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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON
AT YAKIMA

NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION, FEMINIST WOMEN'S HEALTH CENTER, DEBORAH OYER, M.D., and TERESA GALL, F.N.P.,

Plaintiffs,

v.

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

Defendants.

No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

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I. INTRODUCTION AND SUMMARY

1. This suit seeks to enjoin and set aside an unlawful rulemaking by the Department of Health and Human Services ("HHS"), 84 Fed. Reg. 7714 (Mar. 4, 2019) ("New Rule"), that violates Congress's explicit requirements and threatens to decimate the country's only dedicated federally funded program to provide family planning services, Title X of the Public Health Services Act. The New Rule's effective date is May 3, 2019. The published text of the New Rule's regulatory changes is attached as Exhibit A.

2. Plaintiff National Family Planning & Reproductive Health Association ("NFPRHA") is a national, non-profit organization whose membership includes Title X grantees in two territories and 48 states, including the Washington State Department of Health ("DOH"), as well as many Title X subrecipients, including co-Plaintiff Feminist Women's Health Center ("FWHC"). Plaintiffs also include two individual clinicians who provide care in Title X projects.

3. If allowed to take effect, the New Rule will gravely harm Plaintiffs, the Title X program, its patients, and the public health. It abandons regulations that have effectively governed Title X for decades and would reverse principles critical to that past success. The New Rule subjects pregnant Title X patients to involuntary and substandard clinical care; will drive many health care providers from the program; and will leave large gaps in Title X's safety net care, diminishing access to contraceptive and other preventative clinical care and leading to unintended pregnancies, undetected cancers, and other serious repercussions.

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4. The Title X program has been an essential piece of the U.S. health care system since 1970. Congress created the program to address low-income individuals' lack of equal access to the same family planning services, including modern, effective medical contraceptive methods such as "the Pill," available to those with greater economic resources.

5. Title X grants support family planning projects that offer "a broad range of acceptable and effective family planning methods and services" to patients on a voluntary basis, 42 U.S.C. § 300(a), creating a nationwide network of Title X health care providers. Title X gives those with incomes below or near the federal poverty level free or low-cost access to clinical professionals, contraceptive methods and devices, and testing and counseling services related to reproductive health, including pregnancy testing and counseling.

6. Approximately 90 federal grants for Title X projects now fund more than 1000 provider organizations across all the states and in the U.S. territories, with more than 3800 health centers offering Title X care. The Title X program served more than four million patients in 2017.

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

8. Indeed, every year from 1996 to the present, in making appropriations for Title X, Congress has reiterated that it must fund only *voluntary* family

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

9. In the Patient Protection and Affordable Care Act ("PPACA"), which became law in 2010, Congress specifically identified rulemaking that is off limits for HHS, including in the agency's administration of Title X. Section 1554 of the PPACA prohibits the Secretary of HHS from "promulgat[ing] any regulation" that "creates unreasonable barriers" or "impedes timely access to health care services;" interferes with medical providers' communications with patients "regarding a full range of treatment options;" restricts "the full disclosure of all relevant information to patients;" or violates "the ethical standards of health care professionals." 42 U.S.C. § 18114 ("Section 1554").

10. Yet the New Rule violates the Title X voluntariness requirement, the Nondirective Mandate, and Section 1554 in multiple respects: It takes away pregnant patients' voluntary decision-making about their services within Title X; requires directive prenatal referrals for all pregnant patients, regardless of their wishes; further adopts directive counseling by allowing Title X providers to exclude the option of abortion from pregnancy counseling, even when the patient specifically seeks information about abortion; and forbids pregnancy counseling from including any referrals to abortion care, even upon patients' specific request.

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11. Alongside its distortions of pregnancy counseling, the New Rule also imposes sweeping and unworkable changes in the separation it requires between (a) Title X activities and (b) any activities that support access to abortion care—including abortion referrals, the provision of abortion, and education or advocacy efforts—that Title X-funded entities carry out *outside their Title X projects, without federal funds.*

12. The New Rule's separation requirements are so onerous that they would require non-profit and governmental health care entities to duplicate their facilities, staff, reference materials, electronic systems, and more, which they do not have the means or any rational reason to do. The extreme separation requirements will also force entities to choose between either providing Title X care or engaging in the constitutionally protected activities they currently undertake outside the program. And yet, nowhere does HHS demonstrate any problem with Title X projects' compliance with long-standing programmatic and financial separation requirements. The agency fails to support any justification for the extreme version of separation that the New Rule empowers HHS to implement without clear limits.

13. As President Trump has made plain, the New Rule simply aims to ensure that entities that provide abortion care outside the Title X program with non-federal funds are unable to comply and are forced to exit the Title X program. President Trump promised as a candidate, on March 1, 2016, that "we are not going to fund, as long as you have the abortion going on," and followed through on his promise in announcing this regulatory action, declaring that "[m]y

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administration has proposed a rule to prohibit Title X funding from going to any clinic that performs abortions." *Remarks by President Trump at Susan B. Anthony List 11th Annual Campaign for Life Gala*, WhiteHouse.gov (May 22, 2018).

14. The pregnancy counseling distortions, separation requirements, and several other impermissible limits in the New Rule act to force from the Title X network health care providers that also provide abortions (without federal funds and beyond their Title X projects) *or* provide abortion referrals *or* engage in any expression or association that supports abortion access. Furthermore, the New Rule seeks to replace those health care providers—long-standing mainstays of the Title X network, who have served high numbers of Title X patients from the inception of the program—with new participants who, based on conscience, object to core Title X care.

15. Detailed substantive comments from leading medical, family planning and reproductive health, evidence-based research, reproductive justice, and civil rights organizations, among others, as well as individual experts in those fields—and from the many government entities and leaders committed to the Title X program—overwhelmingly opposed the New Rule. HHS's final rulemaking ignores almost all of these well-documented objections, offers explanations that are contrary to the evidence before the agency, fails to grapple with the severe program disruption and harm to patient and public health that the New Rule will provoke, and does not plausibly root its regulatory about-face in any agency expertise or basis in Title X. The notice-and-comment process has made clear that the New Rule is a "solution" in search of a problem and will only cause

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widespread disruption and harm to the Title X program, the four million patients it serves annually, and the public health.

16. As set forth in detail below, the New Rule (i) violates Congress's Nondirective Mandate; (ii) violates Section 1554 of the PPACA; (iii) violates the Title X statute, exceeds the program's proper scope, and contravenes its purpose; and (iv) is an arbitrary and unfounded rulemaking on numerous scores. The New Rule is neither required nor adequately justified by any provisions of Title X or by the "conscience statutes" that HHS attempts to invoke. Furthermore, the New Rule imposes unconstitutionally vague standards and places unconstitutional, viewpoint-based conditions on Title X-funded entities and their medical professionals, unduly limiting their activities both within and outside the Title X program.

17. Plaintiffs sue to maintain the integrity of the Title X program and protect its patients. Plaintiffs ask the Court to enjoin the New Rule in order to preserve Congress's purpose of giving low-income individuals equal access to the same, quality family planning care available to others, to enforce Title X's proper legal framework, and to prevent the avalanche of impending harms.

II. JURISDICTION AND VENUE

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331. The claims asserted arise under the federal Administrative Procedure Act ("APA") and the First and Fifth Amendments to the United States Constitution.

19. This Court is authorized to issue the injunctive and declaratory relief sought here under the APA, 5 U.S.C. §§ 702, 705, 706, the Declaratory Judgment

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Act, 28 U.S.C. §§ 2201, 2202, Federal Rules of Civil Procedure 57 and 65, and the Court's inherent equitable powers.

20. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(e)(1)(C) because Plaintiff FWHC resides in this district. FWHC's corporate headquarters and principal place of business is in Yakima, Washington.

III. PARTIES

21. Plaintiff NFPRHA is a national, non-profit membership association that advances and elevates the importance of family planning in the nation's health care system and promotes and supports the work of family planning providers and administrators, especially those in the safety net (i.e., those who provide care funded through government programs).

22. NFPRHA represents more than 850 health care organizations. NFPRHA's membership includes state, county, and local health departments; private non-profit family planning organizations (including Planned Parenthood affiliates and others); family planning councils; hospital-based health practices; and federally qualified health centers ("FQHCs").

23. Within Title X, NFPRHA's members operate or administer more than 3500 health centers that provide family planning services to more than 3.7 million patients each year. NFPRHA's membership includes at least one Title X grantee or subrecipient of Title X funding in every state.

24. NFPRHA brings this action in a representative capacity on behalf of its member organizations that participate in Title X and their staff, including the members' clinicians and the patients they serve.

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25. The interests that NFPRHA seeks to vindicate in this suit are central to its mission. NFPRHA is the lead national advocacy organization for the Title X family planning program and works to maintain Title X as a critical part of the public health safety net. In addition to its Title X advocacy, NFPRHA provides education, resources, and technical assistance to Title X grantees and subrecipients and concretely supports those entities as they implement Title X.

26. Among other efforts, NFPRHA also advocates and supports maintaining access to abortion services and works to advance health equity through eliminating barriers that contribute to disparities in health care outcomes.

27. Plaintiff FWHC, doing business as Cedar River Clinics, is one of the 16 current subrecipients of the Title X grant awarded to the Washington DOH. FWHC provided more than 3000 Title X patient visits in 2018, including providing pregnancy testing and nondirective counseling to more than 500 patients that year. FWHC is a member of NFPRHA. FWHC sues on behalf of itself, its staff—including its physicians and other clinicians—and its patients.

28. Consistent with Title X's existing financial and other requirements, FWHC also provides abortions with non-Title X funds at its Cedar River Clinics.

29. Plaintiff Deborah Oyer, M.D., oversees the medical care and provides Title X clinical care at FWHC's Cedar River Clinics. Dr. Oyer also provides abortions at Cedar River Clinics outside the Title X program and unsupported by Title X funds. She has provided family planning and other reproductive health care in Washington for more than 25 years and is a graduate of Harvard Medical School. Dr. Oyer sues on behalf of herself and her patients.

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30. Plaintiff Teresa Gall, F.N.P., is a Family Nurse Practitioner who has provided Title X clinical care, including contraceptive care, pregnancy counseling, and well-woman screenings, for 17 years in St. Joseph, Missouri. Ms. Gall practices at the Westside Clinic operated by the Social Welfare Board, which is a subrecipient of the Title X grant awarded to Missouri Family Health Council, Inc. Ms. Gall sues on behalf of herself and her patients.

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

32. Defendant United States Department of Health and Human Services ("HHS") is the agency that promulgated the New Rule.

33. Defendant Diane Foley, M.D., is the Deputy Assistant Secretary, Office of Population Affairs ("OPA"), within HHS. OPA is the HHS office that issued the New Rule. Dr. Foley is sued in her official capacity.

34. Defendant OPA administers and oversees the Title X program.

IV. ALLEGATIONS

A. The Title X Program, Its Decades of Success, and Its Structure

(1) Title X Aims to Equalize Low-Income Patients' Access to Quality Family Planning Care

35. Title X became law as part of the "Family Planning Services and Population Research Act of 1970." Pub. L. No. 91-572, 84 Stat. 1504 (1970).

36. During the 1960s, many low-income women had more children than they desired. This significantly impacted their lives, including interfering with their ability to obtain an education and contribute to the economy, and negatively

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affected maternal and child health. Research established that it was inequitable access to modern, effective contraceptives that made low-income women less able to match their actual childbearing with their desired family size. The two most effective biomedical contraceptives, the new oral contraceptive pill and the copper intrauterine device ("IUD"), were available only through medical professionals and at a high cost, both for the contraceptive itself and for medical visits.

