenes 42 U.S.C. § 18114. Among other fatal flaws, by express design, it would "interfere[] with communications regarding a full range of treatment options between the patient and the provider" and "restrict[] the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions," and is fundamentally at odds with the ethical and professional standards of health care professionals, all in violation of § 18114.

173. **Separation Requirement.** The Separation Requirement imposes extremely onerous and vague "physical and financial" separation requirements on Title X providers that—*outside* the Title X program with *non*-Title X funds—provide women with safe and legal abortion services and advocate for the right to safe and legal abortion.

174. Compliance with the Separation Requirement, at minimum, would require Plaintiffs to make unnecessary and prohibitively expensive renovations to their health care centers, purchase new facilities, duplicate staff positions, and duplicate administrative systems, such as bookkeeping and health records. The costs will be effectively impossible for providers to bear, causing them to exit the Title X program or otherwise limit services to patients.

175. The Separation Requirement therefore violates 42 U.S.C. § 18114 by, among other things, "creat[ing] … unreasonable barriers to the ability of individuals to obtain appropriate medical care," "imped[ing] timely access to health care services," and "interfer[ing] with communications regarding a full range of treatment options between the patient and the provider."

COUNT TWO

APA: THE FINAL RULE IS CONTRARY TO CONSTITUTIONAL RIGHT

176. The allegations in paragraphs 1 through 175 above are incorporated as if fully set forth herein.

177. A court must "hold unlawful and set aside agency action" that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B). The Final Rule violates both the First and Fifth Amendments to the U.S. Constitution.

178. **Gag Requirement.** Injecting the government between a provider and her or his patient, the Final Rule by design imposes impermissible content- and viewpoint-based discrimination. The First Amendment protects Plaintiffs' communications with their patients, including communications concerning safe and legal abortions. The Gag Requirement restricts Plaintiffs' right to engage in such speech and patients' right to receive it—imposing, among other things, an express ban on referrals for abortion services even when a patient wants such a referral—and compels Plaintiffs to espouse the government's view of appropriate options for pregnant women.

179. The government has thus chosen one viewpoint over the other, and seeks to compel medical professionals to espouse only the viewpoint that the government dictates.

180. To be sure, nearly 30 years ago, the Supreme Court upheld against First Amendment challenge a prior iteration of the Gag Requirement in *Rust v. Sullivan*, 500 U.S. 173 (1991). As HHS acknowledges, however, this iteration "differs" from the one addressed in *Rust*, both in its terms and the underlying statutory framework. *See* 84 Fed. Reg. at 7,725. And this iteration should fall—as the Supreme Court's recent First Amendment precedent underscores. *See NIFLA*, 138 S. Ct. at 2374; *Janus v. American Fed'n of State, Cty. & Mun. Emps.*, 138 S. Ct. 2448, 2464 (2018). That is especially the case here given the nearly three decades of practitioner-patient experience with Title X since *Rust* establishing the essential relationship between a Title X practitioner and her or his patient—one that "should enjoy protection under the First Amendment from Government regulation, even when subsidized by the Government," *Rust*, 500 U.S. at 200.

181. **Separation Requirement.** The Separation Requirement is an unconstitutional condition, infringing constitutionally protected rights under the First and Fifth Amendments, and is also impermissibly vague under the Due Process Clause of the Fifth Amendment.

182. The First Amendment protects Plaintiffs' right to speak about abortion, including providing their patients with counseling on and referrals for abortion, and patients' right to receive it. *See, e.g.*, *NIFLA*, 138 S. Ct. at 2371, 2374. The Fifth Amendment protects Plaintiffs' right to provide abortions and their patients' right to obtain abortions. *See, e.g.*, *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2308-2309 (2016).

183. The Separation Requirement imposes an unconstitutional condition on the receipt of Title X funding. The Separation Requirement is so restrictive that it effectively prevents the use of non-Title X money to pursue activities protected by the First and Fifth Amendments. *See, e.g.*, *Agency for Int'l Dev. v. Alliance for Open Society Int'l, Inc.*, 133 S. Ct. 2321, 2328, 2330 (2013).

