UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PLANNED PARENTHOOD OF WISCONSIN, INC.,
302 North Jackson Street
Milwaukee, WI 53202

PLANNED PARENTHOOD OF GREATER OHIO,
206 E. State Street
Columbus, OH 43215

PLANNED PARENTHOOD ASSOCIATION OF UTAH
654 South 900 East
Salt Lake City, UT 84102

Plaintiffs,

v.

ALEX M. AZAR, in his official capacity as United States Secretary of Health and Human Services,
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

VALERIE HUBER, in her official capacity as Acting Deputy Assistant Secretary for the Office of Population Affairs,
U.S. Department of Health and Human Services
1101 Wootton Parkway, Ste 700 Rockville, MD 20852

Defendants.

Civil Action No. 18 Civ. 1035

COMPLAINT

Plaintiffs, by and through their attorneys, hereby allege as follows:

INTRODUCTION

1. Plaintiffs bring this action to defend a family planning assistance program that provides essential reproductive health care for millions of Americans each year. Title X of the Public Health Service Act was created to provide comprehensive family planning services to

low-income patients. But now, the government seeks to shift the Title X program away from its core statutory purpose, by dramatically altering the criteria that determine who can participate in the program. Those unexplained and unjustified changes contravene the Title X program as Congress intended it, violate the government's own existing regulations, and threaten devastating, irreparable harms to the very patients Title X was meant to help.

2. Enacted a half century ago to make good on President Nixon's promise that "no American woman should be denied access to family planning assistance because of her economic condition," Title X provides hundreds of millions of dollars each year "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services." 42 U.S.C. § 300(a). Congress created the Title X program to ensure that all people, and especially low-income women, have access to family planning care.

3. The Title X statute sets forth the considerations that the Department of Health and Human Services ("HHS") "shall take into account" in awarding grants to accomplish Title X's aims, including "the number of patients to be served," and the capacity of the applicant to use Title X funds. 42 U.S.C. § 300(b). HHS has also issued longstanding Title X regulations that further articulate Title X's commitment to providing "a broad range of acceptable and effective medically approved family planning methods," including contraception. 42 C.F.R. § 59.5(a)-(b). Those regulations provide that Title X grants will be awarded based on a set of seven criteria—such as the number of patients served, the demonstrated need for services, and the capacity of the applicant—that are drawn directly from the Title X statute. *See* 42 C.F.R. § 59.7.

4. This statutory and regulatory regime has remained consistent from the start. Accordingly, each and every year, when HHS has issued a "Funding Opportunity

Announcement" ("FOA") for Title X funding, the "application review criteria" in the FOA have been consistent with the Title X statute and with HHS regulations. That consistency has benefited millions of Americans who receive subsidized comprehensive family planning care from qualified Title X grantees like Plaintiffs.

5. Plaintiffs are all dedicated to Title X's core mission. They are Planned Parenthood affiliates from Wisconsin, Ohio, and Utah who have each received Title X grants for decades and who use those funds to serve Americans from diverse regions and backgrounds, from urban centers like Milwaukee and Cleveland to rural areas like Appalachia and southern Utah. Each year, Plaintiffs serve many tens of thousands of patients with the help of Title X funds, especially low-income and rural women who often have no other affordable option for reproductive health care. Plaintiffs provide comprehensive birth control options, cancer screenings, sexually transmitted infection ("STI") testing, and other critical services. Plaintiffs have spent years developing clinical best practices, building an unparalleled network of health centers dedicated specifically to reproductive health, and establishing a reputation for high-quality, accessible, and nonjudgmental care. Plaintiffs routinely offer weekend and after-work hours, same-day appointments, and other measures to make their services broadly accessible.

6. Despite the success and stability of the Title X program, in late February 2018, HHS announced dramatic changes to the longstanding Title X grantmaking criteria. Specifically, the FY2018 FOA for Title X funds shifts the "application review criteria" on which funding decisions are based away from what the statute and regulations require. Under HHS's changes, those "application review criteria" now give the most weight to new "program priorities" and "key issues," such as placing "meaningful emphasis" on abstinence as an approach to birth control (even for adults), providing onsite primary care, and cooperating with faith-based

organizations. Rather than focusing on acceptable and effective family planning methods, the new FOA omits entirely any reference to contraception or to HHS's own previously published standards for evidence-based family planning care. Those changes are designed to disadvantage reproductive health care providers like Plaintiffs—and ultimately, to warp the nature of the Title X program itself and undermine its intended function of supporting comprehensive family planning care.

7. HHS's changes to the application process for Title X funds violate the Administrative Procedure Act, 5 U.S.C. § 701 *et seq*., in at least three ways.

8. *First*, HHS's changes are contrary to law—both to the Title X statute itself, and to the regulations promulgated thereunder. The Title X statute, along with HHS's regulations, limits the factors HHS may consider in awarding grants to achieve Title X's aims. And the statute and regulations require that all funded projects provide patients with "a broad range of acceptable and effective family planning methods and services," including contraception and other family planning and reproductive health services. 42 U.S.C. § 300(a); *accord* 42 C.F.R. § 59.5(a)(1); *see also, e.g.*, *id.* § 59.5(b)(1) (grantees generally must "provide for the effective usage of contraceptive devices and practices"). This longstanding framework defines the Title X program's core commitment: providing comprehensive and nondirective family planning care to all who need it. HHS's new FOA would fundamentally reshape Title X, shifting funds away from applicants who fulfill Title X's mission as Congress intended it and as HHS's regulations require.

9. *Second*, HHS's changes to the FOA are arbitrary and capricious. HHS has never explained the basis for those changes, or provided reasoning for why the considerations listed in the "program priorities" and "key issues" sections of the FOA should now be the largest factor in

determining a Title X applicant's formal application score. Nor did HHS attempt to justify why it was deviating from its longstanding prior practice.

10. *Third*, even if the dramatic changes to the Title X program were lawful (which they are not), and even if HHS had offered a reasoned explanation for them (which it did not), HHS failed to engage in notice-and-comment rulemaking before adding an entirely new "application review criterion" to the seven criteria that HHS may consider under its own longstanding regulations. Going back decades, all previous FOAs have matched the seven criteria in 42 C.F.R. § 59.7 point for point. At the very least, HHS was required to use notice-and-comment rulemaking to alter the application review criteria as set forth in its longstanding regulations. Because HHS did not do so, its changes must be set aside.

11. HHS's attempt to amend the Title X program through the imposition of new application review criteria threatens Plaintiffs and the tens of thousands of patients they serve with serious harms because it improperly forces Plaintiffs to compete for Title X funds with one hand tied behind their backs. Competing applicants, like religious hospitals and organizations that focus on abstinence-only education or primary care services, may now score higher than Plaintiffs, who are committed to providing comprehensive, evidence-based family planning care. Plaintiffs thus face the prospect of losing some or all of the Title X funds on which they and their patients depend—especially in Wisconsin and Ohio, where competing applications are virtually assured—because they will be penalized for their commitment to Title X's core mission.

12. Such an unjustified loss of Title X funds would be a disaster for the low-income patients in Wisconsin, Ohio, and Utah whom Plaintiffs serve. Title X funds form a significant percentage of Plaintiffs' budgets, and losing those funds would result in multi-million-dollar budget shortfalls. Losing Title X funds would mean cuts in services and hours, staff layoffs, and

even health center closures, especially in the most underserved rural areas. All of those consequences would irreparably harm Plaintiffs and portend grave health consequences for their patients who lose access to care.

