UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION,
1025 Vermont Ave., Suite 800
Washington, D.C. 20005

Plaintiff,

v.

ALEX M. AZAR II, in his official capacity as United States Secretary of Health and Human Services,
200 Independence Ave., N.W.
Washington, D.C. 20201

and VALERIE HUBER, in her official capacity as Acting Deputy Assistant Secretary for the Office of Population Affairs,
1101 Wootton Parkway, Suite 700
Rockville, MD 20852

Defendants.

No. 18-cv-_____

COMPLAINT
For Injunctive Relief (Agency Action Contrary to Law)

INTRODUCTION

1. This action challenges Defendants' unjustified, unacknowledged and unlawful redirection of the Title X federal family planning program, away from its unique, long-standing purpose and in pursuit of new requirements that undermine it. Defendants have adopted impermissible criteria to govern Title X grant-making and are on the brink of awarding grants under those criteria, to the grave detriment of the current networks of Title X health care providers and the millions of patients they serve each year.

2. Since 1971, Congress has sought through the Title X program to ensure that all individuals, regardless of their income level, can have access to quality clinical care and the range of acceptable and effective, medically approved family planning methods necessary to allow each patient to determine freely the number and spacing of their children. *See* 42 U.S.C. § 300 *et. seq.* (Title X); 42 C.F.R. Part 59 (Title X regulations).

3. As the 2016 Family Planning Annual Report ("FPAR"), a document published each year by the Office of Population Affairs ("OPA"), a division of the U.S. Department of Health and Human Services ("HHS"), describes, Title X "is the only federal program dedicated solely to supporting the delivery of family planning and related preventive health care." 2016 FPAR at ES-1.

> The program is designed to provide contraceptive supplies and information to all who want and need them, with priority given to persons from low-income families. In addition to offering a broad range of effective and acceptable contraceptive methods on a voluntary and confidential basis, Title X-funded service sites provide contraceptive education and counseling; breast and cervical cancer screening; sexually transmitted disease (STD) and human immunodeficiency virus (HIV) testing, referral, and prevention education; and pregnancy diagnosis and counseling.

Id.

4. In accordance with this mission, for over 45 years, the Title X program has provided critical health care to patients who would otherwise go without. In 2016 (the latest year for which FPAR data is available), more than four million patients, almost 90% of whom were poor or low-income, obtained care through the Title X program. In addition, in 2016 family planning related preventive efforts, Title X-funded facilities provided 5.1 million tests for sexually transmitted infections, including 1.2 million confidential HIV tests, and approximately 700,000 Pap tests. Approximately 80% percent of Title X patients obtain contraception through

the program, which in 2015 meant helping women to avert more than 800,000 unintended pregnancies.

5. Defendants award Title X grants to nonprofit or public grant recipients, which then provide services and/or operate networks of providers. Historically, grants have been awarded for a multi-year period and only a portion of the Title X network has competed for a grant at any given time. In 2017, however, OPA, an office now headed by Defendant Valerie Huber and created in the same 1970 legislation that created the Title X program, and HHS, now headed by Defendant Secretary Alex M. Azar II, abruptly ended all previous multi-year grants. HHS and OPA have ordered that the entire Title X national network of projects instead file new competitive grant applications.

6. Defendants recently announced this new grant-making process through their funding opportunity announcement number PA-FPH-17-001 for Fiscal Year 2018 funds ("2018 FOA"), available at https://www.hhs.gov/opa/grants-and-funding/grant-opportunities/index.html. The 2018 FOA is now binding and will govern grant decision-making as soon as the review of applications begins shortly after the May 24, 2018, application deadline, if the 2018 FOA is not set aside as unlawful by this Court.

7. In the 2018 FOA, Defendants fundamentally alter the grant decision-making criteria that are mandated by the Title X statute and regulations and that have governed the program's grant-making for 47 years. In so doing, they introduce new program requirements for grants that both conflict with the Title X statute and regulations and undermine its effectiveness, and they steer this essential, federally-funded health care network far off course, harming Title X grantees, their health care provider networks, and the millions of individuals with few financial resources who depend on Title X-funded family planning care.

8. Plaintiff National Family Planning & Reproductive Health Association ("NFPRHA") is a national, nonprofit membership organization established in 1971 to ensure access to voluntary, comprehensive, and culturally sensitive family planning and sexual health care services, and to support reproductive freedom for all.

9. NFPRHA represents more than 850 health care organizations and individuals in all 50 states and the District of Columbia. NFPRHA's organizational members include state, county, and local health departments; private, nonprofit family planning organizations (including Planned Parenthood affiliates and others); family planning councils; hospital-based clinics; and Federally Qualified Health Centers.

10. Of particular relevance here, NFPRHA's membership includes 66 of the 79 current Title X grantees, or 84% of all grantees. Altogether, NFPRHA's grantee members operate or fund a network of more than 3,500 Title X health care sites that provide high-quality family planning and related preventive health services to more than 3.7 million low-income, uninsured, or underinsured individuals each year, roughly 93% of all patients served in Title X-funded health centers.

11. As a result of the Defendants' decision to issue the 2018 FOA challenged here, NFPRHA's Title X grantee members are now being forced to compete for 2018 grant funding on terms that are contrary to law and that impermissibly sideline the provision of clinical family planning, while requiring directive messages that violate central, explicit tenets of the Title X program: voluntary and non-coercive services that preserve the dignity of all patients, and afford access to acceptable and effective medical methods and services without regard to marital status or age.

12. Strikingly, the 2018 FOA nowhere mentions the words contraceptive or contraception and erases any mention of the clinical quality standards that have governed Title X health care projects until now. The 2018 FOA also repeatedly ignores and omits the words "medically approved[,]" an explicit part of the Title X regulation that requires projects to provide "a broad range of acceptable and effective medically approved family planning methods" and services. 42 C.F.R. § 59.5(a)(1). Instead, the 2018 FOA repeatedly mentions solely non-biomedical "natural family planning" and "fertility awareness based methods[.]" 2018 FOA at 11.

