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

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, et al.,

Defendants.

NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION, et al.,

Plaintiffs,

v.

ALEX M. AZAR II, et al.,

Defendants.

No. 1:19-cv-03040-SAB

DECLARATION OF CLARE M. COLEMAN IN SUPPORT OF NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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

1. I am the President and CEO of the National Family Planning & Reproductive Health Association ("NFPRHA"), a Plaintiff in this action. I submit this declaration in support of Plaintiffs' motion for a preliminary injunction to preserve the *status quo* during the pendency of this case. A preliminary injunction would allow the Title X program to continue to provide quality family planning care to low-income patients as it has for decades, and prevent Defendants' new regulations (the "New Rule") from disrupting and undermining that critical health care program.

2. I submit this declaration to provide information about NFPRHA's membership, on whose behalf it sues. I also provide background information about how the Title X program works and its history, which is important context for understanding and assessing the current dispute. Finally, I set forth facts showing the irreparable harms that will ensue if the New Rule is allowed to take effect. These harms will affect not only Plaintiffs—including their clinicians and their patients—but also the general public health across the country.

3. As explained below, the New Rule would immediately constrain Title X care and reduce the Title X network of dedicated, effective health care providers, diminishing low-income patients' access to family planning services. In order for providers to continue in the program, the New Rule would force them to turn away

from compliance with HHS's own national clinical standards and to become coercive, rather than fully voluntary and nondirective, in their pregnancy counseling. At the same time, the New Rule affirmatively seeks new providers that object to core aspects of Title X care, including making the full range of FDA-approved contraceptives available to patients. The New Rule conflicts with Title X's central principles. It would harm the missions of NFPRHA and of its dedicated members—who now anchor the Title X program as grantees and grant sub-recipients across the country—and deprive patients with limited economic resources of the information, options, and health care they deserve.

NFPRHA and Its Membership

4. NFPRHA is a national, non-profit membership association that advances and elevates the importance of family planning in the nation's health care system and promotes and supports the work of family planning providers and administrators, especially those in the safety net (i.e., those providing publicly funded care). NFPRHA envisions a nation where all people can access high-quality, client-centered, affordable, and comprehensive family planning and sexual and reproductive health care from providers of their choice.

5. NFPRHA represents more than 850 health care organizations in all 50 states, the District of Columbia, and the U.S. territories, and also includes in its membership individual professionals with ties to family planning care. NFPRHA's

organizational members include state, county, and local health departments; private non-profit family planning organizations (including Planned Parenthood affiliates and many others); family planning councils; hospital-based health practices; and federally qualified health centers ("FQHCs").

6. NFPRHA's members include current Title X grantees in 48 states and two territories. And when grant sub-recipients (which in a few instances are sub-recipients of sub-recipients) are also considered, NFPRHA's membership includes at least one Title X grantee or one grant sub-recipient in every state.

7. NFPRHA currently has more than 65 Title X grantee members and almost 700 Title X sub-recipient members. These NFPRHA member organizations operate or fund a network of more than 3,500 health centers that provide family planning services to more than 3.7 million Title X patients each year.

8. The interests that NFPRHA seeks to vindicate in this suit are central to its mission. NFPRHA is the lead national advocacy organization for the Title X family planning program, and it works to maintain Title X as a critical part of the public health safety net. In addition to its Title X advocacy, NFPRHA provides education, expert resources, and technical assistance to Title X grantees and sub-recipients, and concretely supports the work of those entities on an ongoing basis as they implement Title X. In addition to its direct membership assistance, NFPRHA's meetings and conferences enable members to share expertise and

experiences. If necessary, NFPRHA engages in litigation to ensure that Title X operates lawfully.

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

10. The Washington State Department of Health, the Public Health Department for Seattle and King County, Washington, and Plaintiff Feminist Women's Health Center, doing business as Cedar River Clinics, are all NFPRHA members. Likewise, the Indiana Family Health Council and the Contraceptive Choice Center in St. Louis, Missouri, are also NFPRHA members. The Social Welfare Board in St. Joseph, Missouri, is another NFPRHA member, where NFPRHA's co-plaintiff Teresa Gall, F.N.P., is a clinician with long-term experience in Title X care.

11. The declarations submitted by representatives of these organizations, including some of their clinicians who currently work in Title X, will provide the Court with additional background information about a small sampling of NFPRHA's members—including how those members, their staff, and their patients will suffer and the Title X mission will be harmed if the new regulations are allowed to govern the program.

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

13. My work experience also includes significant time as a senior staff person on Capitol Hill, with an emphasis on health care and appropriations-related efforts, and as a legislative representative for Planned Parenthood Federation of America.

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

15. The Acting Director of OPA appointed me to serve as a member of the Expert Working Group that advised the CDC and OPA throughout their development of the QFP. The Expert Working Group advised on the structure and

content of the QFP recommendations and helped make those recommendations as feasible and relevant to the needs of the field as possible.

16. Through my professional experience, my interactions with NFPRHA members and with OPA and other federal agencies, my related work with Congress, and my review of literature and historical material, I am well-versed in the history of Title X, all aspects of Title X programs (including best practices for providing family planning services and ensuring compliance with federal funding restrictions), and the process of Title X grant-making, and am regarded as an expert in the field.

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

The History and Purpose of Title X

18. 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). NFPRHA was founded just a year after Title X's enactment.

19. 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 it negatively affected maternal and child health. Research established that inequitable access to modern, effective contraceptives 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 ("the 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.

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

21. With overwhelming bipartisan support, Congress responded by enacting Title X. Congress's concern was the "medically indigent"—the low-income individuals who desired but could not access the contraceptive methods that more affluent members of society could, and 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). Congress emphasized that the "problems of excess fertility for the poor result to a large extent from the inaccessibility of family planning information and services." H.R. Rep. No. 91-1472, at 6 (1970).

22. At the same time Congress emphasized that it sought to establish a comprehensive family planning program and to make quality services readily available to those with low-incomes—not simply expand the number of individuals served. *See id.* at 10; 84 Stat. 1504. The statute requires that persons from low-income families be given priority in the Title X program and that no charge may be made for the services and supplies provided for those persons.

23. Congress also recognized that, in this area of individuals' reproductive 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." S. Rep. No. 91-1004, at 12.

24. Thus, Congress sought to provide low-income patients with biomedical contraceptives, with equal access to high-quality family planning medical care, and with the true freedom to make their own decisions about whether and when to have children. Those purposes remain the Title X program's central focus. Congress amended the statue in 1975 to also explicitly permit Title X projects to include natural family planning (now sometimes known as fertility awareness) in the array of methods and services they offer to patients. Likewise, Title X was amended in 1978 to explicitly cover adolescent patients, who had been using Title X care from the start, and to include infertility services among those that Title X projects offer.

25. Title X became, and remains, the only dedicated source of federal funding for family planning services in this country. Funding for services is distributed as grants under Section 1001 of Title X.

26. Separate funding under Section 1003 of Title X provides for training and professional development for Title X project staff. OPA funds both the Family Planning National Training Center and the National Clinical Training Center for Family Planning, which help support the national network of Title X-funded organizations and their family planning clinicians in this very specialized area of health care.

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

28. Though this funding is critical, it is not nearly enough to meet the need. To fully meet the country's need for subsidized family planning care, the Title X program would require in excess of $737 million annually.

29. Moreover, the flat funding year after year makes it more difficult each year for the Title X grantees to serve even the same number of patients with the same high-quality family planning care as the year before.

Congress's Repeated Requirements That Counseling Be Voluntary and Non-Directive

30. As set forth in NFPRHA's Complaint, the statutory and regulatory legal framework for Title X family planning has remained remarkably consistent over the program's almost 5 decades.

31. 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 choices and limits information when Title X patients find themselves pregnant.