184. As stated, compliance with the Separation Requirement would, at minimum, require Plaintiffs to make unnecessary and prohibitively costly renovations to their health care centers, purchase new facilities, duplicate staff positions, and duplicate administrative systems, such as bookkeeping and health records. The costs of this requirement will be prohibitively expensive, and the timeframe the Final Rule permits for coming into compliance is inadequate, so that Plaintiffs and their affiliates will have to choose between exercising their First and Fifth Amendment rights and receiving Title X funding. If Plaintiffs were to accede to this unconstitutional condition and stop speaking about and providing abortions, it would violate their constitutional rights under the First and Fifth Amendments and impose an undue burden on their patients' access to abortion under the Fifth Amendment.

185. Again, the Supreme Court upheld against an unconstitutional-conditions challenge a prior iteration of the Separation Requirement in *Rust*. But again, this iteration differs from the one addressed in *Rust*, as HHS acknowledges, and this iteration should fall.

186. Moreover, the Separation Requirement is void for vagueness in violation of the Due Process Clause.

187. It is "[a] fundamental principle in our legal system … that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox Tel. Stations, Inc.*, 567 U.S. 239, 253 (2012). "This requirement of clarity in regulation is essential to the protections provided by the Due Process Clause." *Id.*

188. The Separation Requirement fails to satisfy this bedrock constitutional requirement. In particular, while the Separation Requirement lists various "factors" that are "relevant," it ultimately sets forth the governing standard as the following: "objective integrity and independence from prohibited activities," which the Secretary will determine in his sole discretion based on a case-by-case "review of facts and circumstances."

189. Clarity in regulation is critical in the Title X context, where Title X providers rely heavily on grant funding and must plan in advance and submit detailed applications for that funding. Yet the Separation Requirement's standard fails to give Plaintiffs fair notice of what is required of them—thus requiring Plaintiffs to assume the absolute worst—encourages seriously discriminatory enforcement, and will chill constitutionally-protected speech and conduct as Plaintiffs are compelled to over-comply for fear of losing all Title X funding.

190. Plaintiffs accordingly face an unacceptable risk of arbitrarily losing their Title X funding, and do not have constitutionally sufficient guidance to prepare applications for new Title X funding.

COUNT THREE

APA: THE FINAL RULE IS ARBITRARY AND CAPRICIOUS

191. The allegations in paragraphs 1 through 190 above are incorporated as if fully set forth herein.

192. An agency rule or action that is arbitrary or capricious is invalid. 5 U.S.C. § 706(2)(A). Among other things, agency rules or actions that are not "reasoned" are invalid as arbitrary and capricious. *E.g.*, *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

193. The Final Rule reverses a previous, settled agency position—one grounded in, among other things, national standards of health care and core ethical requirements of the medical profession—on which Plaintiffs and their members and affiliates have relied for decades.

194. Yet the Final Rule provides no reasoned explanation for its drastic changes to the Title X program, while simultaneously disregarding or otherwise failing to meaningfully consider and address material facts and evidence submitted during the comment period on the proposed rule. *See, e.g.*, *FCC v. Fox Tel. Stations, Inc.*, 556 U.S. 502, 516 (2009) ("[A] reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy.").

195. Moreover, Defendants' justifications for the Final Rule are arbitrary and capricious, including the following.

196. **Gag Requirement.** HHS fails to justify the Gag Requirement on legal or practical grounds and fails to account for its many negative health consequences. Those consequences include that it would force health care professionals to violate medical ethics and professional responsibility rules by prohibiting them from providing full information or certain referrals to patients, and produce worse health outcomes for patients. The Gag Requirement also undermines the congressional goal of providing comprehensive family-planning services for low-income people by forcing Planned Parenthood and many other providers out of the program. Even if HHS were

able to find providers to take their place (which is highly unlikely), those providers will not have the expertise or ability to provide the same volume and quality of care that the program has provided for decades, meaning that patients will face irreparable harm. And encouraging health care providers who refuse to provide counseling and referrals for abortion—and thus refuse to comply with the ethical principles of the medical profession and HHS's own guidelines for quality care—to participate in Title X will only undermine the efficacy of the program and result in the provision of substandard care.