13. This Court should act to prevent these harms. Title X reflects Congress's judgment that everyone deserves comprehensive reproductive health care, including a full range of family planning methods and services. HHS's own regulations have long served that goal. But HHS's changes to the FY2018 FOA are contrary to Title X and HHS regulations, arbitrary and capricious, and at odds with the fundamental purpose of Title X. Defendants should be enjoined from evaluating Title X applications under HHS's unlawful new FOA.

PARTIES

14. Plaintiff Planned Parenthood of Wisconsin, Inc. ("PPWI") is a not-for-profit corporation organized under the laws of Wisconsin and, as discussed further below, is a member-affiliate of Planned Parenthood Federation of America ("PPFA").

15. Plaintiff Planned Parenthood of Greater Ohio ("PPGOH") is a not-for-profit corporation organized under the laws of Ohio and is also a member-affiliate of PPFA.

16. Plaintiff Planned Parenthood Association of Utah ("PPAU") is a not-for-profit corporation organized under the laws of Utah and is also a member-affiliate of PPFA.

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

18. 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

19. The Court has subject matter jurisdiction over this Administrative Procedure Act ("APA") action under 28 U.S.C. § 1331. The Court is authorized to issue the relief sought here under the APA, 5 U.S.C. §§ 702, 705, 706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202.

20. Venue is proper under 28 U.S.C. § 1391(e) because the defendants, who are sued in their official capacity as HHS officials, reside in Washington, D.C.

FACTUAL ALLEGATIONS

I. CONGRESS FUNDS EFFECTIVE AND COMPREHENSIVE FAMILY PLANNING CARE WITH TITLE X

21. Enacted in 1970, the Family Planning Program, Title X of the Public Health Service Act (42 U.S.C. § 300 *et seq.*), makes family planning services available for free or at low cost to Americans in every State. Title X is the only domestic federal program devoted solely to family planning for uninsured, underinsured, and low-income people. It funds a broad range of services, including contraceptive services, information, and education; natural family planning methods; infertility services; services to adolescents; STI and HIV testing and referral; basic preventive care such as well-woman visits and breast and cervical cancer screenings; pregnancy testing and counseling; and training for providers and clinic personnel. (The use of Title X funds for abortion services is prohibited, 42 U.S.C. § 300a-6, and this case does not concern abortion.)

22. The Title X program sought to fulfill President Nixon's 1969 promise that "no American woman should be denied access to family planning assistance because of her economic condition." The program arose from a growing recognition of the effects of unintended childbearing on poverty levels, educational attainment, and adverse maternal and child health outcomes—and of the fact that newly available contraceptive options like oral

contraceptives (i.e., "the pill") were unaffordable for too many Americans. When it passed with broad bipartisan support, Congress declared that Title X's "purpose" was "making comprehensive voluntary family planning services readily available to all persons desiring such services." Pub. L. No. 91–572, § 2, 84 Stat. 1506 (1970).

23. Title X requires that grant recipients "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).[1] Elaborating on that statutory requirement, HHS's Title X regulations require that Title X projects "consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children." 42 C.F.R. § 59.1. HHS's Title X regulations have always required grantees to provide a broad range of family planning options, including contraception. To be awarded a Title X grant, a grantee "must … [p]rovide a broad range of acceptable and effective medically approved family planning methods." 42 C.F.R. § 59.5(a)(1). Moreover, absent an exception for good cause, grantees must also "[p]rovide for medical services related to family planning (including … contraceptive supplies) …, and provide for the effective usage of contraceptive devices and practices." 42 C.F.R. § 59.5(b)(1). All of those requirements have remained unchanged since HHS first promulgated its Title X regulations in 1971, shortly after the statute was enacted. *See* 45 Fed. Reg. 37,433, 37,436-37,437 (June 3, 1980) (setting forth language of current regulation); *compare* 36 Fed. Reg. 18,465, 18,466-18,467 (Sept. 15, 1971) (above terms all found at former 42 C.F.R. §§ 59.3, 59.5(d), (f), (g)).

24. Title X also requires that the acceptance of any family planning services must be "voluntary." *See* 42 U.S.C. § 300a-5; *accord id.* § 300(a). Consistent with that statutory text, the

[1] "Natural family planning," as used in Title X, refers to a variety of methods of tracking ovulation to avoid pregnancy.

Title X regulations require that Title X services must be provided "without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning." 42 C.F.R. § 59.5(a)(2). Moreover, Title X projects must "[p]rovide services in a manner which protects the dignity of the individual." *Id.* § 59.5(a)(3). A Title X patient's information "must be held confidential" by a grantee. *Id.* § 59.11. Again, these regulations have remained unchanged for decades. *See* 45 Fed. Reg. at 37,437-37,438; *compare* 36 Fed. Reg. at 18,466-18,467 (former 42 C.F.R. §59.5(a)(3) and 59.10).

25. The statute also sets forth particular criteria to be used to determine which organizations will receive Title X funding. The statutory criteria provide that, "[i]n making grants and contracts under this section 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). Consistent with the statutory text, HHS's regulations have provided, since the inception of the Title X program, that HHS is permitted to take into account seven factors when determining whether to award a Title X grant:

> "(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;
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> (4) the capacity of the applicant to make rapid and effective use of the federal assistance;
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> (5) the adequacy of the applicant's facilities and staff;
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> (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
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> (7) the degree to which the project plan adequately provides for the requirements set forth in these regulations."

42 C.F.R. § 59.7; *compare* 36 Fed. Reg. at 18,466-18,467 (providing for nearly identical set of criteria). HHS's official description of the Title X program further confirms that these seven factors "are the criteria HHS uses to determine which family planning projects to fund and in what amount."[2]

26. The Title X statute and regulations define the program's fundamental mission of supporting comprehensive family planning care, and constrain HHS from awarding Title X funds based on considerations outside the criteria provided by Title X's legal and regulatory framework, which has remained unchanged for decades.

27. Title X's impact on the reproductive health of low-income Americans cannot be overstated. Every year, Title X providers serve more than four million women, men, and young people. In 2016, Title X centers served 2.8 million contraceptive patients, and Title X funds helped provide 5.1 million STI tests, including 1.2 million confidential HIV tests, nearly 700,000 Pap tests, and nearly 1 million clinical breast exams. More than two thirds of people receiving preventive care through the Title X program live in poverty and 88% have incomes that are at or below 250% of the federal poverty level.

28. Title X sites provide significantly better access to contraceptive care than public non-Title X sites and private providers. Indeed, a study published by HHS administrators (the "OPA Study") showed that Title X providers do a better job overall than non-Title X centers in providing safety-net reproductive health care that is consistent with current, evidence-based

[2] HHS Office of Population Affairs, *Program Requirements for Title X Funded Family Planning Projects* 9 (April 2014), https://www.hhs.gov/opa/sites/default/files/ogc-cleared-final-april.pdf.

clinical guidelines.[3] As just one example, Title X sites are more likely to offer intra-uterine devices ("IUDs") and contraceptive implants onsite.[4] Those contraceptive methods, often grouped under the umbrella term "LARCs," or long-acting reversible contraceptives, are by far the most effective contraceptive methods.

29. Title X's impact on public health is also significant. Title X providers are critical in the effort to identify and treat STIs, for example, screening for chlamydia and treating it early to prevent infertility from an untreated infection. Title X sites are more likely than other public non-Title X providers and private providers to follow chlamydia screening guidelines for testing those most at risk for chlamydia.[5] In addition to STI testing, Title X providers also perform hundreds of thousands of screenings for breast, cervical, and testicular cancer each year.