37. President Richard M. Nixon therefore called on Congress to establish a national family planning program to expand such services for "all those who want them but cannot afford them." President Nixon, *Special Message to the Congress on Problems of Population Growth* (July 18, 1969). He stressed that "no American woman should be denied access to family planning assistance because of her economic condition." *Id.*

38. With overwhelming bipartisan support, Congress responded by enacting Title X. Congress's concern was the "medically indigent"—the low-income individuals who were:

> forced to do without, or to rely heavily on the least effective nonmedical techniques for fertility control unless they happen to reside in an area where family planning services are made readily available by public health services or voluntary agencies.

S. Rep. No. 91-1004, at 9 (1970). At the same time, Congress emphasized that it sought to establish a comprehensive family planning program and to provide quality services to those with low-incomes—not simply expand the number of individuals served. *See id*. at 10.

39. Congress also recognized that, in this area of individuals' reproductive

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decision-making, Title X required "explicit safeguards to insure that the acceptance of family planning services and information relating thereto must be on a purely voluntary basis by the individuals involved." *Id.* at 12.

40. In short, Congress sought to provide low-income patients with effective contraceptives, with equal access to quality family planning clinical care, and with the true freedom to make their own decisions about family planning and when or if to have children.

(2) Title X Succeeds in Opening Quality Family Planning Care to Low-Income Patients

41. Over almost five decades, Title X funding has built and sustained a national network of family planning health centers that delivers high-quality care. It has enabled millions of low-income patients to prevent unintended pregnancies and protect their reproductive health.

42. The Centers for Disease Control and Prevention ("CDC") named family planning one of the most important achievements in U.S. public health in the 20th century, and highlighted the role of public funding in that success.

43. OPA's current Program Requirements for Title X summarize:

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

OPA, *Program Requirements for Title X Funded Family Planning Projects*, at 5

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(Apr. 2014), https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf ("Program Requirements"). Title X projects also provide basic infertility services, such as testing and counseling.

44. When Title X patients visit a health center that provides Title X-funded care, they see and experience an ordinary health care facility. These medical professionals' offices and treatment rooms are not identified by any signs that say, "Title X," nor are they distinguishable by any other physical or substantive differences from typical outpatient medical care. Patients come to these health center sites because Title X providers do community outreach and other patients spread the word about them, including about their free or low-cost care based on income. A central premise of Title X is that the patient care it funds should not be second-class, but rather the same as that available to patients with higher incomes who access private care.

45. Many Title X-funded organizations have been providing care in the network for decades, often from the very beginning of the Title X program. Title X health care providers have developed deep expertise and high responsiveness to patient needs. For example, Title X providers offer a greater number of contraceptive method options to their patients than do non-Title X health care providers; are more likely to offer those options onsite rather than requiring a woman to go to a pharmacy or to another provider for supplies or insertion of an IUD or implant; and spend more time with patients during an initial contraceptive visit and other counseling than do clinicians at non-Title X sites.

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46. Roughly seven in ten Title X patients receive their care from a reproductive health-focused Title X site, as opposed to a site that offers a wide range of medical care. Patients often prefer receiving care from these specialized health centers, which are operated both by nonprofit organizations and government health departments or other government entities. Many patients depend on the same Title X service site year after year.

47. In 2017, the more than 3800 individual Title X health center sites around the country served more than four million patients, with more than 6.6 million family planning visits. OPA, *Family Planning Annual Report: 2017 National Summary*, at ES-1 (2018).

48. Title X providers have succeeded in reaching the low-income patients that are the program's priority. In 2017, 67% of Title X patients had household incomes at or below 100% of the federal poverty level, and 23% of patients had incomes ranging from 101% to 250% of that threshold. *Id.* at 21. The federal poverty level was $12,060 for a single person in 2017, and $20,420 for a household of three.

49. While the greatest proportion of Title X patients are young adults in their 20s, Title X providers serve individuals throughout their reproductive years. In 2017, 47% of Title X patients were aged 20 to 29, 35% were 30 or older, and 17% were younger than 20. *Id.* at 9.

50. Title X patients are disproportionately Black or Latino/a. In 2017, 22% of Title X patients self-identified as Black or African American and 33% as

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Hispanic or Latino/a, compared to 12% and 18% of the nation, respectively. *Id.* at 12.

51. The Title X low-income patient population includes many who are marginalized by society and who experience multiple challenges in accessing health care, but whom the Title X network has succeeded in reaching and serving by offering vital, voluntary family planning information and services. For example, 14% of Title X patients reported having limited English language proficiency. *Id.* at 22. Title X patients also include people who are homeless.

(3) The Structure of Title X Grants and Grantees' Title X Projects

52. Each year, HHS distributes Title X funding to support care in geographic service areas throughout the country. In recent years, this funding for Title X services has totaled approximately $260 million, spread among approximately 90 grantees to fund their Title X "projects."

53. Each Title X project supplements its federal funding with service reimbursement payments, such as from Medicaid or private insurance, patient-paid fees for those with incomes above the poverty line and subject to Title X's schedule of discounts (or "sliding fee scale"), and/or state, local, or private sources, to comprise the project's overall budget. All care within any Title X project is bound by the federal law, regulations, and clinical and administrative standards that apply under Title X.

54. Within each Title X project, there are typically three levels: (i) the grantee entity, (ii) subrecipient organizations, and (iii) individual service sites run by either grantees or subrecipients (or subrecipients of subrecipients).

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55. In some states, the state health department is the sole grantee; other states have a non-profit organization as the sole grantee; and in other states there may be multiple Title X grantees. Some grantees handle only overall program direction, funding, administration, and oversight, and the subrecipients include all of the service sites. In other instances, the grantee itself operates service sites and may also have subrecipients who operate additional sites. NFPRHA's membership includes grantees that fall into each of these categories, and also includes the majority of Title X subrecipients.

56. A number of NFPRHA's grantee members, including some state health departments and non-profit administrative grantees, administer and oversee their grant from a single location. Some NFPRHA Title X subrecipients also operate out of a single facility. Within these single workplaces, non-Title X activity is also occurring, including, for example, administration of other grants, education and advocacy activities, and/or non-Title X health care.

B. The Legal Requirements for the Title X Program

(1) <u>The Central Statutory and Long-Standing Regulatory Rules That Have Defined the Title X Program</u>

57. Title X authorizes the Secretary of HHS to fund "public or non-profit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services." 42 U.S.C. § 300(a). In making grants, the statute specifies "the Secretary shall take into account the number of patients to be served, the extent to which family planning services are needed locally, the relative

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need of the applicant, and its capacity to make rapid and effective use of such assistance." 42 U.S.C. § 300(b).

58. The essential requirement that Title X projects provide solely "voluntary" care is emphasized not only in Section 300(a), above, and in the annual HHS appropriations legislation, but also in Title X's Section 300a-5. The latter provides that "acceptance by any individual of family planning services or family planning or population growth information (including educational materials) provided through financial assistance under this title … shall be voluntary and shall not be a prerequisite" for other services or assistance from an entity or individual. 42 U.S.C. § 300a-5(a).

59. A grant for a family planning services project can be made only upon assurances that "(1) priority will be given in such project" to furnishing services to persons from low-income families and "(2) no charge will be made in such project … for services provided to any person from a low-income family except to the extent that payment will be made by a third party … authorized or under legal obligation to pay such charge." 42 U.S.C. § 300a-4(c).

60. The Title X statute has always provided that "[n]one of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6 ("Section 1008").

61. A comprehensive set of Title X regulations finalized in 2000 remains in effect, unless and until the New Rule is implemented. The substance of those 2000 regulations, found at 42 C.F.R. Part 59, closely tracks the regulations adopted

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at the inception of the program and that have governed its operation for virtually all of the Title X program's history.

62. Section 59.1 of the existing regulations specifies that the "voluntary family planning projects" funded by Title X grants "shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children." 42 C.F.R. § 59.1. Section 59.5(a)(2) further requires that Title X projects provide all services "without subjecting individuals to any coercion to accept services." 42 C.F.R. § 59.5(a)(2).

63. Priority in the provision of those family planning services must be given to "persons from low-income families." 42 C.F.R. § 59.5(a)(6). "Low-income family" is defined to include those whose annual income does not exceed 100% of the federal poverty level. It also includes other individuals who are determined to be unable to pay, such as minors who seek confidential services and whose own resources place them below the federal poverty level. 42 C.F.R. § 59.2.

64. As required by the statute, persons that fall within the defined scope of low-income families pay nothing for Title X services. 42 C.F.R. § 59.5(a)(7). Persons from families whose annual incomes are between 101 and 250% of the federal poverty level pay according to a sliding schedule of discounts based on ability to pay. 42 C.F.R. § 59.5(a)(8). If a third party is "authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts." 42 C.F.R § 59.5(a)(9).

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65. Title X services must also be provided "in a manner which protects the dignity of the individual" and without discrimination, including based on patients' religion, race, national origin, age, sex, number of pregnancies, or marital status. 42 C.F.R. § 59.5(a)(3), (4).

66. The existing regulations require that each project provide "a broad range of acceptable and effective medically approved" family planning methods and services. 42 C.F.R. § 59.5(a)(1). Title X projects must conduct their medical services under the overall "direction of a physician with special training or experience in family planning" and provide "orientation and in-service training for all project personnel." 42 C.F.R. § 59.5(b)(4), (6). Most Title X clinical care is provided to patients by nurse practitioners, certified nurse midwives, physician assistants, or registered nurses with an expanded scope of practice.

67. In addition to the family planning services offered within the Title X project, Title X health centers are required to provide referrals to other medical providers when medically indicated or when the care sought by patients is beyond the services offered by the Title X provider. 42 C.F.R. § 59.5(b)(1), (2), (8).

68. The obligation to provide referrals upon request is specifically emphasized for Title X providers' pregnancy testing and counseling. Section 59.5(a)(5) makes clear that while Title X projects do "[n]ot provide abortion as a method of family planning," a project must:

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

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(C) Pregnancy termination.

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

69. The existing regulations also include provisions related to the grant application process and the governing criteria for Title X grant-making. The seven specific regulatory criteria, 42 C.F.R. § 59.7, for HHS's application review and grant decision-making have remained the same since the 1970s.

70. Title X services grants are competitive grants that, like other HHS discretionary grants, are awarded only after extremely detailed applications are submitted in response to funding opportunity announcements ("FOAs"). The applications are reviewed and ranked by objective merits review panels convened by OPA through HHS's 10 regional offices and made up of outside reviewers knowledgeable about family planning. This process is described in and governed by 45 C.F.R. Part 75. If Title X grants are awarded through this competitive process for project periods of multiple years, HHS nonetheless reviews renewal applications from multi-year grantees annually and must approve their yearly continuation funding. 42 C.F.R. § 59.8.

71. Finally, the current regulations make clear that "[a]ny funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR part 75." 42 C.F.R. § 59.9.

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72. HHS has supplemented the Title X regulations with agency guidance in the Program Requirements. Those Program Requirements make clear that Title X projects are governed by the national standards of clinical family planning care set forth in the CDC/OPA publication, *Providing Quality Family Planning Services* (2014), https://www.cdc.gov/mmwr/ pdf/rr/rr6304.pdf ("QFP"), and any QFP updates. Program Requirements at 5.

73. In addition, in 2000, HHS issued specific guidance on how to provide Title X family planning services that may involve discussion of abortion, such as pregnancy counseling, contraceptive counseling, and the provision of neutral, factual educational information. *Provision of Abortion-Related Services in Family Planning Services Projects*, 65 Fed. Reg. 41,281 (July 3, 2000). The 2000 guidance also addresses the service protocols, pro-rated cost allocations, and other financial separation steps that Title X projects implement to ensure that abortion care itself is separate from all Title X activities.

