No. 19-35394

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION, ET AL.,
Plaintiffs-Appellees,

v.

ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services, ET AL.,
Defendants-Appellants.

On Appeal from the United States District Court
for the Eastern District of Washington Nos. 19-cv-3040, 19-cv-3045 (Bastian, J.)

SUPPLEMENTAL EXCERPTS OF RECORD

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

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, et al.,

Defendants.

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

Plaintiffs,

v.

ALEX M. AZAR II, et al.,

Defendants.

No. 1:19-cv-03040-SAB

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

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

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

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

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

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

NFPRHA and Its Membership

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The History and Purpose of Title X

18. Title X became law as part of the "Family Planning Services and Population Research Act of 1970." Pub. L. No. 91-572, 84 Stat. 1504 (1970). NFPRHA was founded just a year after Title X's enactment.

19. During the 1960s, many low-income women had more children than they desired. This significantly impacted their lives, including interfering with their ability to obtain an education and contribute to the economy, and it negatively affected maternal and child health. Research established that inequitable access to modern, effective contraceptives made low-income women less able to match their

actual childbearing with their desired family size. The two most effective biomedical contraceptives—the new oral contraceptive pill ("the Pill") and the copper intrauterine device ("IUD")—were available only through medical professionals and at a high cost, both for the contraceptive itself and for medical visits.

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

21. With overwhelming bipartisan support, Congress responded by enacting Title X. Congress's concern was the "medically indigent"—the low-income individuals who desired but could not access the contraceptive methods that more affluent members of society could, and who were:

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

S. Rep. No. 91-1004, at 9 (1970). Congress emphasized that the "problems of excess fertility for the poor result to a large extent from the inaccessibility of family planning information and services." H.R. Rep. No. 91-1472, at 6 (1970).

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

23. Congress also recognized that, in this area of individuals' reproductive decision-making, Title X required "explicit safeguards to insure that the acceptance of family planning services and information relating thereto must be on a purely voluntary basis by the individuals involved." S. Rep. No. 91-1004, at 12.

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

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

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

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

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

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

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

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

31. There has been only one previous attempt by the executive branch to remake the program from one intended to be about equality of access to quality clinical family planning services so that low-income individuals can freely determine their own reproductive decisions, into a directive, ideological and coercive program that imposes choices and limits information when Title X patients find themselves pregnant.

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

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

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

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

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

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

37. For example, while the 1988 rules and Bush directive were still enmeshed in litigation, both houses of Congress in 1992 passed the Family Planning Amendments Act (initially known in the Senate as the Title X Pregnancy

Counseling Act of 1991). The Senate overrode President Bush's veto of that act, but the House fell short of doing so. In the 1992 act, Congress specified that the "Secretary may not make an award of a grant … unless the applicant for the award agrees that the family planning project involved will provide to individuals information regarding pregnancy management options upon request of the individuals." H. Rep. No. 102-767 (Conference Report) (1992). Congress there defined "information regarding pregnancy management options" to include "nondirective counseling and referrals" regarding all options. *Id*. *See generally 5*8 Fed. Reg. 7462.

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

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

Overview of the Structure and Scope of Title X Service Provision

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Title X Grant-making Process

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IOM Review at 129.

Title X's Financial Separation and Independence from Abortion Care

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

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

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

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

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

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

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

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

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

65 Fed. Reg. 41276.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

123. Upon its effective date, the New Rule will cause all current NFPRHA member grantees, sub-recipients, and their individual Title X clinicians to face a Hobson's Choice between two imperfect paths that each harm patients as well as the providers: (1) attempt to stay in the Title X program out of a commitment to low-income individuals' access to family planning care, despite the compromised care newly mandated by the rule, especially for pregnant patients, or (2) leave Title X because the New Rule requires providers to depart from medical ethics principles and standards of care—thereby shrinking the Title X network, reducing patients' access to contraceptives and other care, and triggering cascading harms.

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

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

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

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

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

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

128. For example, our members that are non-profit administrative Title X grantees without their own service sites typically also administer other funding streams or engage in some other activities, especially education and advocacy,

beyond their Title X project. Many of our Title X provider organizations and their individual health center sites also offer services in addition to Title X, such as federally-funded primary care, women and infant care, or teen pregnancy prevention, among many examples. Hospital-run or university-run clinics, federally-qualified health centers ("FQHCs"), and nurse-family partnership programs also collocate with Title X providers (or are one and the same), offering many different types of health care and education in the same space; with exactly the same or overlapping staff; and with integrated systems and administrative functions.

129. None of these arrangements means that Title X funding is subsidizing other types of care, including when a Title X project operates in the same location as abortion care or shares staff or operational systems with abortion care. The Title X funds pay only Title X project expenses—and, as explained above, federal Title X funds make up only part of the overall Title X project budget, because no Title X grant can cover 100% of that budget, *see supra* ¶ 80.

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

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

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

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

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

133. Similarly, NFPRHA members who are independent, non-profit health care providers would be forced by the New Rule to make irrational choices to create wholly duplicative stand-alone clinics and offices, with duplicative staffs and operational systems—steps they are not in the financial position to take, since these duplications would involve massive outlays for no benefit to their health care missions. But this kind of extreme wastefulness and effort would be required in order to quarantine their Title X project from any health care that might involve abortion referral, from any other activities that might assist women in obtaining abortions, and from any abortion-related advocacy or association.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

I declare under penalty of perjury that the foregoing is true and correct. This declaration was executed on April 10, 2019, in Washington, D.C.

Clare M. Coleman

EXHIBIT A

Program Requirements for Title X Funded Family Planning Projects

Version 1.0 April 2014

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Links

Title X Statute http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/statutes-and-regulations/

Title X Regulations http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/statutes-and-regulations/

Appropriations Language/Legislative Mandates http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/legislative-mandates/

Sterilization of Persons in Federally Assisted Family Planning Projects Regulations http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/statutes-and-regulations/

Department of Health and Human Services Regions http://www.hhs.gov/opa/regional-contacts/

ACRONYMS

The following is a list of acronyms and abbreviations used throughout this document.

ACRONYM/ ABBREVIATION	
CFR	Code of Federal Regulations
FDA	U.S. Food and Drug Administration
FPL	Federal Poverty Level
HHS	U.S. Department of Health and Human Services
HIV	Human Immunodeficiency Virus
I&E	Information and Education
NOA	Notice of Award
OASH	Office of the Assistant Secretary for Health
OGM	Office of Grants Management
OMB	Office of Management and Budget
OPA	Office of Population Affairs
OSHA	Occupational Safety and Health Administration
PHS	U.S. Public Health Service
STD	Sexually Transmitted Disease

COMMONLY USED REFERENCES

As a Federal grant program, requirements for the Title X Family Planning Program are established by Federal law and regulations. For ease of reference, the law and regulations most cited in this document are listed below. Other applicable regulations and laws are cited throughout the document.

Law	Title X Public Law ("Family Planning Services and Population Research Act of 1970")	Public Law 91-572
Law	Title X Statute ("Title X of the Public Health Service Act")	42 U.S.C.300, *et seq.*
Regulation	Sterilization Regulations ("Sterilization of persons in Federally Assisted Family Planning Projects")	42 CFR part 50, subpart B
Regulation	Title X Regulations ("Project Grants for Family Planning Services") (	42 CFR part 59, subpart A
Regulation	HHS Grants Administration Regulations	45 CFR parts 74

	("Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations" (part 74) and "Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments" (part 92))	and 92
Regulation	"Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-profit Organizations"	2 CFR 215 (OMB Circular A-110)
OMB Circular	"Grants and Cooperative Agreements with State and Local Governments"	OMB Circular A-102

INTRODUCTION

To assist individuals in determining the number and spacing of their children through the provision of affordable, voluntary family planning services, Congress enacted the Family Planning Services and Population Research Act of 1970 (Public Law 91-572). The law amended the Public Health Service (PHS) Act to add Title X, "Population Research and Voluntary Family Planning Programs." Section 1001 of the PHS Act (as amended) authorizes grants "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 (including natural family planning methods, infertility services, and services for adolescents)."

The Title X Family Planning Program is the only Federal program dedicated solely to the provision of family planning and related preventive health services. 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. All Title X-funded projects are required to offer a broad range of acceptable and effective medically (U.S. Food and Drug Administration (FDA)) approved contraceptive methods and related services on a voluntary and confidential basis. Title X services include the delivery of related preventive health services, including patient education and counseling; cervical and breast cancer screening; sexually transmitted disease (STD) and human immunodeficiency virus (HIV) prevention education, testing, and referral; and pregnancy diagnosis and counseling. By law, Title X funds may not be used in programs where abortion is a method of family planning.

The Title X Family Planning Program is administered by the Office of Population Affairs (OPA), Office of the Assistant Secretary for Health (OASH), within the U.S. Department of Health and Human Services (HHS). OASH is responsible for facilitating the process of evaluating applications and setting funding levels according to the criteria set forth in 42 CFR 59.7(a). Final award decisions are made by the Regional Health Administrator for the applicable Public Health Service Region in consultation with the Deputy Assistant Secretary for Population Affairs and the Assistant Secretary for Health or their designees. The HHS Regional Offices monitor program performance of Title X grantees in each respective region.

The Title X Family Planning Guidelines consist of two parts, 1) *Program Requirements for Title X Funded Family Planning Projects* (hereafter referred to as *Title X Program Requirements*) and 2) *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*.

These documents have been developed to assist current and prospective grantees in understanding and implementing the family planning services grants program authorized by Title

X of the PHS Act (42 U.S.C. 300 *et seq.*). These documents also form the basis for monitoring projects under the Title X program.

OVERVIEW OF PROGRAM REQUIREMENTS

This document is organized into 16 sections that describe the various requirements applicable to the Title X program, as set out in the Title X statute and implementing regulations (42 CFR part 59, subpart A), and in other applicable Federal statutes, regulations, and policies. Links to the Title X statute and implementing regulations, other statutory provisions that are applicable to the Title X program, regulations related to sterilization, and additional resources to maximize the quality of services offered by Title X projects are provided on page 2 of this document.

The concise explanation of general program requirements that follows can be used to help prepare a grant application or monitor funded programs for compliance with Title X requirements. In addition, prospective applicants and grantees should consult all of the resources and references identified in this document for more complete information and to ensure that the project application and program operations comply with these and other Federal requirements.

Additional documents, including the annual *Announcement of Anticipated Availability of Funds for Family Planning Services Grants* (Title X Funding Opportunity Announcement), other Funding Opportunity Announcements for OPA priority areas, and relevant language in Federal appropriations laws, contain the most current information about Title X program requirements and are generally updated annually. The Title X Funding Opportunity Announcement includes the most recent list of program priorities and key issues, and identifies geographic areas where there will be a grant competition for the applicable fiscal year. Subject to the availability of funds, the funding announcement is published annually and posted on the HHS Grants.gov Website Portal. The *Program Requirements for Title X Funded Family Planning Projects* is posted on the OPA website (http://www.hhs.gov/opa). In general, the requirements that apply to the direct recipients of Title X funds also apply to sub-recipients and contractors (HHS Grants Policy Statement, 2007).

1. APPLICABILITY

As stated above, the requirements set forth in this document apply to the award of grants under section 1001 of the PHS Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These 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 CFR 59.1).

2. DEFINITIONS

Terms used throughout this document include:

TERM	DEFINITION
The Act or Law	Title X of the Public Health Service Act, as amended
Family	A social unit composed of one person, or two or more persons living together, as a household
Low-income family	A family whose total annual income does not exceed 100% of the most recent Federal Poverty Guidelines; also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. Unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources
Grantee	The entity that receives Federal financial assistance via a grant and assumes legal and financial responsibility and accountability for the awarded funds and for the performance of the activities approved for funding
Nonprofit	Any private agency, institution, or organization for which no part of the entity's net earnings benefit, or may lawfully benefit, any private stakeholder or individual.
Project	Activities described in the grant application and any incorporated documents supported under the approved budget. The "scope of the project" as defined in the funded application consists of activities that the total approved grant-related project budget supports.
Secretary	The Secretary of Health and Human Services and any other officer or employee of the U.S. Department of Health and Human Services to whom the authority involved has been delegated.
Service Site	The clinics or other locations where services are provided by the grantee or sub-recipient.
Sub-recipients	Those entities that provide family planning services with Title X funds

	under a written agreement with a grantee. May also be referred to as delegates or contract agencies.
State	Includes the 50 United States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Mid-way, Wake, et. al), the Marshall Islands, the Federated States of Micronesia and the Republic of Palau.

3. ELIGIBILITY

Any public or nonprofit private entity located in a state (which includes the 50 United States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Mid-way, Wake, et. al), the Marshall Islands, the Federated States of Micronesia and the Republic of Palau) is eligible to apply for a Title X family planning services project grant (42 CFR 59.2, 42 CFR 59.3).

Even where states apply for a family planning services grant, local and regional entities may also apply directly to the Secretary for a family planning services grant. Faith-based organizations and American Indian/Alaska Native/Native American organizations are eligible to apply for Title X family planning services grants. Private nonprofit entities must provide proof of nonprofit status during the application process.

Although State agencies are eligible for funding, the Title X statute specifically protects the right of local and regional entities to apply directly to the Secretary for a family planning services grant (Section 1001(b), PHS Act).

4. APPLICATION

The Office of Population Affairs publishes, at a minimum, an annual announcement of the availability of Title X family planning services grant funds that sets forth specific application requirements and evaluation criteria. Applications must be submitted to OASH, Office of Grants Management (OGM) on the forms required by HHS, in the manner required, and approved by an individual authorized to act for the applicant. The application process is conducted through an electronic grants system.

If an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential sub-

recipients that have previously provided or propose to provide family planning services to the area to be served by the applicant (42 CFR 59.5 (a)(10)(i)).

Unless otherwise instructed, applicants should respond to the standard instructions contained in the grant application package as well as any HHS supplemental instructions.

Successful applications must include:

- a narrative description of the project and the manner in which the applicant intends to conduct the project and comply with all requirements of the law and regulations;
- a budget that includes an estimate of project income and costs, with justification of the amount of grant funds requested (42 CFR 59.4(c)(2)) and which is consistent with the terms of Section 1006(a) of the Act, as implemented by regulation (42 CFR 59.7(b));
- a description of the standards and qualifications the project will use for all personnel and facilities; and
- other pertinent information as may be required by the Secretary (42 CFR 59.4(c)(4)).

Title X grant funds cannot constitute 100% of a project's estimated costs; therefore, applicants must clearly specify all other sources of funding that will be used to support the Title X project (42 CFR 59.7(c)).

5. CRITERIA FOR FUNDING

Within the limits of funds available for these purposes, grants are awarded for the establishment and operation of projects that will best promote the purposes of Section 1001 of Title X of the PHS Act. The application must address all seven points contained in section 59.7(a) of the regulations. These are the criteria HHS uses to determine which family planning projects to fund and in what amount.

In making funding decisions, HHS takes into account:

- the number of patients, and, in particular, the number of low-income patients to be served;
- the extent to which family planning services are needed locally;
- the relative need of the applicant;
- the capacity of the applicant to make rapid and effective use of the Federal assistance;
- the adequacy of the applicant's facilities and staff;
- 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
- the degree to which the project plan adequately provides for the requirements set forth in the Title X regulations.

Funding of applications that propose to rely on other entities to provide services will take into

consideration the extent to which the applicant indicates it will be inclusive in considering all entities that are eligible to receive Federal funds to best serve individuals in need throughout the anticipated service areas.

6. NOTICE OF AWARD

The Notice of Award (NOA) is the document that informs the grantee of the duration of HHS support for the project without requiring it to recompete for funds (42 CFR 59.8 (a)). This period of funding is called the "project period." The project is generally funded in increments known as "budget periods." Each budget period is typically 12 months, although shorter or longer budget periods may be established for compelling administrative or programmatic reasons.
Decisions regarding whether and at what level to continue awards are based on factors such as the adequacy of the grantee's programmatic progress, management practices, compliance with the terms and conditions of the previous award, program priorities, and the availability of appropriations. In all cases, subsequent budget periods, also known as non-completing continuation awards, require a determination by HHS that continued funding is in the best interest of the government.

The U.S. government is not obligated to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application (42 CFR 59.8(c)).

Grantees must provide the awarding agency with timely and unrestricted access to examine all records, books, papers, and documents related to the award (45 CFR 74.53 and 92.42). Records must be maintained generally for 3 years from submission of the final federal financial report (45 CFR 74.53)

7. USE OF GRANT FUNDS

All funds granted for Title X family planning services projects must be expended only for the purpose for which the funds were awarded and in accordance with the approved application and budget. Funds may not be used for prohibited activities, such as abortion as a method of family planning, or lobbying. The Notice of Award (NOA) provides other stipulations regarding the use of funds. Funds must be used in accordance with the Title X family planning services projects regulations, the terms and conditions of the award, and the HHS grants administration regulations set out at 45 CFR parts 74 and 92.

8. PROJECT MANAGEMENT AND ADMINISTRATION

All projects receiving Title X funds must provide services of high quality and be competently and efficiently administered.

8.1 Voluntary Participation

Family planning services are to be provided solely on a voluntary basis (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a)(2)). Clients cannot be coerced to accept services or to use or not use any particular method of family planning (42 CFR 59.5 (a)(2)).

A client's acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other services, assistance from, or participation in any other program that is offered by the grantee or sub-recipient (Section 1007, PHS Act; 42 CFR 59.5 (a)(2)).

Personnel working within the family planning project must be informed that they may be subject to prosecution if they coerce or try to coerce any person to undergo an abortion or sterilization procedure (Section 205, Public Law 94-63, as set out in 42 CFR 59.5(a)(2) footnote 1).

8.2 Prohibition of Abortion

Title X grantees and sub-recipients must be in full compliance with Section 1008 of the Title X statute and 42 CFR 59.5(a)(5), which prohibit abortion as a method of family planning. Grantees and sub-recipients must have written policies that clearly indicate that none of the funds will be used in programs where abortion is a method of family planning. Additional guidance on this topic can be found in the July 3, 2000, Federal Register Notice entitled *Provision of Abortion-Related Services in Family Planning Services Projects*, which is available at 65 Fed. Reg. 41281, and the final rule entitled *Standards of Compliance for Abortion-Related Services in Family Planning Services Projects*, which is available at 65 Fed. Reg. 41270.

Grantees are also responsible for monitoring sub-recipients' compliance with this section.

8.3 Structure and Management

Family planning services under a Title X grant may be offered by grantees directly and/or by sub-recipient agencies operating under the umbrella of a grantee. However, the grantee is accountable for the quality, cost, accessibility, acceptability, reporting, and performance of the grant-funded activities provided by sub-recipients. Where required services are provided by referral, the grantee is expected to have written agreements for the provision of services and reimbursement of costs as appropriate.

8.3.1 The grantee must have a written agreement with each sub-recipient and establish written standards and guidelines for all delegated project activities consistent with the appropriate section(s) of the Title X Program Requirements, as well as other applicable requirements (45 CFR parts 74 and 92).