30. Title X's role is even more important because many women seek out specialists for their family planning care. Studies have shown that, even where women do have primary care options available, they prefer to get reproductive health and family planning care from clinicians who specialize in those areas—as Plaintiffs and most Title X providers do. As one study explained, "[l]arge majorities of women … said that they chose the family planning clinic because the staff is knowledgeable about—or easy to talk to about—sexual and reproductive

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[3] Carter, et al., *Four aspects of the scope and quality of family planning services in US publicly funded health centers: Results from a survey of health center administrators*, 94 J. Contraception 340 (2016), http://dx.doi.org/10.1016/j.contraception.2016.04.009.

[4] *See, e.g.*, Bocanegra, et al., *Onsite Provision of Specialized Contraceptive Services: Does Title X Funding Enhance Access?*, J. Women's Health (May 2014), https://www.liebertpub.com/doi/full/10.1089/jwh.2013.4511 (finding IUD availability at 90% of Title X clinics, as opposed to 51% of public non-Title X clinics and 38% of private clinics; and finding onsite contraceptive implant availability at 58% of Title X clinics, as opposed to 19% of public non-Title X clinics and 7% of private clinics).

[5] Chow, et al., *Comparison of adherence to chlamydia screening guidelines among Title X providers and non-Title X providers in the California Family Planning, Access, Care, and Treatment Program*, J. Women's Health (Aug. 2012), https://www.ncbi.nlm.nih.gov/pubmed/22694761.

issues or because the clinic makes it easy for them to get the contraceptive method they want, and to do so directly, without having to make a separate trip to a pharmacy to have a prescription filled."[6] Because healthy women of child-bearing age tend to seek out such specialized care, Title X health centers facilitate a crucial "touch" (and the potential for referrals) with medical personnel that might otherwise not have happened.

31. The Title X program's impact is particularly significant in rural areas, and for communities of color. Of the 4 million patients served across the Nation by Title X health centers in 2016, over half were people of color. And in rural areas, Title X health centers are often the only provider of reproductive health services for low-income individuals. For example, in one out of five rural counties in America, a Title-X-backed health center is the *only* comprehensive family planning option for people without the means to see a private physician.

II. HHS AWARDS TITLE X FUNDS BASED ON LONGSTANDING CRITERIA

32. The basic function of Title X is to fund family planning services for people who are unable to pay for them. Title X accomplishes this by providing funding for grantees who either offer direct services to low-income Americans or contract with sub-grantees to offer those services, or both. Title X funds operate as a "payer of last resort" for grantees and sub-grantees, allowing them to serve all comers by charging on a sliding scale, based on ability to pay, and to offer free or reduced-price services to patients who are not covered by Medicaid or private insurance and cannot pay out of pocket. Title X makes such broad-based care for low-income people possible by filling the financial gaps for grantees.

33. In recent years, Congress has appropriated nearly $300 million per year under Title X to help fund reproductive health care for low-income Americans. Funding is distributed

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[6] *E.g.*, Frost, et al., *Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Women's Health Care Needs*, 22 *Women's Health Issues* 519 (2012), https://doi.org/10.1016/j.whi.2012.09.002.

through competitively awarded grants, and, as discussed above, funding decisions must be based on the criteria set forth in Title X and regulations promulgated thereunder. Since at least 1990, HHS has issued Funding Opportunity Announcements, or FOAs, that invite applications for Title X funds and that govern the application process for Title X funding.

34. Each FOA contains "application review criteria" that are used to score applications for Title X funding. For the past 30 years, the "application review criteria" in every single Title X FOA have tracked the seven criteria listed in the longstanding Title X regulation. *See* 42 C.F.R. § 59.7. Although some explanatory text has been added to the FOA over time, and HHS began assigning point values to each of the seven criteria around 2001, the substance of the criteria themselves has not changed, and until now has directly reflected the underlying regulation, 42 C.F.R. § 59.7, which in turn reflects criteria for awarding funds that are provided in the Title X statute, *see* 42 U.S.C. § 300(b).

35. In addition to the application review criteria, FOAs typically contain "program priorities" and "key issues" sections, which list various specific suggestions and goals for applicants to consider in developing their project plans. But under every Administration until now, the "program priorities" and "key issues" sections of prior FOAs have *never* been part of the application review criteria, on which actual funding decisions are based.

36. After an initial period of "eligibility screening" (which on information and belief is no more than a few weeks), HHS forwards Title X applications to independent review panels composed of reproductive health experts from within and outside the federal government. The panels then evaluate the applications in light of the application review criteria. As mentioned, in more recent years, each FOA has assigned a point value to each application review criterion, totaling 100 points, with no criterion ever being worth more than 20 points (and almost all being

worth between 10 and 20). In its review, the independent review panels score the applications in light of the point allotment for each criterion. The reviewers then forward their scores to HHS administrators.

III. FOR DECADES, PLAINTIFFS HAVE FULFILLED THE CORE MISSION OF TITLE X

37. Since the inception of Title X a half century ago, PPFA's nationwide network of affiliates—including Plaintiffs—has played a central role in fulfilling Title X's mission.

38. Founded more than a century ago, Planned Parenthood is at the forefront of providing high-quality reproductive health care to individuals and communities facing serious barriers to obtaining such care—especially low-income individuals, individuals in rural and other medically underserved areas, and communities of color. PPFA's 56 member-affiliates operate more than 600 health centers across the Nation and serve approximately 2.4 million patients each year, providing vital health care services such as contraception, cancer screenings, testing and treatment for STIs, sexual health information, and abortion services. Planned Parenthood health centers provide comprehensive, nonjudgmental care and education pursuant to current, evidence-based guidelines.

39. In 2015, PPFA-affiliated health centers served more than 40% of the patients who received care subsidized by Title X. That number is significantly higher for Plaintiffs, especially in Utah and Wisconsin, where PPWI and PPAU serve the vast majority of all such patients.

40. PPFA-affiliated centers focus on providing high-quality, accessible reproductive health care. PPFA-affiliated centers play a different role than federally qualified health centers ("FQHCs"), which provide a wide range of primary, behavioral, and dental care in medically underserved areas, and which are eligible to receive federal funding under a different section of the same larger statute that includes Title X. Unlike most FQHCs, PPFA-affiliated centers

specialize in reproductive health care, and consistently provide the full range of birth-control methods onsite, consistently offer LARCs on a same-day basis, and consistently offer shorter wait times and longer health center hours.[7] Indeed, the OPA Study noted above, which was published by HHS administrators, showed that Planned Parenthood health centers provided the highest level of safety-net reproductive health and family planning care under the Title X program across a number of metrics. *See supra* ¶ 28 & n.3.

41. Plaintiffs are accredited PPFA member-affiliates in Wisconsin, Ohio, and Utah, respectively. They exemplify how PPFA-affiliated centers perform an irreplaceable function in the Title X regime, especially (but not only) with respect to access to contraception for rural and low-income women.

42. Plaintiffs' health centers offer a full range of reproductive health care services: well-woman preventive care visits, breast exams, Pap smears, general health assessment, a wide range of contraception methods, risk assessment for pregnant women to screen for high-risk issues and referral services for pregnant women, pregnancy testing, urinary tract infection treatment, and cervical and testicular cancer screening. Care at Plaintiffs' health centers is typically provided by specially trained nurse practitioners, using standards and protocols for effective, appropriate, confidential care that are developed by PPFA based on medical evidence. Plaintiffs' health centers also offer culturally competent services for LGBTQ people.