74. This legal framework for Title X family planning has remained remarkably consistent over the program's almost five decades. There has been only one previous attempt by the executive branch to remake the program from one intended to be about equality of access to quality clinical family planning services so that low-income individuals can freely determine their own reproductive decisions, into a directive, ideological, and coercive program that imposes care on and limits information for pregnant patients.

75. In 1988, HHS promulgated a similar rulemaking as the one challenged here, though not nearly as expansive and insidious. In 1991, the Supreme Court

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rejected certain legal arguments made against the 1988 rulemaking. *See Rust v. Sullivan*, 500 U.S. 173 (1991). But that aberrant rulemaking was never implemented nationwide and never permitted to sabotage Title X's success and deprive Title X patients of quality care.

76. The 1988 rule remained enjoined and in limbo until shortly before February 1993, when the agency rescinded it. HHS made clear in February 1993 that the standards that had been in place for years before the 1988 attempt to redirect and fundamentally alter the Title X program continued to govern. *See Standards of Compliance for Abortion-Related Services in Family Planning Service Projects*, 58 Fed. Reg. 7464 (Feb. 5, 1993). Under those standards, Title X projects provided "nondirective counseling to the patient on options relating to her pregnancy, including abortion" and were required "to refer her for abortion, if that is the option she selects." *Id.*

(2) Congress's Additional Mandates for Title X from 1996 to the Present

77. In legislative enactments subsequent to this 1988 attempt to steer the program astray, Congress itself has repeatedly and emphatically rejected the notion that directive, misleading medical care could permissibly be injected into the Title X program.

78. With the Nondirective Mandate, Congress has explicitly required every year since 1996 that "all pregnancy counseling [in Title X projects] shall be nondirective." Pub. L. No. 115-245, 132 Stat. at 3070-71. That substantive requirement for the Title X program has been a condition of every Title X funding

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appropriation for 25 years, including in the most recent HHS appropriations act already passed for this fiscal year. *See id.*

79. In addition, in the PPACA, Congress prohibited HHS from promulgating any regulations that interfere with medical providers' communication of full information and the full range of options to their patients; violate informed consent and ethical principles; or create other barriers to timely accessing health care services.

80. Section 1554 of the PPACA specifically requires that the Secretary of 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; [or]
> (5) violates the principles of informed consent and the ethical standards of health care professionals; ….

42 U.S.C. § 18114(1)-(5). Section 1554 is one of the generally-applicable provisions in the PPACA that protects against specified forms of interference with access to medical care.

C. The New Rule and Its Unlawful Interference With Title X Care

81. As Congress has repeatedly made plain in recent years, HHS cannot hijack the Title X program to require directive pregnancy counseling, force pregnant patients toward "favored" reproductive decisions, or violate ethical health

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care principles and HHS's own national standards of family planning care articulated in the QFP.

82. Title X exists to provide patients voluntary access to quality care, and prioritizes low-income patients receiving that care. Its purpose is sabotaged if removing long-established, high-quality providers instead becomes the priority, as with the New Rule, and HHS seeks to replace them with providers that *oppose* much of the quality family planning that Title X exists to offer patients. The New Rule, in its interconnected parts and as a whole, unlawfully interferes with central aspects of the Title X program and should be set aside.

(1) The New Rule's Many Legal Failings

83. The New Rule violates Title X, the Nondirective Mandate, and Section 1554 of the PPACA; exceeds HHS's rulemaking authority; is arbitrary and capricious; arises from a faulty rulemaking process; and conflicts with constitutional protections. Its legal failings are set forth in turn, organized by the New Rule's substantive categories.

a. The New Rule Mandates Directive Pregnancy Counseling

i. The New Rule's Counseling Distortions Are Contrary to Law

84. In multiple respects, the New Rule drastically shifts how pregnancy counseling must take place within Title X and directly conflicts with Title X's voluntariness requirement, the Nondirective Mandate, and most of the prohibitions on HHS rulemaking in Section 1554 of the PPACA.

85. First, the New Rule's Section 59.14(b) requires that when a Title X patient "is medically verified as pregnant," the Title X provider "shall" refer her

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"for medically necessary prenatal health care." 84 Fed. Reg. at 7789. This directive referral must occur for all pregnant patients, regardless of their individual wishes or consent to the referral.

86. Second, the New Rule also allows what it calls "nondirective pregnancy counseling," Section 59.14(b)(1), but there is no permitted scenario in which that counseling is in fact nondirective for patients who might be considering abortion. Every patient must receive the mandatory prenatal referral as part of their pregnancy counseling. In addition, a Title X physician or some advanced-practice clinicians could also choose to provide so-called "nondirective pregnancy counseling," but discuss only carrying the pregnancy to term and adoption, and refuse to mention abortion or respond to patients' questions about it. Conversely, the provider can never solely discuss the option of abortion, even if that is the only option in which the patient is interested. Instead, the provider must always include mandatory prenatal referral and involuntary counseling about carrying the pregnancy to term. 84 Fed. Reg. at 7747.

87. Third, the New Rule specifically allows Title X-funded entities to provide other types of directive (and non-voluntary) pregnancy counseling to patients. The New Rule provides that any Title X staff member may provide pregnant patients with a referral to adoption agencies and/or "information about maintaining the health of the mother and unborn child during pregnancy," regardless of the individual patient's wishes, requests, or plans. Section 59.14(b)(iii), (iv); 84 Fed. Reg. at 7789.

88. Finally, the New Rule prohibits any person within a Title X project

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from counseling pregnant patients in a manner that (i) directly refers a pregnant patient to an abortion provider, (ii) identifies any abortion provider for the patient, or (iii) indirectly assists the patient in finding a referral for abortion care, even when a patient has explicitly asked the provider for help with an abortion referral or for information about accessing abortion. *See* Sections 59.5(a)(5), (b)(1), (b)(8), 59.13, 59.14(a) & (c), and 59.16; 84 Fed. Reg. at 7788-90.

89. The complete prohibition against abortion referrals during pregnancy counseling applies even when a patient specifically asks for such a referral. At most, Title X providers can give any pregnant patient a list of "comprehensive primary health care providers (including providers of prenatal care)," which may or may not include any that might provide abortion. Section 59.14(b)(1)(ii), (2); 84 Fed. Reg. at 7789. If any of those "comprehensive primary health care providers" do provide abortions, they cannot be identified as such for the patient, and cannot be more than a minority of the entities on the list. *Id.* A patient who receives the list will not know whether it includes any abortion providers, even if she receives it in response to a direct request solely for abortion access information. The Title X provider is prohibited from telling her which (if any) provider on the list performs abortions, even if the patient asks about that.

90. In addition, the New Rule's sections requiring physical separation, limiting infrastructure spending, and forbidding expressive activities that may assist women in obtaining abortions also limit and interfere with Title X's proper nondirective pregnancy counseling. Section 59.15(d) instructs Title X projects to make "material referencing abortion … absent" from their physical facilities. 84

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Fed. Reg. at 7789. Sections 59.16 and 59.18 forbid using Title X funds to create or disseminate written materials that may encourage abortion or assist women in obtaining it. These new restrictions forbid the use of pregnancy options workbooks and other written summaries about pregnancy options that are important aspects of truly nondirective pregnancy counseling when a Title X patient has just been informed she is pregnant and asks for written materials outlining the relevant medical facts and options to inform her decision-making.

91. All of these provisions establishing Title X's new treatment of pregnant patients, Sections 59.2, 59.5(a)(5), (b)(1), (b)(8), 59.13 through 59.16, and 59.18, are collectively referred to herein as the "Counseling Distortions."

92. The New Rule's Counseling Distortions are plainly contrary to law in at least three ways. They violate:

- *Congress's Nondirective Mandate*. Pub. L. No. 115-245, 132 Stat. at 3070-71. Under the New Rule, (a) all patients must receive a directive referral for prenatal care, and (b) Title X providers are free to provide additional counseling that directs a patient toward continuing the pregnancy and excludes the option of abortion, even if the patient desires counseling regarding abortion. All of this pregnancy counseling pushes patients toward one reproductive outcome, namely childbirth;

- *Congress's requirement that all Title X services be voluntary and not coercive*. *Id.*; 42 U.S.C. §§ 300, 300a-5. Under the New Rule, patients not interested in prenatal care and seeking only abortion information are

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nonetheless subjected to involuntary prenatal pregnancy counseling, including a forced referral; and

- *Congress's unequivocal requirements in Section 1554* that HHS not promulgate any regulations that, *inter alia*, restrict the ability of health care providers to fully disclose all relevant information to patients making health care decisions, violate ethical standards of health care, or interfere with treatment-option discussions or timely access to care. 42 U.S.C. § 18114.

93. The New Rule in all those ways imposes substandard care on the low-income patients that Title X serves. HHS's own national standards of clinical care in the QFP specifically instruct that, in the context of "pregnancy testing and counseling," full options information and the full array of possible referrals, including abortion and according to patients' own preferences, should be available. QFP at 13-14. The QFP further emphasizes that patients' access to referral care, including abortion if desired, should be expedited and not delayed. *Id.*

94. The relevant professional medical associations likewise explain that patients should have full access to information and the opportunity to discuss all options. Those professional bodies specify that a clinician withholding information from patients or presenting only directive, biased information about reproductive health options is not consistent with medical ethics. In addition, medical ethical principles further dictate that if a patient may need care that falls outside a treating clinician's practice, the clinician is obligated to refer to or consult with other professionals who provide that out-of-practice care. *See, e.g.*, American College of Obstetricians and Gynecologists ("ACOG") Comment Letter

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at 3-6 (July 31, 2018); American Medical Association ("AMA") Comment Letter at 3 (July 31, 2018) ("[C]hanges on counseling and referral … would not only undermine the patient-physician relationship, but also force physicians to violate their ethical obligations."); American Academy of Nursing ("AAN") Comment Letter at 4 (July 26, 2018).

95. The New Rule makes abortion the only medical care outside Title X projects' scope to which Title X clinicians are barred from providing patients with a referral. Now, even medically indicated referrals to abortion providers based on specific patient health risks are barred by the New Rule, as discussed below.

96. Instead, the New Rule mandates that clinicians, at most, can respond to a patient seeking an abortion referral with misleading, unlabeled, and artificially limited information—including a list that may include no abortion providers at all—that will only confuse and delay that patient in accessing abortion care. Any Title X provider can now choose to discuss only carrying the pregnancy to term and adoption with a patient distressed by her pregnancy, and need not in any way discuss abortion as an option, even upon a patient's request.

97. The New Rule's limitations on "indirect referrals" and its expansive separation requirements, as described below, also bar clinicians from making patients aware that more complete counseling may be available to them outside the Title X project, whether from that very same clinician or from others. But the New Rule would allow a provider within the Title X project to explicitly condemn or discourage the option of abortion—in addition to the new Title X pregnancy counseling requirement that explicitly directs all patients toward prenatal care.

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98. For Title X patients denied accurate, neutral counseling about abortion, some of whom may be young and/or non-English speaking and most of whom have extremely limited financial resources, HHS's rulemaking suggests information "on the internet" is a sufficient alternative channel of communication. 84 Fed. Reg. at 7746. This is a complete abdication of Congress's Nondirective Mandate and wholly ignores the priority of Title X to provide patients with limited economic resources access to quality medical care.

ii. The Counseling Distortions Are Also Arbitrary and Capricious

99. The Counseling Distortions are not only flatly contrary to the statutory provisions discussed above, but are also the result of an unreasoned, arbitrary decision-making process by HHS in promulgating them. As referenced elsewhere in the Complaint, HHS ignored its own QFP standards, did not consider any specifics of currently-applicable medical ethics principles, and refused to confront medical experts' virtually unanimous condemnation of the New Rule's Counseling Distortions and their requirement of coercive, directive, and substandard care for patients. In all these ways, the agency engaged in unfounded and impermissible decision-making.