8.3.2 If a sub-recipient wishes to subcontract any of its responsibilities or services, a written agreement that is consistent with Title X Program Requirements and approved by the grantee must be maintained by the sub-recipient (45 CFR parts 74 and 92).

8.3.3 The grantee must ensure that all services purchased for project participants will be authorized by the project director or his designee on the project staff (42 CFR 59.5(b)(7)).

8.3.4 The grantee must ensure that services provided through a contract or other similar arrangement are paid for under agreements that include a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate that these rates are reasonable and necessary (42 CFR 59.5(b)(9)).

8.3.5 Sub-recipient agencies must be given an opportunity to participate in the establishment of ongoing grantee policies and guidelines (42 CFR 59.5 (a)(10)).

8.3.6 The grantee and each sub-recipient must maintain a financial management system that meets Federal standards, as applicable, as well as any other requirements imposed by the Notice of Award, and which complies with Federal standards that will support effective control and accountability of funds. Documentation and records of all income and expenditures must be maintained as required (45 CFR parts 74.20 and 92.20).

8.4 Charges, Billing, and Collections

The grantee is responsible for the implementation of policies and procedures for charging, billing, and collecting funds for the services provided by the projects. Clients must not be denied project services or be subjected to any variation in quality of services because of inability to pay.

Projects should not have a general policy of no fee or flat fees for the provision of services to minors, or a schedule of fees for minors that is different from other populations receiving family planning services

8.4.1 Clients whose documented income is at or below 100% of the Federal Poverty Level (FPL) must not be charged, although projects must bill all third parties authorized or legally obligated to pay for services (Section 1006(c)(2), PHS Act; 42 CFR 59.5(a)(7)).

Within the parameters set out by the Title X statute and regulations, Title X grantees have a large measure of discretion in determining the extent of income verification activity that they believe is appropriate for their client population Although not required to do so, grantees that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients self-report.

8.4.2 A schedule of discounts, based on ability to pay, is required for individuals with family

incomes between 101% and 250% of the FPL (42 CFR 59.5(a)(8)).

8.4.3 Fees must be waived for individuals with family incomes above 100% of the FPL who, as determined by the service site project director, are unable, for good cause, to pay for family planning services (42 CFR 59.2).

8.4.4 For persons from families whose income exceeds 250% of the FPL, charges must be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services. (42 CFR 59.5(a)(8)).

8.4.5 Eligibility for discounts for unemancipated minors who receive confidential services must be based on the income of the minor (42 CFR 59.2).

8.4.6 Where there is legal obligation or authorization for third party reimbursement, including public or private sources, all reasonable efforts must be made to obtain third party payment without the application of any discounts(42 CFR 59.5(a)(9)).

Family income should be assessed before determining whether copayments or additional fees are charged. With regard to insured clients, clients whose family income is at or below 250% FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.

8.4.7 Where reimbursement is available from Title XIX or Title XX of the Social Security Act, a written agreement with the Title XIX or the Title XX state agency at either the grantee level or sub-recipient agency is required (42 CFR 59.5(a)(9)]

8.4.8 Reasonable efforts to collect charges without jeopardizing client confidentiality must be made.

8.4.9 Voluntary donations from clients are permissible; however, clients must not be pressured to make donations, and donations must not be a prerequisite to the provision of services or supplies.

8.5 Project Personnel

Title X grantees must have approved personnel policies and procedures.

8.5.1 Grantees and sub-recipients are obligated to establish and maintain personnel policies that comply with applicable Federal and State requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, Title I of the Americans with Disabilities Act, and the annual appropriations language. These policies should include,

but are not to be limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, and grievance procedures.

8.5.2 Project staff should be broadly representative of all significant elements of the population to be served by the project, and should be sensitive to, and able to deal effectively with, the cultural and other characteristics of the client population (42 CFR 59.5 (b)(10)).

8.5.3 Projects must be administered by a qualified project director. Change in Status, including Absence, of Principal Investigator/Project Director and Other Key Personnel requires pre-approval by the Office of Grants Management. For more information, see HHS Grants Policy Statement, 2007 Section II-54.

8.5.4 Projects must provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning (42 CFR 59.5 (b)(6).

8.5.5 Appropriate salary limits will apply as required by law.

8.6 Staff Training and Project Technical Assistance

Title X grantees are responsible for the training of all project staff. Technical assistance may be provided by OPA or the Regional Office.

8.6.1 Projects must provide for the orientation and in-service training of all project personnel, including the staff of sub-recipient agencies and service sites (42 CFR 59.5(b)(4)).

8.6.2 The project's training plan should provide for routine training of staff on Federal/State requirements for reporting or notification of child abuse, child molestation, sexual abuse, rape or incest, as well as on human trafficking

8.6.3 The project's training plan should provide for routine training on involving family members in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities.

8.7 Planning and Evaluation

Grantees must ensure that the project is competently and efficiently administered (42 CFR 59.5 (b) (6) and (7)). In order to adequately plan and evaluate program activities, grantees should develop written goals and objectives for the project period that are specific, measurable, achievable, realistic, time-framed, and which are consistent with Title X Program Requirements. The program plan should be based on a needs assessment. Grantee project plans must include an evaluation component that identifies indicators by which the program measures the

achievement of its objectives. For more information on quality improvement, see *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs.*

9. PROJECT SERVICES AND CLIENTS

Projects funded under Title X are intended to enable all persons who want to obtain family planning care to have access to such services. Projects must provide for comprehensive medical, informational, educational, social, and referral services related to family planning for clients who want such services.

9.1 Priority for project services is to persons from low- income families (Section 1006(c)(1), PHS Act; 42 CFR 59.5(a)(6)).

9.2 Services must be provided in a manner which protects the dignity of the individual (42 CFR 59.5 (a)(3)).

9.3 Services must be provided without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status (42 CFR 59.5 (a)(4)).

9.4 Projects must provide for social services related to family planning including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance (42 CFR 59.5 (b)(2)).

9.5 Projects must provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs (42 CFR 59.5 (b)(8).

9.6 All grantees should assure services provided within their projects operate within written clinical protocols that are in accordance with nationally recognized standards of care, approved by the grantee, and signed by the physician responsible for the service site.

9.7 All projects must provide for medical services related to family planning and the effective usage of contraceptive devices and practices (including physician's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) as well as necessary referrals to other medical facilities when medically indicated (42 CFR 59.5(b)(1)). This includes, but is not limited to emergencies that require referral. Efforts may be made to aid the client in finding potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of

this care.

9.8 All projects must 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 CFR 59.5(a)(1)).

9.9 Services must be provided without the imposition of any durational residency requirement or requirement that the client be referred by a physician (42 CFR 59.5(b)(5)).

9.10 Projects must provide pregnancy diagnosis and counseling to all clients in need of this service (42 CFR 59.5(a)(5)).

9.11 Projects must offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:

- prenatal care and delivery;
- infant care, foster care, or adoption; and
- pregnancy termination.

If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any options(s) about which the pregnant woman indicates she does not wish to receive such information and counseling (42 CFR 59.5(a)(5)).

9.12 Title X grantees must comply with applicable legislative mandates set out in the HHS appropriations act. Grantees must have written policies in place that address these legislative mandates:

"None of the funds appropriated in the Act may be made available to any entity under Title X of the Public Health Service Act unless the applicant for the award certifies to the Secretary of Health and Human Services that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities."

"Notwithstanding any other provision of law, no provider of services under Title X of the Public Health Service Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest."

10. CONFIDENTIALITY

Every project must have safeguards to ensure client confidentiality. Information obtained by the project staff about an individual receiving services may not be disclosed without the individual's documented consent, except as required by law or as may be necessary to provide services to the individual, with appropriate safeguards for confidentiality. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual (42 CFR 59.11).

11. COMMUNITY PARTICIPATION, EDUCATION, AND PROJECT PROMOTION

Title X grantees are expected to provide for community participation and education and to promote the activities of the project.

11.1 Title X grantees and sub-recipient agencies must provide an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served; and by persons in the community knowledgeable about the community's needs for family planning services (42 CFR 59.5(b)(10)).

11.2 Projects must establish and implement planned activities to facilitate community awareness of and access to family planning services (42 CFR 59.5(b)(3)). Each family planning project must provide for community education programs (42 CFR 59.5(b)(3)). The community education program(s) should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.

11.3 Community education should serve to enhance community understanding of the objectives of the project, make known the availability of services to potential clients, and encourage continued participation by persons to whom family planning may be beneficial (42 CFR 59.5 (b)(3).

12. INFORMATION AND EDUCATION MATERIALS APPROVAL

Every project is responsible for reviewing and approving informational and educational materials. The Information and Education (I&E) Advisory Committee may serve the community participation function if it meets the requirements, or a separate group may be identified .

12.1 Title X grantees and sub-recipient agencies are required to have a review and approval process, by an Advisory Committee, of all informational and educational materials developed or made available under the project prior to their distribution (Section 1006

(d)(2), PHS Act; 42 CFR 59.6(a)).

12.2 The committee must include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of the population or community for which the materials are intended (42 CFR 59.6 (b)(2)).

12.3 Each Title X grantee must have an Advisory Committee of five to nine members, except that the size provision may be waived by the Secretary for good cause shown (42 CFR 59.6(b)(1)). This Advisory Committee must review and approve all informational and educational (I&E) materials developed or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X (Section 1006(d)(1), PHS Act; 42 CFR 59.6(a)).

12.4 The grantee may delegate I&E functions for the review and approval of materials to sub-recipient agencies; however, the oversight of the I&E review process rests with the grantee.

12.5 The Advisory Committee(s) may delegate responsibility for the review of the factual, technical, and clinical accuracy to appropriate project staff; however, final responsibility for approval of the I&E materials rests with the Advisory Committee.

12.6 The I&E Advisory Committee(s) must:

- consider the educational and cultural backgrounds of the individuals to whom the materials are addressed;
- consider the standards of the population or community to be served with respect to such materials;
- review the content of the material to assure that the information is factually correct;
- determine whether the material is suitable for the population or community to which it is to be made available; and
- establish a written record of its determinations (Section 1006(d), PHS Act; 42 CFR 59.6(b)).

13. ADDITIONAL ADMINISTRATIVE REQUIREMENTS

This section addresses additional requirements that are applicable to the Title X program and are set out in authorities other than the Title X statute and implementing regulations.

13.1 Facilities and Accessibility of Services

Title X service sites should be geographically accessible for the population being served. Grantees should consider clients' access to transportation, clinic locations, hours of operation, and other factors that influence clients' abilities to access services.

Title X clinics must have written policies that are consistent with the HHS Office for Civil Rights policy document, *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons* (August 4, 2003) (HHS Grants Policy Statement 2007, II-23).

Projects may not discriminate on the basis of disability and, when viewed in their entirety, facilities must be readily accessible to people with disabilities (45 CFR part 84).

13.2 Emergency Management

All grantees, sub-recipients, and Title X clinics are required to have a written plan for the management of emergencies (29 CFR 1910, subpart E), and clinic facilities must meet applicable standards established by Federal, State, and local governments (e.g., local fire, building, and licensing codes).

Health and safety issues within the facility fall under the authority of the Occupational Safety and Health Administration (OSHA). Disaster plans and emergency exits are addressed under 29 CFR 1910, subpart E. The basic requirements of these regulations include, but are not limited to:

- Disaster plans (e.g. fire, bomb, terrorism, earthquake, etc.) have been developed and are available to staff.
- Staff can identify emergency evacuation routes.
- Staff has completed training and understand their role in an emergency or natural disaster.
- Exits are recognizable and free from barriers.

13.3 Standards of Conduct

Projects are required to establish policies to prevent employees, consultants, or members of governing/advisory bodies from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others (HHS Grants Policy Statement 2007, II-7).

13.4 Human Subjects Clearance (Research)

Research conducted within Title X projects may be subject to Department of Health and Human Services regulations regarding the protection of human subjects (45 CFR Part 46). The grantee/sub-recipient should advise their Regional Office in writing of any research projects that involve Title X clients (HHS Grants Policy Statement 2007, II-9).

13.5 Financial and Reporting Requirements

Audits of grantees and sub-recipients must be conducted in accordance with the HHS grants administration regulations (45 CFR parts 74.26 and 92.26), as applicable, by auditors meeting established criteria for qualifications and independence (OMB A-133).

Grantees must comply with the financial and other reporting requirements set out in the HHS grants administration regulations (45 CFR parts 74 and 92), as applicable. In addition, grantees must have program data reporting systems which accurately collect and organize data for program reporting and which support management decision making and act in accordance with other reporting requirements as required by HHS.

Grantees must demonstrate continued institutional, managerial, and financial capacity (including funds sufficient to pay the non-Federal share of the project cost) to ensure proper planning, management, and completion of the project as described in the award (42 CFR 59.7(a)).

Grantees must reconcile reports, ensuring that disbursements equal obligations and drawdowns. HHS is not liable should the recipient expenditures exceed the actual amount available for the grant.

14. ADDITIONAL CONDITIONS

With respect to any grant, HHS may impose additional conditions prior to or at the time of any award, when, in the judgment of HHS, these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds (42 CFR 59.12).

15. CLOSEOUT

Within 90 days of the end of grant support, grantees must submit:

- a final Federal Financial Report (FFR)
- a final progress report

Following closeout, the recipient remains obligated to return funds due as a result of later refunds, corrections, or other transactions, and the Federal Government may recover amounts based on the results of an audit covering any part of the period of grant support (HHS Grants Policy Statement, II-90).

For a complete list of requirements, grantees should review the HHS Grants Policy Statement, available at http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf

16. OTHER APPLICABLE HHS REGULATIONS AND STATUTES

Attention is drawn to the following HHS Department-wide regulations that apply to grants under Title X. These include:

- 37 CFR Part 401: Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements;
- 42 CFR Part 50, Subpart D: Public Health Service grant appeals procedure;
- 45 CFR Part 16: Procedures of the Departmental Grant Appeals Board;
- 45 CFR Part 74: Uniform administrative requirements for awards and sub-awards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments, and Indian tribal governments;
- 45 CFR Part 80: Nondiscrimination under programs receiving Federal assistance through HHS effectuation of Title VI of the Civil Rights Act of 1964;
- 45 CFR Part 81: Practice and procedure for hearings under Part 80 of this Title;
- 45 CFR Part 84: Nondiscrimination on the basis of disability in programs and activities receiving or benefitting from Federal financial assistance;
- 45 CFR Part 91: Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance;
- 45 CFR Part 92: Uniform administrative requirements for grants and cooperative agreements to State and local governments; and
- 45 CFR Part 100: Intergovernmental Review of Department of Health and Human Services Programs and Activities.

In addition, the following statutory and regulatory provisions may be applicable to grants under Title X:

- The Patient Protection and Affordable Care Act (Public Law 111-148);
- The Trafficking Victims Protection Act of 2000, as amended (Public Law 106-386);
- Sex Trafficking of Children or by Force, Fraud, or Coercion (18 USC 1591);
- The Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191); and
- Appropriations language that applies to the Title X program for the relevant fiscal year.

EXHIBIT B

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 63 / No. 4
April 25, 2014

Providing Quality Family Planning Services

Recommendations of CDC and the U.S. Office of Population Affairs

Continuing Education Examination available at http://www.cdc.gov/mmwr/cme/conted.html.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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Disclosure of Relationship

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Providing Quality Family Planning Services

Recommendations of CDC and the U.S. Office of Population Affairs

Prepared by
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Summary

This report provides recommendations developed collaboratively by CDC and the Office of Population Affairs (OPA) of the U.S. Department of Health and Human Services (HHS). The 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. The primary audience for this report is all current or potential providers of family planning services, including those working in service sites that are dedicated to family planning service delivery as well as private and public providers of more comprehensive primary care.

The United States continues to face substantial challenges to improving the reproductive health of the U.S. population. Nearly one half of all pregnancies are unintended, with more than 700,000 adolescents aged 15–19 years becoming pregnant each year and more than 300,000 giving birth. One of eight pregnancies in the United States results in preterm birth, and infant mortality rates remain high compared with those of other developed countries.

This report can assist primary care providers in offering family planning services that will help women, men, and couples achieve their desired number and spacing of children and increase the likelihood that those children are born healthy. The report provides recommendations for how to help prevent and achieve pregnancy, emphasizes offering a full range of contraceptive methods for persons seeking to prevent pregnancy, highlights the special needs of adolescent clients, and encourages the use of the family planning visit to provide selected preventive health services for women, in accordance with the recommendations for women issued by the Institute of Medicine and adopted by HHS.

Introduction

The United States continues to face challenges to improving the reproductive health of the U.S. population. Nearly half (49%) of all pregnancies are unintended (*1*). Although adolescent birth rates declined by more than 61% during 1991–2012, the United States has one of the highest adolescent pregnancy rates in the developed world, with >700,000 adolescents aged 15–19 years becoming pregnant each year and >300,000 giving birth (*2,3*). Approximately one of eight pregnancies in the United States results in a preterm birth, and infant mortality rates remain high compared with other developed countries (*3,4*). Moreover, all of these outcomes affect racial and ethnic minority populations disproportionately (*1–4*).

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Family planning services can help address these and other public health challenges by providing education, counseling, and medical services (*5*). Family planning services include the following:

- providing contraception to help women and men plan and space births, prevent unintended pregnancies, and reduce the number of abortions;
- offering pregnancy testing and counseling;
- helping clients who want to conceive;
- providing basic infertility services;
- providing preconception health services to improve infant and maternal outcomes and improve women's and men's health; and
- providing sexually transmitted disease (STD) screening and treatment services to prevent tubal infertility and improve the health of women, men, and infants.

This report provides recommendations developed collaboratively by CDC and the Office of Population Affairs (OPA) of the U.S. Department of Health and Human Services (HHS). The recommendations outline how to provide family planning services by:

- defining a core set of family planning services for women and men,
- describing how to provide contraceptive and other clinical services, serve adolescents, and perform quality improvements, and
- encouraging the use of the family planning visit to provide selected preventive health services for women, in accordance with the recommendations for women issued by the Institute of Medicine (IOM) and adopted by HHS (*6*).

The collaboration between CDC and OPA drew on the strengths of both agencies. CDC has a long-standing history of developing evidence-based recommendations for clinical care, and OPA's Title X Family Planning Program (*7*) has served as the national leader in direct family planning service delivery since the Title X program was established in 1970.

This report provides recommendations for providing care to clients of reproductive age who are in need of family planning services. These recommendations are intended for all current or potential providers of family planning services, including those funded by the Title X program.