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[7] *See, e.g.*, Zolna & Frost, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*, The Guttmacher Institute (2016), https://www.guttmacher.org/sites/default/files/report_pdf/publicly-funded-family-planning-clinic-survey-2015_1.pdf; *see also* Hasstedt, *Understanding Planned Parenthood's Critical Role in the Nation's Family Planning Safety Net*, Guttmacher Institute (January 12, 2017), https://www.guttmacher.org/gpr/2017/01/understanding-planned-parenthoods-critical-role-nations-family-planning-safety-net.

43. Both HHS studies (*i.e.*, the OPA Study mentioned above) and Plaintiffs' internal studies have confirmed that Plaintiffs' health centers are more accessible than other safety-net providers such as FQHCs or health department clinics. Plaintiffs' centers offer more STI testing and more contraceptive options than safety-net providers like FQHCs. Plaintiffs' centers generally offer same-day IUD insertion and same-day access to other LARCs, while most other centers require an appointment, if they provide those services at all. Plaintiffs' centers also offer weekend and after-work hours, 24-hour online booking, and walk-in appointments for Title X covered services. They have telephonic translation services in 25 different languages, and bilingual staff in many areas.

A. Planned Parenthood of Wisconsin

44. Established in 1935, PPWI is the leading provider of family planning and reproductive health care and education in Wisconsin. PPWI operates 21 family planning health centers in 15 counties throughout Wisconsin. Nine of those are Title X health centers. Those centers rely on Title X funding for between 23% and 33% of their entire revenue. PPWI's centers serve the most populous southeastern counties, including urban Milwaukee, as well as rural areas in the eastern and central parts of the State. PPWI also sub-grants some Title X funding to two delegates that operate several clinics in the western and southern regions of the State, as permitted by Title X.

45. In 2017 alone, PPWI had more than 110,000 patient visits, provided almost 140,000 units of contraceptives, performed more than 91,000 STI tests, and conducted almost 8,000 breast or cervical cancer screenings. Title X funding subsidized much of this care. Title X allowed PPWI to provide more than 55,000 STI tests and 10,000 HIV tests to low-income patients. Almost 5,000 low-income women were able to obtain cervical cancer screenings, and

more than 30,000 accessed birth control services, including 8,000 who chose oral contraceptives and 10,000 who chose IUDs or LARCs.

46. In addition to providing family planning care to tens of thousands of Wisconsinites, PPWI conducts outreach and provides sex education that is comprehensive, age-appropriate, medically accurate, and culturally competent to adolescent and adult audiences. Title X funding supports approximately 50% of PPWI's education work. Among other things, PPWI uses Title X funding to support its highly-successful Promotoras Comunitarias Training Program, which was created to address the lack of access to reproductive health care and sexuality information in the Latino community. "Promotoras" are Latina women who receive training to provide peer-to-peer health education on HIV prevention, STIs, talking to children about sexuality, self-esteem, women's health, and other topics.

47. Many of the areas PPWI serves have been deemed Medically Underserved Areas (MUAs) or Health Professional Shortage Areas (HPSAs).[8] In Milwaukee County, the most populous county in Wisconsin, more than 32% of women ages 18 to 44 live in an MUA and more than 34% live in a primary care HPSA. PPWI serves more than 23,000 women ages 18 to 44 at its six health centers across the county.

[8] MUA designations are based on the Index of Medical Underservice ("IMU"), which is calculated based on four criteria: (1) the population to provider ratio; (2) the percent of the population below the federal poverty level, (3) the percent of the population over age 65; and (4) the infant mortality rate. IMUs range from 0-100, where zero represents the completely underserved. Areas with IMUs of 62.0 or less qualify for designation as an MUA. *See* 42 C.F.R. § 51c.102. Health Professional Shortage Areas ("HPSAs") are areas and population groups experiencing a shortage of health professionals—i.e., primary care, mental health, or dental providers. The primary factor used to determine an HPSA designation is the number of health professionals relative to the population with consideration of high need. For primary medical care, the population-to-provider ratio must be at least 3,500 to 1 (or 3,000 to 1 if there are unusually high needs in the community). *See* 42 C.F.R. § 5, App. A.

48. PPWI also provides critical health care services to rural patients whose needs would otherwise go unmet. In seven of the fifteen counties with PPWI clinics (specifically, Columbia, Manitowoc, Racine, Sheboygan, Walworth, Washington, and Winnebago), underserved individuals would have no accessible family planning options if those clinics closed. Another four counties (Dane, Outagamie, Waukesha, and Wood) have only one alternative provider of family planning services for low-income people.

49. PPWI has received Title X funds to support its work since the first year that grants were provided under the program. In the most recent award year, PPWI received $2.8 million in Title X funds for its own use, and an additional $700,000 for its two sub-grantees. This funding enabled 36,000 patients to receive free or subsidized care from PPWI and its delegates, and literally kept the doors open at numerous rural health centers.

50. There is no other provider network in Wisconsin with the capacity to provide comprehensive family planning services for tens of thousands of low-income people, as PPWI does. The state health department lacks that capacity. FQHCs—as mentioned above, federally funded primary care centers in underserved areas—also lack that capacity, and indeed, in Wisconsin FQHCs do not even receive Title X funds from HHS.

51. In fact, PPWI centers have developed strong working relationships whereby they refer their patients to FQHCs or other primary care facilities when a need arises. Conversely, FQHCs and primary care providers frequently refer their patients to PPWI for any reproductive health and family planning needs.

B. Planned Parenthood of Greater Ohio

52. Established in 1966, PPGOH is the leading provider of family planning and reproductive health care and education in its Ohio service area. PPGOH operates 17 Title X

health centers across the state, and serves patients from 68 of Ohio's 80 counties, from Cleveland and Ohio's industrial north to the communities of Appalachia in Ohio's rural southeast.

53. PPGOH had nearly 120,000 patient visits in the 2017 fiscal year. That year, PPGOH provided more than 50,000 patients with contraception, including tens of thousands of oral contraceptives and NuvaRing cycles, more than 2,000 IUD insertions, and more than 21,000 hormonal birth control injections. PPGOH also performed more than 125,000 STI tests, more than 13,000 HIV tests, more than 26,000 pregnancy tests, almost 4,000 cervical cancer screenings via Pap smear, and more than 4,000 breast cancer screenings. PPGOH served over 60% of the Ohioans who benefitted from Title X in 2017, and used Title X to subsidize care for about a third of its patients.

54. PPGOH also conducts extensive outreach and provides sex education that is comprehensive, age-appropriate, medically accurate, and culturally competent to adolescent and adult audiences, and this work is partially subsidized by Title X funds as permitted by the program. These outreach efforts, at local community centers, health centers, and schools, are the primary way that PPGOH reaches underserved rural areas, especially Appalachia. PPGOH's research shows that a significant number of patients at PPGOH centers were first engaged through these outreach and education efforts. Overall, PPGOH engaged at least 34,000 Ohioans through education and outreach.

55. PPGOH has received Title X funds to support its work for decades, and has been a direct grantee since 1974. In FY2017, PPGOH received $4.2 million in Title X funds, and PPGOH health centers served about twice as many patients using Title X funds as did FQHCs or State health centers. Tens of thousands of PPGOH patients are able to receive free or subsidized care by virtue of Title X funding.

56. There is no other provider network in PPGOH's service area with the capacity to provide comprehensive family planning services for tens of thousands of low-income people, as PPGOH does.

C. Planned Parenthood Association of Utah

57. Established in 1970, PPAU is the leading provider of family planning and reproductive health care and education in Utah. PPAU operates seven Title X health centers across the state, from Logan in the north to St. George on the southern border with Arizona.