100. In addition, HHS also acted arbitrarily by failing to acknowledge—and not addressing at all—the specific evidence before it that the Counseling Distortions, including the bar on abortion referrals, would trigger widespread departures by current Title X providers and massively disrupt the Title X program.

101. The Counseling Distortions will start a ripple effect of harms that will extend far beyond the immediate, direct denial of truly nondirective pregnancy

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counseling to patients. As NFPRHA described in detail in its comments to HHS, these pregnancy counseling changes "will drive a number of Title X providers from the program, shrink and diminish the effectiveness of the Title X network, harm patients' health, attempt to exert coercion over and impose dignitary harms on patients, and damage the trusted clinician-patient relationships for which Title X is known." NFPRHA Comment Letter at 4 (July 31, 2018).

102. Planned Parenthood Federation of America ("PPFA") in its comments repeatedly alerted HHS that if "the proposed ban on abortion referrals" were finalized, all Planned Parenthood providers "would be forced to decline Title X funds" because such a ban is "fundamentally at odds" with medical professionals' obligations. PPFA Comment Letter at 77 (July 31, 2018). PPFA also made explicit what HHS already knew: that Planned Parenthood sites currently treat a high number of Title X patients, including in areas not served by any other family planning resources. In particular, while the Planned Parenthood health centers "represent only 13 percent of Title X service sites, they serve *over 40 percent of the program's patients*." *Id*. at 78 (emphasis added). "Fifty-six percent of Planned Parenthood health centers are in health provider deserts, where residents live in areas that are medically underserved and they may have nowhere else to go to access essential health services without Planned Parenthood." *Id.*

103. Other current Title X participants and public health experts also warned that the New Rule's interference with nondirective pregnancy counseling, including barring referrals upon request for abortion, would trigger significant provider withdrawals, create holes in the Title X network, and interfere with

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patients' access to family planning care. *See, e.g.*, Guttmacher Institute Comment Letter at 9-10 (July 31, 2018); Gov. Andrew M. Cuomo, State of New York Comment Letter at 2 (July 31, 2018); Gov. David Y. Ige, State of Hawaii Comment Letter at 1 (July 30, 2018). Many also emphasized the negative individual and public health effects that would ensue as Title X capacity diminishes.

104. Despite having all of this information in the record, HHS failed to consider the consequences of Title X service sites as well as individual clinicians departing the program because of the New Rule's forced compromises of medical professionals' standards for pregnancy counseling. HHS posits that there are as-yet-unidentified providers with religious objections to nondirective pregnancy counseling who might in the future seek to join the Title X network, but HHS offers no evidence of such providers who would apply to offer Title X care. Even if HHS did offer some prospects, there is no basis for believing such providers would have the capacity, if eventually funded, to treat significant numbers of Title X patients or to offer care where the New Rule creates huge gaps—much less to accommodate all of the roughly 40% of patients treated by Planned Parenthood and those treated by other providers who would leave the network in response to the New Rule. In its attempted defense of the New Rule, HHS willfully turned a blind eye and failed to consider the problem of provider departures and shortages, their serious disruption to the Title X program, and the resulting gaps in contraceptive care and other family planning services, multiplying harms for patients.

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105. The New Rule also introduces a limitation on who can provide certain Title X pregnancy counseling that is arbitrary and capricious. In Section 59.14(b)(1)(i), the New Rule specifies that what it calls "nondirective pregnancy counseling" can only be provided by physicians or Advanced Practice Providers ("APPs"), while at the same time the New Rule does not limit which Title X staff can provide the other pregnancy counseling, all directed toward patients' continuing their pregnancy to term, that is described and permitted in Section 59.14(b)(1)(ii)-(iv). 84 Fed. Reg. at 7789. HHS's rulemaking fails to explain or justify its new, too-narrow universe of Title X providers qualified to provide "nondirective pregnancy counseling" or to justify why Title X staff who do not qualify—by HHS's estimation—to provide that counseling under subpart (i) may nevertheless provide counseling about prenatal care or maintaining the health of the "unborn child" under subparts (ii)-(iv). *Id.*

106. This provision replaces one arbitrary distinction set out in the notice of proposed rulemaking (between physicians and all others) with another (between APPs and all others) to limit, in a different way, Title X pregnancy counseling to an overly narrow set of Title X providers. *See* 83 Fed. Reg. 25,502, 25,531 (June 1, 2018) ("NPRM"). In adopting this new "APPs" approach, HHS ignored comments that urged it to impose no limit on scope of practice separate from any state licensing requirements. *See, e.g.,* Association of State and Territorial Health Officials ("ASTHO") Comment Letter at 7 (July 31, 2018). ("Many state public health agencies regulate healthcare professions and their scope of practice. ASTHO believes that any healthcare provider permitted to provide this counseling

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should not be restricted, in any manner or form, from providing their scope of services."). HHS has not identified nor justified any need to allow only some subset of the trained Title X service providers qualified to provide pregnancy counseling to do so.

107. In addition, the specific line drawn by the definition of APPs is itself also arbitrary and capricious. This new APP category, which arose only in the final New Rule and was not contemplated by the NPRM, excludes without explanation or reason, for example, registered nurses with bachelor's degrees who have an advanced scope of practice under state licensing rules. Those registered nurses are treated by OPA itself for purposes of Title X clinical care reporting as within the same category of "expanded scope of practice" clinical service providers as those HHS here calls APPs.

108. The New Rule's Counseling Distortions also employ other terms inconsistently and leave important terms undefined or vague, creating additional uncertainty that has not been supported by reasoned decision-making and will further interfere with quality Title X care. For example, without proposing to do so in the NPRM, HHS now in the final New Rule replaces the phrase "medically indicated" with "medically necessary" in Section 59.5(b)(1). *See* 84 Fed. Reg. at 7788. The agency offers no definition for its use of "medically necessary" nor does it give any reason why this Title X regulation's use of "medically indicated" for decades should be now changed.

109. Likewise, although the New Rule asserts that a referral for "prenatal health care" is always "medically necessary" for all pregnant women, even those

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who are certain they will terminate the pregnancy, it erroneously fails to consider abortion medically necessary for those patients choosing that medical care option. *Id.* at 7788-89.

110. The New Rule further appears to preclude all medically indicated or medically necessary direct or indirect referral for abortion, short of an emergency situation. Referral "for abortion because of an emergency medical situation" is the only example that HHS identifies in the Supplementary Information as medically justified and not constituting referral for "abortion as a method of family planning," a phrase that the New Rule does not define. *Id.* at 7762.

111. These and other undefined and confusing restrictions on Title X pregnancy counseling—such as the limitation of any Section 59.14(b)(2) list to "comprehensive primary health care providers," which has changed without explanation from the NPRM's proposal of "comprehensive health service providers," *see* 83 Fed. Reg. at 25,531, and will diminish the ability to include any abortion providers on that list even more, and the New Rule's inconsistency in making new preconception versus postconception distinctions—make the Counseling Distortions arbitrary and capricious in numerous respects, in addition to their direct conflicts with the governing statutes. These aspects of the New Rule will tie the hands of Title X providers, interfere with proper care, and harm patients, without any reasoned justification.

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b. The New Rule's Unjustified Separation Requirements and Infrastructure Spending Limitations Interfere with the Feasibility and Operation of Title X Projects, Contrary to Congress's Intent

i. The Separation Requirements Are Contrary to Law and Impose Excessive Restrictions To Address a Nonexistent "Problem"

112. The New Rule imposes excessive, infeasible, and counterproductive "physical and financial" separation requirements without any showing of need for this change. *See* Sections 59.13-59.16; 84 Fed. Reg. at 7788-90 (the "Separation Requirements"). These new Separation Requirements erect unreasonable barriers to medical care, impede timely access to care, interfere with access to patients' full medical records, and restrict Title X pregnancy counseling regarding the full range of care options when a patient is pregnant—all contrary to Section 1554. The Separation Requirements, further, will push high-quality providers and experienced administrators from the Title X program, as explained below. They frustrate the operation of the Title X program and also reach outside it to limit funded entities' expression and association based on viewpoint, without any sufficient justification.

113. HHS adopted the Separation Requirements based on purported rationales of "potential comingling and confusion" or a "risk" of the "appearance and perception" of a misuse of Title X funds, 84 Fed. Reg. at 7764-65, but there is no evidence in the rulemaking record of the need for such drastic facilities, staff, and systems separation.

114. Both the text in Sections 59.13 through 59.16 and HHS's explanation of these new Separation Requirements sweep more expansively than even the aberrant separation rule promulgated in 1988, which never actually governed the

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Title X program. HHS has detailed knowledge about ongoing Title X program implementation, but nevertheless it does not justify its current rulemaking by pointing to any recent instances of purported misuse of funds contrary to Title X's Section 1008 (the limitation that Title X funding not be "used in programs where abortion is a method of family planning"), nor to any other facts that establish a need for the extreme and onerous Separation Requirements. Nor does HHS adequately consider and plausibly address those new requirements' program, health, and private and public fiscal costs. Based on this rulemaking record, the Separation Requirements are arbitrary and capricious agency action.

115. HHS regulations and Title X grants already require that a project's federal funds be used solely for Title X purposes, and not any others. Title X funds must be kept and spent separately from non-Title X monies or expenses.

116. In addition, Title X grant-making and HHS oversight ensures that the agency has approved how a grantee and its subrecipients will spend funds before their federal funding is drawn down, and then that funding is spent in accordance with the grant's HHS-approved budget and workplan. Title X funding, like other federal grants, comes with detailed grant-management requirements, including auditing and financial reporting to HHS, that effectively implement this fiscal accountability. Title X grantees, subrecipients, and service sites also undergo periodic program reviews by HHS and other on-site examinations.

117. In particular, pursuant to Section 1008 and current Title X regulations, Title X providers already ensure that no Title X funds are used for abortion. If an entity provides abortion and Title X care, its Title X finances are completely

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separate and federal funding (and the full Title X project budget) pays only Title X expenses. In addition, such Title X providers use "counseling and service protocols, intake and referral procedures, material review procedures," and other administrative means to keep their Title X program distinct from abortion care. 65 Fed. Reg. at 41,282. Shared facilities for both a Title X program and an abortion practice, including shared waiting rooms, records systems, and staff, however, are explicitly permitted by HHS at present and have been for decades. *Id.*

118. What the New Rule in Section 59.15 calls "physical and financial separation" goes beyond the current differentiation to impose an unnecessary and drastic new scheme. The New Rule's Section 59.15 requires that a "Title X project must be organized so that it is physically and financially separate" with "an objective integrity and independence from prohibited activities." 84 Fed. Reg. at 7789. The rule, however, does not identify any decipherable "objective" standard for those subject to it or that HHS will apply when assessing whether a Title X project has satisfied this requirement.

119. Under Section 59.15, participants in a Title X project can only engage in "prohibited activities," *without* Title X funds and outside that project, if the Secretary of HHS is satisfied those participants have imposed "physical" separation and sufficient "objective integrity." *Id.* The "prohibited activities" include not just abortion care, but also include any activities outside the Title X project that treat "abortion as a method of family planning" or that are described within Sections 59.14 and 59.16, including providing referrals for abortion,

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speeches, litigation, or paying dues to membership organizations that protect access to abortion. *See id.* at 7789-90.

120. The factors that Section 59.15 uses to describe "physical" separation span from the physical building—such as treatment, counseling, and waiting rooms, and entrances and exits—to workstations, phone numbers, websites, and electronic health record ("EHR") systems; to personnel; and finally, to signs and an absence of written materials "referencing" abortion. *Id.* at 7789.