Current Context of Family Planning Services

Women of reproductive age often report that their family planning provider is also their usual source of health care (*8*). As the U.S. health-care system evolves in response to increased efforts to expand health insurance coverage, contain costs, and emphasize preventive care (*9*), providers of family planning services will face new challenges and opportunities in care delivery. For example, they will have increased opportunities to serve new clients and to serve as gateways for their clients to other essential health-care services. In addition, primary care and other providers who provide a range of health-care services will be expected to integrate family planning services for all persons of reproductive age, including those whose primary reason for their health-care visit might not be family planning. Strengthened, multidirectional care coordination also will be needed to improve health outcomes. For example, this type of care coordination will be needed with clients referred to specialist care after initial screening at a family planning visit, as well as with specialists referring clients with family planning needs to family planning providers.

Defining Quality in Family Planning Service Delivery

The central premise underpinning these recommendations is that improving the quality of family planning services will lead to improved reproductive health outcomes (*10*–*12*). IOM defines health-care quality as the extent to which health-care services improve health outcomes in a manner that is consistent with current professional knowledge (*10*,*13*). According to IOM, quality health care has the following attributes:

- **Safety.** These recommendations integrate other CDC recommendations about which contraceptive methods can be provided safely to women with various medical conditions, and integrate CDC and U.S. Preventive Services Task Force (USPSTF) recommendations on STD, preconception, and related preventive health services.
- **Effectiveness.** These recommendations support offering a full range of Food and Drug Administration (FDA)–approved contraceptive methods as well as counseling that highlights the effectiveness of contraceptive methods overall and, in specific patient situations, draws attention to the effectiveness of specific clinical preventive health services and identifies clinical preventive health services for which the potential harms outweigh the benefits (i.e., USPSTF "D" recommendations).
- **Client-centered approach.** These recommendations encourage taking a client-centered approach by 1) highlighting that the client's primary purpose for visiting the service site must be respected, 2) noting the importance of confidential services and suggesting ways to provide them, 3) encouraging the availability of a broad range of contraceptive methods so that clients can make a selection based on their individual needs and preferences, and 4) reinforcing the need to deliver services in a culturally competent manner so as to meet the needs of all clients, including adolescents, those with limited English proficiency, those with disabilities, and those who are lesbian, gay, bisexual, transgender, or questioning their sexual identity (LGBTQ). Organizational policies, governance structures, and individual attitudes and practices all contribute to the cultural competence of a health-care entity and its staff. Cultural competency within a health-care setting refers to attitudes, practices, and policies that enable professionals to work effectively in cross-cultural situations (*14*–*16*).
- **Timeliness.** These recommendations highlight the importance of ensuring that services are provided to clients in a timely manner.
- **Efficiency.** These recommendations identify a core set of services that providers can focus on delivering, as well as ways to maximize the use of resources.
- **Accessibility.** These recommendations address how to remove barriers to contraceptive use, use the family planning visit to provide access to a broader range of primary care and behavioral health services, use the primary care visit to

provide access to contraceptive and other family planning services, and strengthen links to other sources of care.
- **Equity.** These recommendations highlight the need for providers of family planning services to deliver high-quality care to all clients, including adolescents, LGBTQ persons, racial and ethnic minorities, clients with limited English proficiency, and persons living with disabilities.
- **Value.** These recommendations highlight services (i.e., contraception and other clinical preventive services) that have been shown to be very cost-effective (*17–19*).

Methods

Recommendations Development Process

The recommendations were developed jointly under the auspices of CDC's Division of Reproductive Health and OPA, in consultation with a wide range of experts and key stakeholders. More information about the processes used to conduct systematic reviews, the role of technical experts in reviewing the evidence, and the process of using the evidence to develop recommendations is provided (Appendix A). A multistage process was used to develop the recommendations that drew on established procedures for developing clinical guidelines (*20*,*21*). First, an Expert Work Group* was formed comprising family planning clinical providers, program administrators, and representatives from relevant federal agencies and professional medical associations to help define the scope of the recommendations. Next, literature about three priority topics (i.e., counseling and education, serving adolescents, and quality improvement) was reviewed by using the USPSTF methodology for conducting systematic reviews (*22*). The results were presented to three technical panels† comprising subject matter experts (one panel for each priority topic) who considered the quality of the evidence and made suggestions for what recommendations might be supported on the basis of the evidence. In a separate process, existing clinical recommendations on women's and men's preventive services were compiled from more than 35 federal and professional medical associations, and these results were presented to two technical panels of subject matter experts, one that addressed women's clinical services and one that addressed men's clinical services. The panels provided individual feedback about which clinical preventive services should be offered in a family planning setting and which clinical recommendations should receive the highest consideration.

CDC and OPA used the input from the subject matter experts to develop a set of core recommendations and asked the Expert Work Group to review them. The members of the Expert Work Group were more familiar with the family planning service delivery context than the members of the Technical Panel and thus could better comment on the feasibility and appropriateness of the recommendations, as well as the supporting evidence. The Expert Work Group considered the core recommendations by using the following criteria: 1) the quality of the evidence; 2) the positive and negative consequences of implementing the recommendations on health outcomes, costs or cost-savings, and implementation challenges; and 3) the relative importance of these consequences, (e.g., the likelihood that implementation of the recommendation will have a substantial effect on health outcomes might be considered more than the logistical challenges of implementing it) (*20*). In certain cases, when the evidence from the literature reviews was inconclusive or incomplete, recommendations were made on the basis of expert opinion. Finally, CDC and OPA staff considered the individual feedback from Expert Work Group members when finalizing the core recommendations and writing the recommendations document. A description of how the recommendations link to the evidence is provided together with the rationale for the inclusion of each recommendation in this report (Appendix B).

The evidence used to prepare these recommendations will appear in background papers that will be published separately. Resources that will help providers implement the recommendations will be provided through a web-based tool kit that will be available at http://www.hhs.gov/opa.

Audience for the Recommendations

The primary audience for this report is all providers or potential providers of family planning services to clients of reproductive age, including providers working in clinics that are dedicated to family planning service delivery, as well as private and public providers of more comprehensive primary care. Providers of dedicated family planning services might be less familiar with the specific recommendations for the delivery of preconception services. Providers of more comprehensive primary care might be less familiar with the delivery of contraceptive services, pregnancy testing and counseling, and services to help clients achieve pregnancy.

This report can be used by medical directors to write clinical protocols that describe how care should be provided. Job aids and other resources for use in service sites are being developed and will be made available when ready through OPA's website (http://www.hhs.gov/opa).

*A list of the members of the Expert Work Group appears on page 52.
†A list of the members of the technical panels appears on pages 52 and 53.

In this report, the term "provider" refers to any staff member who is involved in providing family planning services to a client. This includes physicians, physician assistants, nurse practitioners, nurse-midwives, nursing staff, and health educators. The term "service site" represents the numerous settings in which family planning services are delivered, which include freestanding service sites, community health centers, private medical facilities, and hospitals. A list of special terms used in this report is provided (Box 1).

The recommendations are designed to guide general clinical practice; however, health-care providers always should consider the individual clinical circumstances of each person seeking family planning services. Similarly, these recommendations might need to be adapted to meet the needs of particular populations, such as clients who are HIV-positive or who are substance users.

Organization of the Recommendations

This report is divided into nine sections. An initial section provides an overview of steps to assess the needs of a client and decide what family planning services to offer. Subsequent sections describe how to provide each of the following services: contraceptive services, pregnancy testing and counseling, helping clients achieve pregnancy, basic infertility services, preconception health services, STD services and related preventive health services. A final section on quality improvement describes actions that all providers of family planning services should consider to ensure that services are of high quality. More detailed information about selected topics addressed in the recommendations is provided (Appendices A–F).

These recommendations focus on the direct delivery of care to individual clients. However, parallel steps might need to be taken to maintain the systems required to support the provision of quality services for all clients (e.g., record-keeping procedures that preserve client confidentiality, procedures that improve efficiency and reduce clients' wait time, staff training to ensure that all clients are treated with respect, and the establishment and maintenance of a strong system of care coordination and referrals).

Client Care

Family planning services are embedded within a broader framework of preventive health services (Figure 1). In this report, health services are divided into three main categories:

- **Family planning services.** These include contraceptive services for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STD services (including HIV/AIDS), and other preconception health services (e.g., screening for obesity, smoking, and mental health). STD/HIV and other preconception health services are considered family planning services because they improve women's and men's health and can influence a person's ability to conceive or to have a healthy birth outcome.
- **Related preventive health services.** These include services that are considered to be beneficial to reproductive health,

BOX 1. Definitions of quality terms used in this report

Accessible. The timely use of personal health services to achieve the best possible health outcomes.*

Client-centered. Care is respectful of, and responsive to, individual client preferences, needs, and values; client values guide all clinical decisions.†

Effective. Services are based on scientific knowledge and provided to all who could benefit and are not provided to those not likely to benefit.†

Efficient. Waste is avoided, including waste of equipment, supplies, ideas, and energy.†

Equitable. Care does not vary in quality because of the personal characteristics of clients (e.g., sex, race/ethnicity, geographic location, insurance status, or socioeconomic status).†

Evidence-based. The process of integrating science-based interventions with community preferences to improve the health of populations.§

Health-care quality. The degree to which health-care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.†

Process. Whether services are provided correctly and completely and how clients perceive the care they receive.¶

Safe. Avoids injuries to clients from the care that is intended to help them.†

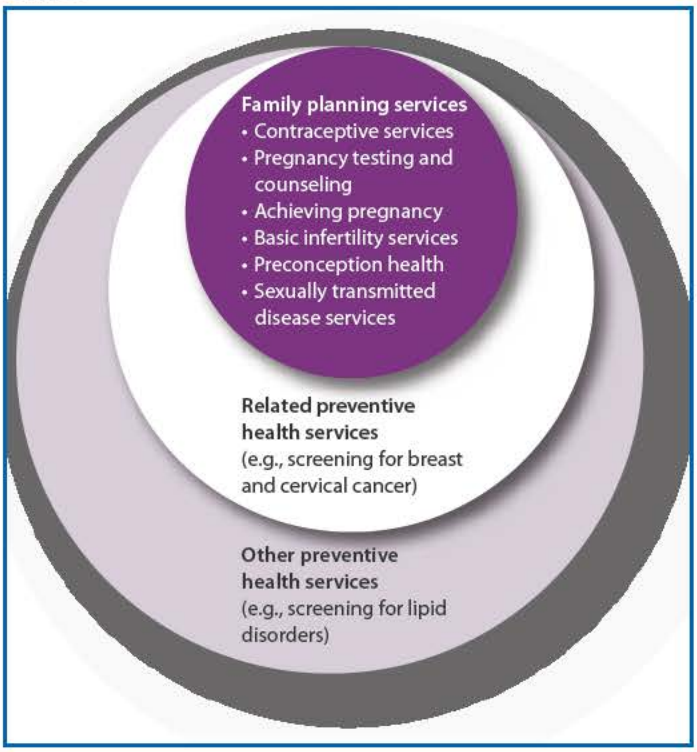
Structure. The characteristics of the settings in which providers deliver health care, including material resources, human resources, and organizational structure.¶

Timely. Waits and sometimes harmful delays for both those who receive and those who provide care are reduced.†

Value. The care provides good return relative to the costs involved, such as a return on investment or a reduction in the per capita cost of health care.*

* Source: Institute of Medicine. Future directions for the national healthcare quality and disparities reports. Ulmer C, Bruno M, Burke S, eds. Washington, DC: The National Academies Press; 2010.
† Source: Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century. Committee on Quality of Health Care in America, ed. Washington, DC: National Academies of Science; 2001.
§ Source: Kohatsu ND, Robinson JG, Torner JC. Evidence-based public health: an evolving concept. Am J Prev Med 2004;27:417–21.
¶ Source: Donabedian A. The quality of care. JAMA 1988;260:1743–8.

FIGURE 1. Family planning and related and other preventive health services



are closely linked to family planning services, and are appropriate to deliver in the context of a family planning visit but that do not contribute directly to achieving or preventing pregnancy (e.g., breast and cervical cancer screening).

- **Other preventive health services.** These include preventive health services for women that were not included above (*6*), as well as preventive services for men. Screening for lipid disorders, skin cancer, colorectal cancer, or osteoporosis are examples of this type of service. Although important in the context of primary care, these have no direct link to family planning services.

Providers of family planning services should be trained and equipped to offer all family planning and related preventive health services so that they can provide optimal care to clients, with referral for specialist care, as needed. Other preventive health services should be available either on-site or by referral, but these recommendations do not address this category of services. Information about preventive services that are beyond the scope of this report is available at http://www.uspreventiveservicestaskforce.org.

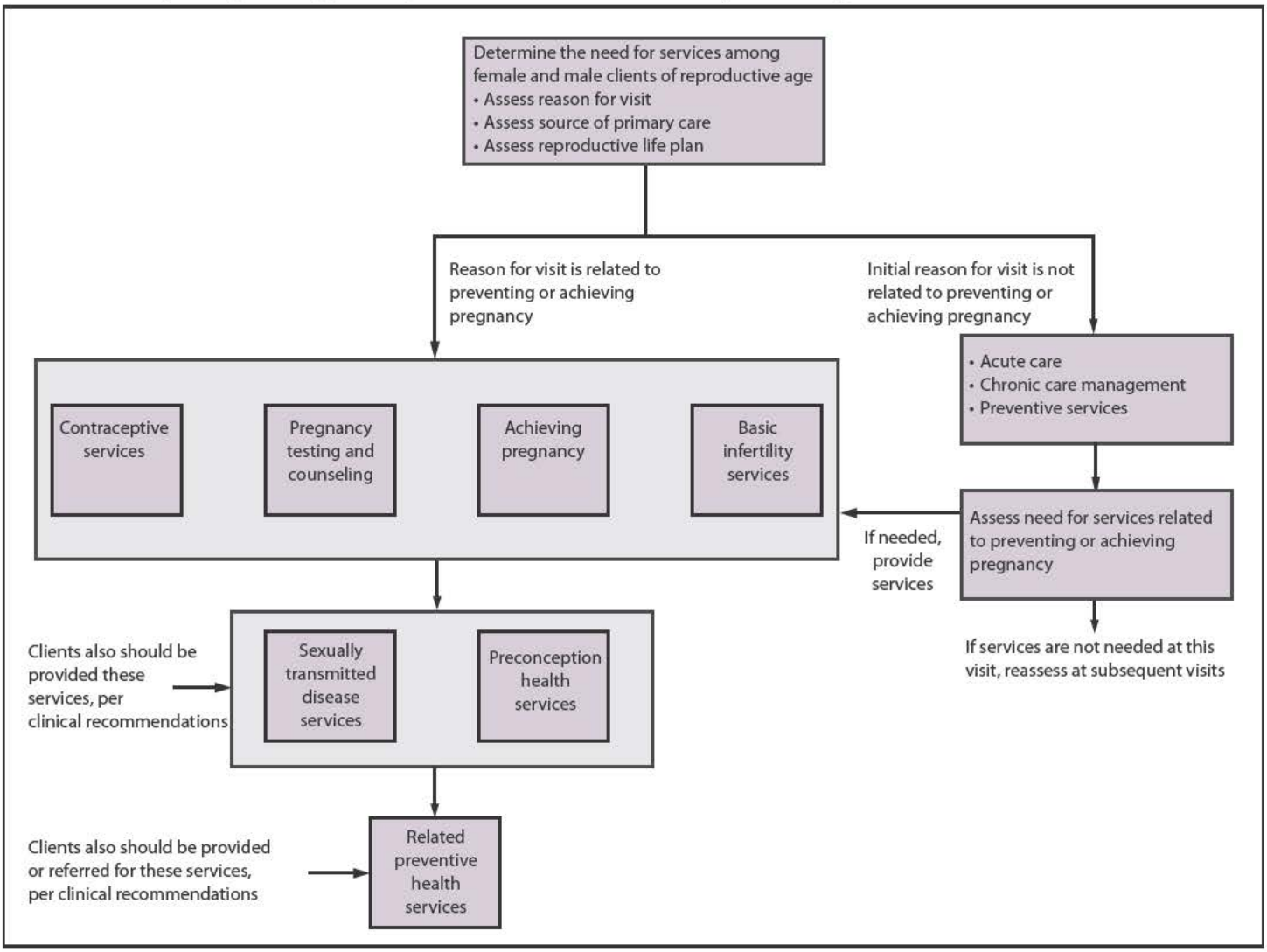
Determining the Client's Need for Services

These recommendations apply to two types of encounters with women and men of reproductive age. In the first type of encounter, the primary reason for a client's visit to a health-care provider is related to preventing or achieving pregnancy, (i.e., contraceptive services, pregnancy testing and counseling, or becoming pregnant). Other aspects of managing pregnancy (e.g., prenatal and delivery care) are not addressed in these recommendations. For clients seeking to prevent or achieve pregnancy, providers should assess whether the client needs other related services and offer them to the client. In the second type of encounter, the primary reason for a client's visit to a health-care provider is not related to preventing or achieving pregnancy. For example, the client might come in for acute care (e.g., a male client coming in for STD symptoms or as a contact of a person with an STD), for chronic care, or for another preventive service. In this situation, providers not only should address the client's primary reason for the visit but also assess the client's need for services related to preventing or achieving pregnancy.

A clinical pathway of family planning services for women and men of reproductive age is provided (Figure 2). The following questions can help providers determine what family planning services are most appropriate for a given visit.

- **What is the client's reason for the visit?** It is essential to understand the client's goals for the visit and address those needs to the extent possible.
- **Does the client have another source of primary health care?** Understanding whether a provider is the main source of primary care for a client will help identify what preventive services a provider should offer. If a provider is the client's main source of primary care, it will be important to assess the client's needs for the other services listed in this report. If the client receives ongoing primary care from another provider, the provider should confirm that the client's preventive health needs are met while avoiding the delivery of duplicative services.
- **What is the client's reproductive life plan?** An assessment should be made of the client's reproductive life plan, which outlines personal goals about becoming pregnant (*23–25*) (Box 2).The provider should avoid making assumptions about the client's needs based on his or her characteristics, such as sexual orientation or disabilities. For clients whose initial reason for coming to the service site was not related to preventing or achieving pregnancy, asking questions about his or her reproductive life plan might help identify unmet reproductive health-care needs. Identifying a need for contraceptive services might be particularly important given the high rate of unintended pregnancy in the United States.
  - If the client does not want a child at this time and is sexually active, then offer contraceptive services.
  - If the client desires pregnancy testing, then provide pregnancy testing and counseling.
  - If the client wants to have a child now, then provide services to help the client achieve pregnancy.

FIGURE 2. Clinical pathway of family planning services for women and men of reproductive age



– If the client wants to have a child and is experiencing difficulty conceiving, then provide basic infertility services.