197. Moreover, for those providers and practitioners who remain in the Title X program, the Gag Requirement leaves practitioners with only two options on referrals: deny abortion referrals entirely or provide patients who request abortion referrals with incomplete and misleading information. As to the latter, as discussed, the Final Rule authorizes only an intentionally misleading and incomplete list of providers. The Final Rule provides no justification for this, and with good reason: there is none. It deceives patients about their provider options and would delay patients' access to wanted medical care.

198. The Gag Requirement also adds an unexplained speaker-based ban on any abortion counseling—and going further still, "nondirective *pregnancy* counseling," 84 Fed. Reg. at 7,761 (emphasis added)—by medical personnel other than physicians and APPs. As a result, registered nurses and health care assistants, for example, would not be able to provide "nondirective pregnancy counseling," including nondirective counseling on abortion. HHS provided no justification for this ban, much less the speaker-based distinction it draws, and it would cause massive disruption and delays in care. Indeed, by HHS's own estimates, nearly a quarter of all 2017 "family planning encounters"—that is, "documented, face-to-face contact[s] between an individual and a family planning provider"—were with *non*-APP medical professionals. Christina Fowler et al., Office of Population Affairs, *Title X Family Planning Annual Report 2017 National Summary*, at 50-51 (Aug. 2018),

https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2017-national-summary.pdf. And in 2016, the Final Rule acknowledges, non-APP practitioners "were involved with 1.7 million Title X family planning encounters." 84 Fed. Reg. at 7,778. Yet under the Final Rule, none of these qualified, effective practitioners would be able to provide "nondirective pregnancy" counseling.

199. The Gag Requirement is also arbitrary and capricious because it provides only a limited exception for abortion referrals in the case of "emergenc[ies]." The Final Rule purports to allow "medically necessary" referrals. 84 Fed. Reg. at 7,788 (to be codified at 42 C.F.R. § 59.5(b)(1)). But such referrals must be "consistent with § 59.14(a)," *id.*—under which referrals for abortions are banned—and the Final Rule otherwise states that an abortion referral for only an "*emergency* medical situation" would fall outside the "restrictions concerning abortion as a method of family planning," *id.* at 7,762 (emphasis added); *see id.* at 7,730 ("may refer for abortion for documented *emergency* care reasons" (emphasis added)). At a minimum, the Gag Requirement is unclear whether a Title X project may refer a patient to an abortion provider for a medically indicated but non-"emergency" abortion, and Title X providers would necessarily have to assume the worst. This will needlessly and harmfully cause patients to delay medically necessary abortions. Moreover, "in cases involving rape and/or incest," the Gag Requirement would prohibit the Title X project from referring a patient to a specialized abortion provider, permitting it only to refer her to a "licensed, qualified, comprehensive health services provider who *also* provides abortion." *Id.* at 7,747 n.76 (emphasis added). HHS provided no justification for this.

200. HHS also failed to account for the economic impact of the Gag Requirement, including the significant health-related costs arising from forcing out of the Title X program Planned Parenthood and numerous other Title X providers. Indeed, despite the fact that Planned Parenthood expressly raised in its comments that all of its affiliates and numerous States would be

forced to withdraw from Title X entirely if the Gag Requirement went into effect, HHS nowhere even acknowledged, much less addressed, the point.

201. **Separation Requirement.** HHS nowhere meaningfully explains why the current rules are inadequate to comply with the statutory mandate that Title X funds not be used to provide abortions. As discussed, HHS regulations have long made clear that Title X funds may be used "solely for the purpose for which the funds were granted in accordance with … applicable cost principles," 42 C.F.R. § 59.9, and may not be used to "provide abortion," *id.* § 59.5(a)(5). Moreover, the current regulations have long required that Title X providers ensure that "[n]on-Title X abortion activities … be separate and distinct from Title X project activities." 65 Fed. Reg. at 41,282. And Title X grantees are already subject to audit and financial risk assessment, and, among other things, must provide quarterly financial reporting. HHS has not demonstrated that these rules are inadequate, nor has it otherwise justified the additional extreme burden of requiring physical and administrative separation.