13. Indeed, the 2018 FOA prioritizes non-clinical, non-family planning objectives. Its scoring criteria and terms allow, for example, an advocacy or faith-based non-profit to apply for and operate a Title X project, with separate and minimal clinical care provided only through referrals to "documented partners[.]" 2018 FOA at 11, 23.

14. At the same time, the 2018 FOA's scoring criteria require providers to adopt a "meaningful emphasis" on counseling that extols, for clients of all ages, the virtues of "avoiding sexual risk" or "returning to a sexually-risk free status" and the benefits of marriage (code words for remaining abstinent except in the context of marriage). 2018 FOA at 11. The FOA likewise requires messages that "do not normalize" sexual behavior for their adolescent patients seeking family planning services. *Id.* Mandating these one-size-fits-all directives for Title X family planning patients runs exactly contrary to the principles of voluntariness, respect for the dignity of the patient, and non-discrimination that the Title X statute and regulations explicitly require.

15. The requirement of directive counseling, the lack of any reference to biomedical family planning methods, the elimination of any mention of the recognized clinical guidelines, the minimizing of the importance of direct medical care, and other changes made by the FOA

favor grant applicants with little or no experience in providing high-quality family planning care and push aside existing Title X networks that have for decades specialized in providing this care. This will harm patients, because research demonstrates that specialized family planning health centers provide more comprehensive care and more effectively serve a higher volume of patients.

16. As shown below, the 2018 FOA violates the Administrative Procedure Act in multiple ways: it is contrary to the Title X statute; it is inconsistent with numerous Title X regulations; it was issued without any acknowledgement of, or justifications for, its arbitrary and capricious change of direction and new criteria; and it was adopted without any opportunity for public comment or the required formal rule-making for binding rules of this kind.

17. Unless Defendants are enjoined from using the 2018 FOA by this Court, NFPRHA's members and the millions of patients they serve each year will suffer irreparable harm. NFPRHA seeks declaratory and injunctive relief to preserve the integrity of the Title X program; enable its members to continue in their roles as Title X grantees; preserve its members' high quality, voluntary, comprehensive, and culturally sensitive family planning projects; avoid the diversion of Title X resources toward priorities that do not lawfully belong in Title X projects; and ensure that the millions of people who depend on this important safety-net program are not deprived of the critical health services that Title X was created by Congress to provide.

PARTIES

18. Plaintiff National Family Planning & Reproductive Health Association ("NFPRHA") is a not-for-profit corporation with its headquarters and principal place of business in Washington, D.C.

19. As described above, NFPRHA's members include the vast majority of current Title X grantees. Its members are currently preparing applications under the 2018 FOA to

attempt to continue their roles in the Title X program. Many of those members will face competition governed by the impermissible terms of the 2018 FOA for the Title X funds available for their geographic areas, including from state governments that are bound by recently enacted state laws to compete for this funding or that have declared they will do so, and whose applications will be unfairly advantaged by the unlawful criteria challenged here.

20. In addition, if grant-making decisions under the 2018 FOA are allowed to proceed, it is virtually certain that some NFPRHA members will suffer reduced funding or be excluded entirely from any Title X grant because of the challenged criteria. Because of the 2018 FOA, NFPRHA members' program content, clinical services, and patients will be hurt. NFPRHA's members are being and will continue to be harmed by the 2018 FOA unless it is declared unlawful and enjoined.

21. 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 believes Title X is a critical part of the public health safety-net infrastructure. NFPRHA advocates preserving and strengthening these federally funded projects to ensure that the millions of women and men who rely on the network of providers participating in Title X can continue to access high-quality family planning methods and services there.

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

23. Defendant Valerie Huber is the acting Deputy Assistant Secretary for the Office of Population Affairs, the office within the Department of Health and Human Services that administers the Title X program. She is sued in her official capacity.

JURISDICTION AND VENUE

24. Pursuant to 28 U.S.C. § 1331, this Court has jurisdiction over Plaintiff's claims arising under the federal Administrative Procedure Act ("APA").

25. The Court is authorized to issue the injunctive and declaratory relief sought here under the APA, 5 U.S.C. §§ 702, 705, 706, the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, Federal Rules of Civil Procedure 57 and 65, and the inherent equitable powers of this Court.

26. Venue is proper in the District of Columbia under 28 U.S.C. § 1391(e) because Plaintiff NFPRHA resides in this district and because Defendant Azar, one of the two officials of an agency of the United States sued in their official capacities, also resides in this district.

FACTUAL ALLEGATIONS

The Origins and Purpose of Title X

27. Title X became law as part of the "Family Planning Services and Population Research Act of 1970." Pub. L. No. 91-572.

28. That statute was enacted a decade after the Food and Drug Administration's first approval of the oral contraceptive pill ("the pill"). At that time, the pill, like the other most effective contraceptive, the copper intrauterine device ("IUD"), was available only through physicians and at a high cost.

29. During the 1960s, many low-income women had more children than they desired and this had a significant effect on poverty levels, individuals' ability to obtain an education, and maternal and child health. Research established that it was inequitable access to contraceptives that made low-income women less able to match their actual childbearing with their desired family size.

30. 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, *271 – Special Message to the Congress on Problems of Population Growth* (July 18, 1969), available at http://www.presidency.ucsb.edu/ws/?pid=2132.

31. With overwhelming bipartisan support, Congress responded by enacting Title X. Congress' 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 declared as the first purpose of the legislation that included Title X "making comprehensive voluntary family planning services readily available to all persons desiring such services." Pub. L. No. 91-572, § 2(1).

32. Title X became, and remains, the only dedicated source of federal funding for family planning services in this country.

33. While providing low-income patients with biomedical contraceptives, the medical care required for their use, and the freedom to make their own decisions about whether and when to have children led to Title X and remains its central focus, Congress amended the statue in 1975 to also explicitly permit Title X projects to include natural family planning (now known as fertility awareness) in the array of methods they offer. Likewise, Title X was amended in 1978 to explicitly cover adolescent patients and to include infertility services.