58. PPAU delivered health care to nearly 46,000 patients in FY2017, including more than 36,000 through Title X. PPAU served the vast majority of all patients benefitting from Title X dollars in Utah in 2017, and used Title X to subsidize contraception, STI tests, Pap tests, well-woman visits, pregnancy tests, and HPV vaccines for its patients.

59. Because of the rural nature of the state, PPAU now offers tele-medical services at some centers so that even patients in rural parts of the state can have same-day access to clinicians. Since 1983, PPAU has also operated a rural health program in which it pays rural health care providers to provide family planning services to patients who would otherwise not be able to afford care.

60. PPAU also conducts outreach and provides comprehensive sexuality education that is age-appropriate, medically accurate, and culturally competent to adolescent and adult audiences, including programs related to LGBTQ youth and for parents of adolescents. PPAU's successful "Growing Up Comes First" program for fifth and sixth graders is supported by Title X funds as permitted by the program.

61. PPAU has received Title X funds to support its work since Title X's inception almost without interruption, and has been the sole grantee in Utah since the 1980s. In the most

recent award year, PPAU received almost $2 million in Title X funds. Tens of thousands of PPAU patients are able to receive no-cost or subsidized care by virtue of Title X funding.

62. There is no other provider network in Utah with the capacity to provide comprehensive family planning services for tens of thousands of low-income people, as PPAU does. The state health department lacks that capacity. FQHCs in Utah lack that capacity, and have not even received Title X funds from HHS. In fact, FQHCs generally refer patients to PPAU to meet their reproductive health needs.

63. In light of their extensive networks, their commitment to high-quality care and accessibility, and their decades of experience serving low-income women, Plaintiffs have developed a deserved reputation as the premier provider for reproductive health services in their States, especially for those who cannot afford private care. In this way, Plaintiffs fulfill the core mission of Title X: providing comprehensive family planning and reproductive care for low-income Americans.

IV. THE ADMINISTRATION ISSUES A NEW FOA THAT CHANGES THE APPLICATION REVIEW CRITERIA FOR TITLE X FUNDING AND ALTERS THE TITLE X PROGRAM ITSELF

64. The FOA that is the subject of this lawsuit is not the only step that the current Administration has taken to emphasize discredited reproductive health strategies like abstinence-only education (which this Administration and others have rebranded as "sexual risk avoidance") over access to contraception. In October 2017, for example, the Administration canceled a well-supported rule requiring employers to provide insurance coverage for contraception, including more expensive LARCs, despite the consensus among experts in the fields of medicine and public health that LARCs, which are 99% effective, are a uniquely effective form of birth control for sexually active people. HHS also issued a surprise termination of multi-year funding for the Teen Pregnancy Prevention Program ("TPPP"), a program designed to fund a wide range of

interventions that have been proven effective in reducing teen pregnancy. HHS then offered a new FOA for that program that attempts to remake the TPPP into a program that supports abstinence-only education, which has been proven ineffective at preventing unintended pregnancies or the spread of STIs.

65. Those actions and others are intended to implement senior Administration officials' long-held policy goals, in particular to replace a focus on effective contraception with an emphasis on abstaining from sex. Defendant Huber, prior to her work at HHS, worked in Ohio and nationally as an advocate for abstinence-only sex education. Researchers at Case Western Reserve University found that the sexual education programs Ms. Huber ran and promoted while working in Ohio state government provided "false and misleading information" and presented "religious convictions as scientific fact."[9]

66. In 2017, HHS announced that it was terminating all multi-year grants under Title X. As a result, even though competitive Title X grants had previously been awarded on overlapping three-year cycles, all Title X grantees would need to submit a new competitive application for Title X funds in FY2018. In February 2018, HHS announced that it would provide "continuation funding" for the terminated grants through September 2018, when it expected to issue awards under its new FY2018 FOA.[10]

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[9] Frank, *Report on Abstinence-Only-Until-Marriage Programs in Ohio*, Case Western Reserve University (2005), *available at* http://www.aidstaskforce.org/wp-content/uploads/2010/12/Abstinence_Report_June051.pdf.

[10] The FOA at issue purports to be for FY2018, and involves funds appropriated by Congress for FY2018. However, HHS has stated that it intends to make funding available under the FOA no earlier than September 1, 2018—one month before the start of the 2019 fiscal year. Despite the fact that it appears to cover only a single month of FY2018 funding, the FOA is referred to in this Complaint as the "FY2018 FOA."

67. At the same time, HHS issued the FY2018 FOA ("the FOA"), which dramatically and impermissibly alters the Title X program.[11]

68. Most obviously, HHS added a new, eighth application review criterion, "criterion (h)," to the set of seven permissible criteria provided by longstanding HHS regulations.

69. Criterion (h) provides that 25 points out of 100 total will be assessed based on "[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 [in] this funding announcement." In addition, HHS also added language to another criterion, criterion (e), which now asks reviewers to consider "[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*" (added language in italics). Criterion (e) is worth 10 points. Thus, up to 35 out of 100 points of an applicant's score will now be based on the applicant's compliance with the requirements set forth in the FOA's "policy priorities" and "key issues" sections. Previously, no single criterion had ever been worth more than 20 points.

70. The FOA's "program priorities" and "key issues" sections have in turn been re-written from previous years to focus on everything *but* comprehensive reproductive health care.

71. All mentions of contraception have been excised from the FOA. The FY2017 FOA's "program priorities" and "key issues" sections contained nine mentions of contraceptives or LARCs; for FY2018, that number is zero. Moreover, the FOA eliminates all references to *Providing Quality Family Planning Services: Recommendations of CDC and the US Office Population Affairs*, otherwise known as "the QFP," an authoritative set of clinical

[11] A copy of the FY2018 FOA is appended to this Complaint as Exhibit A and incorporated by reference into this Complaint.

recommendations and standards for reproductive health care developed by HHS and the Centers for Disease Control and Prevention that was first published in 2014.[12] The government developed the QFP "by conducting an extensive review of published evidence, seeking expert opinion, and synthesizing existing clinical recommendations from CDC" and other agencies and medical organizations (including PPFA). There had been eight references to the QFP in prior FOAs; now there are none. And the FOA also eliminates all references to HHS's *Program Requirements for Title X Funded Family Planning Projects* (the "Title X Program Requirements"), HHS's official, detailed description of the Title X program, which incorporates the QFP and which directly states that Title X "is designed to provide contraceptive supplies and information to all who want and need them."[13]

72. The FY2018 FOA's "program priorities" and "key issues" sections (and thus a large chunk of an applicant's formal review score) are instead focused on issues like abstinence promotion (for healthy adults as well as adolescents), parental and family involvement (again, for adults as well as adolescents), cooperation with faith-based organizations, and onsite primary care.

73. Some of the newly added "program priorities" in the FY2018 FOA include:

> 2. Assuring activities that promote positive family relationships for the purpose of increasing family participation in family planning and healthy decision-making; education and counseling that prioritize optimal health and life outcomes for every

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[12] The most recent version of the QFP was published in 2017, and is available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6650a4.htm.

[13] HHS Office of Population Affairs, *Program Requirements for Title X Funded Family Planning Projects* 9 (April 2014), https://www.hhs.gov/opa/sites/default/files/ogc-cleared-final-april.pdf. HHS's failure to include these authoritative, HHS-authored statements is itself a significant departure from prior practice. Previously, every FOA included a program description that referred to the full set of governing authorities, including documents like the Title X Program Requirements, and stated that "[a]ll activities funded under this announcement must be consistent with the Title X statute, regulations and legislative mandates, and are expected to be in compliance with" the Program Requirements.