32. In that one instance, at the end of the Reagan Administration in 1988, HHS promulgated a rule with similarities to the one challenged here, though it was not nearly as expansive and insidious. Those 1988 rules were enjoined immediately, remained enjoined through years of litigation, and—although the Supreme Court in 1991 rejected the arguments against the rules made at that time—the rules were not actually implemented to hamper Title X providers and patients across the country.

33. On November 5, 1991, then-President George H.W. Bush issued a Memorandum for the Secretary of Health and Human Services instructing HHS to at least back away from the 1988 rules' withholding of information about abortion

in the counseling of pregnant women by doctors and to attempt to ensure that "[n]othing in these regulations is to prevent a woman from receiving complete medical information about her condition from a physician."

34. Further litigation ensued, led by NFPRHA, given the unworkable narrowness of this directive and the conflict between it and the 1988 rules themselves. The 1988 rules remained enjoined and in limbo until shortly before February 1993, when the 1988 rulemaking was completely and finally rescinded.

35. HHS made clear in February 1993 that the agency standards that had been in place for years—before the 1988 attempt to alter the fundamental nature of the Title X program—again controlled. Under those standards, Title X projects were required "to provide nondirective counseling to the patient on options relating to her pregnancy, including abortion, and to refer her for abortion, if that is the option she selects." 58 Fed. Reg. 7462; *see also* 1981 Title X Guidelines.

36. Moreover, Congress itself has repeatedly and emphatically made clear that the 1988 changes or similar missteps should not be undertaken by HHS in implementing the Title X program—but they are nevertheless now advanced in the 2019 New Rule.

37. For example, while the 1988 rules and Bush directive were still enmeshed in litigation, both houses of Congress in 1992 passed the Title X Pregnancy Counseling Act; the House overrode President Bush's veto of that act

but a Senate majority narrowly fell short of the ability to override by six votes. In passing the Title X Pregnancy Counseling Act, Congress sought to undo the limitations on pregnancy counseling and referrals in the 1988 rulemaking and to avoid any artificial limitation of counseling to physicians. Congress declared in that 1992 act that "no health professional providing services in any project receiving assistance under title X … shall be prohibited by the Secretary … from providing, upon request, information" to pregnant patients (including referrals) about any of their options, including abortion. 137 Cong. Rec. 10103 (1991); *see* 102 Cong. Rec. 9862 (1992); 58 Fed. Reg. 7462.

38. In addition, just as the agency restored nondirective options counseling as an explicit regulatory requirement of the Title X program in early 1993, Congress has acted annually since 1996 to demand that "all pregnancy counseling [in Title X projects] shall be nondirective." Pub. L. 115-245, 132 Stat. at 3017-71.

39. That requirement for all Title X-funded family planning projects has been included in every HHS appropriations enactment from 1996 to the present, including the appropriations act already passed and signed by the President for this fiscal year, which runs through September 2019.

Overview of the Structure and Scope of Title X Service Provision

40. HHS awards grants to fund Title X care in geographic service areas throughout the country and in the U.S. territories. In recent years, the grants have funded approximately 90 grants to support 90 Title X "projects," as each grantee's program is known, for particular geographic locations. Title X coverage across the nation, whether urban, rural, or suburban, is wide. In 2015, as Guttmacher Institute has reported, 60% of U.S. counties had at least one health center supported by Title X, and 90% of women in need of publicly funded family planning care lived in those counties.

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

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

42. Within each Title X project, there are typically three levels: (1) the grantee entity, (2) sub-recipient organizations, and (3) individual health centers, also referred to as service sites, run by either grantees or sub-recipients.

43. In some states and territories, the state or territorial health department is the sole grantee operating the single Title X project for the state or territory; other states or territories have a non-profit organization as the sole grantee; and in other states or territories there may be multiple Title X grantees with multiple projects. Of the approximately 90 grantees, roughly half are governmental entities and half are non-profit institutions. Some grantees handle only overall program direction, funding, administration, and oversight, while their sub-recipients provide all clinical care at their service sites. In other instances, the grantee itself operates direct service sites and may or may not also have sub-recipients who operate additional sites. NFPRHA's membership includes entities in all of these categories.

44. Title X projects are substantial undertakings. A project grantee is responsible for (i) annually securing the Title X funding and other funding for its

project, (ii) administering the project's large overall budget (typically multi-millions of dollars) to (iii) provide Title X's specialized care according to Title X's standards – usually through many sub-recipients and dozens of service sites operated by the grantee and/or its sub-recipients – while (iv) ensuring administrative, financial and clinical compliance, (v) ensuring detailed, patient-service-level, financial, and other reporting to OPA, and (vi) conducting trainings, community outreach, and cultivation of referral relationships. Then each year throughout the term of the project, which historically has run three to five years, the grantee repeats this extensive array of responsibilities.

45. The recruitment, vetting, training, and coordination of sub-recipients (and their staffs) and the oversight of their portions of the grantee's overall Title X project are especially intense tasks. Likewise, special budgeting, invoicing, recordkeeping, and other administrative processes must be put in place and maintained to comply with existing Title X requirements in each Title X-funded organization and at all service sites.

46. Title X grant recipients and each of their sub-recipients must comply with HHS's detailed grant administration regulations and use-of-funds policies that apply to HHS grants generally; these limit the use of federal funds as specified by the terms of the respective HHS grant program – here, Title X. Similarly, Title X grantees are also subject to financial risk assessment before they can receive

grants, and to ongoing HHS grants management oversight of their funds use and financial systems, as I describe in more detail below.

47. In addition to the exacting financial oversight that already occurs, Title X grantees and their sub-recipients also undergo clinical and administrative program reviews and site visits. This ongoing monitoring by HHS, including from its 10 regional offices, helps confirm grantees' and their providers' compliance with the governing legal framework, program requirements, and national standards of clinical care.

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

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

OPA, *Program Requirements for Title X Funded Family Planning Projects*, at 5 (Apr. 2014) (attached hereto as Exhibit A). Title X projects also provide basic infertility services, such as infertility testing and counseling. The Program

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

49. A Title X project is defined by the proposed family planning activities to be conducted by the grantee and any sub-recipients that are described in detail in the grantee's application to HHS and then funded through the finalized grant. *See* 84 Fed. Reg. at 7787 (a "program or project" is a "sequence of activities" funded by Title X). A Title X project is not a physical space or entity, though HHS's New Rule may, in its "physical separation" requirements, create the impression that it is.

50. Similarly, it is vital to understand that Title X-funded health centers are physically and functionally just like other outpatient medical facilities. Title X-funded entities use these service sites for purposes of their Title X project, but they may and often do also house medical care that has no relation to Title X.

51. When a patient comes to a Title X-funded health center, she or he sees and experiences it as a place to gain access to clinical care by medical professionals—just like any other health center or doctor's office. Title X projects do outreach to educate community members that free or low-cost care is available at these health centers. Thus patients become aware that the centers have special funding available, but the phrase "Title X" rarely if ever enters into that dialogue. Title X health centers do not bear signs, inside or out, that say, for example, "Title X Clinic." In all my years working in the Title X community and traveling to Title

X sites in many states, I have never seen any project using "Title X" signage or other identifying materials for current or prospective patients.

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

53. In fact, in my experience and based upon my knowledge of the field, Title X patients often have a heightened need to be able to trust, understand, and rely upon the medical professionals that provide them with this safety-net care. That is because Title X patients often have had a previous negative experience in attempting to navigate the health care system as low-income persons and have fewer personal connections to health care professionals that they can draw upon. They often have no or limited other options for care. They also often face multiple challenges in receiving appropriate and complete clinical care, such as language barriers, cultural differences, a history of trauma or abuse, and/or other vulnerabilities. And Title X care touches on the most intimate and sensitive areas of life, again requiring a high degree of trust between patient and health care provider to allow the communication that is essential for this clinical care and education. For all these reasons, Title X patients especially need to be able to

count on the professionalism, thoroughness, and sensitivity to patients' concerns from the medical providers they encounter within Title X health centers.