202. Furthermore, HHS has not considered, and indeed, simply ignored many of the harms that would be imposed by the Separation Requirement. That requirement would impose enormous costs of renovation, relocation, and duplication. It would also harm patients by making it more difficult for Title X grantees to provide coordinated care. It would force many health care providers to leave the Title X program, which would cause many health care centers to close, depriving many patients of access to needed services. HHS has failed to properly account for these and other costs of the rule. Moreover, misuse of Title X funds is—as the Final Rule itself concedes—a nonexistent problem. The costs of the unjustified Separation Requirement thus vastly outweigh any potential benefit.

203. **"Transition Provisions."** The Final Rule's "transition provisions"—that is, the compliance dates of the rule—are unworkable, and thus arbitrary and capricious. Title X grantees will be unable to comply with the "physical separation" requirement within one year of publication of the Final Rule. This would require, at minimum, either renovating existing facilities or building or acquiring new facilities, as well as hiring new staff, and implementing new health record systems. Many Title X grantees may be forced to leave the program simply because they do not have adequate time to comply with the Final Rule.

204. Defendants' repeated failures to justify the Final Rule is unsurprising and underscores yet another reason why the Final Rule is fatally flawed: It is the result of Defendants' prejudgment with an "unalterably closed mind." *Alaska Factory Trawler Ass'n*, 831 F.2d at 1467 (Agency action is an abuse of discretion when the officials responsible had "an unalterably closed mind on matters critical to the disposition of the proceeding.").

COUNT FOUR

APA: THE FINAL RULE WAS ADOPTED WITHOUT PROCEDURE REQUIRED BY LAW

205. The allegations in paragraphs 1 through 204 above are incorporated as if fully set forth herein.

206. The Final Rule is a substantive, legislative regulation.

207. Such regulations adopted without the notice-and-comment procedure required by 5 U.S.C. § 553 of the APA are invalid. *See* 5 U.S.C. § 706(2)(D).

208. HHS adopted the Final Rule without following the process required for notice-and-comment rulemaking concerning its new speaker-based ban on "nondirective pregnancy" counseling.

209. Under the Final Rule, as discussed, "[n]ondirective pregnancy counseling" is permitted *only* when "provided by physicians or advanced practice providers." 84 Fed. Reg. at 7,789

(to be codified at 42 C.F.R. § 59.14(b)(1)); *accord id.* at 7,761 ("*[O]nly* physicians and APPs may provide any nondirective *pregnancy* counseling." (emphasis added)).

210. This speaker-based ban on any nondirective pregnancy counseling is not a "'logical outgrowth'" of the proposed rule, *Natural Resources Defense Council v. U.S. EPA*, 279 F.3d 1180, 1186 (9th Cir. 2008). Indeed, it far exceeds the scope of what HHS indicated it was considering in the proposed rule, and interested parties could not have reasonably foreseen that HHS was going to expand the scope of the Final Rule in this way. Moreover, had they known that HHS was even considering this option, they would have made clear to HHS that this ban is irrational, contrary to longstanding medical practice, and would have significant negative consequences—including, for example, drastic workflow alterations at Planned Parenthood health centers and major delays in patient care.

211. Accordingly, the Final Rule should be held unlawful and set aside under 5 U.S.C. §§ 553 and 706(2)(D).

RELIEF REQUESTED

Plaintiffs request that this Court:

a) Declare that the Final Rule is contrary to law, contrary to constitutional right, arbitrary and capricious, and invalid;

b) Set aside and vacate the Final Rule;

c) Issue preliminary and permanent injunctive relief, without bond, restraining the enforcement, operation, and execution of the Final Rule, by enjoining Defendants, their agents, employees, appointees, or successors, from enforcing, threatening to enforce, or otherwise applying the provisions of the Final Rule against Plaintiffs and their affiliates and members and patients.

d) Award Plaintiffs their costs and attorney's fees in pursuing this action under 28 U.S.C. § 2412; and

e) Grant such other relief as this Court may deem proper.

Dated: March 5, 2019.

Respectfully submitted.

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