- **Does the client need preconception health services?** Preconception health services (such as screening for obesity, smoking, and mental health) are a subset of all preventive services for women and men. Preconception health care is intended to promote the health of women and men of reproductive age before conception, with the goal of improving pregnancy-related outcomes (*24*). Preconception health services are also important because they improve the health of women and men, even if they choose not to become pregnant. The federal and professional medical recommendations cited in this report should be followed when determining which preconception health services a client might need.
- **Does the client need STD services?** The need for STD services, including HIV/AIDS testing, should be considered at every visit. Many clients requesting contraceptive services also might meet the criteria for being at risk of one or more STDs. Screening for chlamydia and gonorrhea is especially important in a family planning context because these STDs contribute to tubal infertility if left untreated. STD services are also necessary to maximize preconception health. The federal recommendations cited in this report should be followed when determining which STD services a client might need. Aspects of managing symptomatic STDs are not addressed in these recommendations.
- **What other related preventive health services does the client need?** Whether the client needs related preventive health services, such as breast and cervical cancer screening for female clients, should be assessed. The federal and professional medical recommendations cited in this report should be followed when determining which related preventive health services a client might need.

BOX 2. Recommended questions to ask when assessing a client's reproductive life plan

Providers should discuss a reproductive life plan with clients receiving contraceptive, pregnancy testing and counseling, basic infertility, sexually transmitted disease, and preconception health services in accordance with CDC's recommendation that all persons capable of having a child should have a reproductive life plan.*

Providers should assess the client's reproductive life plan by asking the client questions such as:

- Do you have any children now?
- Do you want to have (more) children?
- How many (more) children would you like to have and when?

* Source: CDC. Recommendations to improve preconception health and health care—United States: a report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care. MMWR 2006;55(No. RR-6).

The individual client's needs should be considered when determining what services to offer at a given visit. It might not be feasible to deliver all the needed services in a single visit, and they might need to be delivered over the course of several visits. Providers should tailor services to meet the specific needs of the population they serve. For example, clients who are trying to achieve pregnancy and those at high risk of unintended pregnancy should be given higher priority for preconception health services. In some cases, the provider will deliver the initial screening service but then refer to another provider for further diagnosis or follow-up care.

The delivery of preconception, STD, and related preventive health services should not become a barrier to a client's ability to receive services related to preventing or achieving pregnancy. For these clients, receiving services related to preventing or achieving pregnancy is the priority; if other family planning services cannot be delivered at the initial visit, then follow-up visits should be scheduled.

In addition, professional recommendations for how to address the needs of diverse clients, such as LGBTQ persons (*26–32*) or persons with disabilities (*33*), should be consulted and integrated into procedures, as appropriate. For example, as noted before, providers should avoid making assumptions about a client's gender identity, sexual orientation, race, or ethnicity; all requests for services should be treated without regard to these characteristics. Similarly, services for adolescents should be provided in a "youth-friendly" manner, which means that they are accessible, equitable, acceptable, appropriate, comprehensive, effective, and efficient for youth, as recommended by the World Health Organization (*34*).

Contraceptive Services

Providers should offer contraceptive services to clients who wish to delay or prevent pregnancy. Contraceptive services should include consideration of a full range of FDA-approved contraceptive methods, a brief assessment to identify the contraceptive methods that are safe for the client, contraceptive counseling to help a client choose a method of contraception and use it correctly and consistently, and provision of one or more selected contraceptive method(s), preferably on site, but by referral if necessary. Contraceptive counseling is defined as a process that enables clients to make and follow through on decisions about their contraceptive use. Education is an integral component of the contraceptive counseling process that helps clients to make informed decisions and obtain the information they need to use contraceptive methods correctly.

Key steps in providing contraceptive services, including contraceptive counseling and education, have been outlined (Box 3). These key steps are in accordance with the five principles of quality counseling (Appendix C). To help a client who is initiating or switching to a new method of contraception, providers should follow these steps. These steps most likely will be implemented iteratively when working with a client and should help clients adopt, change, or maintain contraceptive use.

Step 1. Establish and maintain rapport with the client. Providers should strive to establish and maintain rapport. Strategies to achieve these goals include the following:

- using open-ended questions;
- demonstrating expertise, trustworthiness, and accessibility;
- ensuring privacy and confidentiality;
- explaining how personal information will be used;
- encouraging the client to ask questions and share information;
- listening to and observing the client; and
- being encouraging and demonstrating empathy and acceptance.

Step 2. Obtain clinical and social information from the client. Providers should ask clients about their medical history to identify methods that are safe. In addition, to learn more about factors that might influence a client's choice of a contraceptive method, providers should confirm the client's pregnancy intentions or reproductive life plan, ask about the client's contraceptive experiences and preferences, and conduct a sexual health assessment. When available, standardized tools should be used.

- **Medical history.** A medical history should be taken to ensure that methods of contraception being considered by a client are safe for that particular client. For a female client, the medical history should include menstrual history (including last menstrual period, menstrual frequency, length and amount of bleeding, and other

BOX 3. Steps in providing contraceptive services, including contraceptive counseling* and education

- Establish and maintain rapport with the client.
- Obtain clinical and social information from the client.
- Work with the client interactively to select the most effective and appropriate contraceptive method.
- Conduct a physical assessment related to contraceptive use, only when warranted.
- Provide the contraceptive method along with instructions about correct and consistent use, help the client develop a plan for using the selected method and for follow up, and confirm client understanding.

* Key principles of providing quality counseling including education have been outlined (Appendix C).

patterns of uterine/vaginal bleeding), gynecologic and obstetrical history, contraceptive use, allergies, recent intercourse, recent delivery, miscarriage, or termination, and any relevant infectious or chronic health condition and other characteristics and exposures (e.g., age, postpartum, and breastfeeding) that might affect the client's medical eligibility criteria for contraceptive methods (*35*). Clients considering combined hormonal contraception should be asked about smoking tobacco, in accordance with CDC guidelines on contraceptive use (*35*). Additional details about the methods of contraception that are safe to use for female clients with specific medical conditions and characteristics (e.g., hypertension) are addressed in previously published guidelines (*35*). For a male client, a medical history should include use of condoms, known allergies to condoms, partner use of contraception, recent intercourse, whether his partner is currently pregnant or has had a child, miscarriage, or termination, and the presence of any infectious or chronic health condition. However, the taking of a medical history should not be a barrier to making condoms available in the clinical setting (i.e., a formal visit should not be a prerequisite for a client to obtain condoms).

- **Pregnancy intention or reproductive life plan.** Each client should be encouraged to clarify decisions about her or his reproductive life plan (i.e., whether the client wants to have any or more children and, if so, the desired timing and spacing of those children) (*24*).
- **Contraceptive experiences and preferences.** Method-specific experiences and preferences should be assessed by asking questions such as, "What method(s) are you currently using, if any?"; "What methods have you used in the past?"; "Have you previously used emergency contraception?"; "Did you use contraception at last sex?"; "What difficulties did you experience with prior methods if any (e.g., side effects or noncompliance)?"; "Do you have a specific method in mind?"; and "Have you discussed method options with your partner, and does your partner have any preferences for which method you use?" Male clients should be asked if they are interested in vasectomy.
- **Sexual health assessment.** A sexual history and risk assessment that considers the client's sexual practices, partners, past STD history, and steps taken to prevent STDs (*36*) is recommended to help the client select the most appropriate method(s) of contraception. Correct and consistent condom use is recommended for those at risk for STDs. CDC recommendations for how to conduct a sexual health assessment have been summarized (Box 4).

Step 3. Work with the client interactively to select the most effective and appropriate contraceptive method. Providers should work with the client interactively to select an effective and appropriate contraceptive method. Specifically, providers should educate the client about contraceptive methods that the client can safely use, and help the client consider potential barriers to using the method(s) under consideration. Use of decision aids (e.g., computerized programs that help a client to identify a range of methods that might be appropriate for the client based on her physical characteristics such as health conditions or preferences about side effects) before or while waiting for the appointment can facilitate and maximize the utility of the time spent on this step.

Providers should inform clients about all contraceptive methods that can be used safely. Before the health-care visit, clients might have only limited information about all or specific methods of contraception (*37*). A broad range of methods, including long-acting reversible contraception (i.e., intrauterine devices [IUDs] and implants), should be discussed with all women and adolescents, if medically appropriate.

Providers are encouraged to present information on potential reversible methods of contraception by using a tiered approach (i.e., presenting information on the most effective methods first, before presenting information on less effective methods) (*38*,*39*). This information should include an explanation that long-acting reversible contraceptive methods are safe and effective for most women, including those who have never given birth and adolescents (*35*). Information should be tailored and presented to ensure a client-centered approach. It is not appropriate to omit presenting information on a method solely because the method is not available at the service site. If not all methods are available at the service site, it is important to have strong referral links in place to other providers to maximize opportunities for clients to obtain their preferred method that is medically appropriate.

BOX 4. Steps in conducting a sexual health assessment*

- **Practices:** Explore the types of sexual activity in which the patient engages (e.g., vaginal, anal, or oral sex).
- **Pregnancy prevention:** Discuss current and future contraceptive options. Ask about current and previous use of methods, use of contraception at last sex, difficulties with contraception, and whether the client has a particular method in mind.
- **Partners:** Ask questions to determine the number, gender (men, women, or both), and concurrency of the patient's sex partners (if partner had sex with another partner while still in a sexual relationship with the patient). It might be necessary to define the term "partner" to the patient or use other, relevant terminology.
- **Protection from sexually transmitted diseases (STDs):** Ask about condom use, with whom they do or do not use condoms, and situations that make it harder or easier to use condoms. Topics such as monogamy and abstinence also can be discussed.
- **Past STD history:** Ask about any history of STDs, including whether their partners have ever had an STD. Explain that the likelihood of an STD is higher with a past history of an STD.

*Source: CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR 2010;59(No. RR-12).

For clients who have completed childbearing or do not plan to have children, permanent sterilization (female or male) is an option that may be discussed. Both female and male sterilization are safe, are highly effective, and can be performed in an office or outpatient surgery setting (*40*,*41*). Women and men should be counseled that these procedures are not intended to be reversible and that other highly effective, reversible methods of contraception (e.g., implants or IUDs) might be an alternative if they are unsure about future childbearing. Clients interested in sterilization should be referred to an appropriate source of care if the provider does not perform the procedure.

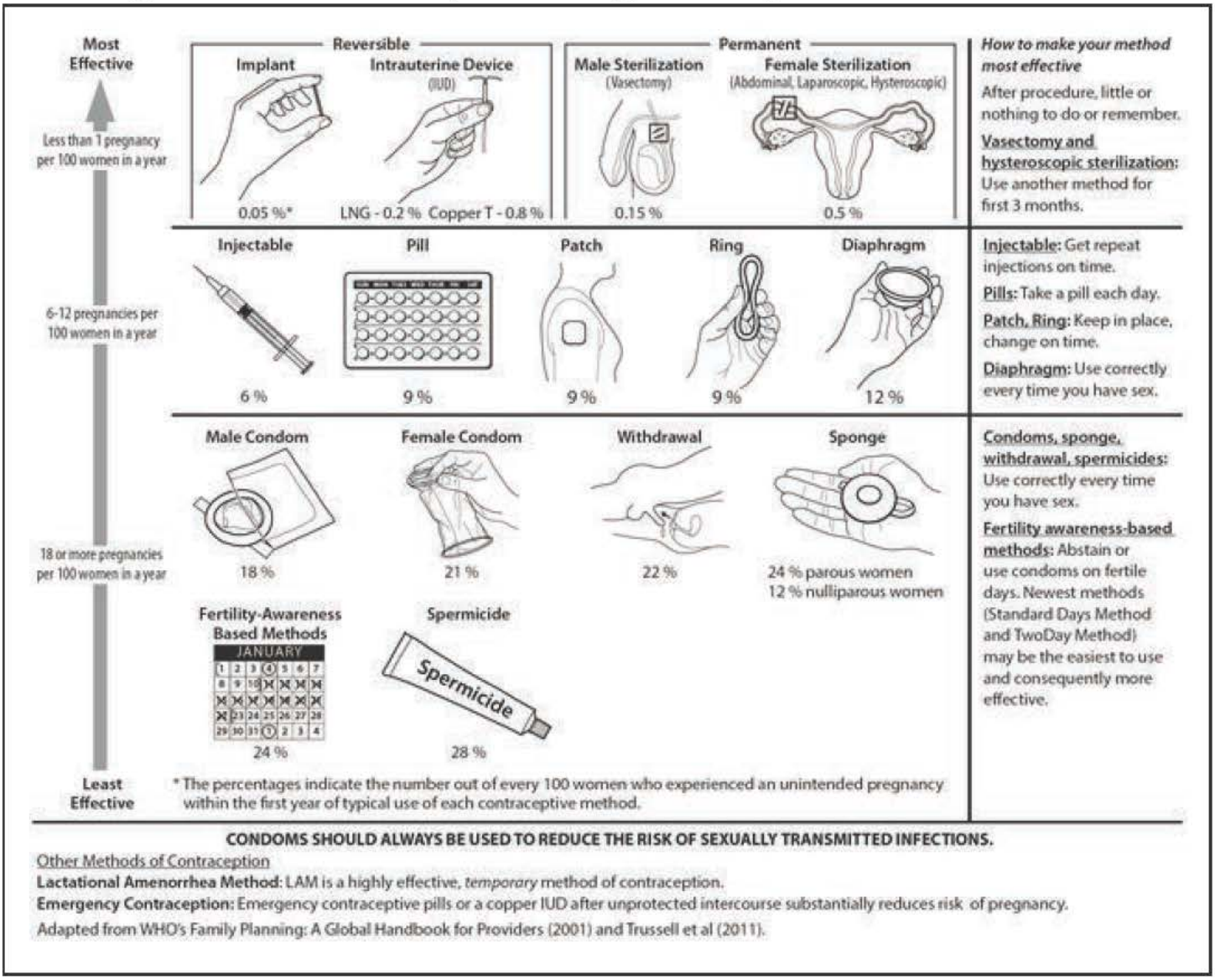
When educating clients about contraceptive methods that the clients can use safely, providers should ensure that clients understand the following:

- **Method effectiveness.** A contraceptive method's rate of typical effectiveness, or the percentage of women experiencing an unintended pregnancy during the first year of typical use, is an important consideration (Figure 3; Appendix D) (*38*,*42*).
- **Correct use of the method.** The mode of administration and understanding how to use the method correctly might be important considerations for the client when choosing a method. For example, receiving a contraceptive injection every 3 months might not be acceptable to a woman who fears injections. Similarly, oral contraceptives might not be acceptable to a woman who is concerned that she might not be able to remember to take a pill every day.
- **Noncontraceptive benefits.** Many contraceptives have noncontraceptive benefits, in addition to preventing pregnancy, such as reducing heavy menstrual bleeding. Although the noncontraceptive benefits are not generally the major determinant for selecting a method, awareness of these benefits can help clients decide between two or more suitable methods and might enhance the client's motivation to use the method correctly and consistently.
- **Side effects.** Providers should inform the client about risks and side effects of the method(s) under consideration, help the client understand that certain side effects of contraceptive methods might disappear over time, and encourage the client to weigh the experience of coping with side effects against the experience and consequences of an unintended pregnancy. The provider should be prepared to discuss and correct misperceptions about side effects. Clients also should be informed about warning signs for rare, but serious, adverse events with specific contraceptive methods, such as stroke and venous thromboembolism with use of combined hormonal methods.
- **Protection from STDs, including HIV.** Clients should be informed that contraceptive methods other than condoms offer no protection against STDs, including HIV. Condoms, when used correctly and consistently, help reduce the risk of STDs, including HIV, and provide protection against pregnancy. Dual protection (i.e., protection from both pregnancy and STDs) is important for clients at risk of contracting an STD, such as those with multiple or potentially infected partner(s). Dual protection can be achieved through correct and consistent use of condoms with every act of sexual intercourse, or correct and consistent use of a condom to prevent infection plus another form of contraception to prevent pregnancy. (For more information about preventing and treating STDs, see STD Services.)

When educating clients about the range of contraceptive methods, providers should ensure that clients have information that is medically accurate, balanced, and provided in a nonjudgmental manner. To assist clients in making informed decisions, providers should educate clients in a manner that can be readily understood and retained. The content, format, method, and medium for delivering education should be evidence-based (see Appendix E).

When working with male clients, when appropriate, providers should discuss information about female-controlled methods

FIGURE 3. The typical effectiveness of Food and Drug Administration–approved contraceptive methods



(including emergency contraception) encourage discussion of contraception with partners, and provide information about how partners can access contraceptive services. Male clients should also be reminded that condoms should be used correctly and consistently to reduce risk of STDs, including HIV.

When working with any client, encourage partner communication about contraception, as well as understanding partner barriers (e.g., misperceptions about side effects) and facilitators (e.g., general support) of contraceptive use (*43–46*).

The provider should help the client consider potential barriers to using the method(s) under consideration. This includes consideration of the following factors:

- **Social-behavioral factors.** Social-behavioral factors might influence the likelihood of correct and consistent use of contraception (*47*). Providers should help the client consider the advantages and disadvantages of the method(s) being considered, the client's feelings about using the method(s), how her or his partner is likely to respond, the client's peers' perceptions of the method(s), and the client's confidence in being able to use the method correctly and consistently (e.g., using a condom during every act of intercourse or remembering to take a pill every day) (*37*).
- **Intimate partner violence and sexual violence.** Current and past intimate partner sexual or domestic violence might impede the correct and consistent use of contraception, and might be a consideration when choosing a method (*47–49*). For example, an IUD might

be preferred because it does not require the partner's participation. The medical history might provide information on signs of current or past violence and, if not, providers should ask clients about relationship issues that might be potential barriers to contraceptive use. In addition, clients experiencing intimate partner violence or sexual violence should be referred for appropriate care.

- **Mental health and substance use behaviors.** Mental health (e.g., depression, anxiety disorders, and other mental disorders) and substance use behaviors (e.g., alcohol use, prescription abuse, and illicit drug use) might affect a client's ability to correctly and consistently use contraception (*47*,*50*). The medical history might provide information about the signs of such conditions or behaviors, and if not, providers should ask clients about substance use behaviors or mental health disorders, such as depression or anxiety, that might interfere with the motivation or ability to follow through with contraceptive use. If needed, clients with mental health disorders or risky substance use behaviors should be referred for appropriate care.

Step 4. Conduct a physical assessment related to contraceptive use, when warranted. Most women will need no or few examinations or laboratory tests before starting a method of contraception. Guidance on necessary examinations and tests related to initiation of contraception is available (*42*). A list of assessments that need to be conducted when providing reversible contraceptive services to a female client seeking to initiate or switch to a new method of reversible contraception is provided (Table 1) (*42*). Clinical evaluation of a client electing permanent sterilization should be guided by the clinician who performs the procedure. Recommendations for contraceptive use are available (*42*). Key points include the following:

- Blood pressure should be taken before initiating the use of combined hormonal contraception.
- Providers should assess the current pregnancy status of clients receiving contraception (*42*), which provides guidance on how to be reasonably certain that a woman is not pregnant at the time of contraception initiation. In most cases, a detailed history provides the most accurate assessment of pregnancy risk in a woman about to start using a contraceptive method. Routine pregnancy testing for every woman is not necessary.
- Weight measurement is not needed to determine medical eligibility for any method of contraception because all methods generally can be used among obese women. However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.
- Unnecessary medical procedures and tests might create logistical, emotional, or economic barriers to contraceptive access for some women, particularly adolescents and low-income women, who have high rates of unintended pregnancies (*1*,*51*,*52*). For both adolescent and adult female clients, the following examinations and tests are not needed routinely to provide contraception safely to a healthy client (although they might be needed to address other non-contraceptive health needs) (*42*):
  - pelvic examinations, unless inserting an intrauterine device (IUD) or fitting a diaphragm;
  - cervical cytology or other cancer screening, including clinical breast exam;
  - human immunodeficiency virus (HIV) screening; and
  - laboratory tests for lipid, glucose, liver enzyme, and hemoglobin levels or thrombogenic mutations.