Title X's Success in Reaching Low-Income, Vulnerable Patients

54. Title X-funded family planning organizations typically have deep expertise in the care they provide and the federally regulated framework in which they provide it. And they are highly responsive to patient concerns and needs. Many current grantees and sub-recipients have been part of the Title X network for decades. A number have been part of Title X care from the very beginning of the program. The experience and intense dedication of current Title X providers to their patients' reproductive health shows in the quality of their care.

55. Title X family planning providers, for example, typically offer a greater number of contraceptive method options to their patients than do non-Title X health care providers. Title X providers are more likely to offer those options onsite rather than requiring a woman to go to a pharmacy or to another provider for insertion of an IUD or implant. And Title X providers spend more time with patients during an initial contraceptive visit and other counseling than do clinicians at non-Title X sites. Equally important, Title X providers create a welcoming, non-judgmental atmosphere and openness to Title X patients' own stated needs, and respect each individual patient's values and autonomy. That kind of respectful and neutral atmosphere allows providers to quickly build and maintain trust,

whether with a new patient at that site or a returning one. This has been as important to Title X's historical success as the scope and expertise of its clinical care.

56. The CDC named family planning one of the most important public health achievements of the 20th century. It explained that:

> [T]he hallmark of family planning has been the ability to achieve desired birth spacing and family size…. Smaller families and longer birth intervals have contributed to the better health of infants, children, and women, and have improved the social and economic role of women…. Modern contraception and reproductive health-care systems that became available later in the century further improved couples' ability to plan their families. Publicly supported family planning services prevent an estimated 1.3 million unintended pregnancies annually.

CDC, *Achievements in Public Health, 1990-1999: Family Planning*, 48 Morbidity & Mortality Weekly Report 1073, 1073-80 (Dec. 3, 1999).

57. Such myriad positive impacts from Title X's federal funding of family planning continue today. In 2017, there were more than 1,000 Title X project sub-recipients of federal funding from the approximately 90 grants, and more than 3,800 individual Title X service sites around the country. Those Title X sites served more than 4 million patients, with approximately 6.6 million family planning patient visits that year.[1] (Many patients visit their Title X provider multiple times in a given year, or on a regular basis over many years, while others

[1] Title X-funded entities must all track client visits and submit standardized information sets for inclusion in the Family Planning Annual Report ("FPAR"), which is published by OPA annually.

are first-time Title X patients; though I have not seen data on all Title X sites, the split between returning and new patients at some Title X sites is roughly 50/50.)

58. The Title X program is reaching low-income patients as Congress intended. In 2017, as the Family Planning Annual Report ("FPAR") shows, 67% of Title X patients had household incomes at or below 100% of the federal poverty level; Title X projects are required to provide those patients with free care. That year, 23% of patients had incomes ranging from 101% to 250% of the federal poverty threshold, and must receive sliding-scale discounted care. The federal poverty level was $12,060 for a single-person household in 2017, and $20,420 for a household of three.

59. While the greatest proportion of Title X patients are young adults in their 20s, Title X providers serve individuals throughout the 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.

60. Title X patients are disproportionately people of color and ethnic minorities. In 2017, 22% self-identified as Black or African American and 33% as Hispanic or Latino, compared to 12% and 18% of the nation, respectively. Fourteen percent of Title X patients reported having limited English language proficiency.

61. Among women patients in 2017, 61% relied on a "most effective" or "moderately effective" contraceptive method as of their last encounter that year with the program, as classified by HHS in the QFP and the FPAR, while 18% chose a less effective method. Less than 0.5% of Title X patients across the country selected a natural family planning or fertility awareness method, though those are offered in all Title X projects. Nine percent chose no method because they were pregnant or seeking to become pregnant. Three percent of patients reported being abstinent.

62. In addition to contraceptive counseling and supplies, and pregnancy testing and counseling, Title X providers also play a critical role in cervical and breast cancer screening and sexually transmitted infection ("STI") and HIV services. Title X providers conducted, for example, more than 650,000 Pap tests in 2017; 14% percent of those tests identified results that required further evaluation and possible treatment related to cervical cancer. Providers also performed more than 900,000 chlamydia tests, 2.4 million gonorrhea tests, and 1.2 million HIV tests; more than 2000 of the HIV tests were positive for HIV.

The QFP Clinical Standards and the Typical Clinicians That Care for Title X Patients

63. Because Title X aims to provide low-income patients equal access to quality, up-to-date family planning methods and services, HHS has periodically adopted and revised clinical standards and other program guidance toward that end. These HHS directives govern grantees and their provider networks to help ensure that Title X programs are offering evidence-based clinical care consistent with current nationally recognized standards.

64. In 2009, in a memorandum distributed to Title X grantees, OPA acknowledged that its directives had in some respects fallen behind then-currently recognized clinical standards; this triggered an extensive updating process. The process culminated in April 2014 with the publication of two documents that currently comprise OPA's main Title X program guidance: (1) OPA's Title X Program Requirements; and (2) the QFP – the joint CDC and OPA publication on clinical standards for providing quality family planning services, as updated periodically. (A copy of the QFP is attached as Exhibit B.) The CDC has since published updates on additional research related to the QFP, including as recently as December 2017, which have continued to reinforce the validity of the QFP standards discussed here.

65. OPA has explicitly incorporated the QFP into its current directions for and monitoring of all Title X projects. Program Requirements (Ex. A) at 5-6. The

QFP also plays a central role at the two HHS-funded Title X training centers mentioned above, *see supra* ¶ 25.

66. The QFP describes clinical standards for any family planning provider, whether funded by Title X or not. The QFP set these new national standards through a lengthy process involving dozens of technical experts and the Expert Working Group of which I was a part. It drew on the CDC's "long-standing history of developing evidence-based recommendations for clinical care" and the fact that "OPA's Title X Family Planning Program has served as the national leader in direct family planning service delivery" since 1970. QFP (Ex. B) at 2.

67. The QFP's recommendations "outline how to provide quality family planning services, which include contraceptive services, pregnancy testing and counseling, helping clients achieve pregnancy, basic infertility services, preconception health services, and sexually transmitted disease services." QFP at 1. These recommendations are used by medical directors "to write clinical protocols that describe how care should be provided." QFP at 3.

68. As described in the QFP, chief among the essential attributes of quality care (discussed immediately after safety and effectiveness) is a "client-centered" approach. Client-centered care means starting from the client's own reason for seeking family planning information or services. QFP at 2, 4. It is also

essential that care "is respectful of, and responsive to, individual client preferences, needs, and values" and that individual "client values guide all clinical decisions." QFP at 4. Thus, under the QFP standards, providers' own preferences do not determine patient care. Instead, providers are trained and work hard to provide patients in a culturally sensitive and individualized way, with the information and assistance each patient needs to make informed decisions consistent with the patient's own priorities and beliefs.

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

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

71. The QFP specifically instructs, in a section entitled "Pregnancy Testing and Counseling," that pregnancy "test results should be presented to the client, followed by a discussion of options and appropriate referrals. Options

counseling should be provided in accordance with the recommendations from professional medical associations, such as ACOG [the American College of Obstetricians and Gynecologists] and AAP [the American Academy of Pediatrics]." QFP at 14. It states that "[r]eferral to appropriate providers of follow-up care should be made at the request of the client" and not delayed. QFP at 14.

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

73. The QFP also endorses an approach to contraceptive counseling that emphasizes sharing with patients information about effectiveness of contraceptive choices. It "support[s] offering a full range of Food and Drug Administration (FDA)-approved contraceptive methods," as long as each is safe for the particular patient, "as well as counseling that highlights the effectiveness of contraceptive methods" so that "clients can make a selection based on their individual needs and preferences." QFP at 2, 8.