34. Within each services project funded by Title X, there are typically three levels: the grantee, sub-recipients, and individual service sites run by either grantees or sub-recipients. In some states, the state health department is the sole grantee; other states have a non-profit organization as the sole grantee; and in other states there may be multiple Title X grantees. Some grantees handle only overall program direction, funding, administration, and oversight, and the sub-recipients include all of the 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 grantees that fall into each of these categories.

The High Quality Clinical Care That Title X Grantees Have Provided for Decades

35. Over the last four decades, Title X has built and sustained a national network of family planning health centers, delivered high-quality family planning in a cost-effective manner, enabled millions to prevent unintended pregnancies, and allowed Title X patients to instead plan for the children they desire.

36. The Centers for Disease Control and Prevention ("CDC") named family planning one of the most important achievements in public health in the 20th century, noting that the "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(47) Morbidity and Mortality

Weekly Report 1073-80 (December 3, 1999), available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4847a1.htm.

37. In 2015, alone, for example, services provided by health centers that received Title X funding helped women avert 822,300 unintended pregnancies, thus preventing 387,200 unplanned births and 277,800 abortions. Without the services provided by Title X-funded sites, the U.S. unintended pregnancy rate would have been 31% higher and the rate among teens would have been 44% higher.

38. As reported in the FPAR, Title X projects in 2016 served 4,007,552 clients. Women made up 89% of those served, men 11%. Title X projects are required to serve patients without regard to age or marital status. In 2016, 92% of project users were adults and 8% were under the age of 18; 9% were 18 or 19 years of age, 48% were between 20 and 29, 34% were 30 or older. Title X projects serve a racially and ethnically diverse population, including a disproportionately high percentage of black and Latina clients; in 2016 54% of program users identified as white, 21% as black or African-American, 32% as Hispanic or Latina, 3% as Asian, and 1% as either Native Hawaiian or Other Pacific Islander or American Indian or Alaska Native.

39. Consistent with Title X's purpose, providers in a Title X project must give priority in the provision of services to persons with limited incomes. In fact, Title X clients are overwhelmingly poor or low-income. In 2016, 88% of clients had incomes at or below 250% of the federal poverty level and 64% had incomes at or below the federal poverty level (for 2016, $11,880 for one person; $24,300 for a family of four). As required by the Title X regulations, clients with incomes below the federal poverty line do not pay anything for the services or supplies they receive from a Title X provider. For clients with incomes not below the federal

poverty line but less than 250% of that level, Title X providers use a schedule of discounts to the reasonable cost of providing services or supplies.

40. The recently-passed Fiscal Year 2018 omnibus appropriations legislation provides $286,479,000 for Title X funding. To fully meet the need for subsidized family planning care, the program would require in excess of $700 million annually. Title X today satisfies approximately one-fifth of the need for publicly funded contraceptive services and supplies. And among women who obtain publicly-funded contraceptive care at some type of safety-net health center, six in ten receive that care from a Title X-supported site.

41. Title X projects are substantial undertakings. A project grantee is responsible for millions of project dollars to provide specialized care (often with multiple sub-recipients and dozens of service sites operated by the grantee and/or sub-recipients), and subject to elaborate regulatory, compliance and reporting requirements. The recruitment, vetting, training, and coordination of sub-recipients are especially intense tasks as a project's network of providers is first established. Likewise, special budgeting, billing and other administrative processes must be put in place to comply with Title X requirements. Thus, the initial establishment of a Title X project's service network, clinical protocols, and administrative processes typically takes many months to accomplish. Over time, the Title X primary grantees and sub-recipients have been relatively stable, and many now have deep expertise and decades of experience in providing family planning methods and services to their primarily low-income patients.

42. Because Title X aims to best advance equal access to effective and medically approved family planning methods and services, OPA has specified clinical standards for the program, incorporating periodic updates. These help ensure that Title X projects are providing evidence-based clinical care consistent with current nationally recognized protocols, and are

accomplishing the purpose of Title X. In April 2014, OPA and the CDC published new national clinical standards, "Providing Quality Family Planning Services," (the "QFP"), which are relevant for any providers. QFP, 63:4 Morbidity and Mortality Weekly Report (April 25, 2014), available at https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf. OPA required these standards for Title X care by incorporating the QFP into its program guidance for Title X services projects, "Program Requirements for Title X Funded Family Planning Projects" ("Program Requirements"), also published in April 2014. The 2018 FOA does not reference, or otherwise require proposed projects to comply with, either the Program Requirements or the QFP.

43. The QFP 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 1971. QFP at 2.

44. 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, for example, are used by medical directors "to write clinical protocols that describe how care should be provided." QFP at 3. The QFP emphasizes that a truly client-centered approach is essential. This means starting from and respecting the client's reason for seeking family planning care. QFP at 2, 4. Individual "client values guide all clinical decisions." QFP at 4. The "primary purpose for visiting the service site must be respected." QFP at 2.

45. The QFP also prioritizes effectiveness and, for example, "support[s] offering a full range of Food and Drug Administration (FDA)-approved contraceptive methods 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. The QFP further emphasizes equitable, evidence-based care consistent with current professional knowledge, so that family planning care does not vary in quality because of the personal characteristics of clients. QFP at 4.

46. Compared with publicly funded health centers that do not receive Title X funding, health centers supported by Title X are more likely to offer the full range of contraceptive methods, especially the most effective methods, and to better help clients start and effectively use their chosen methods.

47. The vast majority of Title X providers (72%) focus on reproductive health care and the vast majority of contraceptive clients who receive care from the publicly funded care network (70%) are served by specialized family planning centers. The care in these specialized health centers more fully incorporates up-to-date clinical options. For example, 74% of all specialized family planning centers offer the full range of FDA approved contraceptive methods on site compared with the 48% of primary care focused centers that do so. Specialized family planning centers are also more likely to offer clients long acting reversible contraceptives like IUDs and implants (74-83% vs. 51-60%), which are among the most effective methods.