For male clients, no physical examination needs to be performed before distributing condoms.

Step 5. Provide the contraceptive method along with instructions about correct and consistent use, help the client develop a plan for using the selected method and for follow-up, and confirm client understanding.

- A broad range of FDA-approved contraceptive methods should be available onsite. Referrals for methods not available onsite should be provided for clients who indicate they prefer those methods. When providing contraception, providers should instruct the client about correct and consistent use and employ the following strategies to facilitate a client's use of contraception:
  - Provide onsite dispensing;
  - Begin contraception at the time of the visit rather than waiting for next menses (also known as "quick start") if the provider can reasonably be certain that the client is not pregnant (*42*). A provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria (*42*,*53*):
    - is ≤7 days after the start of normal menses,
    - has not had sexual intercourse since the start of last normal menses,
    - has been using a reliable method of contraception correctly and consistently,
    - is ≤7 days after spontaneous or induced abortion,
    - is within 4 weeks postpartum,
    - is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and <6 months postpartum;
  - Provide or prescribe multiple cycles (ideally a full year's supply) of oral contraceptive pills, the patch, or the ring

TABLE 1. Assessments to conduct when a female client is initiating a new method of reversible contraception

	Cu-IUD and LNG-IUD	Implant	Injectable	Combined hormonal contraception	Progestin-only pills	Condom	Diaphragm or cervical cap	Spermicide
Examination								
Blood pressure	C	C	C	A*	C	C	C	C
Weight (BMI) (weight [kg]/height [m]^2)	—†	—†	—†	—†	—†	C	C	C
Clinical breast examination	C	C	C	C	C	C	C	C
Bimanual examination and cervical inspection	A	C	C	C	C	C	A§	C
Laboratory test								
Glucose	C	C	C	C	C	C	C	C
Lipids	C	C	C	C	C	C	C	C
Liver enzymes	C	C	C	C	C	C	C	C
Hemoglobin	C	C	C	C	C	C	C	C
Thrombogenic mutations	C	C	C	C	C	C	C	C
Cervical cytology (Papanicolaou smear)	C	C	C	C	C	C	C	C
STD screening with laboratory tests	—¶	C	C	C	C	C	C	C
HIV screening with laboratory tests	C	C	C	C	C	C	C	C

Source: CDC. U.S. selected practice recommendations for contraceptive use 2013. MMWR 2013;62(No. RR-5).
Abbreviations: A = Class A: essential and mandatory in all circumstances for safe and effective use of the contraceptive method; B = Class B: contributes substantially to safe and effective use, but implementation might be considered within the public health and/or service context (the risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available); C = Class C: does not contribute substantially to safe and effective use of the contraceptive method; Cu-IUD = copper-containing intrauterine device; LNG-IUD = levonorgestrel releasing intrauterine device.
* In cases in which access to health care might be limited, the blood pressure measurement can be obtained by the woman in a nonclinical setting (e.g., pharmacy or fire station) and self-reported to the provider.
† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. Medical Eligibility Criteria 1) or generally can be used (U.S. Medical Eligibility Criteria 2) among obese women (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.
§ A bimanual examination (not cervical inspection) is needed for diaphragm fitting.
¶ Most women do not require additional STD screening at the time of IUD insertion, if they have already been screened according to CDC's STD treatment guidelines (Sources: CDC. STD treatment guidelines. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at http://www.cdc.gov/std/treatment. CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR. 2010;59[No. RR-12]). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. Medical Eligibility Criteria 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. Medical Eligibility Criteria 3) (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

to minimize the number of times a client has to return to the service site;
  - Make condoms easily and inexpensively available; and
  - If a client chooses a method that is not available on-site or the same day, provide the client another method to use until she or he can start the chosen method.
- Help the client develop a plan for using the selected method. Using a method incorrectly or inconsistently and having gaps in contraceptive protection because of method switching both increase the likelihood of an unintended pregnancy (*37*). After the method has been provided, or a plan put into place to obtain the chosen method, providers should help the client develop an action plan for using the selected method.

  Providers should encourage clients to anticipate reasons why they might not use their chosen method(s) correctly or consistently, and help them develop strategies to deal with these possibilities. For example, for a client selecting oral contraceptive pills who might forget to take a pill, the provider can work with the client to identify ways to routinize daily pill taking (e.g., use of reminder systems such as daily text messages or cell phone alarms). Providers also may inform clients about the availability of emergency contraceptive pills and may provide clients an advance supply of emergency contraceptive pills on-site or by prescription, if requested.

  Side effects (e.g., irregular vaginal bleeding) are a primary reason for method discontinuation (*54*), so providers should discuss ways the client might deal with potential side effects to increase satisfaction with the method and improve continuation (*42*).
- Develop a plan for follow-up. Providers should discuss an appropriate follow-up plan with the client to meet their individual needs, considering the client's risk for discontinuation. Follow-up provides an opportunity to inquire about any initial difficulties the client might be experiencing, and might reinforce the perceived accessibility of the provider and increase rapport. Alternative modes of follow-up other than visits to the service site, such as telephone, e-mail, or text messaging, should be considered (assuming confidentiality can be assured), as needed.

  As noted previously, if a client chooses a method that is not available on-site or during the visit, the provider

should schedule a follow-up visit with the client or provide a referral for her or him to receive the method. The client should be provided another method to use until she or he can start the chosen method.
- Confirm the client's understanding. Providers should assess whether the client understands the information that was presented. The client's understanding of the most important information about her or his chosen contraceptive method should be documented in the medical record (e.g., by a checkbox or written statement).

The teach-back method may be used to confirm the client's understanding by asking the client to repeat back messages about risks and benefits and appropriate method use and follow-up. If providers assess the client's understanding, then the check box or written statement can be used in place of a written method-specific informed consent form. Topics that providers may consider having the client repeat back include the following: typical method effectiveness; how to use the method correctly; protection from STDs; warning signs for rare, but serious, adverse events and what to do if they experience a warning sign; and when to return for follow-up.

Provide Counseling for Returning Clients

When serving contraceptive clients who return for ongoing care related to contraception, providers should ask if the client has any concerns with the method and assess its use. The provider should assess any changes in the client's medical history, including changes in risk factors and medications that might affect safe use of the contraceptive method. If the client is using the method correctly and consistently and there are no concerns about continued use, an appropriate follow-up plan should be discussed and more contraceptive supplies given (*42*). If the client or provider has concerns about the client's correct or consistent use of the method, the provider should ask if the client would be interested in considering a different method of contraception. If the client is interested, the steps described above should be followed.

Counseling Adolescent Clients

Providers should give comprehensive information to adolescent clients about how to prevent pregnancy (*55–57*). This information should clarify that avoiding sex (i.e., abstinence) is an effective way to prevent pregnancy and STDs. If the adolescent indicates that she or he 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 is a safe and effective option for many adolescents, including those who have not been pregnant or given birth (*35*).

Providers of family planning services should offer confidential services to adolescents and observe all relevant state laws and any legal obligations, such as notification or reporting of child abuse, child molestation, sexual abuse, rape, or incest, as well as human trafficking (*58,59*). Confidentiality is critical for adolescents and can greatly influence their willingness to access and use services (*60–67*). As a result, multiple professional medical associations have emphasized the importance of providing confidential services to adolescents (*68–70*).

Providers should encourage and promote communication between the adolescent and his or her parent(s) or guardian(s) about sexual and reproductive health (*71–86*). Adolescents who come to the service site alone should be encouraged to talk to their parents or guardians. Educational materials and programs can be provided to parents or guardians that help them talk about sex and share their values with their child (*72,87*). When both parent or guardian and child have agreed, joint discussions can address family values and expectations about dating, relationships, and sexual behavior.

In a given year, approximately 20% of adolescent births represent repeat births (*88*), so in addition to providing postpartum contraception, providers should refer pregnant and parenting adolescents to home visiting and other programs that have been demonstrated to provide needed support and reduce rates of repeat teen pregnancy (*89–94*).

Services for adolescents should be provided in a "youth-friendly" manner, which means that they are accessible, equitable, acceptable, appropriate, comprehensive, effective, and efficient for youth as recommended by the World Health Organization (*34*).

Pregnancy Testing and Counseling

Providers of family planning services should offer pregnancy testing and counseling services as part of core family planning services, in accordance with recommendations of major professional medical organizations, such as the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP) (*95–97*).

Pregnancy testing is a common reason for a client to visit a provider of family planning services. Approximately 65% of pregnancies result in live births, 18% in induced abortion, and 17% spontaneous fetal loss (*98*). Among live births, only 1% of infants are placed for adoption within their first month of life (*99*).

The visit should include a discussion about her reproductive life plan and a medical history that includes asking about any coexisting conditions (e.g., chronic medical illnesses, physical disability, psychiatric illness) (*95,96*). In most cases,

a qualitative urine pregnancy test will be sufficient; however, in certain cases, the provider may consider performing a quantitative serum pregnancy test, if exact hCG levels would be helpful for diagnosis and management. The test results should be presented to the client, followed by a discussion of options and appropriate referrals.

Options counseling should be provided in accordance with recommendations from professional medical associations, such as ACOG and AAP (*95*–*97*). A female client might wish to include her partner in the discussion; however, if a client chooses not to involve her partner, confidentiality must be assured.

Positive Pregnancy Test

If the pregnancy test is positive, the clinical visit should include an estimation of gestational age so that appropriate counseling can be provided. If a woman is uncertain about the date of her last normal menstrual period, a pelvic examination might be needed to help assess gestational age. In addition, clients should receive information about the normal signs and symptoms of early pregnancy, and should be instructed to report any concerns to a provider for further evaluation. If ectopic pregnancy or other pregnancy abnormalities or problems are suspected, the provider should either manage the condition or refer the client for immediate diagnosis and management.

Referral to appropriate providers of follow-up care should be made at the request of the client, as needed. Every effort should be made to expedite and follow through on all referrals. For example, providers might provide a resource listing or directory of providers to help the client identify options for care. Depending upon a client's needs, the provider may make an appointment for the client, or call the referral site to let them know the client was referred. Providers also should assess the client's social support and refer her to appropriate counseling or other supportive services, as needed.

For clients who are considering or choose to continue the pregnancy, initial prenatal counseling should be provided in accordance with the recommendations of professional medical associations, such as ACOG (*97*). The client should be informed that some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (e.g., an obstetrician or midwife). In addition, the client should be encouraged to take a daily prenatal vitamin that includes folic acid; to avoid smoking, alcohol, and other drugs; and not to eat fish that might have high levels of mercury (*97*). If there might be delays in obtaining prenatal care, the client should be provided or referred for any needed STD screening (including HIV) and vaccinations (*36*).

Negative Pregnancy Test

Women who are not pregnant and who do not want to become pregnant at this time should be offered contraceptive services, as described previously. The contraceptive counseling session should explore why the client thought that she was pregnant and sought pregnancy testing services, and whether she has difficulties using her current method of contraception. A negative pregnancy test also provides an opportunity to discuss the value of making a reproductive life plan. Ideally, these services will be offered in the same visit as the pregnancy test because clients might not return at a later time for contraceptive services.

Women who are not pregnant and who are trying to become pregnant should be offered services to help achieve pregnancy or basic infertility services, as appropriate (see "Clients Who Want to Become Pregnant" and "Basic Infertility Services"). They also should be offered preconception health and STD services (see "Preconception Health Services" and "STD services").

Clients Who Want to Become Pregnant

Providers should advise clients who wish to become pregnant in accordance with the recommendations of professional medical organizations, such as the American Society for Reproductive Medicine (ASRM) (*100*).

Providers should ask the client (or couple) how long she or they have been trying to get pregnant and when she or they hope to become pregnant. If the client's situation does not meet one of the standard definitions of infertility (see "Basic Infertility Services"), then she or he may be counseled about how to maximize fertility. Key points are as follows:

- The client should be educated about peak days and signs of fertility, including the 6-day interval ending on the day of ovulation that is characterized by slippery, stretchy cervical mucus and other possible signs of ovulation.
- Women with regular menstrual cycles should be advised that vaginal intercourse every 1–2 days beginning soon after the menstrual period ends can increase the likelihood of becoming pregnant.
- Methods or devices designed to determine or predict the time of ovulation (e.g., over-the-counter ovulation kits, digital telephone applications, or cycle beads) should be discussed.
- It should be noted that fertility rates are lower among women who are very thin or obese, and those who consume high levels of caffeine (e.g., more than five cups per day).
- Smoking, consuming alcohol, using recreational drugs, and using most commercially available vaginal lubricants should be discouraged as these might reduce fertility.

Basic Infertility Services

Providers should offer basic infertility care as part of core family planning services in accordance with the recommendations of professional medical organizations, such as ACOG, ASRM, and the American Urological Association (AUA) (*96*,*101*,*102*).

Infertility commonly is defined as the failure of a couple to achieve pregnancy after 12 months or longer of regular unprotected intercourse (*101*). Earlier assessment (such as 6 months of regular unprotected intercourse) is justified for women aged >35 years, those with a history of oligo-amenorrhea (infrequent menstruation), those with known or suspected uterine or tubal disease or endometriosis, or those with a partner known to be subfertile (the condition of being less than normally fertile though still capable of effecting fertilization) (*101*). An early evaluation also might be warranted if risk factors of male infertility are known to be present or if there are questions regarding the male partner's fertility potential (*102*). Infertility visits to a family planning provider are focused on determining potential causes of the inability to achieve pregnancy and making any needed referrals to specialist care (*101*,*102*). ASRM recommends that evaluation of both partners should begin at the same time (*101*).

Basic Infertility Care for Women

The clinical visit should focus on understanding the client's reproductive life plan (*24*) and her difficulty in achieving pregnancy through a medical history, sexual health assessment and physical exam, in accordance with recommendations developed by professional medical associations such as ASRM (*101*) and ACOG (*96*). The medical history should include past surgery, including indications and outcome(s), previous hospitalizations, serious illnesses or injuries, medical conditions associated with reproductive failure (e.g., thyroid disorders, hirsutism, or other endocrine disorders), and childhood disorders; results of cervical cancer screening and any follow-up treatment; current medication use and allergies; and family history of reproductive failure. In addition, a reproductive history should include how long the client has been trying to achieve pregnancy; coital frequency and timing, level of fertility awareness, and results of any previous evaluation and treatment; gravidity, parity, pregnancy outcome(s), and associated complications; age at menarche, cycle length and characteristics, and onset/severity of dysmenorrhea; and sexual history, including pelvic inflammatory disease, history of STDs, or exposure to STDs. A review of systems should emphasize symptoms of thyroid disease, pelvic or abdominal pain, dyspareunia, galactorrhea, and hirsutism (*101*).

The physical examination should include: height, weight, and body mass index (BMI) calculation; thyroid examination to identify any enlargement, nodule, or tenderness; clinical breast examination; and assessment for any signs of androgen excess. A pelvic examination should assess for: pelvic or abdominal tenderness, organ enlargement or mass; vaginal or cervical abnormality, secretions, or discharge; uterine size, shape, position, and mobility; adnexal mass or tenderness; and cul-de-sac mass, tenderness, or nodularity. If needed, clients should be referred for further diagnosis and treatment (e.g., serum progesterone levels, follicle-stimulating hormone/luteinizing hormone levels, thyroid function tests, prolactin levels, endometrial biopsy, transvaginal ultrasound, hysterosalpingography, laparoscopy, and clomiphene citrate).

Basic Infertility Care for Men

Infertility services should be provided for the male partner of an infertile couple in accordance with recommendations developed by professional medical associations such as AUA (*102*). Providers should discuss the client's reproductive life plan, take a medical history, and conduct a sexual health assessment. AUA recommends that the medical history include a reproductive history (*102*). The medical history should include systemic medical illnesses (e.g., diabetes mellitus), prior surgeries and past infections; medications (prescription and nonprescription) and allergies; and lifestyle exposures. The reproductive history should include methods of contraception, coital frequency and timing; duration of infertility and prior fertility; sexual history; and gonadal toxin exposure, including heat. Patients also should be asked about their female partners' history of pelvic inflammatory disease, their partners' histories of STDs, and problems with sexual dysfunction.

In addition, a physical examination should be conducted with particular focus given to 1) examination of the penis, including the location of the urethral meatus; 2) palpation of the testes and measurement of their size; 3) presence and consistency of both the vas deferens and epididymis; 4) presence of a varicocele; 5) secondary sex characteristics; and 6) a digital rectal exam (*102*). Male clients concerned about their fertility should have a semen analysis. If this test is abnormal, they should be referred for further diagnosis (i.e., second semen analysis, endocrine evaluation, post-ejaculate urinalysis, or others deemed necessary) and treatment. The semen analysis is the first and most simple screen for male fertility.

Infertility Counseling

Counseling provided during the clinical visit should be guided by information elicited from the client during the medical and reproductive history and the findings of the

physical exam. If there is no apparent cause of infertility and the client does not meet the definition above, providers should educate the client about how to maximize fertility (see "Clients Who Want to Become Pregnant"). ACOG notes the importance of addressing the emotional and educational needs of clients with infertility and recommends that providers consider referring clients for psychological support, infertility support groups, or family counseling (*96*).

Preconception Health Services

Providers of family planning services should offer preconception health services to female and male clients in accordance with CDC's recommendations to improve preconception health and health care (*24*).

Preconception health services are beneficial because of their effect on pregnancy and birth outcomes and their role in improving the health of women and men. The term preconception describes any time that a woman of reproductive potential is not pregnant but at risk of becoming pregnant, or when a man is at risk for impregnating his female partner.

Preconception health-care services for women aim to identify and modify biomedical, behavioral, and social risks to a woman's health or pregnancy outcomes through prevention and management. It promotes the health of women of reproductive age before conception, and thereby helps to reduce pregnancy-related adverse outcomes, such as low birthweight, premature birth, and infant mortality (*24*). Moreover, the preconception health services recommended here are equally important because they contribute to the improvement of women's health and well-being, regardless of her childbearing intentions. CDC recommends that preconception health services be integrated into primary care visits made by women of reproductive age, such as family planning visits (*24*).