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

75. In 78% of patient visits or "encounters" tracked in the 2017 FPAR, at least one highly trained medical professional—or what OPA terms in the FPAR "clinical service providers"—participated in the care. These Title X clinical service providers include, most commonly, non-physician clinicians: physician assistants, nurse practitioners, certified nurse midwifes, or registered nurses with an advanced scope of practice. The registered nurses with an advanced scope of practice may have a bachelor's degree or an advanced degree; licensing requirements differ from state to state. Physicians constitute only 23% of Title X clinical staff nationally. 2017 FPAR at 49-50, https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2017-national-summary.pdf.

76. In the remaining 22% of individual visits to Title X sites, other trained health care staff, such as nurses, nurse assistants, health educators, social workers, or clinic assistants, handle the care for patients. 2017 FPAR at 49-50.

77. All of these Title X patient visits are private, confidential encounters between patient and provider, as in other medical settings. The QFP underscores the importance of providing confidential services to each patient. QFP at 2. That is consistent with the explicit Title X regulations that protect the confidentiality of

all individuals receiving services, regardless of age, marital status or other characteristics.

Title X Grants Are Significantly Different Than Medicaid Reimbursement And Serve a Different Function

78. Importantly, Title X is and always has been a grant program that funds specific, agreed-upon expenses and activities within a Title X project ahead of time, and not merely a partial-reimbursement program like Medicaid. While Medicaid might, after-the-fact, pay some of the costs of services already rendered (and only if a patient is eligible to receive Medicaid reimbursement under a particular state's coverage parameters), Title X helps ensure that family planning services can be made available to low-income patients in the first place.

79. Title X does this by granting funds that can help establish, maintain, and update the facilities of service sites; stock them with contraceptive and other supplies; recruit, pay, and train staff; install and operate essential technology resources; pay for laboratory medical testing; and generally build the infrastructure and specialized operations necessary to open and sustain an up-to-date family planning health care project across a geographic area – often a whole state. Title X funds also pay for education, outreach, and administrative expenses to run the projects, as well as for the costs of Title X's ongoing compliance and reporting requirements.

80. From the beginning of the program, Congress has specified that Title X funds are not just for day-to-day service provision, but rather assist entities in the overall "establishment and operation" of family planning projects. 42 U.S.C. § 300(a). Congress stated among its initial purposes, "to enable public and nonprofit private entities to plan and develop comprehensive programs of family planning services," as well as developing materials and providing trained manpower for these programs. 84 Stat. 1504.

81. The requirements necessary to build sustainable, successful Title X programs have changed over the years, but HHS itself has encouraged grantees in many different ways to build projects that will last and that take advantage of technological and other infrastructure advances. For example, in the Fiscal Year 2016 Funding Opportunity Announcement ("FOA") for the Title X grant competition, OPA advised applicants that among the priorities for applicants was "Demonstrating that the project's infrastructure and management practices ensure sustainability of family planning and reproductive health services delivery throughout the proposed service area including," and then specifically referenced the importance of "certified Electronic Health Record (EHR) systems" and systems for third-party billing. 2016 FOA at 9, https://www.hhs.gov/opa/sites/default/files/opa-fy2016.pdf .

82. Under the current Title X regulations, no federal grant may be made for 100% of the Title X project's estimated costs. This means that each Title X services project must raise additional money, beyond the federal grant, to operate its project. Title X providers are also required to bill all third parties (whether government or commercial) that are authorized or legally obligated to pay for any clients' services (including clients with incomes below the federal poverty line) and to make reasonable efforts to collect charges from such third-party payers, while ensuring that client confidentiality beyond the third-party payer is not jeopardized. Medicaid reimbursement, where it is available, generally pays only roughly half of the cost of providing family planning services. Yet even that rate of reimbursement is an important source of funding relied upon by many Title X projects.

83. Thus, the use of Medicaid or private insurance reimbursement where possible is built into the Title X system, already relied on within it, and not a substitute for it. Even with maximum use of available, existing reimbursement methods to supplement federal and other funds, the Title X program still cannot meet the national need among low-income persons for family planning services and every dollar of federal Title X funding matters, including to help sustain the systems, trained personnel, and outreach necessary to run these projects.

84. No two Title X grants are exactly the same. Once HHS has approved a Title X project application, its work plan, and its detailed budget, and finalized HHS's Notice of Award for that grantee, that is how use of the grant must proceed. Unplanned modifications—such as new sub-recipients, reductions in service, the closing of program sites, or significant budget revisions—must be approved by HHS ahead of time, prior to any alterations to the Title X project or any altered spending of federal funds.

85. This grant structure means that each Title X grantee has specified how it will spend the grant funds ahead of time, before it can draw down the federal funding, and then must comply with that spending plan. The rigid budgeting, documentation, and reporting required as part of Title X grants management ensures that federal dollars are not used for any purpose other than the approved budget items. If for some reason the grantee can pay for its approved activities with less than the budgeted amount, as sometimes occurs, the excess funds may be reprogrammed with HHS approval or, in some cases, are returned to the U.S. treasury.

The Title X Grant-making Process

86. OPA initiates the grant-making process by issuing a funding opportunity announcement. Title X grants are competitive grants, and each FOA specifies the regions, states, or territories for which applications are being solicited.

The grant-making competition results in grant awards for what are typically multi-year project periods, most commonly three years. For years two and three of three-year grants, the grantee must still submit a continuation application and detailed yearly budget, among many other documents, to be approved and funded for each year within the full grant period.

87. OPA previously staggered the years in which Title X grants related to particular states or territories were subject to competition—i.e., initial grant-making and the project's first year, rather than subsequent years of a previously awarded continuing grant. In its two most recent Title X FOAs, issued for competitive grants of Fiscal Year 2018 and Fiscal Year 2019 funds, OPA shifted the grant cycles so that services grant applicants in all jurisdictions have competed for new grants in each of 2018 and 2019.

88. OPA set an extraordinarily short, seven-month project period for the 2018 grants, which began on September 1, 2018. This means that all the current 2018 grantees, and any other applicants, are again competing nationwide for new, competitive Title X grants.

89. OPA released the Fiscal Year 2019 FOA on October 22, 2018. That 67-page document solicited applications due January 14, 2019. The FOA describes each state and each of seven territories as a proposed service area, and lists the estimated grant funds available for Fiscal Year 2019 in each state or

territory. For the state service areas, those estimated annual funding amounts range from $800,000 to multimillions, with the vast majority of states receiving less than $6,000,000 per state. Grant applicants can apply for the entire proposed service area or only part of it, and one entity can apply for grants in multiple places, such as in neighboring areas of different states. If there are multiple applicants for a service area, those applicants compete directly against each other. All applicants compete for the Fiscal Year 2019 appropriated funds available. More than one award per jurisdiction may be made.

90. The 2019 FOA estimates that HHS will award three-year grants, but also states that "we may approve longer or shorter project periods." 2019 FOA at 16, https://www.hhs.gov/opa/sites/default/files/FY2019-FOA-FP-services-amended.pdf. The anticipated start date for new grants is April 1, 2019. This corresponds to the fact that all current Title X services grant awards end on March 31, 2019.

91. In the FOA, HHS specifies that its "goal" is to complete Notices of Awards under the 2019 FOA 10-15 days prior to the April 1, 2019 anticipated start date. At the time of my signing this declaration, that has not yet occurred, which is not unusual. HHS award decisions always come very close to the start of a new Title X grant period, and often HHS completes the Notices of Awards only a

couple of days before the grant period start date. On occasion, the awards have been finalized slightly after the start date.