121. HHS makes clear in the New Rule's Supplementary Information that there are "deal breakers"—certain stringent facility, staff, and system separation requirements that it will apply in enforcing Section 59.15's unclear and subjective standard—but neither Section 59.15 nor HHS's statements impose any limit on how far HHS can take "physical" separation. For example, HHS explains that separate staffing is not sufficient and that "two distinct services within a single colocated space," one a Title X project and the other including "prohibited activities," will not be approved. *Id.* at 7783. Further, HHS refers to "the requirement for separate electronic health records" and treats that as a must for any sufficient physical separation. *Id.* at 7763.

122. If these new physical, systems, and staff duplication requirements were ever attempted, they would harmfully remove Title X providers from central features of modern, integrated health care provision, to the detriment of patients. But it simply makes no sense to separate unitary medical records systems; dismantle shared online, email, or phone access points for health care systems; and end the part-time use of highly-trained clinical staff that provide care within an

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entity's multiple programs—either from the perspective of quality health care or financially. Nor has HHS shown any evidence that such destructive steps are needed in order to ensure compliance with Title X's existing prohibition against using Title X funds for abortion.

123. As HHS itself acknowledges in the New Rule, Title X projects are a "sequence of activities," per Section 59.2 (defining a Title X "program or project"). 84 Fed. Reg. at 7787. Title X projects are not physical places, nor are they standalone entities dedicated solely to Title X.

124. Non-profit administrative Title X grantees without their own service sites typically also administer other funding streams or engage in some other activities, especially education and advocacy, beyond their Title X project. Many Title X provider organizations and individual health center sites also offer health care in addition to Title X, which could be federally-funded primary care, women and infant care or teen pregnancy prevention, among many examples. Hospital-run or university-run clinics, federally-qualified health centers ("FQHCs"), and nurse-family partnership programs might co-locate with a Title X provider or be one, offering many different types of health care and education in the same space; with exactly the same or overlapping staff; and with integrated systems and administrative functions.

125. None of these arrangements means that Title X funding is subsidizing other types of care, including when a Title X project operates in the same location as abortion care or shares staff or operational systems with abortion care. The Title X project pays only Title X project expenses—and, as explained above, federal

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Title X funds make up only a part of the overall Title X project budget, because no Title X grant can cover 100% of that budget.

126. Against this backdrop, the New Rule's Separation Requirements will wreak havoc on Title X-funded entities of every type and at every level, from individual Title X-funded sites to central offices that administer a Title X grant for subrecipient providers. For example, a government health department whose sole Title X role is to administer a grant, from the department's single administrative office, would be required to divide that public office into two separate locations, with two separate staffs, in order to divorce its administration of a Title X project from other health department activities that might involve distributing non-Title X funds for, or undertaking, any prohibited abortion-related activities or education under Sections 59.14 and 59.16 of the New Rule. This makes no sense, and would, impossibly, require the public entity's receipt of Title X funds to dictate how a territory, state, or county health department operated overall.

127. Similarly, independent, non-profit health care providers would be forced by the New Rule to make irrational choices to create wholly duplicative stand-alone clinics and offices, with duplicative staffs and operational systems—steps they are not in the financial position to take—in order to quarantine their Title X project from any health care that might involve abortion referral, from any other activities that might assist women in obtaining abortions, and from any abortion-related advocacy or association.

128. As many current Title X participants, health care experts, and other commenters explained to HHS, mandating "physical" separation as required in the

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New Rule and its Supplementary Information is cost-prohibitive and unworkable. It will push current Title X participants, including but not limited to those that provide abortion care (beyond their Title X project), from the Title X program altogether and stand in the way of other qualified health care organizations joining the program in the future.

129. Ending the Title X care previously provided at those organizations' sites and reducing the organizations' funding, by the amount of the lost Title X grant funds, will significantly diminish low-income individuals' access to family planning care. With fewer points of access, and the loss of Title X's free or sliding-scale care, some patients will newly go without family planning care—and lose access to the most effective biomedical contraceptives, STD testing and treatment, and cancer screening. These new gaps in Title X care will increase individuals' risk of unintended pregnancy and leave important reproductive health issues untreated, undercutting the long-standing public health success of the Title X program. HHS's unsupported assertion that it "does not anticipate any loss of Title X providers that will exacerbate health inequalities or harm patient care" is contrary to the evidence in the rulemaking record, which strongly shows those harms will occur. 84 Fed. Reg. at 7766.

130. In addition, the New Rule's Separation Requirements restrict constitutionally protected expression, association, and advocacy undertaken without federal funds. The Separation Requirements are so expansive and so open to subjective enforcement by HHS that, if they ever take effect, they will chill and prevent Title X-funded entities from engaging in activities, with non-Title X funds,

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that might assist women to obtain abortions or "encourage, promote or advocate abortion," as interpreted by HHS—such as creating materials or writing a speech, participating in litigation, distributing non-Title X state grants, or paying dues to another entity. But the New Rule imposes no such restriction on activities to condemn or restrict women's access to legal, constitutionally-protected abortion care.

ii. The New Rule's Limits on Infrastructure Funding and Other Proper Title X Spending Are Also Contrary to Law and Arbitrary

131. Congress created Title X grants explicitly "to assist in the establishment and operation of" family planning projects, 42 U.S.C. § 300, and Title X grant support of infrastructure needs has played a critical part in the program's ongoing success. Title X grantees and subrecipients use Title X funding, for example, to hire and train staff, invest in technology, buy equipment, stock contraceptive supplies, pay rent and utility expenses, and so on.

132. The New Rule's Section 59.18(a), however, creates a new distinction between "infrastructure" and "direct implementation," and imposes ambiguous and unjustified new standards for the use of Title X funds. That section declares funds "shall only be used … in direct implementation of the funded project," and "shall not be used to build infrastructure for purposes prohibited with these funds." 84 Fed. Reg. at 7790. Grantees and subrecipients are left trying to parse, *inter alia*, what uses constitute "direct implementation" versus what falls outside that term, and what may be deemed to support "infrastructure for purposes prohibited with these funds." *Id.*

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133. Section 59.18(a) further requires that grantees must use "the majority of grant funds to provide direct services to clients," but does not provide any explanation of how to delineate "direct services" in a program that is entirely about serving clients. *Id*. The New Rule does not in any way explain what counts toward this new "majority of grant funds" requirement.

134. Moreover, under a part of the Title X regulations untouched by the New Rule, Title X projects are required to engage in educational and outreach activities to provide information about family planning, inform the community about the availability of Title X services, and promote continued participation in the Title X program. 42 C.F.R. § 59.5(b)(3). These are essential aspects of operating Title X projects, yet the Supplementary Information provided with the New Rule suggests that such direct educational and outreach services should not occur, or that at a minimum they would not count toward "direct services" under Section 59.18. 84 Fed. Reg. at 7773-74.

135. Section 59.18(a) unduly constrains the use of Title X grant funds for infrastructure, education and outreach, and other categories of spending used to "establish[] and operat[e]" Title X projects, contrary to the Title X statute and its purpose. 42 U.S.C. § 300. HHS engaged in unreasoned decision-making by imposing these vague and damaging restrictions when the record shows instead how important Title X grant funds used for these purposes have been to the success of the program. These Section 59.18(a) spending restrictions are arbitrary and capricious, and have not been plausibly supported or even clearly described in HHS's rulemaking process. The new infrastructure restrictions also unreasonably

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interfere with patient access to care and information in violation of Section 1554.

136. The New Rule's infrastructure spending limits and its Separation Requirements apparently together dictate that "Title X projects would not share any infrastructure with abortion-related activities." 84 Fed. Reg. at 7774. This extreme limitation, in particular, finds no support in Section 1008 and instead serves only to arbitrarily and unjustifiably restrict the operation of Title X projects.

137. The New Rule's Separation Requirements and infrastructure rules also fail to take into account the reliance interests created by the existing, long-standing Title X regulations, reliance that HHS has engendered over decades as it has worked closely with current Title X grantees to develop and equip their Title X sites to maximize the benefits of Title X long term.

138. Despite the rulemaking's emphasis on complete physical and infrastructure separation, and the extreme cost burdens that the New Rule would require Title X participating organizations to attempt to shoulder, HHS drastically underestimated the average dollar costs per Title X site and the number of sites and entities that would be affected by its new separation and infrastructure rules. It thus acted arbitrary and capriciously by failing to adequately consider costs in a cost-benefit analysis that, if done correctly, would have shown costs exponentially higher than HHS's estimates and that those costs vastly outweighed even HHS's hypothesized (but not established) purported benefits for the New Rule.

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c. The New Rule Includes Multiple Provisions to Change the Title X Provider Network in Unreasoned and Counterproductive Ways

139. HHS includes several other provisions in the New Rule that will trigger shifts in the types of provider service sites, subrecipient organizations, and grantees included in Title X projects. Each of these new provisions undermines the ability of the Title X program to continue to serve its central purposes and is arbitrary and capricious. Each will diminish the number of health centers providing specialized reproductive health in the Title X program—though these centers are favored by patients and offer especially high-quality family planning.

i. The Rule Blocks Title X Sites in Counties Without Other Care

140. The New Rule's Section 59.5(a)(12) imposes a counterproductive limitation on the location of Title X sites in relation to Title X providers' primary care referral relationships. Among the "requirements" that each Title X project "must" satisfy, the new Section 59.5(a)(12) requires that each Title X service site should have primary care available at the very same site or through "a robust referral linkage with primary health providers who are in close physical proximity to" the Title X site. 84 Fed. Reg. at 7787-88.

141. In many counties in this country a reproductive-health focused Title X site is the only health care of any kind available to low-income patients. There are no primary health care options "in close physical proximity." *Id.* at 7788.

142. This new Section 59.5(a)(12) requirement will have the perverse effect of blocking the establishment of any additional, reproductive-health focused family planning sites in these grossly medically underserved areas and standing in the way of the continued operation of such existing Title X sites, because they do

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not have a "robust referral linkage with primary health providers who are in close proximity." *Id.* The New Rule thereby diminishes the Title X network and forbids care in locations where there are *no* other health care options of any kind for the population Title X aims to serve.

143. Moreover, Section 59.5(a)(12) erects this new obstacle to the continuing effectiveness of the Title X network and the care it provides for the stated purpose of "[p]romoting holistic health and provid[ing] seamless care" beyond Title X services, including somehow, according to HHS, for people who may be pregnant but not yet know that. *Id.* at 7788. Title X providers already establish referral relationships and assist their patients in finding appropriate, accessible primary and other medical care outside Title X, even if it is necessary for patients to travel beyond close proximity. With this new "close proximity" requirement, however, HHS *diminishes* Title X's effectiveness in the name of purportedly advancing "health care *outside* of Title X services," *id.* at 7749 (emphasis added), not a permissible use of its Title X regulatory power. HHS acts beyond its Title X authority and has done so in a fashion that also is irrational and contrary to the evidence in the rulemaking record.

ii. The New Rule Harmfully Allows Single-Contraceptive-Method Sites and Methods That Are Not "Medically Approved" While at the Same Time Seeking Grantees and Subrecipients with Religious or Moral Objections to Core Title X Health Care

144. The New Rule explicitly seeks to open the Title X program to grantees and subrecipients that refuse to provide abortion counseling based on their "moral convictions" and further to ensure that "conscience concerns may [also] be

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taken into account when grantees or subrecipients determine which methods [of family planning] they will offer within their scope of services." 83 Fed. Reg. at 25,516, 25,526. Within this changed Title X program that would newly encourage moral objectors to certain core, long-standing Title X services to join its provider network, the New Rule emphasizes that a "participating entity" may "offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services." Section 59.5(a)(1); 84 Fed. Reg. at 7787. Combined, these changes are especially damaging to Title X's purpose and will unduly limit patients' access to the broad range of methods and services and full counseling information that Title X projects must offer, under the Title X statute, the Nondirective Mandate, and Section 1554. These provisions of the New Rule combine to violate those laws and are arbitrary and capricious.