> individual and couple; and other related health services, contextualizing Title X services within a model that promotes optimal health outcomes for the client.
>
> …
>
> 4. Promoting provision of comprehensive primary health care services to make it easier for individuals to receive both primary health care and family planning services preferably in the same location, or through nearby referral providers, and increase incentive for those individuals in need of care choosing a Title X provider.
>
> …
>
> 6. Encouraging participation of families, parents, and/or legal guardians in the decision of minors to seek family planning services; ….

74. And some of the newly added "key issues" include:

> 3. Cooperation with community-based and faith-based organizations;
>
> …
>
> 5. 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;
>
> 6. Activities for adolescents that do not normalize sexual risk behaviors, but instead clearly communicate the research informed benefits of delaying sex or returning to a sexually risk-free status.

75. These "program priorities" and "key issues," which are now part of the formal application review criteria through the addition of criterion (h) and modifications to criterion (e), are inconsistent with providing comprehensive, evidence-based reproductive health care, as required by the Title X statute and regulations.

76. For example, HHS's new "program priorities" and "key issues" repeatedly emphasize abstinence-focused sex education and counseling, using terms like "sexual risk avoidance" and "optimal health," which are well-known euphemisms for an abstinence-only

approach to family planning.[14] Plaintiffs already discuss abstinence in medically effective and appropriate ways, particularly as one out of many reproductive health strategies, and particularly for younger adolescents. But there is no evidence to support the claim that singling out abstinence (as opposed to incorporating abstinence within a comprehensive approach) has any effect on adolescent behavior or health outcomes. Indeed, emphasizing abstinence has been proven ineffective at decreasing STIs and unwanted pregnancies with respect to adolescents.[15]

77. Emphasizing abstinence as an approach to family planning is a particularly improper requirement for Title X grantees in light of the statutory requirement that Title X projects must provide "acceptable and effective" family planning methods. *E.g.*, 42 U.S.C. § 300. Abstinence prevents pregnancy and STIs when used perfectly, but in reality it has extremely high rates of "user failure"—that is, people often decide to have sex, even if they had previously intended to abstain from sex.[16] Abstinence is also unacceptable to patients, as shown

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[14] *E.g.*, Boyer, *New Name, Same Harm: Rebranding of Federal Abstinence-Only Programs* The Guttmacher Institute (Feb. 18, 2018), https://www.guttmacher.org/gpr/2018/02/new-name-same-harm-rebranding-federal-abstinence-only-programs.

[15] *See, e.g.*, Santelli, et al., *Abstinence-Only-Until-Marriage Policies and Programs: An Updated Position Paper of the Society for Adolescent Health and Medicine*, 61 J. Adolescent Health 400 (2017), https://www.jahonline.org/article/S1054-139X(17)30297-5/fulltext ("The weight of scientific evidence finds that [abstinence-only-until-marriage] programs are not effective in delaying initiation of sexual intercourse or changing other sexual risk behaviors," and "inherently withhold information about human sexuality and may provide medically inaccurate and stigmatizing information[.]"); Lindberg, et al., *Understanding the Decline in Adolescent Fertility in the United States, 2007–2012*, 59 J. Adolescent Health 577 (2016), http://www.jahonline.org/article/S1054-139X(16)30172-0/abstract ("[A]bstinence-only programs have not demonstrated effectiveness in changing adolescent sexual behavior or in reducing teen pregnancy or sexually transmitted infections.").

[16] *E.g.*, Ott, et al., *Counseling Adolescents about Abstinence in the Office Setting*, 20 J. Pediatric Adolescent Gynocology 39 (2007), https://www.ncbi.nlm.nih.gov/pubmed/17289516 ("Clinical experience and data suggest that adolescents who use sexual abstinence as a method of pregnancy and STI prevention often fail to remain abstinent for extended periods of time, or until marriage. … [D]ata from the National Longitudinal Survey of Adolescent Health examining virginity pledges suggests that [the typical use efficacy rate of sexual abstinence] is quite low.").

by the very small number who choose abstinence as an approach to family planning. Promoting abstinence despite this unpopularity would also violate Title X's non-coercion rule, *see* 42 C.F.R. § 59.11.

78. Emphasizing abstinence to adult patients would be particularly inappropriate.[17] Indeed, placing a "meaningful emphasis" on abstinence until marriage to an unmarried, healthy adult woman who wishes to be sexually active, and who comes to a health center for an IUD, would not only be a coercive and egregious clinical practice, but would disrespect the patient's dignity as an individual, in violation of 42 C.F.R. § 59.5(a)(3), and could be understood as refusing service based on marital status, in violation of 42 C.F.R. § 59.5(a)(4).

79. The FOA also repeatedly emphasizes natural family planning methods (also known as "fertility awareness based methods" or the "rhythm method"), in addition to abstinence, promoting them as adding potential "breadth and variety" to the Title X program. Natural family planning was mentioned only once in the FY2017 FOA, but is now mentioned six times, including in the "program priorities" section. To be sure, those methods are already part of the Title X program. But those methods are also well understood to be among the least effective methods of family planning, and are accordingly chosen by only a small minority of patients. Adding "breadth" to the Title X program by increasing the emphasis on the least acceptable and least effective methods of birth control is also contrary to Title X's overarching goals.

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[17] For example, one study surveyed clinicians serving high-risk populations and found that they discussed abstinence with "young kids" or "very young teens," not adult patients. *See* Harper, et al., *Abstinence and Teenagers: Prevention Counseling Practices of Health Care Providers Serving High-Risk Patients in the United States*, 42 Perspectives on Sexual and Reprod. Health 125 (2010), https://onlinelibrary.wiley.com/doi/abs/10.1363/4212510.

80. The newly required "program priorities" and "key issues" also state a "preference" for onsite primary care. But Title X is meant to support the provision of reproductive health care, and specialized reproductive health centers are better at fulfilling that responsibility. Plaintiffs often receive referrals from primary care providers, who recognize Plaintiffs' comparative advantage in offering reproductive health care. Studies show that Plaintiffs' health centers provide more comprehensive and accessible reproductive health care than FQHCs and comparable health centers, which are generalist, primary-care focused facilities. Again, the Title X statute and the regulations emphasize the importance of grantees' abilities to deliver comprehensive reproductive health and family planning care, not primary care. Giving an advantage to primary care providers in the application process for Title X funds is inconsistent with that requirement.

81. The new "program priorities" and "key issues" also emphasize parental and family involvement in reproductive health decisions, both for minors and seemingly for adults as well. Consistent with best practices, Plaintiffs always encourage minor patients in particular to speak with a parent or trusted adult about family planning decisions. But again, consistent with best practices and HHS's standing regulations against coercing any decision "to employ or not to employ any particular methods of family planning," 42 C.F.R. § 59.5(a)(2), Plaintiffs cannot refuse to provide contraception to patients, or strong-arm patients into unwanted family involvement. And, consistent with both evidence-based best practices and Title X regulations, *id.* § 59.11, Plaintiffs are also obligated to keep any patient information confidential, including from family members if so directed by the patient.

82. The new "program priorities" and "key issues" also emphasize partnerships with faith-based groups. Plaintiffs frequently work with community-based groups of all kinds,

including faith-based groups like local churches, youth groups, and others, to provide age-appropriate sex education. But some faith-based groups are opposed to comprehensive family planning care—the very thing that that the Title X program supports. Advantaging applicants based on their partnerships with such groups could undermine the very purpose of the Title X program.