92. If the new award process under the 2019 FOA is not completed on a timetable that allows HHS to begin the new grant periods on April 1, 2019, the department can extend the previous grants through a process called continuation funding. As with later years of multi-year project periods, however, each grantee would still have to apply to HHS through a somewhat less involved, non-competitive process and be approved for any continuation funding to continue to receive Title X funds until new grants under the 2019 FOA (or some subsequent FOA) could be awarded and commenced.

93. Each FOA gives Title X grant applicants precise information about the format and requirements for their proposal. As reflected in the 2019 FOA, grant applications typically consist of a project narrative (not to exceed 65 pages), which is a substantive description and the most important part of the application, and a budget narrative (with tables) that can be even longer than 65 pages. The budget information provides not only a detailed, line-item budget for the proposed project's grantee and sub-recipients, but also includes justifications for expenditures and a plan for oversight of and controls for the project's federal fund use. In particular, applicants must describe "organizational systems that demonstrate effective control over and accountability for federal funds and

program income, compare outlays with budget amounts, and provide accounting records supported by source documentation." 2019 FOA at 36.

94. Applications also include, among other components, a proposed project work plan for the entire project period, including information about all family planning services to be provided, a list of all sub-recipients and the criteria used to select them, and a coverage map of the areas the project proposes to serve, with all service sites shown. The entire application must not be longer than 150 pages. Applicants routinely use that full page limit, and must devote considerable staff time and other resources to the application preparation process.

95. Similarly, HHS's review of the applications and its decision-making process for awarding Title X competitive grants also typically takes months. HHS requires, in its discretionary grant-making, that "[f]or competitive grants or cooperative agreements," the HHS awarding sub-agency (here, OPA) "must design and execute a merit review process for applications." 45 C.F.R. § 75.204. This objective merits review process must involve at least three unbiased reviewers (a "review panel") with expertise in the programmatic area—here, family planning—as explained in HHS's governing Grants Policy Statement at I-29.

96. The merits review panels are convened to review and score each Title X application. The scoring process has historically been built upon the application review criteria specified in the Title X statutes and current regulations. HHS's

electronic scoring tool for those panels limits the reviewers solely to the specified grant-making criteria that have been reprinted in the FOA, and it requires each reviewer to assign a score to each one of those criteria. Consistent with HHS's Grant Policy Statement (at I-30), the highest scored Title X applications receive priority for funding. The applicants that succeed in this merits review are also evaluated for financial risk and controls before an award is finalized. 45 C.F.R. § 75.205.

97. This exhaustive application process and merits-based application review by experts in the field has contributed to a high-performance national network of Title X providers, with much consistency year-to-year. As an in-depth Institute of Medicine review of the Title X program in 2009 explained:

> [M]ost current grantees have been Title X grantees for many years. Most of the state health departments that emerged as grantees from the consolidation of grants at the state level in the early 1980s have remained in that role. Among nongovernmental organizations, grantees are often refunded through many cycles. They have demonstrated understanding of the needs of the geographic area to be served, success in developing networks of care and serving patients in their communities, the interest and skills necessary to carry out the subcontracting required, and the ability to meet [OPA] standards in collecting data and monitoring the performance of [sub-recipients]. Continuity with high-performing grantees ensures continuity in service delivery through a well-established and -functioning network.

Institute of Medicine, *A Review of the HHS Family Planning Program*, at 112 (2009) ("IOM Review").

98. Since that 2009 review, the success of the Title X program has continued. In August 2017, for example, the Executive Summary of OPA's 2016 Title X FPAR concluded:

> The FPAR data for 2016, and over time, show that Title X providers continue to make important gains in delivering high-quality, evidence-based contraceptive and related preventive care to a vulnerable population. While declining revenue over time has resulted in fewer funded health centers and users, trends in the use of most and moderately effective contraceptive methods, as well as cervical cancer screening and chlamydia testing, demonstrate the program's continued dedication to delivering services that meet the highest national standards. This dedication to service quality is matched by efforts to respond to health system changes and to increase the efficiency and financial sustainability of service operations through investments in health information technology and revenue diversification.

2016 FPAR at ES-3-ES-4, https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf; *see also* 2017 FPAR at ES-3 ("Despite the recent decline in [total Title X project] revenue, the number of clients served has remained almost level since 2015, and the delivery of recommended preventive health care remains high, both of which attest to the network's efforts to deliver care meeting the highest national standards.").

Title X's Extensive, Ongoing Programmatic, Administrative and Financial Monitoring

99. OPA and the HHS regional offices undertake Comprehensive Program Reviews ("CPRs") of each Title X grantee, employing both HHS staff and outside expert consultants. The CPRs involve a multi-day process of

investigation by medical, administrative, and financial reviewers who must be given access to all aspects of the grantee's operations and to any sub-recipient sites they seek to visit. It is common for the CPRs to visit multiple sites in their review of the grantee. A CPR occurs approximately every three years, the typical project period for Title X grants.

100. The CPRs result in written reports, and if the investigation has identified any violations of the Title X statute or regulations, those are set forth in findings. The grantee then must provide a remediation plan and promptly correct any findings within a time frame specified by OPA. In addition to the CPRs, regional HHS offices also make periodic on-site visits with grantees to conduct orientations, share information, and assess progress in the project.

101. The grantees also undertake the same pattern of comprehensive program reviews and site visits for each of their sub-recipients, using the same Program Review Tool that HHS uses with grantees. The grantees thereby ensure that clinical, administrative, and financial compliance extends throughout the Title X provider network.

102. Because Title X grant awards are generally of a size (greater than $750,000) that federal grants management rules require annual independent financial audits of the grantee organization. In addition, Title X grantees must

provide quarterly financial reports and quarterly cash reporting for their Title X project to HHS.

103. I know from my interactions with them that OPA and HHS take these enforcement responsibilities very seriously. But because the Title X grantees' compliance record overall has been excellent, any negative enforcement actions—such as shortened or terminated grant periods for poor performance—are exceedingly rare in this grant program. I can recall only one performance-based termination of a Title X grant in the last decade. In my experience, any compliance issues, whether medical, administrative, or financial, are readily identified by HHS's comprehensive or annual reviews and are quickly corrected.

104. The Institute of Medicine's 2009 review of the Title X program noted, in particular, that financial oversight and financial management work smoothly:

> [The] financial audit in the CPR provides adequate oversight of the coordination and use of multiple funding sources. Financial consultants that serve on the review team evaluate accounting records and the management of funding. The consultants are regarded highly for their ability to identify issues (such as a grantee not funneling fee-for-service reimbursements back into the Title X program) and to provide constructive and educational guidance to grantees. From the standpoint of funding, [HHS's Regional Program Coordinators] and grantees identified no obvious areas of duplication or lack of coordination.

IOM Review at 129.

Title X's Financial Separation and Independence from Abortion Care

105. Since its initial passage, Title X has always included the limitation that "[n]one of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." Section 1008, codified at 42 U.S.C. § 300a-6. Likewise, since inception of the Title X program, entities that also provide abortions—without Title X funds and outside their Title X projects, though often under the same roof—have always participated as grantees and sub-recipients in this family planning program.

106. As HHS itself acknowledged in 2017, Title X financial program review and its financial management requirements are rigorous and have been successful in ensuring that grantees use Title X funds properly, including in compliance with Section 1008 of the statute.

> According to OPA, family planning projects that receive Title X funds are closely monitored to ensure that federal funds are used appropriately and that funds are not used for prohibited activities such as abortion. The prohibition on abortion does not apply to all activities of a Title X grantee, but only to activities that are part of the Title X project. The grantee's abortion activities must be "separate and distinct" from the Title X project activities. Safeguards to maintain this separation include (1) careful review of grant applications to ensure that the applicant understands the requirements and has the capacity to comply with all requirements; (2) independent financial audits to examine whether there is a system to account for program-funded activities and nonallowable program activities; (3) yearly comprehensive reviews of the grantees' financial status and budget report; and (4) periodic and comprehensive program reviews and site visits by OPA regional offices.