48. Many women actively choose reproductive health-focused providers for contraceptive care, even when there is a primary care-focused site available, because family planning patients feel more respected by staff, know they are able to obtain confidential services there, and recognize that staff are well-versed in women's health.

The Governing Title X Statute and Regulations

49. Title X, in the portion of the title enacted as Section 1001, authorizes the Secretary of HHS to make grants for "voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)." 42 U.S.C. § 300(a).

50. The statute further provides that, in making grants, the Secretary "shall take into account the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance." 42 U.S.C. § 300(b).

51. A grant may be made only upon assurances that priority will be given for such services to "persons from low-income families[,]" which shall be defined by the Secretary "so as to insure that economic status shall not be a deterrent to participation in" Title X projects. 42 U.S.C. § 300a-4(c). Title X also stresses that the acceptance of services and information provided in the program must be voluntary, and may not be required as a condition for obtaining other services. 42 U.S.C. § 300a-5.

52. Furthermore, the statute provides that Title X grants "shall be made in accordance with such regulations as the Secretary may promulgate." 42 U.S.C. § 300a-4(a).

53. After Title X's passage, the Secretary immediately undertook a formal rule-making process and promulgated detailed regulations. Essential aspects of those regulations, reaffirmed through subsequent rulemakings, remain in place today. From the outset, the Secretary specified that "eligible projects" were "voluntary family planning projects consisting of the educational, comprehensive medical, and social services necessary to aid individuals

freely to determine the number and spacing of their children." 36 Fed. Reg. 18,465, 18,466 (Sept. 15, 1971); *see also* 42 C.F.R. § 59.1.

54. In 1971, the Secretary also specified the seven criteria that HHS would take into account for purposes of awarding any Section 1001 grants, which still govern today: (1) the number of patients, and, in particular, the number of low-income patients to be served; (2) the extent to which family planning services are needed locally; (3) the relative need of the applicant; (4) the capacity of the applicant to make rapid and effective use of the federal assistance; (5) the adequacy of the applicant's facilities and staff; (6) the relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project; and (7) the degree to which the project plan adequately provides for the requirements set forth in the Title X regulations. 42 C.F.R. § 59.7; *compare* 36 Fed. Reg. 18,465, 18,466-18,467 (Sept. 15, 1971) (providing for same seven criteria in virtually identical language).

55. As a comparison with 42 U.S.C. § 300(b) shows, *see* ¶ 50, *supra*, the first four criteria in this governing regulation repeat the language of that section of the statute, then the fifth criterion isolates a particular aspect – facilities and staff – of the applicant's ability to make rapid and effective use of the funds (number 4), the sixth isolates a particular aspect of the relative need (numbers 2 & 3), and the seventh incorporates the Title X regulations' requirements into these criteria for grant decision-making.

56. The regulations reinforce the statutory requirement and primary purpose of the program. They require that each family planning project must, *inter alia*:

> (1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, it may participate as part of a

> project as long as the entire project offers a broad range of family planning services.

42 C.F.R. § 59.5(a)(1).

57. In addition, the regulations mandate that all projects must also provide "medical services related to family planning (including physician's consultation, examination[,] prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices," unless the Secretary waives this requirement for a particular project upon its establishment of good cause. 42 C.F.R. § 59.5(b)(1). Upon information and belief, the Secretary has never waived that requirement over the almost five decades of the Title X program.

58. Like the statute, the regulations make clear that the acceptance of any service within a Title X project must be voluntary; Title X funded entities cannot condition the client's ability to receive a desired service on the acceptance of another, undesired service, and must treat patients with dignity.

59. Specifically the regulations state that all Title X funded projects must:

> (2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the applicant.
>
> (3) Provide services in a manner which protects the dignity of the individual.

42 C.F.R. § 59.5(a)(2)-(3).

60. In addition, such projects must "[p]rovide services without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status." 42 C.F.R. § 59.5(a)(4).

61. In keeping with the clinical and highly personal nature of Title X services, the regulations provide for stringent confidentiality protections for all patients. 42 C.F.R. § 59.11.

62. The regulations do not make any assumptions about family composition, and define "family" to mean "a social unit composed of one person, or two or more persons living together, as a household." 42 C.F.R. § 59.2.

How Funding Opportunity Announcements Govern Title X Grant-making

63. Grants for Title X projects, like other HHS grants, are awarded through a process that begins with a funding opportunity announcement ("FOA"). Once OPA issues a particular Title X FOA, it is bound to use the detailed parameters set forth therein to award any funds to which the announcement applies. An FOA is final agency action with regard to the nature of the projects that may be funded and the specific criteria that must govern the review of applications and ultimate decisions.

64. Until now, the FOAs for Title X competitive services grants have each provided that the seven criteria in 42 C.F.R. § 59.7 must govern the substantive application review and grant decision-making.

65. In the early 2000s, Title X FOAs – like other HHS FOAs – added scoring for each of the governing criteria, with the relative values of the seven Title X criteria adding up to 100.

66. In addition to describing the fundamental Title X program, and its legal and clinical requirements, FOAs for some time have also referenced HHS's or OPA's "overarching goals" in any given year, calling them program priorities and key issues. Those topical "goals" statements, however, have never been part of the criteria that govern Title X application review, scoring, or grant awards.

67. After the voluminous Title X applications, which include a project narrative, budget narrative, work plan, and other required parts and appendices, are filed with HHS, they are first reviewed for any disqualifying characteristics. Then the FOA is given, along with all non-disqualified applications, to merits review panels for those panels' scoring of the proposed projects under the governing criteria. Once the applications are scored, OPA makes the awards, with a geographic spread across the Title X service areas covered by the FOA.