145. HHS tries to justify the single-service or limited-service sites the New Rule's Section 59.5(a)(1) endorses by pointing to similar language in prior Title X regulations and by pointing to its desire to protect new Title X providers that might offer only a single or limited family planning method(s) "for reasons of conscience." *Id.* at 7741-43. The joining of those two purported justifications is telling: A rule that earlier may not have imposed significant harms—when all Title X grantees and subrecipients were committed to Title X's historical, comprehensive family planning care—has a much different and more damaging impact when coupled with the New Rule's goal of expanding the Title X network to grantees and subrecipients with objections to medical contraception and to full

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nondirective pregnancy counseling, including abortion referrals, which are core aspects of Title X care.

146. Many Title X projects cover an entire state. HHS has failed to engage in reasoned decision-making, ignored the impact on patients, acted contrary to Title X and Section 1554, and undermined the Title X program by adopting this permission to have single-method and limited-access sites within the context of this New Rule: It would allow, for example, single- and limited-method service sites to predominate in a state or in a large geographic swath of a service area, and requires only that such a project include some contraceptive care at one site and provide "a broad range of acceptable and effective family planning methods and services" only among different sites spread widely across its entire area. *Compare* 42 U.S.C. § 300(a) *with* Section 59.5(a)(1), 84 Fed. Reg. at 7787.

147. Contrary to HHS's assertion, patients are not "free … to select" from a broad range of methods and services if the broad range is not offered at the project site the patients visit. *Id.* at 7742. That is especially the case where, as under the New Rule, there is no requirement that the site inform patients about its limited scope or help them access methods and services that might be offered somewhere else in that Title X project, even if far away and offered only by another organization.

148. In addition, the New Rule's embrace of providers' moral and religious objections, and of single- and limited-method sites, is exacerbated by HHS's deletion of the existing "medically approved" requirement for Title X "services and methods." *Compare* 42 C.F.R. § 59.5(a)(1) *with* 84 Fed. Reg. at 7787. HHS

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attempts to justify that removal by claiming, "it is far from clear what that undefined phrase requires." 84 Fed. Reg. at 7740. HHS does not acknowledge that both the agency and Title X providers already must have an understanding of the meaning of medically approved, because that requirement is now and has long been enforced by the agency. HHS fails to rationally explain its rejection of the alternative of providing a definition for that term in the New Rule, rather than omitting it altogether, and its omission of "medically approved" is arbitrary.

149. As commenters warned, these changes invite entities to apply for Title X funding even if they only provide methods and services that are not evidence-based, that are contrary to the QFP, and that would deprive Title X patients of access to "acceptable and effective" methods of contraception or other care. The rulemaking record does not support HHS's assertion that its changes would, instead, improve client care. *Id*. at 7741.

iii. The Rule Adds a Vague, Impermissible Application-Eligibility Test, and Adopts New Application Review Criteria That Are Arbitrary and Undermine Merits-Based Title X Grant-Making

150. The New Rule also imposes a new, all-encompassing eligibility threshold for all Title X grant applications. HHS thereby vests itself with new, subjective authority to refuse even to consider certain applications (even if they are complete and meritorious). In addition, the New Rule adopts changed application review criteria that interfere with the effectiveness of the merits-based, objective review that HHS must provide, under separate regulations, to competitive grant applicants and would give some Title X applicants an unjustified, arbitrary advantage—for example, per Section 59.7(c)(2), if they show a "broad" array of

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"diverse subrecipients," including those that are "nontraditional" provider organizations within Title X. 84 Fed. Reg. at 7788; *see id.* at 7754.

151. Again, as explained further below, these changes empower HHS to push high-quality Title X family planning providers—that also offer abortions (without Title X funds) or are committed to including abortion referrals, upon patient request, in nondirective pregnancy counseling—out of the Title X program based on HHS's hostility to such providers. At the same time, they empower HHS to give proposed projects with more "nontraditional" and "diverse" entities, including religious objectors opposed to women's access to the full range of reproductive health care, an arbitrary advantage in obtaining Title X funding. The New Rule adopts this substantive restructuring of Title X grant-making contrary to the Title X statute, its purpose, and without reasoned rulemaking, including because it violates HHS's own general grant-making rules.

152. Section 59.7(b) requires each applicant to attempt to satisfy the new eligibility threshold of "clearly address[ing]" and providing a description of its "plans for affirmative compliance" with every single aspect of the lengthy New Rule. 84 Fed. Reg. at 7788. HHS then is empowered to make the subjective judgment as to whether the applicant has sufficiently complied with these vague standards: whether it has been "clear[]" enough, and sufficiently described thorough enough "plans for affirmative compliance" with all of the regulations, including the vague and subjective separation requirements and infrastructure spending limitations, among others, to have its application even considered. *Id.*

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153. With this new Section 59.7(b), HHS can deem an application "ineligible for funding" and block it from proceeding to the mandatory, objective application review process for competitive federal grants that applies to Title X, *see* 45 C.F.R. Part 75, before that review process even begins. 84 Fed. Reg. at 7788. If this happens, the New Rule provides no procedure by which an excluded applicant could contest HHS's unilateral determination.

154. By contrast, HHS's Grants Policy Statement and general competitive grant-making regulations emphasize that eligibility (or "go-no-go") requirements in federal grant-making should be objective and specifically stated for prospective applicants. HHS has provided no reasoned explanation for inserting in the Title X context such a burdensome, unbounded descriptive hurdle for applicants and opportunity for HHS unilaterally to weed out applicants based on this unclear threshold requirement. Indeed, the other uncertain standards within the other sections of the New Rule compound Section 59.7(b)'s uncertainty and HHS's unbridled discretion. Section 59.7(b)'s subjective eligibility standard is not transparent or objective; instead it would allow HHS to eliminate applicants based on HHS's political or ideological objection to those who provide or support abortion, or based on any number of arbitrary and unstated distinctions regarding what is a "clear[]" and "affirmative" enough plan for compliance with the underlying vague standards in other new Title X regulations, without any recourse for the applicant.

155. Moreover, this new threshold requirement will cause current grantees and new applicants to interpret all sections of the New Rule as stringently as they

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might apply, resolving any uncertainty in favor of restriction. That is the only way to minimize the risk of HHS deeming their applications to be insufficiently clear or affirmative enough in planned compliance with all aspects of the New Rule, and to increase the chance that their applications will at least be considered.

156. Grant applicants, for example, will have to err on the side of (i) forbidding any expressive or other activities that might tangentially relate to access to abortion, including but not limited to abortion care itself, by the grantee and all subrecipients and on their physical premises, (ii) prohibiting patient referrals to any health care, social service, or other organization that might support access to abortion, and (iii) in other ways imposing potentially excessive separation, infrastructure spending, referral relationship, medical record-keeping, and similar New Rule limitations on the grantee's own operations and on all subrecipients whose work will be included in the grant proposal (and eventual Title X project, which must conform to the application)—all in order to try to clear this Section 59.7(b) eligibility test.

157. In addition, the New Rule abandons the seven application review criteria that have governed the objective review of Title X applications since the program's inception. *See* 42 C.F.R. § 59.7. In their stead, the New Rule establishes four convoluted criteria in Section 59.7 that will make the objective review of applications by merits review panels more difficult, and that introduce arbitrary distinctions and different standards for different types of applicants.

158. For example, the second criterion includes an applicant's "ability to procure a broad range of diverse subrecipients, as applicable," Section 59.7(c)(2),

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84 Fed. Reg. at 7788, but HHS states that this will not apply to some applicants, "such as community health centers," that propose providing all the Title X services through their own sites, rather than using grant subrecipients, *id.* at 7754. HHS leaves unclear how applicants subject to this "diverse" criterion and those not subject to it might fairly compete against each other, and how merits review panels can fairly apply it.

159. In addition, giving an advantage to applicants if they propose "diverse" subrecipients or "non-traditional" provider entities does not serve the purpose of the Title X program. Indeed, there is nothing in the rulemaking record that supports HHS's conclusion that this is an important or beneficial objective. Contrary to HHS's conflation, the nature of the provider organization does not determine whether it is advancing "new ways to better provide service to patients." 84 Fed. Reg. at 7754. Instead, this new criterion disadvantages, for no reason other than provider identity, very effective Title X projects that provide the most advanced and effective care, but have more uniform and/or more experienced Title X providers. This provider-diversity advantage is not consistent with Congress's directives in Title X, including 42 U.S.C. § 300(b), and is arbitrary and capricious.

160. Similarly, Congress specifically instructed HHS to take into account "the number of patients to be served" in making Title X grant decisions. 42 U.S.C. § 300(b). The New Rule instead combines that criterion with a consideration that in some instances may cut in the other direction—the degree to which the application targets "areas that are more sparsely populated"—and does not resolve how those two different considerations are to be treated by review panels or

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presented by applicants in the face of this single, combined criterion. Section 59.7(c)(3); 84 Fed. Reg. at 7788.

161. Nor does HHS have any evidentiary support for its bare assertions that the new selection criteria will "better ensur[e] the selection of quality applicants" or more widely distribute Title X care, which is today prevalent in areas where no other safety net care exists, as described above. *Id.* at 7718. To the contrary, the rulemaking record shows that these new selection criteria are less clear and not designed in a way that will objectively differentiate the best applications. In adopting Section 59.7, the New Rule engages in unreasoned decision-making, undermining the Title X program in order to prioritize providers who simply are unlike those who have been its backbone.

d. The New Rule's "Low-Income Family" Definition Adds Yet More Arbitrary and Capricious Distinctions

i. The New Rule Subjects Minors Seeking Confidential, Free Services Based on Their Own Resources to an Unequal, More Stringent Requirement of Encouraging Family Participation

162. Title X explicitly requires that its services be provided to adolescents. 42 U.S.C. § 300(a). This access has long been protected by the current Title X definition of "low-income family," which requires that all "unemancipated minors who wish to receive services on a confidential basis must be considered [for "low income" free services] on the basis of their own resources" as individuals and not based on their family's resources. 42 C.F.R. § 59.2.

163. Now, however, the New Rule tells Title X projects that for minors seeking to qualify for free care based on their own income, the provider must

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encourage involvement of the minor's parents or guardian, regardless of the minor's family circumstances. The only exception is if the provider suspects "child abuse or incest," has "reported the situation to relevant" state or local authorities, and documents that reporting in the medical record instead. Section 59.2 (defining, in part (a), "low-income family"); 84 Fed. Reg. at 7787.

164. The New Rule, however, sets a less exacting requirement for encouraging family involvement if the minor can self-pay or use insurance for services. In Section 59.5(a)(14), it gives providers the option of documenting any "specific reason why … family participation was not encouraged," and allows a broader factual context and the clinician's professional judgment to operate. *Id.* at 7788. As commenters to HHS explained, this better accommodates circumstances that make pushing a minor to involve parents or other family members dangerous or otherwise harmful for the minor patient. *See, e.g.*, Community Health Network Comment Letter at 3-4 (Aug. 1, 2018) (noting risk to some minors of being kicked out of their homes or suffering newly-initiated violence *if* their sexual health care were disclosed to family members); NFPRHA Comment Letter at 22. Yet the much larger group of minors who will seek free services must be encouraged to involve their family except in the very narrow circumstances of already-reported child abuse or incest.