In the family planning setting, providers may prioritize screening and counseling about preconception health for couples that are trying to achieve pregnancy and couples seeking basic infertility services. Women who are using contraception to prevent or delay pregnancy might also benefit from preconception health services, especially those at high risk of unintended pregnancy. A woman is at high risk of unintended pregnancy if she is using no method or a less effective method of contraception (e.g., barrier methods, rhythm, or withdrawal), or has a history of contraceptive discontinuation or incorrect use (*38*,*39*). A woman is at lower risk of unintended pregnancy if she is using a highly effective method, such as an IUD or implant, or has an established history of using methods of contraception, such as injections, pills, patch, or ring correctly and consistently (*38*,*39*). Clients who do not want to become pregnant should also be provided preconception health services, since they are recommended by USPSTF for the purpose of improving the health of adults.

Recommendations for improving the preconception health of men also have been identified, although the evidence base for many of the recommendations for men is less than that for women (*103*). This report includes preconception health services that address men as partners in family planning (i.e., both preventing and achieving pregnancy), their direct contributions to infant health (e.g., genetics), and their role in improving the health of women (e.g., through reduced STD/HIV transmission). Moreover, these services are important for improving the health of men regardless of their pregnancy intention.

In a family planning setting, all women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid, in accordance with the USPSTF recommendation (Grade A) (*104*).

Other preconception health services for women and men should include discussion of a reproductive life plan and sexual health assessment (Boxes 2 and 4), as well as the screening services described below (*24*,*103*,*105*). Services should be provided in accordance with the cited clinical recommendations, and any needed follow up (further diagnosis, treatment) should be provided either on-site or through referral.

Medical History

For female clients, the medical history should include the reproductive history, history of poor birth outcomes (i.e., preterm, cesarean delivery, miscarriage, and stillbirth), environmental exposures, hazards and toxins (e.g., smoking, alcohol, other drugs), medications that are known teratogens, genetic conditions, and family history (*24*,*105*).

For male clients, the medical history should include asking about the client's past medical and surgical history that might impair his reproductive health (e.g., genetic conditions, history of reproductive failures, or conditions that can reduce sperm quality, such as obesity, diabetes mellitus, and varicocele) and environmental exposures, hazards and toxins (e.g., smoking) (*103*).

Intimate Partner Violence

Providers should screen women of childbearing age for intimate partner violence and provide or refer women who screen positive to intervention services, in accordance with USPSTF (Grade B) recommendations (*106*).

Alcohol and Other Drug Use

For female and male adult clients, providers should screen for alcohol use in accordance with the USPSTF recommendation (Grade B) for how to do so, and provide behavioral counseling

interventions, as indicated (*107*). Screening adults for other drug use and screening adolescents for alcohol and other drug use has the potential to reduce misuse of alcohol and other drugs, and can be recommended (*105*,*108*,*109*). However, the USPSTF recommendation for screening for other drugs in adults, and for alcohol and other drugs in adolescents, is an "I," and patients should be informed that there is insufficient evidence to assess the balance of benefits and harms of this screening (*107*,*110*).

Tobacco Use

For female and male clients, providers should screen for tobacco use in accordance with the USPSTF recommendation (*111*,*112*) for how to do so. Adults (Grade A) who use tobacco products should be provided or referred for tobacco cessation interventions, including brief behavioral counseling sessions (<10 minutes) and pharmacotherapy delivered in primary care settings (*111*). Adolescents (Grade B) should be provided intervention to prevent initiation of tobacco use (*112*).

Immunizations

For female and male clients, providers should screen for immunization status in accordance with recommendations of CDC's Advisory Committee on Immunization Practices (*113*) and offer vaccination, as indicated, or provide referrals to community providers for immunization. Female and male clients should be screened for age-appropriate vaccinations, such as influenza and tetanus–diphtheria–pertussis (Tdap), measles, mumps, and rubella (MMR), varicella, pneumococcal, and meningococcal. In addition, ACOG recommends that rubella titer be performed in women who are uncertain about MMR immunization (*108*). (For vaccines for reproductive health-related conditions, i.e., human papillomavirus and hepatitis B, see "Sexually Transmitted Disease Services.")

Depression

For all clients, providers should screen for depression when staff-assisted depression care supports are in place to ensure accurate diagnosis, effective treatment, and follow-up (*114*,*115*). Staff-assisted care supports are defined as clinical staff members who assist the primary care clinician by providing some direct depression care, such as care support or coordination, case management, or mental health treatment. The lowest effective staff supports consist of a screening nurse who advises primary care clinicians of a positive screen and provides a protocol facilitating referral to behavioral therapy.

Providers also may follow American Psychiatric Association (*116*) and American Academy of Child and Adolescent Psychiatry (*117*) recommendations to assess risk for suicide among persons experiencing depression and other risk factors.

Height, Weight, and Body Mass Index

For all clients, providers should screen adult (Grade B) and adolescent (Grade B) clients for obesity in accordance with the USPSTF recommendation, and obese adults should be referred for intensive counseling and behavioral interventions to promote sustained weight loss (*118*,*119*). Clients likely will need to be referred for this service. These interventions typically comprise 12 to 26 sessions in a year and include multiple behavioral management activities, such as group sessions, individual sessions, setting weight-loss goals, improving diet or nutrition, physical activity sessions, addressing barriers to change, active use of self-monitoring, and strategizing how to maintain lifestyle changes.

Blood Pressure

For female and male clients, providers should screen for hypertension in accordance with the USPSTF's recommendation (Grade A) that blood pressure be measured routinely among adults (*120*) and the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure's recommendation that persons with blood pressure less than 120/80 be screened every 2 years, and every year if prehypertensive (i.e., blood pressure 120–139/80–89) (*121*). Providers also may follow AAP's recommendation that adolescents receive annual blood pressure screening (*109*).

Diabetes

For female and male clients, providers should follow the USPSTF recommendation (Grade B) to screen for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) >135/80 mmHg (*122*).

Sexually Transmitted Disease Services

Providers should offer STD services in accordance with CDC's STD treatment and HIV testing guidelines (*36*,*123*,*124*). It is important to test for chlamydia annually among young sexually active females and for gonorrhea routinely among all sexually active females at risk for infection because they can cause tubal infertility in women if left untreated. Testing for syphilis, HIV/AIDS, and hepatitis C should be conducted as recommended (*36*,*123*,*124*). Vaccination for human papillomavirus (HPV) and hepatitis B are also important parts of STD services and preconception care (*113*).

STD services should be provided for persons with no signs or symptoms suggestive of an STD. STD diagnostic management recommendations are not included in these guidelines, so providers should refer to CDC's STD treatment guidelines

(36) when caring for clients with STD symptoms. STD services include the following steps, which should be provided at the initial visit and at least annually thereafter:

Step 1. Assess: The provider should discuss the client's reproductive life plan, conduct a standard medical history and sexual health assessment (see text box above), and check immunization status. A pelvic exam is not indicated in patients with no symptoms suggestive of an STD.

Step 2. Screen: A client who is at risk of an STD (i.e., sexually active and not involved in a mutually monogamous relationship with an uninfected partner) should be screened for HIV and the other STDs listed below, in accordance with CDC's STD treatment guidelines (*36*) and recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings (*123*). Clients also should follow CDC's recommendations for testing for hepatitis C (*124*), and the Advisory Committee on Immunization Practice's recommendations on reproductive health-related immunizations (*113*). It is important to follow these guidelines both to ensure that clients receive needed services and to avoid unnecessary screening.

Chlamydia

For female clients, providers should screen all sexually active women aged ≤25 years for chlamydia annually, in addition to sexually active women aged >25 years with risk factors for chlamydia infection (*36*). Women aged >25 years at higher risk include sexually active women who have a new or more than one sex partner or who have a partner who has other concurrent partners. Females with chlamydia infection should be rescreened for re-infection at 3 months after treatment. Pregnant women should be screened for chlamydia at the time of their pregnancy test if there might be delays in obtaining prenatal care (*36*).

For male clients, chlamydia screening can be considered for males seen at sites with a high prevalence of chlamydia, such as adolescent clinics, correctional facilities, and STD clinics (*36*,*125*,*126*). Providers should screen men who have sex with men (MSM) for chlamydia at anatomic sites of exposure, in accordance with CDC's STD treatment guidelines (*36*). Males with symptoms suggestive of chlamydia (urethral discharge or dysuria or whose partner has chlamydia) should be tested and empirically treated at the initial visit. Males with chlamydia infection should be re-screened for reinfection at 3 months (*36*).

Gonorrhea

For female clients, providers should screen clients for gonorrhea, in accordance with CDC's STD treatment guidelines (*36*). Routine screening for *N. gonorrhoeae* in all sexually active women at risk for infection is recommended annually (*36*). Women aged <25 years are at highest risk for gonorrhea infection. Other risk factors that place women at increased risk include a previous gonorrhea infection, the presence of other STDs, new or multiple sex partners, inconsistent condom use, commercial sex work, and drug use. Females with gonnorrhea infection should be re-screened for re-infection at 3 months after treatment. Pregnant women should be screened for gonorrhea at the time of their pregnancy test if there might be delays in obtaining prenatal care (*36*).

For male clients, providers should screen MSM for gonorrhea at anatomic sites of exposure, in accordance with CDC's STD treatment guidelines (*36*). Males with symptoms suggestive of gonorrhea (urethral discharge or dysuria or whose partner has gonorrhea) should be tested and empirically treated at the initial visit. Males with gonorrhea infection should be re-screened for reinfection at 3 months after treatment (*36*,*126*–*128*).

Syphilis

For female and male clients, providers should screen clients for syphilis, in accordance with CDC's STD treatment guidelines (*36*). CDC recommends that persons at risk for syphilis infection should be screened. Populations at risk include MSM, commercial sex workers, persons who exchange sex for drugs, those in adult correctional facilities and those living in communities with high prevalence of syphilis (*36*). Pregnant women should be screened for syphilis at the time of their pregnancy test if there might be delays in obtaining prenatal care (*36*).

HIV/AIDS

For female and male clients, providers should screen clients for HIV/AIDS, in accordance with CDC HIV testing guidelines (*123*). Providers should follow CDC recommendations that all clients aged 13–64 years be screened routinely for HIV infection and that all persons likely to be at high risk for HIV be rescreened at least annually (*123*). Persons likely to be at high risk include injection-drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and MSM or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test. CDC further recommends that screening be provided after the patient is notified that testing will be performed as part of general medical consent unless the patient declines (opt-out screening) or otherwise prohibited by state law. The USPSTF also recommends screening for HIV (Grade A) (*129*).

Hepatitis C

For female and male clients, CDC recommends one-time testing for hepatitis C (HCV) without prior ascertainment of HCV risk for persons born during 1945–1965, a population with a disproportionately high prevalence of HCV infection

and related disease. Persons identified as having HCV infection should receive a brief screening for alcohol use and intervention as clinically indicated, followed by referral to appropriate care for HCV infection and related conditions. These recommendations do not replace previous guidelines for HCV testing that are based on known risk factors and clinical indications. Rather, they define an additional target population for testing: persons born during 1945–1965 (*124*). USPSTF also recommends screening persons at high risk for infection for hepatitis C and one-time screening for HCV infection for persons in the 1945–1965 birth cohort (Grade B) (*130*).

Immunizations Related to Reproductive Health

Female clients aged 11–26 years should be offered either human papillomavirus (HPV) 2 or HPV4 vaccine for the prevention of HPV and cervical cancer if not previously vaccinated, although the series can be started in persons as young as age 9 years (*113*); recommendations include starting at age 11–12 years and catch up vaccine among females aged 13–26 who have not been vaccinated previously or have not completed the 3-dose series through age 26. Routine hepatitis B vaccination should be offered to all unvaccinated children and adolescents aged <19 years and all adults who are unvaccinated and do not have any documented history of hepatitis B infection (*113*).

Male clients aged 11–21 years (minimum age: 9 years) should be offered HPV4 vaccine, if not vaccinated previously; recommendations include starting at age 11–12 years and catch up vaccine among males aged 13–21 years who have not been vaccinated previously or have not completed the 3-dose series through age 21 years; vaccination is recommended among at-risk males, including MSM and immune-compromised males through age 26 years if not vaccinated previously or males who have not completed the 3-dose series through age 26 years. Heterosexual males aged 22–26 years may be vaccinated (*131*). Routine hepatitis B vaccination should be offered to all unvaccinated children and adolescents aged <19 years, and all unvaccinated adults who do not have a documented history of hepatitis B infection (*113*).

Step 3. Treat: A client with an STD and her or his partner(s) should be treated in a timely fashion to prevent complications, re-infection and further spread of the infection in the community in accordance with CDC's STD treatment guidelines; clients with HIV infection should be linked to HIV care and treatment (*36*,*123*). Clients should be counseled about the need for partner evaluation and treatment to avoid reinfection at the time the client receives the positive test results. For partners of clients with chlamydia or gonorrhea, one option is to schedule them to come in with the client; another option for partners who cannot come in with the client is expedited partner therapy (EPT), as permissible by state laws, in which medication or a prescription is provided to the patient to give to the partner to ensure treatment. EPT is a partner treatment strategy for partners who are unable to access care and treatment in a timely fashion. Because of concerns related to resistant gonorrhea, efforts to bring in for treatment partners of patients with gonorrhea infection are recommended; EPT for gonorrhea should be reserved for situations in which efforts to treat partners in a clinical setting are unsuccessful and EPT is a gonorrhea treatment of last resort.

All clients treated for chlamydia or gonorrhea should be rescreened 3 months after treatment; HIV-infected females with *Trichomonas vaginalis* should be linked to HIV care and rescreened for *T. vaginalis* at 3 months. If needed, the client also should be vaccinated for hepatitis B and HPV (*113*). Ideally, STD treatment should be directly observed in the facility rather than a prescription given or called in to a pharmacy. If a referral is made to a service site that has the necessary medication available on-site, such as the recommended injectable antimicrobials for gonorrhea and syphilis, then the referring provider must document that treatment was given.

Step 4. Provide risk counseling: If the client is at risk for or has an STD, high-intensity behavioral counseling for sexual behavioral risk reduction should be provided in accordance with the USPSTF recommendation (Grade B) (*132*). One high-intensity behavioral counseling model that is similar to the contraceptive counseling model is Project Respect (*133*), which could be implemented in family planning settings. All sexually active adolescents are at risk, and adults are at increased risk if they have current STDs, had an STD in the past year, have multiple sexual partners, are in nonmonogamous relationships, or are sexually active and live in a community with a high rate of STDs.

Other key messages to give infected clients before they leave the service site include the following: a) refrain from unprotected sexual intercourse during the period of STD treatment, 2) encourage partner(s) to be screened or to get treatment as quickly as possible in accordance with CDC's STD treatment guidelines (partners in the past 60 days for chlamydia and gonorrhea, 3 to 6 months plus the duration of lesions or signs for primary and secondary syphilis, respectively) if the partner did not accompany the client to the service site for treatment, and 3) return for retesting in 3 months. If the partner is unlikely to access treatment quickly, then EPT for chlamydia or gonorrhea should be considered, if permissible by state law.

A client using or considering contraceptive methods other than condoms should be advised that these methods do not protect against STDs. Providers should encourage a client who is not in a mutually monogamous relationship with an

uninfected partner to use condoms. Patients who do not know their partners' infection status should be encouraged to get tested and use condoms or avoid sexual intercourse until their infection status is known.

Related Preventive Health Services

For many women and men of reproductive age, a family planning service site is their only source of health care; therefore, visits should include provision of or referral to other preventive health services. Providers of family planning services that do not have the capacity to offer comprehensive primary care services should have strong links to other community providers to ensure that clients have access to primary care. If a client does not have another source of primary care, priority should be given to providing related reproductive health services or providing referrals, as needed.

For clients without a primary care provider, the following screening services should be provided, with appropriate follow-up, if needed, while linking the client to a primary care provider. These services should be provided in accordance with federal and professional medical recommendations cited below regarding the frequency of screening, the characteristics of the clients that should be screened, and the screening procedures to be used.

Medical History

USPSTF recommends that women be asked about family history that would be suggestive of an increased risk for deleterious mutations in BRCA1 or BRCA2 genes (e.g., receiving a breast cancer diagnosis at an early age, bilateral breast cancer, history of both breast and ovarian cancer, presence of breast cancer in one or more female family members, multiple cases of breast cancer in the family, both breast and ovarian cancer in the family, one or more family members with two primary cases of cancer, and Ashkenazi background). Women with identified risk(s) should be referred for genetic counseling and evaluation for BRCA testing (Grade B) (*134*). The USPSTF also recommends that women at increased risk for breast cancer should be counseled about risk-reducing medications (Grade B) (*135*).

Cervical Cytology

Providers should provide cervical cancer screening to clients receiving related preventive health services. Providers should follow USPSTF recommendations to screen women aged 21–65 years with cervical cytology (Pap smear) every 3 years, or for women aged 30–65 years, screening with a combination of cytology and HPV testing every 5 years (Grade A) (*136*).

Cervical cytology no longer is recommended on an annual basis. Further, it is not recommended (Grade D) for women aged <21 years (*136*). Women with abnormal test results should be treated in accordance with professional standards of care, which may include colposcopy (*96*,*137*). The need for cervical cytology should not delay initiation or hinder continuation of a contraceptive method (*42*).

Providers should also follow ACOG and AAP recommendations that a genital exam should accompany a cervical cancer screening to inspect for any suspicious lesions or other signs that might indicate an undiagnosed STD (*96*,*97*,*138*).

Clinical Breast Examamination

Despite a lack of definitive data for or against, clinical breast examination has the potential to detect palpable breast cancer and can be recommended. ACOG recommends annual examination for all women aged >19 years (*108*). ACS recommends screening every 3 years for women aged 20–39 years, and annually for women aged ≥40 years (*139*). However, the USPSTF recommendation for clinical breast exam is an I, and patients should be informed that there is insufficient evidence to assess the balance of benefits and harms of the service (*140*).

Mammography

Providers should follow USPSTF recommendations (Grade B) to screen women aged 50–74 years on a biennial basis; they should screen women aged <50 years if other conditions support providing the service to an individual patient (*140*).

Genital Examination

For adolescent males, examination of the genitals should be conducted. This includes documentation of normal growth and development and other common genital findings, including hydrocele, varicocele, and signs of STDs (*141*). Components of this examination include inspecting skin and hair, palpating inguinal nodes, scrotal contents and penis, and inspecting the perinanal region (as indicated).

Summary of Recommendations for Providing Family Planning and Related Preventive Health Services

The screening components for each family planning and related preventive health service are provided in summary checklists for women (Table 2) and men (Table 3). When considering how to provide the services listed in these recommendations (e.g., the screening components for each

service, risk groups that should be screened, the periodicity of screening, what follow-up steps should be taken if screening reveals the presence of a health condition), providers should follow CDC and USPSTF recommendations cited above, or, in the absence of CDC and USPSTF recommendations, the recommendations of professional medical associations. Following these recommendations is important both to ensure clients receive needed care and to avoid unnecessary screening of clients who do not need the services.