68. Different service areas – states or territories – have in the past competed for Title X services grants at different times. Upon information and belief, it has been decades since OPA has sought to evaluate competitive grant applications for the entire nationwide network at the same time.

69. By 2017, all competitive Title X services grants started on either April 1 or July 1 of a given year. The FOA for the Title X competitions, typically for three-year grant periods, would come out several months before those dates.

70. In July 2017, however, all competitive awards – as well as all continuing awards from previous competitions on the July cycle – were issued only for a one-year period, to end on June 30, 2018. Similarly, all grants that had started on an April 1 date and had project periods not scheduled to end on March 31, 2018, received a notice in 2017 from HHS stating that their grants too would nonetheless end on March 31, 2018, and that they would be receiving revised notices of award that reflected that change.

71. When grantees inquired about these unexpected changes to the award periods and the shortening of already-awarded grants, OPA referred to changes in priorities. Grantees were told to anticipate a new FOA in September or October 2017 that would reflect the changed approach.

72. OPA did not release that new 2018 FOA until February 23, 2018. Because it takes months to coordinate the content of and prepare a Title X services grant application, and then takes months for the merits review and OPA's awards, this meant that new awards could not possibly be awarded by April 1 or July 1, 2018.

73. Instead, OPA notified current Title X grantees whose previous awards ended in March 2018 or will end in June 2018 that continuation grants (known as "cost extensions") are available to continue their funding until new award decisions are made and the grant period for new Fiscal Year 2018 awards begins. The grantees whose awards ended in March are now operating under such cost extensions.

74. Applications in response to the 2018 FOA are due on May 24, 2018. The FOA gives the estimated start date for grants awarded under it as September 1, 2018. The FOA states that HHS "seeks to award funds as much in advance of the anticipated project start date … as practicable, with a goal of 10-15 days. Note this is an estimated start date and award announcements may be made at a later date and with a later project period start date." 2018 FOA at 47.

Defendants' 2018 Funding Opportunity Announcement Impermissibly Changes Course

75. Since 1971 the same seven criteria formally promulgated by HHS, now set forth in 42 C.F.R. § 59.7, have governed the evaluation of Title X services project applications and the applicants that receive any awards.

76. Those seven criteria, and only those criteria, have been specified in all of the past competitive FOAs, occasionally with a word changed or an explanatory phrase added, but without substantive alteration. Since numerical scoring began, each of the seven criteria has been allocated 5-20 points out of a total of 100.

77. The 2017 Title X FOA, for example, ranks the seven criteria this way: 20 points for the adequacy of the applicant's facilities and staff; 20 points for the degree to which the project plan adequately provides for the requirements set forth in the Title X regulations; 20 points for the extent of the need in the proposed service area; 15 points for the capacity of the applicant to make rapid and effective use of the federal assistance; 10 points for the number of low-income patients to be served; 10 points for the relative availability of non-federal resources and their commitment to the project; and 5 points for the relative need of the applicant.

78. Defendants' 2018 FOA now veers off course, redirecting grant-making toward newly-required program efforts that are contrary to the purpose of Title X, its governing statute and its regulations. The 2018 FOA departs in numerous ways from the existing, formally-promulgated regulations; it abandons any reference to the CDC/OPA quality standards (the QFP) that have until now helped ensure state-of-the-art medical contraceptive care and other high quality clinical family planning for Title X patients; and it jettisons the essential patient choice and patient dignity that are required by the statute and regulations and that have been central to this explicitly non-judgmental program to date. Each of these significant alterations has been made without any acknowledgement or justification.

79. The 2018 FOA mandates these changes most obviously by adding a new, eighth application review criterion, "criterion (h)." As spelled out in the 2018 FOA, criterion (h) pulls into the 2018 Title X application scoring, for the first time, the FOA's discussion of "priorities and key issues," makes those priorities and key issues into requirements, and gives 25 points out of the 100 point scale to "[t]he degree to which the project plan adequately provides for the effective and efficient implementation of requirements set forth in the priorities and key issues outlined on pages 9-11 of this funding announcement." 2018 FOA at 44.

80. In addition, Defendants have added language to one of the original seven criteria that also injects the "priorities and key issues" section of the 2018 FOA into a second scoring category. Criterion (e) in the 2018 FOA directs that now 10 points are allocated for "[t]he adequacy of the applicant's facilities and staff, demonstrating that the staff are adequately trained to carry out the program requirements, *as well as the priorities and key issues outlined in this announcement*." 2018 FOA at 43 (emphasis added to new portion of this long-standing facilities-and-staff criterion). Thus, 35 out of 100 points depend upon an applicant's score on the 2018 FOA's new "priorities and key issues" requirements.

81. Further upending Title X's central aims, the 2018 FOA expanded criteria also give more weight to the "relative need of the *applicant*" requesting funds (15 points) (emphasis added) than to the extent to which family planning services are needed locally (10 points) or the number of low-income patients to be served (10 points). All of the other criteria, besides the new 25-point "priorities and key issues" criterion (h) and the need of the applicant criterion (15 points), are relegated to 10 points each, including the degree to which the plan adequately provides for the requirements set forth in the Title X regulations. Thus, when the two criteria incorporating "priorities and key issues" and the additional criterion regarding the applicant's need are combined, that totals 50 out of 100 possible points.

82. In the priorities and key issues, as in the rest of the 2018 FOA, Defendants have cleansed the description of Title X care of any reference to the "broad range of acceptable and effective *medically approved* family planning" methods and services that are required in Title X projects. 42 C.F.R. § 59.5(a)(1) (emphasis added). That phrase is repeatedly used without the "medically approved" language that is explicitly required by regulation. Unlike past competitive FOAs, this FOA also omits any requirement of complying with the clinical family planning

standards of the QFP. "Contraception" or "contraceptive" are not anywhere in the document, including in the 2018 FOA's "priorities and key issues."