165. HHS's decision to uniquely circumscribe health care providers' discretion and require them to encourage all minors who seek free services to involve their parents, regardless of the circumstances, unless they are the subject of an abuse report, is unexplained, impedes access, will harm minors, and interferes

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with the provider-patient relationship. Any conceivable justification for this new, severe limit on clinicians' discretion is undermined by HHS's own determination elsewhere in the New Rule to afford providers more discretion when dealing with minors who are able to self-pay. The New Rule's different treatment and record-keeping requirements for different minors, based upon their ability to pay, has no plausible basis and is contrary to Title X's prioritization of low-income patients.

ii. The New Rule Uniquely Empowers Projects to Offset Income By the Cost of Service for Those Seeking Contraceptives Because of Their Employer's Conscience Objections, But Not for Others

166. The New Rule's definition of "low-income family" also introduces a second arbitrary, unexplained, and unjustified distinction. "For the purpose of considering payment for contraceptive services only," that definition describes in part (b) a special process for assessing income eligibility for women who have "health insurance through an employer that does not provide the contraceptive services sought by the woman because the employer has a" religious or moral objection to that coverage. 84 Fed. Reg. at 7787. For those women, part (b) allows Title X projects to "consider her annual income as being reduced by the total annual out-of-pocket costs of contraceptive services she uses or seeks to use. The project director may determine those costs, or estimate them at $600." *Id.*

167. In all other instances, however, a Title X patient's actual annual income is considered for purposes of assessing whether the patient is eligible for free care or care on a reduced-cost scale based on the patient's income. The New Rule does not adjust other patients' incomes, for purposes of comparing those against federal poverty levels, by the annual cost of family planning services they

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"use[] or seek[] to use." *Id.* at 7737, 7787. They cannot take advantage of an automatic $600 income adjustment, or any other income adjustment, based on the type of Title X services they seek.

168. This unique offset that the New Rule creates for Title X contraceptive patients whose employers have a religious objection to providing insurance coverage for contraceptives was not set out in the proposed rule, is unexplained and unjustified, and is yet another arbitrary and capricious part of this rulemaking.

e. The New Rule Will Trigger Severe Disruption in the Title X Provider Network, Leaving Many Patients Without Title X Care

169. On the New Rule's 60-day effective date, it immediately repeals the current regulation requiring nondirective options counseling, and its ban on pregnancy counseling that includes abortion referral kicks in. 84 Fed. Reg. at 7791 (compliance date for Section 59.5(a)(5), 59.19(d)). All of the approximately 90 Title X grantees, all of their roughly 1000 subrecipients, and all of the individual clinicians at their almost 4000 service sites then face a Hobson's Choice.

170. The New Rule forces each current participant in Title X to go down one of two harmful paths: (1) stay in the Title X program out of a commitment to low-income individuals' access to family planning care, despite the compromised care newly mandated by the rule, especially for pregnant patients, or (2) leave Title X because the New Rule requires providers to deny referral requests from pregnant patients seeking abortion care, in a departure from ethics principles and standards of care. As a result of the New Rule's two bad options, many experienced providers that have for decades formed the backbone of this successful program

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and that serve at least 40% of its patients, will leave Title X, thereby dramatically shrinking the Title X network, reducing patients' access to contraceptives and other care, and adding to the New Rule's cascading harms.

171. At the 120-day effective date, any remaining Title X providers' dilemma will be further compounded by the new requirement of mandatory, coercive prenatal referrals for pregnant patients, even those who will terminate the pregnancy, and the new requirement that any "nondirective pregnancy counseling," under HHS's misuse of that term, must also include not only the mandatory prenatal referral but discussion of options other than abortion, again regardless of the patient's wishes and plans. The New Rule does not explain why some of its Counseling Distortions are effective at 60 days and some are effective at 120 days, but both sets thrust Title X providers onto one of two damaging paths and will drive providers from the program.

172. Likewise, all levels of the Title X network will be faced with the onerous and infeasible new Separation Requirements regarding their facilities, staff, and systems, the new infrastructure funding restrictions, and other new compliance mandates, that will similarly put them between a rock and a hard place. The New Rule's requirements will (1) push providers from the program because they do not have the resources or any rational means to comply, or (2) require them to take extraordinary steps in an attempt to comply, and to censor even their non-Title X activity of references to or any activities supporting access to abortion. Furthermore, the physical Separation Requirements are so onerous that any entity attempting to comply would have to begin taking steps immediately in order to

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achieve compliance by the time those requirements take effect in one year.

173. Faced with the immediate need to contend with the New Rule's imposition of these uniformly bad choices and unworkable options, many grantees, subrecipients and individual clinical providers will decide to leave the network at once. Others will be forced out soon after under the excessive separation and other compliance burdens, for example, or the new subjective eligibility threshold or grant-making criteria. Still others will decide and be able to remain within the Title X program, at least for the short term, and will have to suffer the consequences of the New Rule for their project, their professional standards, and their patients, for the sake of continuing to offer some Title X care for low-income individuals and facilitating access to this vital safety net program.

174. For the grantees that the New Rule immediately pushes from the Title X network, *all* Title X services in their geographic service area will abruptly end and low-income individuals will suddenly find themselves without their Title X providers. To try to fill those gaps, HHS would have to re-compete the grants for those service areas and attempt to find replacement grantees.

175. Under normal circumstances, initiating and administering a Title X services grant competition takes at least five to six months. Under this situation triggered by the sudden departure of numerous Title X grantees mid-grant, potential replacement grantees in many jurisdictions are likely to be especially difficult to find and efforts to recruit any applicants may alone take months. Therefore, this wholesale gap in Title X service for the grantee service areas suddenly without grantees will likely last much longer than five to six months—

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even if replacement grantees to fill in at least some parts of a service area could eventually be found through a new FOA and grant-making process. If new grantees are selected and funded, then those grantees will take more months to get their new Title X projects up and running.

176. In places where a current grantee decides initially to stay in the Title X program, and to attempt to make the counterproductive changes that the New Rule requires, the New Rule will also force all of the subrecipients and individual clinicians in that grantee's network to choose between the New Rule's bad options. Many subrecipients and clinicians will decide to leave the program as soon as the New Rule takes effect, pushed out by its new constraints; while others will try to maintain Title X's purpose of expanding access to care, despite the New Rule's harms and impermissible compromises to Title X's quality of care.

177. All of the departures at the subrecipient and clinician level will create additional, serious gaps in the Title X network, and will likewise be difficult to fill, because the New Rule erects ethical and practical barriers to entry for other health care entities and medical professionals.

178. Moreover, for all of the organizations, health centers, and clinicians that the New Rule suddenly pushes, mid-grant, from Title X funding and the Title X network, budgets will abruptly have significant gaps from the lost Title X funds. They will suffer an immediate inability to offer the same number of patients the same range of free and accessible family planning care. The organizations newly without Title X funding will have to cut back on staff, eliminate offerings, and/or shutter health centers. Some organizations will close.

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179. The New Rule not only will trigger this significant disruption in the Title X network and in Title X patient care at its 60-day initial compliance date, but will trigger future cycles of disruption at day 120 and beyond, as HHS (i) enforces more of the New Rule and its excessive, unjustified restrictions, (ii) wields the new, subjective eligibility threshold for grant application review, and (iii) makes future competitive awards with its newly muddied criteria, to the disadvantage of traditional Title X applicants.

180. To the extent that HHS could eventually find some new grantees and providers to fill these large gaps, which HHS has failed to establish, those new participants in Title X would by definition be willing to submit to the ethical and other compromises to professional standards that the New Rule now requires. They would be selected according to HHS's new aims, which run contrary to the purpose of Title X, to the QFP, and to providing low-income individuals with access to the same kind of patient-driven, quality clinical family planning care that more affluent individuals enjoy.

f. In Issuing the New Rule, HHS Failed to Consider Its Negative Impact on Individual and Public Health and Failed to Answer the Overwhelming Opposition from Medical and Public Health Experts

181. Despite all of these imminent disruptions to the Title X network and harmful constraints on the counseling and care that can remain in the program, HHS's NPRM did not mention any potential harms to patient health, to the public health, or in increased public health costs. In finalizing the New Rule, HHS continued to irrationally push aside such central concerns in the Title X context, despite compelling evidence in numerous sets of comments by experts that the

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New Rule's negative health and welfare effects will be substantial.

182. The leading medical groups were all in accord that the New Rule should be withdrawn completely because of its negative effects on patients' health and its interference with appropriate care. ACOG "urge[d] HHS to immediately withdraw the Proposed Rule" because it "would interfere with the patient-physician relationship, exacerbate disparities for low-income and minority women, men, and adolescents, and harm patient health." ACOG Comment Letter at 15. The American Academy of Pediatrics ("AAP") and the Society for Adolescent Health and Medicine also "urge[d] HHS to immediately withdraw the Proposed Rule." AAP Comment Letter at 11 (Aug. 1, 2018). The AMA "strongly oppose[d] this Proposed Rule" because it was "very concerned that the proposed changes, if implemented, 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." AMA Comment Letter at 1. The association of nurses likewise "strongly oppose[d] the[] proposed changes to the Title X program and urge[d] rescission of the proposed rules." AAN Comment Letter at 2.

183. Expert commenters further explained that the harms would extend widely, endangering public health and imposing great costs on government, for the excess medical costs that could have been avoided through Title X services. The American Public Health Association ("APHA") "strongly urged [HHS] not to finalize the proposed rule," noting, *inter alia*, that the proposed rule "radically underestimates the likely costs it will impose on patients, providers, and society,"

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and "would undermine Title X's goals of providing comprehensive reproductive health services to people with low incomes" and "exacerbate existing health disparities." APHA Comment Letter at 1, 7 (Aug 1, 2018).

184. HHS irrationally ignored the massive weight of expert medical and public health opposition, and responded to those commenters' evidence with conclusory and implausible assertions. HHS also ignored the New Rule's conflict with its own national standards for family planning care, never once contending with its departures from the QFP or justifying its inconsistency with HHS's own quality care principles, which many commenters raised.

185. The New Rule radically remakes a public health program Congress designed to give those with the fewest economic resources access to quality, voluntary care. But at every turn in this rulemaking, HHS ignores the injuries to Title X patients and irrationally states an unsubstantiated belief that the New Rule's changes will lead to a "better" program. 84 Fed. Reg. at 7775.

186. By prioritizing the religious or moral views of hypothetical, prospective Title X grant applicants, allowing single-method and limited-method sites, and abandoning uniform access to real nondirective options counseling, including referrals to abortion upon request, the New Rule's remade Title X program will not only soon have huge geographic gaps, where former providers have been forced to exit the Title X network, but its treatment of patients will also vary in crucial respects across the remaining network despite Title X's promise of delivering quality care to all.

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187. If patients are able to access a Title X site under this new scheme, they will not know when they walk through the door what quality of care they will receive. The nature of that care is now left up to individual providers, rather than ensuring all Title X providers follow national standards of care that require responsiveness to patients' stated needs and that allow patients' own values to control their decision-making. If Title X patients have access only to a site that provides prenatal care and adoption options, or only a few contraceptive choices, their care is especially compromised—and they have nowhere else to turn.

188. Indeed, not only did the agency fail to consider the massive harms created by departing Title X sites and clinicians, but it also failed to address the additional harms created as remaining sites fail to even inform patients that they are receiving incomplete care. As the National Association of Social Workers ("AASW") emphasized, the "proposed rule contemplates that some providers would not provide this counseling for asserted religious or moral reasons, but it does not contain any requirement that those providers advise patients of their refusal. Therefore, patients will not even know if they are getting complete information." AASW Comment Letter at 3 (July 26, 2018). And the Federal AIDS Policy Partnership stated that the proposed rule "does not address whether clients will be informed, at the very least, that they are not receiving complete information because their providers are bound by religious or moral restrictions." Federal AIDS Policy Partnership Comment Letter at 4 (Aug. 1, 2018). "Therefore, clients are neither truly able to provide informed consent to Title X providers concerning their health care options and treatments, nor are they even aware of

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whether they are receiving complete information in order to know to [attempt to] seek care elsewhere." *Id.*

189. In the absence of any evidence that new, alternative Title X applicants along the lines that HHS seeks are available, much less available in such numbers and in such locations that they might replace those ousted, HHS suggests that the New Rule is required by federal law to make space for entities that hold a moral or religious objection to certain aspects of Title X care. But the federal provisions that HHS invokes—the Church, Weldon and Coates-Snowe Amendments—do not require, authorize, or justify the New Rule.