Congressional Research Service, *Title X (Public Health Service Act) Family Planning Program*, at 22 (Aug. 31, 2017).

107. Title X projects already operate with financial separation from non-Title X activities, including abortion-related activities. This financial separation is not mere "technical allocation" of funds or bookkeeping entries, but rather the separate use—and documentation of that separate use—of funds. For example, a single staff member, building, or health records system may be used across an entity's various health care programs, but the Title X program pays its pro-rata share of the cost based on its actual share of usage. Staff members must document their actual time spent on Title X work (after performing the work, rather than ahead of time), and the entity must retain that substantiation for all Title X staff. OPA reviews a grantee's cost-allocation protocols, practices, and records during its program reviews and site visits.

108. In addition to this complete financial separation, Title X grantees also ensure that their project's activities are distinct from activities prohibited by Section 1008. As described in OPA's 2000 guidance, Title X grantees demonstrate that "prohibited abortion-related activities are not part of the Title X project" by means of "counseling and service protocols, intake and referral procedures, material review procedures and other administrative procedures." 65 Fed. Reg.

41282. Again, these systems, protocols, and practices are reviewed as part of OPA's ongoing oversight of grantees.

109. There is no requirement, however, of "physical separation." As HHS explained in 2000,

> The Department has traditionally viewed a grant project as consisting of an identified set of activities supported in whole or in part by grant funds. If a Title X grantee can demonstrate by its financial records, counseling and service protocols, administrative procedures, and other means that—within the identified set of Title X-supported activities—promotion or encouragement of abortion as a method of family planning does not occur, then it is hard to see what additional statutory protection is afforded by the imposition of a requirement for "physical" separation. … Moreover, the practical difficulty of drawing lines in this area … suggests that ["physical" separation] is not likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services.

65 Fed. Reg. 41276.

HHS Seeks to Redirect Title X Funds to Organizations Opposed to the Program's Tenets

110. The New Rule builds on previous efforts by the Trump Administration to divert Title X funds, direct them toward uses that are not properly part of the Title X program, and remove this federal funding from any entities that also provide abortions outside Title X.

111. In the 2018 FOA, for example, HHS sought to require grantees to emphasize education and counseling programs that would encourage "sexual risk avoidance" i.e., abstinence—or "returning to a sexually risk-free status" for

unmarried patients, including adults. 2018 FOA at 11, https://www.hhs.gov/opa/sites/default/ files/FY18-Title-X-Services-FOA-Final-Signed.pdf. The FOA sought to impose a "meaningful emphasis" on abstinence, even though the clear, motivating purpose behind Title X was to help sexually active individuals manage their reproductive capacity through modern contraception, and more than 95% of adult Title X patients are or wish to be sexually active. *Id.* at 11. The 2018 FOA also sought to give priority to providers interested in "a holistic vision of health" and "historically underrepresented" in the Title X program. *Id.* at 7. These were code words for bringing certain providers' values—against sex outside marriage and against abortion—into Title X and efforts to direct grants to those providers.

112. When HHS did not get the number and kind of grant applications from such providers in the Fiscal Year 2018 grant competition that it sought, it imposed a very short grant period (seven months) to trigger another competition of the entire national network. It also moved to publish current grantees' in-depth and proprietary applications on the HHS website to give potential new entrants material to assist in their application efforts. Both the 2018 FOA and the HHS efforts to publicly post current grantees' applications resulted in litigation.

113. The Title X program, of course, has always been open to new applicants and competitors for services grants and should remain so. Several states

and regions within states have had changeovers in grantees through competition in the last decade. NFPRHA staff and NFPRHA members are always on the lookout for health care organizations that might help further expand the Title X network and its effectiveness. Because the program has been around for decades, however, qualified health care organizations that are interested in participating in the Title X network largely have already moved to do so. As a connected expert in the field, I know that there is not a significant reservoir of expert family planning providers or other experienced health care entities that might decide in the future to apply for a Title X grant, but have not done so already.

114. Moreover, it is one thing to encourage and search for new grantees or providers that want to further expand access to quality, state-of-the-art family planning services for more low-income patients, allowing those patients to shape their own reproductive futures, as Congress intended Title X to do. It is another to attempt to limit Title X services overall and constrain Title X care in order to impose on the program the values of a narrow band of potential new providers and reshape it in those providers' image, contrary to the program's intent.

115. The New Rule and HHS's other recent actions to change the composition of the Title X network indicate that HHS seeks the latter—prioritizing certain concerns and values of hypothesized, potential Title X providers over the

needs and wishes of the individual patients who might seek care at sites operated by them.

116. HHS, for example, identified in the Notice of Proposed Rulemaking ("NPRM") these purposes for the New Rule: imposing a new "ethical" screen on the usage of taxpayer dollars; protecting "the rights of individuals and entities who decline to participate in abortion-related activities" to receive federal funding; and ensuring that the Title X program places an "adequate emphasis on holistic family planning services" and mandatory counseling regarding the "unborn child," 83 Fed. Reg. 25510-11, 25523—the type of "holistic" and "life-affirming" perspective used by certain "pro-life" organizations that are opposed to women's access to complete, neutral information and options about pregnancy, and opposed to biomedical contraceptives. *See, e.g.*, Victoria Colliver, "Anti-abortion clinics tapping into federal funds under Trump," https://www.politico.com/story/2018/12/16/abortion-pregnancy-centers-planned-parenthood-1007765. HHS in its new rulemaking explicitly seeks to empower potential new Title X providers to use their religious beliefs to limit the methods of family planning they might offer to patients within the Title X program, without informing patients or ensuring a role for the patient's own beliefs or needs.

How the New Rule Would Cause Serious Harm to the Program and Its Patients

117. If allowed to take effect, the New Rule would immediately damage the integrity of the program's counseling for pregnant Title X patients. As the background above shows, a critical element of Title X is offering low-income patients equal access to clinical care that follows national standards and does not vary from health center to health center. The necessary clinical care for pregnant patients includes offering them counseling about all of their options, offering them referral to any option they are interested in exploring, and letting the patients' values, wishes, and inquiries dictate the scope of the counseling discussion, as the QFP, the professional medical societies to which it refers, and existing Title X regulations all reflect. Clinicians must remain neutral sources of information and referral and function as sounding boards, but must refrain from any kind of directive or coercive approach that attempts to impose a course of action or value system on the patient.

118. Yet the New Rule invites individual providers to limit patient counseling according to the *providers*' beliefs; forbids referrals to and concrete information about abortion providers (or even information about abortion referral sources) that could give a patient interested in abortion access to that care; and mandates a prenatal referral for all, even for those patients who are clear they will not carry the pregnancy to term. In these ways, the rule imposes distorted,

substandard pregnancy counseling throughout the Title X program and forces Title X clinical staff to unethically limit the care they provide to pregnant patients, including by pushing patients to prenatal care and denying them the same kind of out-of-program referrals to abortion care, upon request, that are available within Title X for any other type of medical provider. NFPRHA's member grantees, sub-recipients, and their staff would have to conform to this inadequate and coercive approach to pregnant patient counseling in order to maintain their grants and continue their roles in the Title X network.

119. Contrary to the implication that may be created by HHS, 84 Fed. Reg. at 7783, patients' own expressions of faith and principles of conscience are already fully honored by Title X's current supportive counseling, directed by the patient. The New Rule introduces the opposite: the inappropriate ability of individual Title X providers to use their personal values to limit access to medical information for any pregnant patients that happen to visit the Title X health centers where those providers work. For the vast majority of clinicians that instead aim to provide their patients with full medical information, all their treatment options, and voluntary access to referrals, regardless of the clinicians' personal beliefs, the New Rule forbids them from doing so.