83. Nor are there any mentions of any one of the numerous biomedical contraceptive methods that constitute the "most effective" or "moderately effective" means of preventing pregnancy, as classified by HHS in the QFP, as used within the current Title X program, and as reported in OPA's annual FPAR. The only methods of pregnancy prevention referenced in this 2018 FOA and its priorities and key issues are natural family planning / fertility awareness methods (one of the "less effective methods"), a choice made by less than 0.5% of female Title X patients, and abstinence, a choice made by only 3% of female Title X patients in 2016 – and by only 1-2% of patients between 18 and 39 years of age. 2016 FPAR at 28 & Ex. 19.

84. After excising any reference to contraception, medical methods, or the QFP, the priorities and key issues – now the predominant scoring factor – replace those fundamental components of any legally-compliant Title X project with requirements that impermissibly divert Title X resources and that inject new required actions for Title X projects that are contrary to the Title X statute and regulations.

85. The priorities and key issues, along with other language throughout the 2018 FOA, engraft a required abstinence-only-until-marriage point of view onto a program that instead – according to its governing legal framework and purpose – must enable patient free choice and access to not only abstinence, or fertility awareness methods during marriage, but the broad array of other choices, including the many more effective and medically approved contraceptive methods that are today available to individuals.

86. The priorities and key issues now score Title X grant applications on how effectively the proposed project will, for example, provide:

> A meaningful emphasis on education and counseling that communicates the social science research and practical application of topics related to healthy relationships, to committed, safe, stable, healthy marriages, and the benefits of avoiding sexual risk or returning to a sexually risk-free status, especially (but not only) when communicating with adolescents[.]

2018 FOA at 11 (Key Issue 5). The Key Issues further require "activities for adolescents that do not normalize sexual risk behaviors," but instead "clearly communicate" the "benefits of delaying sex or returning to a sexually risk-free status." *Id.* (Key Issue 6). The priorities and key issues also score the degree of grant applicants' cooperation with "faith-based organizations." *Id.* (Key Issue 4).

87. The priorities and key issues now require Title X grantees to "assur[e] activities that promote positive family relationships[,]" not only with regard to increasing participation in family planning but also to increase "healthy decision-making." 2018 FOA at 10 (Priority 2). Title X projects must also "assur[e] education and counseling that prioritize optimal health and life outcomes for every individual and couple; and other related health services, contextualizing Title X services within a model that promotes optimal health outcomes for the client." *Id.*

88. These terms and phrases may seem generic, but they are in fact the buzzwords of abstinence-only-until-marriage approaches to sex education in schools, now sometimes called "sexual risk avoidance." Abstinence-only and "sexual risk avoidance" are described by their advocates as means of achieving "optimal health" by delaying sexual activity until a faithful marriage. As the advocacy organization Ascend (formerly known as the National Abstinence Education Association) describes it, the sexual risk avoidance sex education that it advocates helps youth achieve "optimal health" and empowers them to make the "healthiest choices." Ascend, Sexual Risk Avoidance Works at 3 (2016), available at https://weascend.org/wp-content/uploads/2017/10/sraworksweb.pdf. Ascend has taken the position that the benefits of

"sexual delay (preferably until marriage)" are "benefits that contraception can never duplicate." *Id.*

89. According to Ascend, the sexual risk avoidance approach "includes a cessation intervention approach" for those who are sexually active, offering the "encouragement and skills to return to an optimally healthy lifestyle free from all sexual risk." *Id.* at 7. The sexual risk avoidance "approach is holistic, linking and contextualizing the value of avoiding sex" with other components of life, including by providing "information on the non-physical consequences" that can accompany sex and on "the practical skills associated with healthy decision-making, and … healthy relationships." *Id.* The 2018 FOA requires a "meaningful emphasis" on this abstinence-only approach not only when communicating with adolescents, but within each Title X project for clients of *all ages*. 2018 FOA at 11 (Key Issue 5); *see also* 2018 FOA at 5-8, 9-10 (Priorities 1 & 2).

90. The priorities and key issues not only require emphasis on abstinence-only, but also newly charge Title X grantees (in Priority 1) with "improve[ing] the overall health of individuals, couples and families," making "core family planning services" only a required "minimum" part of their project. 2018 FOA at 9. The 2018 FOA asks applicants to serve "optimal health" with regard to "physical, emotional and social outcomes." 2018 FOA at 6-7, 9-10. This description imposes virtually no limit on the content of Title X funded projects.

91. Thus, in all these ways and others, the FOA moves program activities away from Title X's statutory purpose of providing access to modern, high-quality family planning clinical care, including contraceptives, regardless of a patient's means and always responsive to a patient's wishes, to instead require a "meaningful emphasis" on advocating the benefits of abstinence-only and promoting a particular model for all patients' lives and relationships. This

not only impermissibly diverts Title X funds, in conflict with governing regulations, but would also substantially undermine the quality provision of clinical family planning care.

92. In particular, these changes – effectuated by the new criterion (h) and the disproportionate share of scoring attributed to the priorities and key issues – are inconsistent with 42 C.F.R. §§ 59.1, 59.5(a)(1)-(4), and 59.7, among other legal requirements. The changes impermissibly mandate services that, for example, do not "protect the dignity of the individual[,]"42 C.F.R. § 59.5(3), do not occur without regard to marital status, and that require as an improper prerequisite for access to any medically approved contraception methods the step of clients (of all ages) first being subjected to a provider's communication of the "benefits of avoiding" sex or "returning to a sexually risk-free status."

93. By contrast, the QFP makes clear that appropriate clinical care should always start with the client's reason for the visit and the client's goals; likewise, it "is respectful of, and responsive to, individual client preferences, needs and values; client values guide all clinical decisions." QFP at 4-5. As the QFP explains, adolescents should be given "comprehensive information … about how to prevent pregnancy" – this includes abstinence – but "[i]f the adolescent indicates that he or she will be sexually active, providers should give information about contraception and help her or him to choose a method that best meets her or his individual needs, including the use of condoms to reduce the risk of STDs. Long-acting reversible contraception ["LARC"] is a safe and effective option for many adolescents …." QFP at 13. In violation of the governing law, the 2018 FOA tells Title X grant applicants and their projects to alter this best-practice approach.