190. When HHS's rulemaking purports to offer justifications for the New Rule's changes, it resorts to conclusory, irrational, and unsupported statements, and refers to aims that fall outside the scope of Title X. The New Rule not only contradicts Congress's demands in Title X and the annual appropriations laws, and the specific substantive limits on HHS rulemaking enumerated in Section 1554 of the PPACA, but also exceeds HHS's authority, gives inadequate weight to central considerations for the Title X program, and rests on assertions that conflict with the record before the agency. The New Rule is an implausible exercise of HHS's proper prerogatives. It is instead an exercise in punishing those who would continue to offer the full array of family planning care and rewarding others, who based on conscience, would not—all to the detriment of Title X's purpose and its patients.

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(2) The Harms The New Rule Imposes on Plaintiffs and Their Patients

191. Through all the means described above, the New Rule injures the Plaintiff entities (including NFPRHA's grantee and subrecipient members), Plaintiffs' Title X clinicians and the named Plaintiff clinicians, and Plaintiffs' patients by causing each of these irreparable harms, among others:

- *Substandard pregnancy counseling, contrary to clinical and ethical standards.* Such counseling will be mandatory and will directly harm the clinicians forced to provide unwanted prenatal referrals and to refuse their patients' requests for information about or referrals for abortion. Their patients will suffer even more, as they are denied the Title X care they need and seek.

- *Loss of Title X service sites and individual clinicians.* Through all the new limitations described above, the New Rule will cause significant numbers of grantees, subrecipients, and individual clinicians to leave the Title X program, immediately reducing the range and capacity of Title X care, hampering the provision of health care for Plaintiff organizations and hurting Plaintiffs' patients who will have greatly reduced, if any, access to Title X services.

- *Harm to patient trust of medical professionals and to entities' and clinicians' reputations.* Under the Hobson's Choice of the New Rule, Plaintiff organizations' and clinicians' reputations will be harmed. In addition, under either path the New Rule forces them down, the New Rule will breed distrust between health care providers and their patients: Plaintiffs'

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patients will either experience disappearing health centers or reduced hours from providers they sought to rely upon or demeaning, involuntary services and unresponsiveness to requests, imposed on the clinician-patient relationship by the New Rule.

- *Loss of grantees' and subrecipients' role in Title X and their grant funds, including mid-way through Title X grants.* The Plaintiff organizations are dedicated to Title X's purpose, have developed deep expertise, and very much want to maintain Title X's service to and benefits for patients. But the New Rule will cause many Plaintiff organizations to have to relinquish their roles in this program, lose their essential funding, and lose institutional and staff knowledge about the program and its requirements. In addition to directly reducing the scope of the Title X network, any effort by the newly excluded providers to continue care will lack the federal funding necessary to assure that low-income patients will obtain free or reduced-cost care from them.

- *Harm to grantees' and subrecipients' governmental and non-profit service missions.* The Plaintiff governmental entities and non-profit organizations each exist to serve the public interest through safety net health care. The New Rule inevitably harms their missions. Losing their roles in Title X and losing the accompanying funding will harm their service missions, as will the other option too—fighting to stay in the program and continuing with care but having to provide substandard care.

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- *Unjustified constraints on Plaintiff entities' and clinicians' First Amendment activity both inside and outside Title X projects*, including with non-federal funds, such as the required removal of hard and electronic materials, new limits on membership in associations and educational activities, and other forbidden expression based on viewpoint, as a condition of entities' and clinicians' participation in Title X.

- *Harm to the health of patients and their families.* By diminishing access to family planning and referral care through all the mechanisms already described, the New Rule makes Title X's contraceptive care and other important health services less available and puts Plaintiffs' patients at greater risk of unintended pregnancies and numerous other harms to their health, including untreated STDs, HIV, and cervical cancer, as well as jeopardizing the health of their families.

192. The New Rule will, tragically, set back the many public health benefits that Title X has provided for almost five decades. Health harms and additional unintended pregnancies will not only cause patients, their families, and their communities personal suffering, but will create unnecessary and high new costs for other publicly-funded medical and social service programs.

193. In order to prevent these harms from unfolding and to avoid devastating damage to Plaintiffs, the Title X program across the country, and the millions of low-income patients who depend on the program for critical care, the New Rule should be enjoined before its 60-day effective date and permanently set aside in full.

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V. CLAIMS FOR RELIEF

Count One
Violation of Section 706 of the Administrative Procedure Act
Contrary to Law

194. Plaintiffs incorporate by reference the allegations of the preceding paragraphs.

195. A final agency regulation that is contrary to a federal law or Congress's legislative purpose in establishing law is not valid.

196. The New Rule as a whole and in its interrelated parts, including each one of Sections 59.2, 59.5, 59.7, 59.13 through 59.16, and 59.18, is contrary to Title X, Congress's Nondirective Mandate, and Section 1554 of the PPACA.

197. The New Rule should be held unlawful and set aside under the APA, 5 U.S.C. § 706(2)(A), (C).

Count Two
Violation of Section 706 of the Administrative Procedure Act
In Excess of Statutory Authority or Limitations

198. Plaintiffs incorporate by reference the allegations of the preceding paragraphs.

199. A final agency regulation that is in excess of the agency's rulemaking authority or statutory limitations on that authority is not valid.

200. The New Rule, as a whole and in its interrelated parts, including each one of Sections 59.2, 59.5, 59.7, 59.13 through 59.16, and 59.18, is in excess of HHS's rulemaking authority and limitations on that authority, including in Title X, Congress's Nondirective Mandate, and Section 1554 of the PPACA.

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201. The New Rule should be held unlawful and set aside under the APA, 5 U.S.C. § 706(2)(C).

Count Three
Violation of Section 706 of the Administrative Procedure Act
Arbitrary, Capricious or Abuse of Discretion

202. The Plaintiffs incorporate by reference the allegations of the preceding paragraphs.

203. A final agency regulation that is arbitrary, capricious, or an abuse of discretion is not valid.

204. HHS' process of rulemaking and arriving at the final New Rule was arbitrary, capricious and an abuse of discretion; likewise, the substantive contents of the New Rule are arbitrary, capricious and an abuse of discretion.

205. In addition, HHS does not in the New Rule reasonably exercise its administrative role in implementing Title X.

206. For each and all the reasons alleged above, the New Rule, as a whole and in its interrelated parts, including each one of Sections 59.2, 59.5, 59.7, 59.13 through 59.16, and 59.18, is arbitrary, capricious, and an abuse of HHS's discretion.

207. The New Rule should be held unlawful and set aside under the APA, 5 U.S.C. § 706(2)(A), (C), (D).

Count Four
Violation of Sections 553 and 706 of the Administrative Procedure Act
Without Procedure Required by Law

208. The Plaintiffs incorporate by reference the allegations of the preceding paragraphs.

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209. The New Rule is a final substantive and legislative regulation.

210. Such regulations adopted without the notice-and-comment procedure required by Section 553 of the APA are not valid.

211. HHS has expressly waived any exemption from Section 553's notice-and-comment rulemaking requirements pursuant to 5 U.S.C. § 553(a)(2).

212. HHS adopted the New Rule without following the process required for notice-and-comment rulemaking.

213. The New Rule, especially Sections 59.2, 59.5, and 59.14, is not a logical outgrowth of the NPRM.

214. The New Rule should be held unlawful and set aside under the APA, 5 U.S.C. §§ 553, 706(2)(D).

Count Five
Unconstitutional Conditions in Violation of the First and Fifth Amendments Of the Constitution and the APA

215. The Plaintiffs incorporate by reference the allegations of the preceding paragraphs.

216. The New Rule imposes unconstitutional conditions on the entities and medical professionals, including both physicians and non-physician clinicians, along with those entities' other staff, who are or who in the future apply to be funded through federal Title X funds to care for patients within or operate Title X projects.

217. The New Rule interferes with clinician-patient communication about medical care and medical information both within Title X projects and outside those projects, including with non-Title X funds. The New Rule interferes with

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Title X entities' educational activities, advocacy, and dissemination of factual information about abortion both within and outside their Title X project. The New Rule also interferes with clinicians and entities' organizational relationships with dues-paying organizations, professional societies, community resources, and other associations within and beyond their work in Title X projects.

218. The New Rule imposes its restrictions on expression and association—including its physical, staff, and electronic-systems separation requirements and its information, membership, and advocacy limitations—in a content-based and viewpoint-discriminatory manner.

219. Title X funding recipients and grant applicants must choose between Title X funding and constitutionally protected expression and association outside the Title X program.

220. The New Rule's excessive restrictions also cause Title X funding recipients to have to choose between their role in the Title X program and providing abortions wholly outside that program, interfering with their ability to offer that medical care and thus harming patients who seek abortions.

221. To the extent that abortion care remains available through some referral providers, the New Rule also causes Title X-funded entities and clinicians, both within and outside their Title X projects, to have to delay and impede their patients' access to abortion services by denying them referrals.

222. By interfering with and punishing constitutionally protected expression, association, and abortion care as a condition of entities and clinicians

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receiving Title X funds, the New Rule violates the First and Fifth Amendments to the U.S. Constitution.

223. The New Rule should be held unlawful and set aside under the APA, 5 U.S.C. § 706(2)(B).

Count Six
Violation of the First and Fifth Amendments—Vagueness

224. The Plaintiffs incorporate by reference the allegations of the preceding paragraphs.

225. Under the New Rule, grantees and subrecipients must proactively ensure compliance with the New Rule in order to continue to receive Title X funds already awarded to them for their current grant period and to be eligible to continue their Title X roles and receive funding in future periods.

226. Central standards for the New Rule's requirements are vague, subjective, and otherwise uncertain, and therefore give the entities regulated by them insufficient guidance and invite inconsistent or biased enforcement by HHS. These include Sections 59.5, 59.7, 59.13 through 59.16, 59.17, 59.18, and 59.19.

227. Because current Title X grantees and subrecipients cannot receive ongoing funding under their current grants or be eligible to apply for future competitive funding unless they fully comply with these uncertain standards, the vagueness of the New Rule will cause them to self-censor and attempt to strip their Title X projects and the organizations in those projects—including their activities undertaken outside the Title X program—of any speech, association, or conduct

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that could conceivably be seen by HHS as running afoul of these ambiguous provisions.

228. By subjecting organizations and clinicians currently funded by Title X to unduly vague standards in order to continue to receive funds under already-awarded grants, and establishing eligibility for the current Title X grantees' future funding on vague and subjective grounds, the New Rule violates the First and Fifth Amendments to the U.S. Constitution.

229. The New Rule should be held unlawful and set aside under the APA, 5 U.S.C. § 706(2)(B).

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the Court to:

A) Issue a preliminary injunction against any use of the New Rule while this matter is pending;

B) Declare the New Rule unlawful and vacate the rule in full;

C) Award permanent injunctive relief;

D) Require no bond for the preliminary or permanent injunction;

E) Award Plaintiffs their costs and attorney's fees in bringing this action pursuant to 28 U.S.C. § 2412; and

F) Grant such other or further relief as this Court may deem just and proper.

DATED: March 7, 2019 By: s/ Emily Chiang

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