120. The new, distorted pregnancy counseling and the coercive stance in which it puts providers, also subjects Title X patients to the harms of loss of

dignity and loss of trust in medical providers. It subverts the voluntariness and patient autonomy that is central to Title X care, and gives low-income pregnant patients only inadequate, second-class care. In so doing, the New Rule fundamentally undermines the uniform, supportive, non-judgmental access for low-income patients to the national standard of care that the Title X program has worked so hard for decades to provide. NFPRHA members would not undertake such counseling voluntarily, and would only do so under the duress of the New Rule.

121. NFPRHA's member grantees and sub-recipients each participate in the Title X network because they are committed to ensuring that low-income persons have access to quality family planning care. I know from my repeated interactions with those health care organizations, and with a large number of individual clinicians working in Title X, that they would not freely choose to depart from ethical standards and offer their Title X patients inappropriately limited access to information and referrals.

122. I also know that it has taken NFPRHA grantees and sub-recipients many years to cultivate and develop well-functioning Title X projects across wide geographic service areas, with numerous health center sites, large numbers of staff, and all of the administrative, financial, and operational systems that Title X requires. NFPRHA member grantees and sub-recipients are very reluctant to give

up providing free Title X care to their communities. Many will fight to preserve their roles in the Title X program, despite the damage required by the New Rule that will fall directly on their patients and also harm the providers' reputations and the provider-patient relationship of trust.

123. Upon its effective date, the New Rule will cause all current NFPRHA member grantees, sub-recipients, and their individual Title X clinicians to face a Hobson's Choice between two imperfect paths that each harm patients as well as the providers: (1) attempt to 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 depart from medical ethics principles and standards of care—thereby shrinking the Title X network, reducing patients' access to contraceptives and other care, and triggering cascading harms.

124. Likewise, all levels of the Title X network, including the many NFPRHA members in that network, will be faced with the New Rule's onerous and infeasible new separation requirements and infrastructure spending limits, regarding their facilities, staff, materials, and electronic systems, and the New Rule's other new compliance mandates, that will similarly put them between a rock and a hard place. The New Rule's requirements will (1) force some providers, including NFPRHA members, from the program because they do not have the

resources or any rational means to comply. And (2) the New Rule will force all other providers, including NFPRHA members, to cleanse even their non-Title X activity of references to or any activities arguably supporting access to abortion, which would be extraordinarily difficult to accomplish, or force them to attempt to satisfy the rule's new, unclear, and extremely burdensome separation and infrastructure provisions. These latter providers that are struggling to comply with the separation and infrastructure provisions will have to cut back on Title X services because major funds and staff time must be diverted to attempt to do so. To try to comply with these new requirements in the too-short timeframes that the New Rule allows, NFPRHA members would have to begin immediately to undertake that effort.

125. HHS instructs that under the New Rule, Title X projects "would not share any infrastructure with [any] abortion-related activities." 84 Fed. Reg. at 7774. This imposes an extraordinary degree of disconnection from abortion-related activities, beyond anything ever proposed for Title X before. The New Rule also erects a new, unclear distinction between infrastructure and "direct implementation" of a Title X project. Section 59.18, 84 Fed. Reg. at 7790.

126. In the related "physical separation" requirements, the New Rule directs projects to separate facilities, staff, electronic systems, signs, and written materials from the Title X project, so that they can prove an unclear "objective

integrity and independence" from any abortion-related activities undertaken *without* Title X funds. The activities from which it is necessary to separate include community education programs, advocacy, or sending dues or other funds to organizations that might advocate for abortion access, provide abortion referrals or otherwise assist women in securing abortions.

127. The infrastructure spending limits and separation requirements will harm all of the NFPRHA member grantees and sub-recipients who attempt to stay in the Title X program. NFPRHA's organizational members now participating in Title X—totaling more than 750 organizations—include, for example, numerous public health department grantees headquartered in a single administrative building, sub-recipients operating out of a single health center, and non-profit grantees that administer the Title X grant out of a single location but also have dozens of sub-recipient sites run by many separate organizations. They also include very large networks like the Washington Department of Health's, which is managed centrally but composed of more than 80 separate sites and 16 different sub-recipients. NFPRHA members will face a virtually unlimited array of complications from these new separation and infrastructure requirements.

128. For example, our members that are 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 of our Title X provider organizations and their individual health center sites also offer services in addition to Title X, such as 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 also collocate with Title X providers (or are one and the same), 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.

129. 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 funds pay only Title X project expenses—and, as explained above, federal Title X funds make up only part of the overall Title X project budget, because no Title X grant can cover 100% of that budget, *see supra* ¶ 80.

130. Against this backdrop, the New Rule's Separation Requirements will wreak havoc on Title X-funded NFPRHA member entities of every type and at every level, from individual Title X-funded sites to central offices that administer a Title X grant for sub-recipient providers. Those rules direct Title X administrators and providers to separate not only facilities, but electronic systems, including

EHR, staff, materials, and contact points, like phone and email. HHS sets forth a subjective, complex multi-factor standard, describes certain absolute "deal breakers" that will not satisfy separation (such as abortion care and a Title X site collocated in a standalone health center), and otherwise suggests that Title X participants seek interaction with HHS "to help grantees successfully implement" the new physical separation and infrastructure requirements. That suggestion, however, does nothing to reduce or clarify the New Rule's onerous standards, or to provide any predictability for grantees and sub-recipients in order to even contemplate an attempt at compliance (and the large financial outlay involved).

131. NFPRHA member grantees and sub-recipients thus confront steps under the New Rule that are irrational when viewed in terms of the relatively small level of federal funding they receive through Title X for their public service missions. While that federal funding is critical to providing family planning care and seeding the budget for each project, on a site-by-site basis it is far from the level that would be needed to revamp or duplicate entire operations and sustain excess locations, systems, and staff indefinitely. Service organizations and government agencies could spend their funds much more effectively than for unnecessary duplication and separation.

132. For example, NFPRHA-member government health departments whose sole Title X role is to administer a grant from the department's single

administrative office would be required by the New Rule's separation and infrastructure terms (Sections 59.14 and 59.16) to divide that public office into two separate locations with two separate staffs. They would have to divorce administration of the Title X project from other health department activities that involve distributing non-Title X funds for, or undertaking, any prohibited abortion-related activities or education. This makes no sense, and would, untenably, require the public entity's receipt of Title X funds to dictate how a territory, state, or county health department operated overall.

133. Similarly, NFPRHA members who are 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, since these duplications would involve massive outlays for no benefit to their health care missions. But this kind of extreme wastefulness and effort would be required 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.

134. Title X providers have expended significant effort placing sites in the most accessible locations—for example, on public bus routes or near other social services. They have built long-term programs with dedicated staff and patients

who count on them. And they have invested in important infrastructure for modern healthcare, including EHR systems (with HHS encouragement, *see e.g.*, 2016 FOA). Dismantling and moving Title X service sites not only negates these and other efforts, but would also directly interfere with patient access because Title X patients will be confused about where their provider has gone, why its website has changed, and how to reach it by phone.

135. Under the sweep of these new rules, separation and infrastructure spending issues would arise for NFPRHA members in innumerable ways. For example, a NFPRHA member, in addition to directly participating in a Title X grant, distributes a separate funding stream to outside providers to perform tubal ligations. Those providers also offer abortion referrals and/or other abortion related services to non-Title X patients. The New Rule apparently dictates that the same administrative staff, accounting functions, and facility cannot be used for the member's Title X activities and this separate, tubal ligation funding relationship.

136. Similarly, Title X sites often contract with a specialized provider to visit and perform a part of their Title X services on site, such as Long-Acting Reversible Contraceptive ("LARC") placements. Those specialized providers are typically ob/gyn practitioners with a full practice of their own, including abortion referrals, and often provide abortion care for their non-Title X patients. The New Rule apparently bars that contractual relationship, since the Title X project cannot

possibly separate administration of that provider's contract from the Title X project without severing it from its very purpose: providing LARCs for Title X patients.