94. The specific, detailed requirements of the priorities and key issues make clear that the 2018 FOA seeks to mandate communication of values-based messages in counseling and

other Title X activities when Title X's legal framework requires fully voluntary, free choice by patients, and care guided by the individual patient's own values.

95. The 2018 FOA also prioritizes and scores (in Priority 4) Title X grant applicants higher for "[p]romoting provision of comprehensive primary health care services" that are "preferably in the same location" as family planning services. 2018 FOA at 10. This is one of several aspects of the priorities and key issues that score a Title X grant applicant higher if it proposes to provide services through a primary care facility, and *not* through a specialized reproductive health center.

96. Yet specialized providers have the most expertise in clinical family planning, have always been the backbone of Title X and, research shows, generally give superior care and serve a higher volume of patients. The 2018 FOA's priorities and key issues, contrary to the purpose of Title X, appear aimed at weeding out certain types of providers.

97. These changes are not only inconsistent with the Title X statute but also come about without any acknowledgement by HHS that it is acting contrary to its existing regulations; without any notice and request for public comment; with inconsistencies, irrationalities and opaqueness in the new FOA mandates; and without any justification, much less a reasoned one, for these alterations. These unlawful changes are causing serious harm to the existing Title X network of grantees as they re-compete for the Fiscal Year 2018 awards and to the Title X program as a whole. If not stopped from governing grant review and awards, the 2018 FOA will most alarmingly harm the millions of predominantly low-income individuals who rely on the program each year for access to sophisticated family planning services and related testing and care – the very access to the same family planning opportunities available to those with greater financial means that Congress through Title X sought to equalize.

The Harm to NFPRHA Members and Their Patients

98. NFPRHA's member grantees – who, either directly or through their networks of sub-recipients, have provided the vast majority of Title X care for decades– are harmed in several ways as they now apply under the 2018 FOA and Defendants use the 2018 FOA criteria to score and decide on the NFPRHA members' applications.

99. First, NFPRHA member applicants are already being required to expend their organizations' staff time and money to attempt to address these impermissible 2018 FOA criteria. As members prepare their applications, the improper FOA criteria are causing applicants to attempt to establish new sub-recipient and referral relationships, to explore changes to their programming and additions to their counseling protocols, to confer with experts and with other Title X grantees, and to undertake various other time-consuming and difficult steps that they would not have undertaken without the unlawful changes adopted by this FOA. This required work, which diverts resources from purposes that advance Title X's aims, will continue after the application submissions as NFPRHA member applicants prepare for a potential award, and into the actual grant period, if applicants succeed in maintaining a Title X role, as they attempt to cope with the improper changes and the program harms imposed by the 2018 FOA's requirements.

100. Second, the 2018 FOA is putting NFPRHA member applicants in the unwinnable situation of either attempting to fully conform their applications' work plan and proposed project to all of the new unlawful requirements, or facing the substantial risk of a greatly diminished or abolished role in Title X care. NFPRHA member applicants are being required to either compromise what those organizations believe is the best family planning project, as they have

been operating it successfully in the past, or seriously jeopardize their funding and any continued participation as a Title X grantee.

101. Third, the 2018 FOA is imposing improper competitive harm on NFPRHA member applicants, who have long served as Title X grantees, many since the Title X program's inception. That is because the FOA's new criteria and other changes impermissibly favor new applicants, especially those, for example, whose application (a) does not rely on family planning specialist clinical providers and (b) prioritizes abstinence-only-until-marriage and other "optimal health" messages for discussion with all clients while *not* requiring QFP-based care, as has until the 2018 FOA been required by Title X. The Title X regulations and QFP-based care include unimpeded access to a broad range of effective medically approved contraceptives in a manner that starts with the client's wishes and defers to the client's values, but the 2018 FOA favors providers who prioritize other, mandated communications or do not specialize in reproductive care. This unfair competitive harm to NFPRHA member applicants will be crystalized the moment that the scoring process begins, shortly after applications are submitted on May 24, 2018, unless this Court acts to prevent Defendants from using the 2018 FOA and its unlawful criteria.

102. Fourth, NFPRHA member applicants face the substantial prospect of the 2018 FOA provisions cutting or ending their funding as Title X grantees completely. If they do not conform to the program disruptions and distortions, and maintain their fully compliant Title X projects as is, the criteria and scoring in this new 2018 FOA will evaluate their applications poorly, and create significant risk to their continued funding. As explained above, many current Title X grantees will score lower while direct competitors will score higher on new criteria that should never have been in the FOA and should not govern grant-making. Existing grantees, for

example, face competition from some state health departments that are forbidden by state law from including many specialist reproductive health providers in their state networks, to the detriment of patients, but those states will score high on the "priorities and key issues" as a result.

103. If the 2018 FOA accomplishes OPA's stated intentions, existing Title X grantees will also face competition from "health collaboratives" and other new types of applicants "with a holistic vision of health and [employing methods] historically underrepresented in the Title X program." 2018 FOA at 3, 7 (further emphasizing that "each Title X project should ensure that family planning is contextualized within a holistic conversation of health"). Defendants have made clear in the 2018 FOA that they seek to distribute awards to new applicants, and not to continue the same array of existing Title X projects.

104. Thus, among the 66 NFPRHA member grantees (84% of the separate organizations now funded by Title X), it is extremely likely that future awards will be reduced or not occur at all, and thus existing Title X grantees will suffer drastic budget cuts and millions of dollars in lost funding. And less or no continued funding for these historical Title X grantees will mean staff layoffs, vastly reduced projects, the closure of health centers, and other negative effects for their organizations, because for many of the NFPRHA member grantees, Title X represents the largest component, by far, of their funding streams.