83. Meanwhile, and as mentioned already, the new FOA, including the new "program priorities" and "key issues" sections, strips out all references to contraception and to the QFP, as well as the Title X Program Requirements. That change stands in stark contrast to HHS regulations governing the Title X application process, which require that grantees provide "a broad range of acceptable and effective medically approved family planning methods," 42 C.F.R. § 59.5(a)(1), including contraception, *id*. § 59.5(b)(1). Indeed, the FOA goes even further: It also includes new language encouraging applications for projects that use birth control methods that are "historically underrepresented in the Title X program." But because Title X providers have, consistent with Title X's basic mission, consistently sought to offer the most effective and up-to-date family planning methods (subject to the patient's choice and direction), a "historically underrepresented" method is almost certain to be one that is less "medically effective," and less "acceptable" with patients, as required by Title X regulations.

84. The net effect of HHS's new criteria, then, is to shift the operation of the Title X program away from its statutory purpose of funding comprehensive family planning care, and towards supporting the types of faith-based, nonscientific practices, like abstinence-only education, that have long been discredited as effective methods of contraception and risk mitigation.

85. Not only was the Administration's addition of a new application review criterion for Title X funding not promulgated through notice and comment rulemaking, as required by law, but HHS has never provided a reasonable explanation for the new substantive requirements in the FY2018 FOA.

86. HHS only even attempted to offer a justification for one of those requirements—the new requirement to promote abstinence—and it did so only after the new FOA had been issued. Specifically, when potential applicants sought an explanation for the change during a March 2018 open technical call, HHS promised that it would provide studies to support its new emphasis on "sexual risk avoidance." HHS later offered citations to several studies that do not support promoting abstinence to healthy, sexually active adults.

87. Meanwhile, with respect to the other new requirements that the FY2018 FOA seeks to add to the application review criteria, like its new emphasis on onsite primary care, HHS made no attempt to explain the basis for these changes to the longstanding Title X program.

88. The end result is that the FOA, which HHS issued with no formal rulemaking and no cogent explanation, runs afoul of the Title X statute and regulations.

V. THE FOA WILL HARM PLAINTIFFS AND THE PATIENTS THEY SERVE

89. Applications under the FY2018 FOA are due on May 24, 2018. Plaintiffs do plan to apply for Title X funds, but they remain committed to following evidence-based best practices for patients' health, and to providing comprehensive family planning care consistent with the core mission of Title X. The FY2018 FOA disadvantages Plaintiffs in earning up to 35 points out of 100 because of their commitment to the Title X mission.

90. Plaintiffs are harmed in several ways as a result.

91. ***Competitive Harm:*** The FY2018 FOA forces Plaintiffs to compete for Title X funds on improper terms, giving an advantage in the funding application process to Plaintiffs'

competitors based on factors that should not be considered by HHS under governing law. Regardless of the outcome of the FOA process, Plaintiffs will suffer harm the moment their applications for Title X funds are first considered using the current application review criteria.

92. ***Loss of Title X Funds:*** Moreover, Plaintiffs are at imminent risk of being denied some or all of their Title X funds on the basis of the new application review criteria. According to the FOA, all award decisions "are final and you may not appeal."

93. In Wisconsin and Ohio in particular, Planned Parenthood affiliates face competition in the Title X application process from their respective state health departments. Wisconsin law now requires the state Department of Health Services to apply for Title X grant funding (and prevents the State from sub-granting any of that money to Planned Parenthood affiliates). And the Ohio State Department of Health (which funded abstinence-focused programming when it employed Defendant Huber) also competes for Title X funding. Even though PPWI and PPGOH are the only provider networks in their respective States with the capacity to provide high-quality, comprehensive reproductive health care services to tens of thousands of patients, they are at serious risk of losing at least some of their funding to these state competitors (who maintain or sub-grant funds to generalist facilities that by definition include onsite primary care, and who have demonstrated a willingness to promote abstinence, among other things) in light of the changes to the application review criteria.

94. ***Layoffs, Closures, and Service Cuts:*** Any such losses of needed Title X funds will in turn result in service denials and cuts, layoffs, and the closures of health centers that are often the only option for low-income patients in need of reproductive care. And many of the health centers that would have to close or cut services as a result of a loss of Title X funding in Wisconsin, Ohio, and Utah could not be reopened without extensive additional investment in

infrastructure. Even if the FOA were later held unlawful at the end of this lawsuit, Plaintiffs will not be able to reopen centers, resume relationships with the patients they have lost, reconstitute the programs and services that were terminated, or recall the employees who were essential to serving those patients.

95. The threats to each Plaintiff and their patients on this score are grave.

96. PPWI will face serious, irreparable harm if the FOA as written is allowed to go into effect. PPWI stands to lose up to $3.5 million out of a $24 million annual budget. Without this funding, PPWI will be forced to close four rural health centers, which care for some of the highest-risk populations in the state. These centers already operate at a loss and cannot be sustained on private insurance or Medicaid reimbursements alone. PPWI will also be forced to close two or three additional centers around Milwaukee. Because of these closures, PPWI will have to lay off 25 clinicians and support staff.

97. Recent history demonstrates the swift, devastating impact of budget cuts on PPWI and its patients. In 2011, after Wisconsin Governor Scott Walker eliminated $1 million in state funding to PPWI, PPWI was forced to close five rural health centers over the next three years. These health centers were the only reproductive health providers in their areas, and subsequent studies and investigation showed that most patients never found another provider, but rather simply went without reproductive health and family planning care, which can have dire consequences.

98. PPGOH will face serious, irreparable harm if the FOA is allowed to go into effect. Title X makes up $4.2 million out of PPGOH's $23 million annual budget. If PPGOH were to lose this funding, it will have to close seven health centers and reduce services and personnel at others. Many of its patients, including the nearly 17,000 whose care at those seven health

centers is subsidized by Title X each year, would have to seek care elsewhere or go without. PPGOH would also be forced to scale back the extensive education and outreach work it conducts even in areas where it does not operate a health care center. These outreach efforts, which are subsidized with Title X funds, are the primary way that PPGOH reaches underserved rural areas, especially Appalachia.

99. PPAU will face serious, irreparable harm if the FOA as written is allowed to go into effect. Title X funding comprises $2 million out of an $11 million budget. PPAU would be forced to close clinics and layoff or furlough providers and staff, threatening access to care for the 46,000 patients it serves annually. Those who live in the many rural parts of the state would be at particular risk of being cut off from health care services. If PPAU lost Title X funding, it would have to scale back or eliminate its rural health programs, leaving thousands with reduced or no access to critical preventive and reproductive health care services.

100. ***Reputational Harm:*** The service cuts and closures from the improper diminution of Title X funds would in turn tarnish Plaintiffs' longstanding reputations as reliable, affordable, and accessible options for patients with nowhere else to turn. Those reputations have been built over decades of work in the communities that Plaintiffs serve, but will be impaired if Plaintiffs are forced to lay off employees or cut back hours or services, or turn patients away because they lack the means to pay for family planning services. At the same time, Plaintiffs' reputations as providers of high-quality and nonjudgmental reproductive health services would also be tarnished if Plaintiffs attempted to meet the new requirements imposed by HHS's changes to the FOA by shifting towards new practices like emphasizing abstinence promotion.

101. ***Harm to Patients:*** In addition to harming Plaintiffs themselves, the FOA poses a serious, grave risk to the health of Plaintiffs' patients, who are low-income individuals already facing barriers to care, as well as to public health generally.