The summary tables describe multiple screening steps, which refer to the following: 1) the process of asking questions about a client's history, including a determination of whether risk factors for a disease or health condition exist; 2) performing a physical exam; and 3) performing laboratory tests in at-risk asymptomatic persons to help detect the presence of a specific disease, infection, or condition. Many screening recommendations apply only to certain subpopulations (e.g., specific age groups, persons who engage in specific risk behaviors or who have specific health conditions), or some screening recommendations apply to a particular frequency (e.g., a cervical cancer screening is generally recommended every 3 years rather than annually). Providers should be aware that the USPSTF also has recommended that certain screening services not be provided because the harm outweighs the benefit (see Appendix F).

When screening results indicate the potential or actual presence of a health condition, the provider should either provide or refer the client for the appropriate further diagnostic testing or treatment in a manner that is consistent with the relevant federal or professional medical associations' clinical recommendations.

Conducting Quality Improvement

Service sites that offer family planning services should have a system for conducting quality improvement, which is designed to review and strengthen the quality of services on an ongoing basis. Quality improvement is the use of a deliberate and continuous effort to achieve measurable improvements in the identified indicators of quality of care, which improve the health of the community (*142*). By improving the quality of care, family planning outcomes, such as reduced rates of unintended pregnancy, improved patient experiences, and reduced costs, are more likely to be achieved (*10*,*12*,*143*,*144*).

Several frameworks for conducting quality improvement have been developed (*144–146*). This section presents a general overview of three key steps that providers should take when conducting quality improvement of family planning services: 1) determine which measures are needed to monitor quality; 2) collect the information needed; and 3) use the findings to make changes to improve quality (*147*). Ideally, these steps will be conducted on a frequent (optimally, quarterly) and ongoing basis. However, since quality cuts across all aspects of a program, not all domains of quality can necessarily be considered at all times. Within a sustainable system of quality improvement, programs can opt to focus on a subset of quality dimensions and their respective measures.

Determining Which Measures Are Needed

Performance measures provide information about how well the service site is meeting pre-established goals (*148*). The following questions should be considered when selecting performance measures (*143*):

- Is the topic important to measure and report? For example, does it address a priority aspect of health care, and is there opportunity for improvement?
- What is the level of evidence for the measure (e.g., that a change in the measure is likely to represent a true change in health outcomes)? Does the measure produce consistent (reliable) and credible (valid) results about the quality of care?
- Are the results meaningful and understandable and useful for informing quality improvement?
- Is the measure feasible? Can it be implemented without undue burden (e.g., captured with electronic data or electronic health records)?

Performance measures should consider the quality of the structure of services (e.g., the characteristics of the settings in which providers deliver health care, including material resources, human resources, and organizational structure), the process by which care is provided (whether services are provided correctly and completely, and how clients perceive the care they receive), and the outcomes of that care (e.g., client behaviors or health conditions that result) (*149*). They also may assess each dimension of quality services (*10*,*13*). Examples of measures that can be used for monitoring the quality of family planning services (*150*) and suggested measures that might help providers monitor quality of care have been listed (Table 6). However, other measures have been developed that also might be useful (*151–153*). Service sites that offer family planning services should select, measure, and assess at least one intermediate or outcome measure on an ongoing basis, for which the service site can be accountable. Structure- and process-based measures that assess the eight dimensions of quality services may be used to better determine how to improve quality (*154*).

Collecting Information

Once providers have determined what information is needed, the next steps are to collect and use that information to improve the quality of care. Commonly used methods of data collection include the following:

TABLE 2. Checklist of family planning and related preventive health services for women

Screening components	Family planning services (provide services in accordance with the appropriate clinical recommendation)					Related preventive health services
	Contraceptive services*	Pregnancy testing and counseling	Basic infertility services	Preconception health services	STD services†	
History						
Reproductive life plan§	Screen	Screen	Screen	Screen	Screen	
Medical history§,**	Screen	Screen	Screen	Screen	Screen	Screen
Current pregnancy status§	Screen					
Sexual health assessment§,**	Screen		Screen	Screen	Screen	
Intimate partner violence §,¶,**				Screen		
Alcohol and other drug use§,¶,**				Screen		
Tobacco use§,¶	Screen (combined hormonal methods for clients aged ≥35 years)			Screen		
Immunizations§				Screen	Screen for HPV & HBV§§	
Depression§,¶				Screen		
Folic acid§,¶				Screen		
Physical examamination						
Height, weight and BMI§,¶	Screen (hormonal methods)††		Screen	Screen		
Blood pressure§,¶	Screen (combined hormonal methods)			Screen§§		
Clinical breast exam**			Screen			Screen§§
Pelvic exam§,**	Screen (initiating diaphragm or IUD)	Screen (if clinically indicated)	Screen			
Signs of androgen excess**			Screen			
Thyroid exam**			Screen			
Laboratory testing						
Pregnancy test **	Screen (if clinically indicated)	Screen				
Chlamydia§, ¶	Screen¶¶				Screen§§	
Gonorrhea§, ¶	Screen¶¶				Screen§§	
Syphilis§,¶					Screen§§	
HIV/AIDS§,¶					Screen§§	
Hepatitis C§,¶					Screen§§	
Diabetes§,¶				Screen§§		
Cervical cytology¶						Screen§§
Mammography¶						Screen§§

Abbreviations: BMI = body mass index; HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus; IUD = intrauterine device; STD = sexually transmitted disease.

* This table presents highlights from CDC's recommendations on contraceptive use. However, providers should consult appropriate guidelines when treating individual patients to obtain more detailed information about specific medical conditions and characteristics (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59(No. RR-4).

† STD services also promote preconception health but are listed separately here to highlight their importance in the context of all types of family planning visits. The services listed in this column are for women without symptoms suggestive of an STD.

§ CDC recommendation.

¶ U.S. Preventive Services Task Force recommendation.

** Professional medical association recommendation.

†† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. Medical Eligibility Criteria 1) or generally can be used (U.S. Medical Eligibility Criteria 2) among obese women (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

§§ Indicates that screening is suggested only for those persons at highest risk or for a specific subpopulation with high prevalence of an infection or condition.

¶¶ Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's STD treatment guidelines (Sources: CDC. STD treatment guidelines. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at http://www.cdc.gov/std/treatment. CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR 2010;59[No. RR-12]). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. Medical Eligibility Criteria 4) women who have a very high individual likelihood of STD exposure (e.g. those with a currently infected partner) generally should not undergo IUD insertion (U.S. Medical Eligibility Criteria 3) (Source: CDC. US medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

- **Review of medical records.** All records that detail service delivery activities can be reviewed, including encounters and claims data, client medical records, facility logbooks, and others. It is important that records be carefully designed, sufficiently detailed, provide accurate information, and have access restricted to protect confidentiality. The use of electronic health records can facilitate some types of medical record review.
- **Exit interview with the client.** A patient is asked (through either a written or in-person survey) to describe what happened during the encounter or their assessment of their satisfaction with the visit. Both quantitative (close-ended questions) and qualitative (open-ended questions) methods can be used. Limitations include a bias toward clients reporting higher degrees of satisfaction, and the

TABLE 3. Checklist of family planning and related preventive health services for men

Screening components and source of recommendation	Family planning services (provide services in accordance with the appropriate clinical recommendation)				Related preventive health services
	Contraceptive services*	Basic infertility services	Preconception health services†	STD services§	
History					
Reproductive life plan¶	Screen	Screen	Screen	Screen	
Medical history¶,††	Screen	Screen	Screen	Screen	
Sexual health assessment¶,††	Screen	Screen	Screen	Screen	
Alcohol & other drug use ¶,**,††			Screen		
Tobacco use¶,**			Screen		
Immunizations¶			Screen	Screen for HPV & HBV§§	
Depression¶,**			Screen		
Physical examination					
Height, weight, and BMI¶,**			Screen		
Blood pressure**,††			Screen§§		
Genital exam††		Screen (if clinically indicated)		Screen (if clinically indicated)	Screen§§
Laboratory testing					
Chlamydia¶				Screen§§	
Gonorrhea¶				Screen§§	
Syphilis¶,**				Screen§§	
HIV/AIDS¶,**				Screen§§	
Hepatitis C¶,**				Screen§§	
Diabetes¶,**			Screen§§		

Abbreviations: HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus virus; STD = sexually transmitted disease.

* No special evaluation needs to be done prior to making condoms available to males. However, when a male client requests advice on pregnancy prevention, he should be provided contraceptive services as described in the section "Provide Contraceptive Services."

† The services listed here represent a sub-set of recommended preconception health services for men that were recommended and for which there was a direct link to fertility or infant health outcomes (Source: Frey K, Navarro S, Kotelchuck M, Lu M. The clinical content of preconception care: preconception care for men. Am J Obstet Gynecol 2008;199[6 Suppl 2]:S389–95).

§ STD services also promote preconception health, but are listed separately here to highlight their importance in the context of all types of family planning visit. The services listed in this column are for men without symptoms suggestive of an STD.

¶ CDC recommendation.

** U.S. Preventive Services Task Force recommendation.

†† Professional medical association recommendation.

§§ Indicates that screening is suggested only for those persons at highest risk or for a specific subpopulation with high prevalence of infection or other condition.

provider's behavior might be influenced if she or he knows clients are being interviewed.

- **Facility audit.** Questions about a service site's structure (e.g., on-site availability of a broad range of FDA-approved methods) and processes (e.g., skills and technical competence of staff, referral mechanisms) can be used to determine the readiness of the facility to serve clients.
- **Direct observation.** A provider's behavior is observed during an actual encounter with a client. Evaluation of a full range of competencies, including communication skills, can be carried out. A main limitation is that the observer's presence might influence the provider's performance.
- **Interview with the health-care provider.** Providers are interviewed about how specific conditions are managed. Both closed- and open-ended questions can be used, although it is important to frame the question so that the 'correct' answer is not suggested. A limitation is that providers tend to over-report their performance.

Consideration and Use of the Findings

After data are collected, they should be tabulated, analyzed, and used to improve care. Staff whose performance was assessed should be involved in the development of the data collection tools and analysis of results. Analysis should address the following questions (*155*):

- What is the performance level of the facility?
- Is there a consistent pattern of performance among providers?
- What is the trend in performance?
- What are the causes of poor performance?
- How can performance gaps be minimized?

Given the findings, service site staff should use a systematic approach to identifying ways to improve the quality of care. One example of a systematic approach to improving the quality of care is the "Plan, Do, Study, and Act" (PDSA) model (*147,156*), in which staff first develop a plan for improving quality, then execute the plan on a small scale, evaluate feedback to confirm or adjust the plan, and finally, make the plan

TABLE 4. Suggested measures of the quality of family planning services

Type of measure and dimension of quality	Measure	Source
Health outcome	• Unintended pregnancy • Teen pregnancy • Birth spacing • Proportion of female users at risk for unintended pregnancy who adopt or continue use of an FDA-approved contraceptive method (measured for any method; highly effective methods; or long-acting reversible methods) [Intermediate outcome]	PIMS*
Safe (Structure)	• Proportion of providers that follow the most current CDC recommendations on contraceptive safety	
Effective (Structure, or the characteristics of the settings in which providers deliver health care, including material resources, human resources, and organizational structure)	• Site dispenses or provides on-site a full range of FDA-approved contraceptive methods to meet the diverse reproductive needs and goals of clients; short-term hormonal, long-acting reversible contraception (LARC), emergency contraception (EC). • Proportion of female users aged ≥24 years who are screened annually for chlamydial infection. • Proportion of female users aged ≥24 years who are screened annually for gonorrhea. • Proportion of users who were tested for HIV during the past 12 months. • Proportion of female users aged ≥21 years who have received a Pap smear within the past 3 years.	PIMS*
Client-centered (Process, or whether services are provided correctly and completely, and how clients perceive the care they receive)	• Proportion of clients who report the provider communicates well, shows respect, spends enough time with the client, and is informed about the client's medical history. • Proportion of clients who report that – Staff are helpful and treat clients with courtesy and respect. – His or her privacy is respected. – She or he receives contraceptive method that is acceptable to her or him.	CAHPS† RQIP§
Efficient (Structure)	• Site uses electronic health information technology or electronic health records to improve client reproductive health.	PIMS*
Timely (Structure and process)	• Average number of days to the next appointment. • Site offers routine contraceptive resupply on a walk-in basis. • Site offers on-site HIV testing (using rapid technology). • Site offers on-site HPV and hepatitis B vaccination.	PIMS*
Accessible (Structure and process)	• Site offers family planning services during expanded hours of operation. • Proportion of total family planning encounters that are encounters with ongoing or continuing users. • Proportion of clients who report that his or her care provider follows up to give test results, has up-to-date information about care from specialists, and discusses other prescriptions. • Site has written agreements (e.g., MOUs) with the key partner agencies for health care (especially prenatal care, primary care, HIV/AIDS) and social service (domestic violence, food stamps) referrals.	PIMS* CAHPS–PCMH item set on care coordination†
Equitable (Structure)	• Site offers language assistance at all points of contact for the most frequently encountered language(s).	PIMS*
Value	• Average cost per client.	CDC¶

Abbreviations: CAPHS = Agency for Healthcare Research and Quality's Consumer Assessment of Health Care Providers and Systems; FDA = Food and Drug Administration; HPV = human papillomavirus; MOU = memorandum of understanding; PIMS = Performance Information and Monitoring System; RQIP = Regional Quality Indicators Program.

* **Source:** Fowler C. Title X Family Planning Program Performance Information and Monitoring System (PIMS): Description of Proposed Performance Measures [DRAFT]. Washington, DC: Research Triangle Institute; 2012.

† **Source:** Agency for Healthcare Research and Quality. Consumer Assessment of Healthcare Providers and Systems (CAHPS). Available at https://www.cahps.ahrq.gov/default.asp.

§ **Source:** John Snow International. The Regional Quality Indicators Project (RQIP). Boston, MA: John Snow International; 2014. Available at http://www.jsi.com/JSIInternet/USHealth/project/display.cfm?ctid=na&cid=na&tid=40&id=2621.

¶ **Sources:** Haddix A, Corso P, Gorsky R. Costs. In: Haddix A, Teutsch S, Corso P, eds. Prevention effectiveness: a guide to decision analysis and economic evaluation. 2nd ed. Oxford, UK: Oxford University Press; 2003; Stiefel M, Nolan K. A guide to measuring the triple aim: population health, experience of care, and per capita cost. Cambridge, MA: Institute for Healthcare Improvements; 2012.

permanent. Examples of steps that may be taken to improve the quality of care include developing job aids, providing task-specific training for providers, conducting more patient education, or strengthening relationships with referral sites through formal memoranda of understanding (*146*).

Conclusion

The United States continues to face substantial challenges to improving the reproductive health of the U.S. population. The recommendations in this report can contribute to improved reproductive health by defining a core set of family planning

services for women and men, describing how to provide contraceptive and other family planning services to both adult and adolescent clients, and encouraging the use of the family planning visit to provide selected preventive health services for women and men. This guidance is intended to assist primary care providers to offer the family planning services that will help persons and couples achieve their desired number and spacing of children and increase the likelihood that those children are born healthy.

Recommendations are updated periodically. The most recent versions are available at http://www.hhs.gov/opa.

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Appendix A

How the Recommendations Were Developed

The recommendations were developed jointly under the auspices of CDC's Division of Reproductive Health (DRH) and the Office of Population Affairs (OPA), in consultation with a wide range of experts and key stakeholders. A multistage process that drew on established procedures for developing clinical guidelines (*1,2*) was used to develop the recommendations. In April 2010, an Expert Work Group (EWG) comprising family planning clinical providers, program administrators, representatives from relevant federal agencies, and representatives from professional medical organizations was created to advise OPA and CDC on the structure and content of the revised recommendations and to help make the recommendations more feasible and relevant to the needs of the field. This group made two key initial recommendations: 1) to examine the scientific evidence for three priority areas of focus identified as key components of family planning service delivery, (i.e., counseling and education, serving adolescents, and quality improvement); and 2) to guide providers of family planning services in the use of various recommendations for how to provide clinical care to women and men.

Developing Recommendations on Counseling, Adolescent Services, and Quality Improvement

Systematic reviews of the published literature from January 1985 through December 2010 were conducted for each priority topic to identify evidence-based and evidence-informed approaches to family planning service delivery. Standard methods for conducting the reviews were used, including the development of key questions and analytic frameworks, the identification of the evidence base through a search of the published as well as "gray literature" (i.e., studies published somewhere other than in a peer-reviewed journal), and a synthesis of the evidence in which findings were summarized and the quality of individual studies was considered, using the methodology of the U.S. Preventive Services Task Force (USPSTF) (*3*). Eight databases were searched (i.e., MEDLINE, PsychInfo, PubMed, CINAHL, Cochrane, EMBASE, POPLINE, and the U.K. National Clearinghouse Service Economic Evaluation Database) and were restricted to literature from the United States and other developed countries. Summaries of the evidence used to prepare these recommendations will appear in background papers that will be published separately.

In May 2011, three technical panels (one for each priority topic) comprising subject matter experts were convened to consider the quality of the evidence and suggest what recommendations might be justified on the basis of the evidence. CDC and OPA used this feedback to develop core recommendations for counseling, serving adolescents, and quality improvement. EWG members subsequently reviewed these core recommendations; EWG members differed from the subject matter experts in that they were more familiar with the family planning service delivery context and could comment on the feasibility and appropriateness of the recommendations as well as on their scientific justification. EWG members met to consider the core recommendations using 1) the quality of the evidence; 2) the positive and negative consequences of implementing the recommendations on health outcomes, costs or cost-savings, and implementation challenges; and 3) the relative importance of these consequences (e.g., the ability of the recommendations to have a substantial effect on health outcomes may be weighed more than the logistical challenges of implementing them) (*1*). In certain cases, when the evidence was inconclusive or incomplete, recommendations were made on the basis of expert opinion (see Appendix B). Finally, CDC and OPA staff considered the feedback from EWG members when finalizing the core recommendations and writing this report.

Developing Recommendations on Clinical Services

DRH and OPA staff members synthesized recommendations for clinical care for women and for men that were developed by >35 federal and professional medical organizations. They were assisted in this effort by staff from OPA's Office of Family Planning Male Training Center and from CDC's Division of STD Prevention, Division of Violence Prevention, Division of Immunization Services, and Division of Cancer Prevention and Control. The synthesis was needed because clinical recommendations are sometimes inconsistent with each other and can vary by the extent to which they are evidence-based. The clinical recommendations addressed contraceptive services, achieving pregnancy, basic infertility services, preconception health services, sexually transmitted disease services, and related health-care services.

An attempt was made to apply the Institute of Medicine's criteria for clinical practice guidelines when deciding which professional medical organizations to include in the review (*2*). However, many organizations did not articulate the process used to develop the recommendations fully, and many did not

conduct comprehensive and systematic reviews of the literature. In the end, to be included in the synthesis, the recommending organization had to be a federal agency or major professional medical organization that represents established medical disciplines. In addition, a recommendation had to be made on the basis of an independent review of the evidence or expert opinion and be considered a primary source that was developed for the United States.