137. There have been extensive discussions of the NPRM and the New Rule among NFPRHA's membership and staff, including with me, and the impact that it will have on the Title X network; there have also been public statements by several state governments and announcements by Planned Parenthood and others about the provider withdrawals and other network changes that the New Rule will trigger.

138. Faced with the immediate need to contend with the New Rule's imposition of these uniformly bad choices and unworkable options, I know that many grantees, sub-recipients and individual clinicians will leave the network at once if the New Rule becomes effective, including many NFPRHA members and/or their staff. Other NFPRHA members would likely be forced out by HHS soon thereafter under the excessive separation or other compliance burdens, for example, or the new subjective eligibility threshold or grant-making criteria.

139. Still other NFPRHA members will decide to and succeed in remaining within the Title X program, at least for the short term. Those NFPRHA members will have to suffer the consequences of the New Rule for their project, their professional standards, their individual clinicians, and their patients, but will at

least maintain a role in this vital safety-net program and continue to offer some Title X care for low-income individuals.

140. The New Rule's fewer and more muddled application review criteria will make merits-based consideration, scoring, and comparison of grant applicants more difficult and arbitrary. Similarly, its new, all-encompassing eligibility screen that allows HHS unilateral discretion to refuse to consider any application that it deems not "clear" or "affirmative" enough in its planned compliance with all of the New Rule's mandates, will permit HHS to make subjective and unreviewable decisions to refuse to consider an application. These changes are contrary to Title X's much simpler eligibility terms and HHS's general rules for fair competitive grant-making.

141. All NFPRHA-member Title X participants would be subject to these altered, arbitrary grant criteria and the sweeping but vague eligibility hurdle if those are allowed to take effect before upcoming grant competitions. These changes would harm the program and harm NFPRHA members by making their applications' fates much more unpredictable and not tied to merit, and by requiring our members to exhaustively describe the strictest compliance possible with every Title X regulation subsection to try to survive the subjective eligibility test and have a chance at maintaining funding.

142. For the NFPRHA grantees and others that the New Rule immediately pushes from the Title X network, their federal funding will disappear, 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.

143. Under normal circumstances, as discussed above, initiating and administering a Title X services grant competition takes at least five to six months. Under the situation triggered by the New Rule's requirements and the sudden departure of numerous Title X grantees mid-grant, potential replacement grantees are likely to be especially difficult to find in many jurisdictions and efforts to recruit any applicants may alone take months. Likewise, with multiple mid-grant departures and other fallout from the New Rule, OPA's own resources may be especially taxed.

144. It is likely that the wholesale gap in Title X services for the grantee service areas suddenly without Title X providers would last longer than five to six months—even assuming replacement grantees for at least some parts of a service area could eventually be found through a new grant-making process. If new grantees are selected and funded, then those grantees would likely take many more

months to get their new Title X projects up and running, and would be constrained by all of the New Rule's ongoing limitations.

145. In addition, grantees are not the only participants in Title X who must comply with the new, compromising rules or leave the program. As the New Rule's effective date occurs, each sub-recipient organization will also have to make that choice. Within any grantees or sub-recipients that decide as an organization to try to stay in the Title X program, their individual clinicians will also each be forced to decide whether they can accept the New Rule's mandate of substandard pregnancy counseling and its emphasis on directing all pregnant patients to prenatal care or whether they must resign from Title X care. Thus, those NFPRHA members that decide to fight to continue participating in the Title X network will nonetheless be at risk for departures by their clinicians and other staff because of the New Rule.

146. NFPRHA members nationwide will suffer the harms of the New Rule. As explained above, none can escape its impact.

147. The New Rule's massive disruption to (a) access to care for low-income and vulnerable people, (b) the current standards of care under the QFP, and (c) the national network of Title X providers is especially damaging and disheartening because of the many years of work that have gone into building the current Title X program. For example, HHS is abandoning its own work, with

dozens of experts and over multiple years, in compiling the QFP, and now telling Title X clinicians to ignore many ethical and professional standards. Similarly, Title X grantees that specialize in administering Title X projects and other grantees (and sub-recipients) have built up tremendous institutional knowledge and use that deep expertise to operate exceptional programs. Once the New Rule causes any of these entities to exit the program, their staff that knows how best to implement Title X will disband and be very difficult to reconstitute. To the extent the New Rule is allowed to take effect, its immediate and snowballing effects will be difficult to reverse.

148. As HHS knows from the Title X projects and budgets it approves, Title X grantees and sub-recipients, including NFPRHA's members, try to stretch their federal and other funds to maximize the number of patients they can reach with Title X services and to operate efficiently. The Title X grant itself is far from sufficient to pay for the full scope of each Title X project, and other sources of income must be found to sustain these projects. Through its technical assistance programs, conferences, and trainings, NFPRHA helps its members make the most of all sources of funding and operate their projects to stretch their limited budgets, best serve their patients, and achieve the greatest individual and public health benefits from those projects as possible.

149. But overall patient need continues to outstrip the financial resources of the Title X network. Because Title X projects are already stretching financially, this reality means that the New Rule's spending and operational constraints, and new information gathering, record-keeping, reporting, and other administrative hurdles, will each divert some of Title X projects' limited resources away from maximizing the effective and state-of-the-art provision of patient care. Siphoned off funds mean that fewer staff, fewer health center hours, fewer locations, etc., can operate within the same Title X budgets.

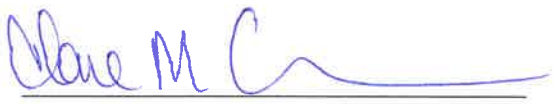
150. For all these reasons, for NFPRHA members—both governmental entities and non-profit organizations—that manage to stay in the Title X program, the New Rule will make pursuing their health care and public service missions much more difficult. It will compromise their operation of vital family planning programs and sites, reduce their ability to employ well-qualified clinicians, limit their staff clinicians' actions, and reduce their Title X project's services and standard of care for patients. For these NFPRHA members and their staff that remain, their reputations will suffer and they may face other professional injuries, because of the New Rule's mandates.

151. For NFPRHA members that the New Rule causes to leave the program, the impact will be even more devastating. Those government and non-profit entities will lose all of their Title X funds and any role in the program, will

no longer have the means to provide free and subsidized care for the same number of poor and low-income patients, and will suffer an array of cutbacks to their family planning efforts. For NFPRHA members that are Title X administrative grantees, many of whom have functioned successfully in that role for decades, leaving the program jeopardizes their very existence and eliminates their core purpose. Some NFPRHA member organizations that provide direct health services or organizations that oversee and administer those services will close.

152. Finally, as high-quality providers leave the program, the New Rule will cause NFPRHA members' patients to suffer diminished access to family planning care, because there will be fewer Title X health center sites and fewer Title X funds available to serve them. In addition, NFPRHA members' patients will lose access to standard, ethical pregnancy counseling and referrals for abortion care. If HHS succeeds in bringing religious objectors into the Title X network, patients will also encounter more sites with only one or a few contraception options and no information about a broader range, further undermining the program. All of these impacts will expose patients to greater health risks and more unintended pregnancies. The New Rule will harm the central purpose of Title X and sacrifice low-income patients' care to these new mandates.

I declare under penalty of perjury that the foregoing is true and correct. This declaration was executed on March 22, 2019, in Washington, D.C.



Clare M. Coleman

DECLARATION OF SERVICE

I hereby declare that on this day I caused the foregoing document to be electronically filed with the Clerk of the Court using the Court's CM/ECF System which will serve a copy of this document upon all counsel of record.

DATED, this 22nd of March, 2019, at Seattle, Washington.

/s/ *Emily Chiang*
Emily Chiang, WSBA No. 50517

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