102. The healthcare infrastructure where Plaintiffs operate cannot absorb the flood of new patients that Plaintiffs would have to turn away after losing Title X funding, and cannot provide high-quality reproductive health and family planning care for thousands of new patients. Plaintiffs care for at least half of all individuals in their respective states who depend on publicly funded family planning services, like Title X and Medicaid, from a health care safety-net provider.[18] Plaintiffs serve many times more contraceptive patients than neighboring FQHCs or health department clinics, and in Plaintiffs' absence, according to one study, the caseloads on FQHCs in particular would at least double (in Wisconsin) or triple (in Ohio and Utah).[19] This is particularly problematic because FQHCs and health departments already have significantly longer average wait times for an initial contraceptive appointment.[20] Closing PPFA-affiliated clinics like Plaintiffs' will leave the remaining care providers badly unable to cope with the level of need in their areas.

103. With nowhere to turn for high-quality reproductive health and family planning care, patients will simply go without. A report by the Congressional Budget Office demonstrates that when PPFA-affiliated clinics close, patients lose access to critical reproductive health and

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[18] Rosenbaum, *Can Community Health Centers Fill the Health Care Void Left by Defunding Planned Parenthood?*, Health Affairs (January 27, 2017), https://www.healthaffairs.org/do/10.1377/hblog20170127.058486/full/.

[19] Frost & Zolna, *Response to Inquiry Concerning the Availability of Publicly Funded Contraceptive Care to U.S. Women*, The Guttmacher Institute (May 1, 2017), https://www.guttmacher.org/article/2017/05/guttmacher-murray-memo-2017.

[20] Planned Parenthood's average wait time for an initial contraceptive visit is 1.2 days, while the average wait time for such a visit is 2.5 days at FQHCs and 4.1 days for health department sites.

family planning services; they do not find those needs served elsewhere.[21] FQHCs and public health departments are not specialists in reproductive health care; they serve primary care needs for everyone from infants to the elderly, including oral and mental health, substance abuse treatment, long-term support services, and early childhood development. They are simply not built to work as specialized, safety-net providers of reproductive health care services.

104. Patients are especially likely to lose contraceptive care, including access to LARCs, the most effective form of contraception for preventing unwanted pregnancies, if Plaintiffs lose Title X funding. Plaintiffs' health centers are considerably more likely to offer patients a broad range of medically approved contraceptive methods, including LARCs, than sites operated by other types of providers. Indeed, nearly all Planned Parenthood centers offer the full range of Food and Drug Administration (FDA)-approved reversible contraceptive methods, compared with just half of FQHCs and two-thirds of state health departments. Unlike many FQHCs and state health departments, nearly all Planned Parenthood centers offer insertion of IUDs and implants on the same day as a client's initial appointment. Because LARCs are so expensive for lower-income patients, patients almost certainly will not obtain them unless they are provided through a Title X grantee with the ability to subsidize the cost.

105. Moreover, in many areas, Plaintiffs are the *only* provider of family planning and reproductive health care services for low-income individuals. Because the unlawful criteria threaten to force Plaintiffs' health centers to close or cut services in those areas, it is not only Title X patients who will lose access to care, but also patients in those areas who depend on Medicaid and even private insurance.

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

106. The 2011 budget cuts to Planned Parenthood centers in Wisconsin provide a stark demonstration of the effect that closures and service cuts have on the health of all patients. After the cuts forced the closure of five PPWI clinics, no other providers took their place.[22] Those in Chippewa County had nowhere to go for STI tests. Staff at the Jefferson County Health Department recommended that women seeking contraception travel to another county that still had a Planned Parenthood health center. The parts of Wisconsin affected by the clinic closures experienced a spike in STIs and long waiting lists at community health centers in other areas. Patients using the Planned Parenthood clinic in Shawano were referred to another clinic in Green Bay—nearly 40 miles away.

107. A study published in *The American Journal of Public Health* showed similarly disastrous results in Texas after state legislation restricted participation in family planning programs, excluding experienced, proven provider networks like Planned Parenthood. A quarter of all clinics statewide closed, and reproductive health specialists lost over half of their patients. The study's authors concluded that, "when specialized family planning providers are marginalized or systematically excluded from public programs … women will lose access to essential preventive services."[23]

108. Unless the FOA is enjoined, those disastrous results will be replicated in Wisconsin, Ohio, and Utah, and across the country. The consequences of the FOA will be disproportionately felt by low-income patients, patients in rural areas, patients who are not

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22 Redden, *Healthcare without Planned Parenthood: Wisconsin and Texas point to dark future*, The Guardian (January 17, 2017), https://www.theguardian.com/us-news/2017/jan/17/planned-parenthood-congress-wisconsin-texas.

23 White, et al, *The Impact of Reproductive Health Legislation on Family Planning Clinic Services in Texas*, 105 Am. J. Pub. Health 851 (2015), http://sites.utexas.edu/txpep/files/2017/04/White-et-al-Impact-of-Reproductive-Health-Legislation-AJPH-pre-print-2015.pdf.

proficient in English, and communities of color in underserved areas. Those patients already face serious barriers to obtaining comprehensive, high-quality family planning care. Congress passed the Title X statute to address that very issue, but unless it is enjoined, the FOA will make the problem worse.

COUNT ONE:

APA: CONTRARY TO LAW

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

110. An agency rule or action that that is "contrary to the statute" is not valid. *E.g.*, *Chevron v. NRDC*, 467 U.S. 837, 844 (1984); *see also* 5 U.S.C. § 706. HHS regulations have the force of law. *E.g.*, *Morton v. Ruiz*, 415 U.S. 199, 235 (1974).

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

112. The new FOA also conflicts with Title X's fundamental purpose and its substantive requirements for supported projects. The purpose of Title X, both the statute itself and the regulations promulgated thereunder, is to support comprehensive, evidence-based family planning projects that "offer a broad range of acceptable and effective family planning methods and services." 42 U.S.C. § 300(a); *see also* 42 C.F.R. §§ 59.1, 59.5. But the new FOA countermands these requirements, by disadvantaging grant applicants based on their commitment to comprehensive, evidence-based family planning services.

COUNT TWO:

APA: ARBITRARY AND CAPRICIOUS

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

114. Agency rules or actions that are not "reasoned" are invalid as arbitrary and capricious. *See, e.g.*, *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

115. HHS's changes to the FOA are not reasoned because they run counter to the best available evidence regarding how to promote comprehensive family planning services for low-income people, or have no evidence-based relationship to that goal.

116. HHS's changes to the FOA are also not reasoned because HHS has offered no explanation for those changes or for HHS's departure from past agency practice.

COUNT THREE:

APA: FAILURE TO ENGAGE IN NOTICE AND COMMENT RULEMAKING

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

118. HHS regulations, including 42 C.F.R. § 59.7, have the force of law. *E.g.*, *Morton v. Ruiz*, 415 U.S. 199, 235 (1974).

119. HHS is required to use notice and comment rulemaking if it wishes to modify those regulations. *See NFPRHA v. Sullivan*, 979 F.2d 227 (D.C. Cir. 1992); *see also* 36 Fed. Reg. 2,532 (Feb. 5, 1971).

120. 42 C.F.R. § 59.7 sets forth the criteria that HHS shall consider in deciding to award Title X funds.

121. The FOA's changes to the application review criteria contravene 42 C.F.R. § 59.7, or constitute an attempt to change 42 C.F.R. § 59.7 without notice and comment rulemaking.

122. The new application review criteria are contrary to HHS regulations and invalid, and should be set aside.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray this Court:

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

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

c) Require that HHS provide any continuation funding necessary to ensure that Title X projects remain funded until HHS issues new Title X grants pursuant to a lawful FOA;

d) Award Plaintiffs their costs and attorney's fees in pursuing 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,

By /s/ Paul R. Q. Wolfson

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