105. Fifth, all of the above harms also involve significant irreparable harms to the population that Title X aims to serve. The 2018 FOA pushes Title X family planning providers (i) to divert money and time away from their patient care efforts in order to attempt to conform to unlawful new grant criteria, (ii) to change their planned projects for Fiscal Year 2018 in ways that provide less effective care, infringe on the dignity and equality of all patients, and spread

family planning funds to agendas that exceed Title X's proper scope, (iii) to compete against and in many cases lose funding to new applicants that will move far away from Title X's lawful focus, and (iv) to thereby spend funds and other resources for purposes not properly permitted by the Title X statute or regulations, thus reducing the number of low-income patients who can gain the access to contraceptives and the non-judgmental, quality clinical care that is the heart of Title X.

106. All of this will have severe and immediate effects on the individuals who rely on the Title X program for essential family planning health care, as well as the public interest generally. Almost 90% of Title X patients are poor or low-income. The disruption of their care, through funding cuts or wholesale network changes, or the imposition of program requirements that demean patients and discourage their seeking ongoing care, will take control over family planning away from individuals with few other resources. Without access to the care that Title X was designed to provide, clients who would otherwise have been seen by NFPRHA's members will lose access to contraception, particularly the most effective (and most expensive) methods; will lose access to preventive testing and care necessary to preserve fertility; and will experience higher rates of unintended pregnancy, infertility, HIV, and other direct harms to their health. Moreover, these clients, and their communities, will experience snowballing harms to their economic and personal lives if this essential access to family planning is decimated.

107. Recent experience is illustrative. When the state of Texas significantly altered its family planning program, including its Title X funded activities, several years ago by, among other things, cancelling contracts with specialized family planning providers and instead giving them to primary care entities with little experience providing this care, as the 2018 FOA is also designed to do, the public health impact was immediate and devastating. Nearly half of Title X

clients lost access to services, making contraception unobtainable for tens of thousands, and the unintended pregnancy rate rose sharply.

108. In order to mitigate all of these harms and to prevent devastating damage to NFPHRA's members, the Title X program, and the millions of patients who depend on the program for critical care, the 2018 FOA should be set aside.

CAUSES OF ACTION

CLAIM ONE
APA: CONTRARY TO LAW

109. Plaintiff incorporates by reference the allegations of the preceding paragraphs.

110. An agency rule or action that is manifestly contrary to a statute and Congress' statutory intent is not valid.

111. HHS regulations, including in 42 C.F.R. Part 59, have the force of law.

112. The 2018 FOA constitutes final agency action.

113. The 2018 FOA is contrary to the Title X statute because it provides that Title X funding decisions will be based on criteria that are not within any permissible construction of 42 U.S.C. § 300(b). The 2018 FOA is also contrary to the Title X regulations, which list seven specific criteria, drawn from the statute, that HHS is to consider. *See* 42 C.F.R. § 59.7.

114. The 2018 FOA also conflicts with Title X's fundamental purpose and its substantive requirements for supported projects. The 2018 FOA departs from Title X, conflicts with its purpose, and is manifestly contrary to Congress' intent to fund "voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services" to allow all individuals, regardless of their income, access to the evidenced-based, comprehensive clinical care they need to freely decide on the spacing and

number of their children. 42 U.S.C. § 300(a); *see also* 42 U.S.C. §§ 300a-4, 300a-5; 42 C.F.R. §§ 59.1, 59.5.

115. The 2018 FOA should be held unlawful and set aside under the Administrative Procedure Act, 5 U.S.C. §§ 706(2)(A) & (C).

CLAIM TWO
APA: ARBITRARY AND CAPRICIOUS

116. Plaintiff incorporates by reference the allegations of the preceding paragraphs.

117. The 2018 FOA, including its criterion (h), its "priorities and key" issues, and the other new requirements contained in it, is arbitrary and capricious because its changes run counter to the best available evidence regarding how to provide comprehensive family planning services for low-income people, or have no evidence-based relationship to that goal.

118. The 2018 FOA is also arbitrary and capricious because it lacks any acknowledgement of its numerous changes from existing regulations and agency guidance; lacks any justification for the new requirements; is internally inconsistent; and is not reasoned agency action.

119. The 2018 FOA should be held unlawful and set aside under the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

CLAIM THREE
APA: FAILURE TO ENGAGE IN NOTICE AND COMMENT RULEMAKING

120. Plaintiff incorporates by reference the allegations of the preceding paragraphs.

121. HHS' previously promulgated Title X regulations, including but not limited to 42 C.F.R. § 59.7, have the force of law. HHS is required to use notice and comment rulemaking if it wishes to modify those regulations. *See* 36 Fed. Reg. 2532 (Feb. 5, 1971).

122. 42 C.F.R. § 59.7 sets forth the criteria that HHS shall consider in deciding to award Title X funds.

123. The 2018 FOA announces new legislative, force of law criteria that govern application review and Title X grant-making.

124. The 2018 FOA's new criteria contravene 42 C.F.R. § 59.7, or constitute an attempt to change 42 C.F.R. § 59.7 without following the required notice and comment rulemaking process.

125. The new application review criteria are contrary to HHS regulations and invalid, and should be set aside under the Administrative Procedure Act, 5 U.S.C. §§ 706(2)(A) & (D).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays this Court to:

a) Declare that the Title X 2018 FOA as issued is contrary to law, arbitrary and capricious, an abuse of discretion, and invalid;

b) Enjoin HHS from using the 2018 FOA as issued to review Title X grant applications;

c) Require that HHS provide any continuation funding necessary to ensure that Title X projects remain funded until such time as HHS awards Fiscal Year 2018 Title X grants pursuant to a legally permissible FOA and based on grant applications submitted in response to such a legally permissible FOA;

d) Award Plaintiff its costs and attorney's fees incurred in bringing this action pursuant to 28 U.S.C. § 2412; and

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

May 2, 2018

Respectfully Submitted,

/s Arthur B. Spitzer

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