In July 2011, two technical panels comprising subject matter experts on clinical services for women and men were convened to review the synthesis of federal and professional medical recommendations, reconcile inconsistent recommendations, and provide individual feedback to CDC and OPA about the implications for family planning service delivery. CDC and OPA used this individual feedback to develop core recommendations for clinical services. The core recommendations were subsequently reviewed by EWG members, and feedback was used to finalize the core recommendations and write this report.

Members of the technical panels recommended that contraceptive services, pregnancy testing and counseling, services to achieve pregnancy, basic infertility care, STD services, and other preconception health services should be considered family planning services. This feedback considered federal statute and regulation, CDC and USPSTF recommendations for clinical care, and EWG members' opinion.

Because CDC's preconception health recommendations include many services, the panel narrowed the range of preconception services that were included by using the following criteria: 1) the Select Panel on Preconception Care (*4*) had assigned an A or B recommendation to that service for women, which means that there was either good or fair evidence to support the recommendation that the condition be considered in a preconception care evaluation (Table 1), or 2) the service was included among recommendations made by experts in preconception health for males (*5*). Services for men that addressed health conditions that affect reproductive capacity or pregnancy outcomes directly were included as preconception health; services that addressed men's health but that were not related directly to pregnancy outcomes were considered to be related preventive health services.

The Expert Work Group noted that more preventive services are recommended than can be offered feasibly in some settings. However, a primary purpose of this report is to set a broad framework within which individual clinics will tailor services to meet the specific needs of the populations that they serve. In addition, EWG members identified specific subgroups that should have the greatest priority for preconception health services (i.e., those trying to achieve pregnancy and those at high risk of unintended pregnancy). Future operational research should provide more information about how to deliver these services most efficiently during multiple visits to clients with diverse needs.

Determining How Clinical Services Should Be Provided

Various federal agencies and professional medical associations have made recommendations for how to provide family planning services. When considering these recommendations, the Expert Work Group used the following hierarchy:

- Highest priority was given to CDC guidelines because they are developed after a rigorous review of scientific evidence. CDC guidelines tailor recommendations for higher risk individuals, (whereas USPSTF focuses on average risk individuals), who are more representative of the clients seeking family planning services.
- When no CDC guideline existed to guide the recommendations, the relevant USPSTF A or B recommendations (which indicate a high or moderate certainty that the benefit is moderate to substantial) were used. USPSTF recommendations are made on the basis of a thorough review of the available evidence.
- If neither a CDC nor a USPSTF A or B recommendation existed, the recommendations of selected major professional medical associations were considered as resources. The American Academy of Pediatrics' (AAP) Bright Futures guidelines (*6*) were used as the primary source of recommendations for adolescents when no CDC or USPSTF recommendations existed.
- For a limited number of recommendations, there were no federal or major professional medical recommendations, but the service was recommended by EWG members on the basis of expert opinion for family planning clients.

In some cases, a service was graded as an I recommendation by USPSTF for the general population (an I recommendation means that the current evidence is insufficient to assess the balance of benefits and harms of the service, so if the service is offered, patients should be informed of this fact), but either CDC, EWG members, or another organization recommended the service for women or men seeking family planning services. The situations in which this occurred and the reasons why the service was recommended despite its receiving an I recommendation by USPSTF have been summarized (Table 2). The approach used to consider the evidence and make recommendations that are used by USPSTF have been summarized (Tables 3 and 4) (*7*).

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TABLE 1. Select Panel on Preconception Care grading system

Quality of the evidence*	
I-a	Evidence was obtained from at least one properly conducted, randomized, controlled trial that was performed with subjects who were not pregnant.
I-b	Evidence was obtained from at least one properly conducted, randomized, controlled trial that was done not necessarily before pregnancy.
II-1	Evidence was obtained from well-designed, controlled trials without randomization.
II-2	Evidence was obtained from well-designed cohort or case-control analytic studies, preferably conducted by more than one center or research group.
II-3	Evidence was obtained from multiple-time series with or without the intervention, or dramatic results in uncontrolled experiments.
III	Opinions were gathered from respected authorities on the basis of clinical experience, descriptive studies and case reports, or reports of expert committees.
Strength of the recommendation	
A	There is good evidence to support the recommendation that the condition be considered specifically in a preconception care evaluation.
B	There is fair evidence to support the recommendation that the condition be considered specifically in a preconception care evaluation.
C	There is insufficient evidence to recommend for or against the inclusion of the condition in a preconception care evaluation, but recommendation to include or exclude may be made on other grounds.
D	There is fair evidence to support the recommendation that the condition be excluded in a preconception care evaluation.
E	There is good evidence to support the recommendation that the condition be excluded in a preconception care evaluation.

Source: Jack B, Atrash H, Coonrod D, Moos M, O'Donnell J, Johnson K. The clinical content of preconception care: an overview and preparation of this supplement. Am J Obstet Gynecol 2008;199(6 Suppl 2):S266–79.

TABLE 2. Services included in these recommendations that received a U.S. Preventive Services Task Force (USPSTF) I recommendation

Service/screen	USPSTF recommendation	Why the service is recommended despite a USPSTF I recommendation
Alcohol	I for adolescents	The recommendations are consistent with CDC's recommendations on preconception health and AAP's Bright Futures* guidelines.
Other drugs	I for adolescents and adults	The recommendations are consistent with CDC's recommendations on preconception health and AAP's Bright Futures guidelines.
Clinical breast exam	I for all women	No CDC recommendation exists, but ACOG and ACS recommend conducting clinical breast exams, and the Expert Work Group endorsed the ACOG recommendation.
Chlamydia	I for all males	The recommendations are consistent with CDC's STD treatment guidelines.
Gonorrhea	I for all males	The recommendations are consistent with CDC's STD treatment guidelines.

Source: US Preventive Services Task Force. USPSTF recommendations. Available at http://www.uspreventiveservicestaskforce.org/recommendations.htm.
Abbreviations: AAP = American Academy of Pediatrics; ACS = American Cancer Society; ACOG = American Congress of Obstetricians and Gynecologists; STD = sexually transmitted disease.
* Source: Committee on Practice and Ambulatory Medicine, Bright Futures Periodicity Schedule Workgroup. 2014 recommendations for pediatric preventive health care. Pediatrics 2014;133;568.

TABLE 3. U.S. Preventive Services Task Force (USPSTF) grades, definitions, and suggestions for practice

Grade	Definition	Suggestions for practice
A	USPSTF recommends the service. There is high certainty that the net benefit is substantial.	This service should be offered or provided.
B	USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.	This service should be offered or provided.
C	Clinicians may provide this service to selected patients depending on individual circumstances. However, for a majority of persons without signs or symptoms there is likely to be only a limited benefit from this service.	This service should be offered or provided only if other considerations support the offering or providing the service in an individual patient.
D	USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Use of this service should be discouraged.
I Statement	USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	The clinical considerations section of USPSTF recommendation statement should be consulted. If the service is offered, patients should be educated about the uncertainty of the balance of benefits and harms.

Source: US Preventive Services Task Force. USPSTF: methods and processes. Available at http://www.uspreventiveservicestaskforce.org/methods.htm.

TABLE 4. Levels of certainty regarding net benefit

Level of certainty*	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as • the number, size, or quality of individual studies; • inconsistency of findings across individual studies; • limited generalizability of findings to routine primary care practice; and • lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes is insufficient because of • the limited number or size of studies, • important flaws in study design or methods, • inconsistency of findings across individual studies, • gaps in the chain of evidence, • findings not generalizable to routine primary care practice, • lack of information on important health outcomes, or • more information required to allow estimation of effects on health outcomes.

Source: US Preventive Services Task Force. USPSTF: methods and processes. Available at http://www.uspreventiveservicestaskforce.org/methods.htm.

* The US Preventive Services Task Force (USPSTF) defines certainty as the likelihood that the USPSTF assessment of the net benefit of a preventive service is correct. The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. USPSTF assigns a certainty level on the basis of the nature of the overall evidence available to assess the net benefit of a preventive service.

Appendix B

The Evidence, Potential Consequences, and Rationales for Core Recommendations

Sixteen core recommendations that were considered by the Expert Work Group (EWG) are presented below. Each recommendation is accompanied by a summary of the relevant evidence (full summaries of which will be published separately), a list of potential consequences of implementing the recommendation, and its rationale. When considering the recommendations, the Expert Work Group was divided into two groups (one comprising seven members and the other five members), and each group considered separate recommendations.

Definition of Family Planning Services

Recommendation: Primary care providers should offer the following family planning services: contraceptive services for women and men who want to prevent pregnancy and space births, pregnancy testing and counseling, help for clients who wish to achieve pregnancy, basic infertility services, sexually transmitted disease (STD) services and preconception health services to improve the health of women, men, and infants.

Quality of evidence: A systematic review was not conducted; the recommendation was made on the basis of federal statute and regulation (*1*,*2*), CDC clinical recommendations (*3*–*5*), and expert opinion.

Potential consequences: Adding preconception health services means that more women and men will receive preconception health services. The recommended services also will promote the health of women and men even if they do not have children. The human and financial cost of providing preconception health services might mean that fewer contraceptive and other services can be offered in some settings.

Rationale: Services to prevent and achieve pregnancy are core to the federal government's efforts to promote reproductive health. Adding preconception health as a family planning service is consistent with this mission; it emphasizes achieving a healthy pregnancy and also promotes adult health. Adding preconception health is also consistent with CDC recommendations to integrate preconception health services into primary care platforms (*3*). All seven EWG members agreed to this recommendation.

Preconception Health — Women

Recommendation: Preconception health services for women include the following screening services: reproductive life plan; medical history; sexual health assessment; intimate partner violence, alcohol, and other drug use; tobacco use; immunizations; depression; body mass index (BMI); blood pressure; chlamydia, gonorrhea, syphilis, and HIV/AIDS; and diabetes. All female clients also should be counseled about the need to take a daily supplement of folic acid. When screening results indicate the presence of a health condition, the provider should take steps either to provide or to refer the client for the appropriate further diagnostic testing and or treatment. Services should be provided in a manner that is consistent with established federal and professional medical associations' recommendations to enable clients who need services to receive them and to avoid over-screening.

Quality of evidence: A systematic review was not conducted; the recommendation was made on the basis of CDC's recommendations to improve preconception health and health care (*3*) and a review of preconception health services by an expert panel on preconception care for women (*6*).

Potential consequences: More women will receive specified preconception health services, which will improve the health of infants and women. The evidence base for preconception health is not fully established. There is a potential risk that a client with a positive screen will not be able to afford treatment if the client is uninsured and not eligible for public programs. The human and financial cost of providing preconception health services might mean that fewer contraceptive and other services can be offered.

Rationale: The potential benefits to the health of women and infants were thought by the panel to be greater than the costs, potential harms, and opportunity costs of providing these services. Implementation (e.g., training and monitoring of providers) can address the issues related to providers over-screening and not following the federal and professional medical recommendations. CDC will continue to monitor related research and modify these recommendations, as needed. Health-care reform might make follow-up care more available to low-income clients. All seven EWG members agreed to this recommendation.

Preconception Health — Men

Recommendation: Preconception health services for men include the following screening services: reproductive life plan; medical history; sexual health assessment; alcohol and other drug use; tobacco use; immunizations; depression; BMI; blood pressure; chlamydia, gonorrhea, syphilis, and HIV/AIDS; and diabetes. When screening results indicate the presence of a health condition, the provider should take

steps either to provide or to refer the client for the appropriate further diagnostic testing and or treatment. Services should be provided in a manner that is consistent with established federal and professional medical associations' recommendations to ensure that clients who need services receive them and to avoid over-screening.

Quality of evidence: A systematic review was not conducted; the recommendation was made on the basis of CDC's recommendations to improve preconception health and health care (*3*) and a review of preconception health services for men (*7*).

Potential consequences: More men will receive preconception health services, which might improve infant and men's health. The evidence base for preconception health is not well established and is less than that for women's preconception health. There is a risk of over-screening if recommendations are not followed. There is a potential risk that a client with a positive screen might not be able to afford treatment if the client is uninsured and not eligible for public programs. The human and financial cost of providing preconception health services might mean that fewer contraceptive and other services can be offered.

Rationale: The potential benefits to men and infant health were thought by the panel to be greater than the costs, potential harms, and opportunity costs of not providing these services. Implementation (e.g., training and monitoring of providers) can address the issues related to providers over-screening and not following the federal and professional medical recommendations. CDC will continue to monitor related research and modify these recommendations, as needed. Health-care reform might make follow-up care more available to low-income clients. All seven EWG members agreed to this recommendation.

Contraceptive Services — Contraceptive Counseling Steps

Recommendation: To help a client who is initiating or switching to a new method of contraception, providers should follow these steps, which are in accordance with the key principles for providing quality counseling: 1) establish and maintain rapport with the client; 2) obtain clinical and social information from the client; 3) work with the client interactively to select the most effective and appropriate contraceptive method for her or him; 4) provide a physical assessment related to contraceptive use, when warranted; and 5) provide the contraceptive method along with instructions about correct and consistent use, help the client develop a plan for using the selected method and for follow-up, and confirm understanding.

Quality of evidence: Twenty-two studies were identified that examined the impact of contraceptive counseling in clinical settings and met the inclusion criteria. Of the 16 studies that focused on adults or mixed populations (adolescents and adults) (*8–23*), 11 found a statistically significant positive impact of counseling interventions with low (*11*,*12*,*14–16*,*18–21*), moderate (*8*), or unrated (*22*) intensity on at least one outcome of interest; study designs included two cross-sectional surveys (*14*,*22*), one pre-post study (*21*), one prospective cohort study (*8*), one controlled trial (*15*), and six randomized controlled trials (RCTs) (*11*,*12*,*16*,*18–20*). Six studies examined the impact of contraceptive counseling among adolescents (*24–29*), with four finding a statistically significant positive impact of low-intensity (*27*) or moderate-intensity (*24*,*25*,*29*) counseling interventions on at least one outcome of interest; study designs included two pre-post studies (*24*,*30*), one controlled trial (*29*), and one RCT (*27*). In addition, five studies were identified that examined the impact of reminder system interventions in clinical settings on family planning outcomes and met the inclusion criteria (*31–35*); of these, two found a statistically significant positive impact of reminder systems on perfect oral contraceptive compliance, a retrospective historical nonrandomized controlled trial that examined daily reminder email messages (*31*) and a cohort study that examined use of a small reminder device that emitted a daily audible beep (*34*). In addition, two studies examined the impact of reminder systems among depot medroxyprogesterone acetate users (DMPA) (*33*,*35*) with one, a retrospective cohort study, finding a statistically significant positive impact of receiving a wallet-sized reminder card with the date of the next DMPA injection and a reminder postcard shortly before the next injection appointment on timely DMPA injections. Statements about safety and unnecessary medical examinations and tests are made on the basis of CDC guidelines on contraceptive use (*36*,*37*).

Potential consequences: Fewer clients will use methods that are not safe for them, there will be increased contraceptive use, increased use of more effective methods, increased continuation of method use, increased use of dual methods, increased knowledge, increased satisfaction with services, and increased use of repeat or follow-up services.

Rationale: Making sure that a contraceptive method is safe for an individual client is a fundamental responsibility of all providers of family planning services. Removing medical barriers to contraceptive use is key to increasing access to contraception and helping clients prevent unintended pregnancy. Consistent use of contraceptives is needed to prevent unintended pregnancies, so appropriate counseling is critical to ensure clients make the best possible choice of methods for their unique circumstances, and are supported in continued

use of the chosen method. The principles of quality counseling, from which the steps listed in the recommendations are based, are supported by a substantial body of evidence and expert opinion. Future research to evaluate the five principles will be monitored and the recommendations modified, as needed. All seven EWG members agreed to this recommendation.

Contraceptive Services — Tiered Approach to Counseling

Recommendation: For clients who might want to get pregnant in the future and prefer reversible methods of contraception, providers should use a tiered approach to presenting a broad range of contraceptive methods (including long-acting reversible contraception such as intrauterine devices and contraceptive implants), in which the most effective methods are presented before less effective methods.

Quality of evidence: National surveys have demonstrated low rates of LARC use overall (*38,39*). However, Project CHOICE has demonstrated high uptake of long-acting reversible contraception (approximately two thirds of clients when financial barriers are removed) and a very substantial reduction in rates of unintended pregnancy (*40*). Further, a recent study of postpartum contraceptive use shows that 50% of teen mothers with a recent live birth are using long-acting reversible contraception postpartum in Colorado, which demonstrates high levels of acceptance in the context of a statewide program to remove financial barriers (*41*).

Potential consequences: Use of long-acting reversible contraception has the potential to help many more persons prevent unintended pregnancy because of its ease of use, safety, and effectiveness. Several questions were raised about ethical issues in using a tiered approach to counseling. First, is it ethical to educate about long-acting reversible contraception when the methods are not all available on-site? Second, conversely, is it ethical not to inform clients about the most effective methods? In other health service areas, the standard of care is to inform the client about the most effective treatment (e.g., blood pressure medications), so the client can make a fully informed decision, and this standard should apply in this instance as well. On the basis of historic experiences, there is a need to ensure that methods always are offered on a completely voluntary and noncoercive basis. Health-care reform might make contraceptive services more available to the majority of clients.

Rationale: Providers have an obligation to inform clients about the most effective methods available, even if they cannot provide them. Further, health-care reform will reduce the financial barriers to long-acting reversible contraception for many persons. The potential increase in use of long-acting reversible contraception and other more effective methods is likely to help reduce rates of unintended pregnancy. All seven EWG members agreed to this recommendation.

Contraceptive Services — Broad Range of Methods

Recommendation: A broad range of methods should be available on-site or through referral.

Quality of evidence: Three descriptive studies from the review of quality improvement literature identified contraceptive choice as an important aspect of quality care (*42–44*).

Potential consequences: Clients will be more likely to select a method that they will use consistently and correctly.

Rationale: A central tenet of quality health care is that it be client-centered. Being able to provide a client with a method that best fits her or his unique circumstances is essential for that reason. All seven EWG members agreed to this recommendation.

Contraceptive Services — Education

Recommendation: The content, format, method, and medium for delivering education should be evidence-based.

Quality of evidence: Seventeen studies were identified that met the inclusion criteria for this systematic review. Of these, 15 studies looked at knowledge of correct method use or contraceptive risks and benefits, including side effects and method effectiveness (*45–59*). All but one study (*56*) found a statistically significant positive impact of educational interventions on increased knowledge. These studies included six randomized controlled trials with low risk for bias.

Potential consequences: Clients will make more informed decisions when choosing a contraceptive method. More clients will be satisfied with the process of selecting a contraceptive method.

Rationale: Knowledge obtained through educational activities, as integrated into the larger counseling model, is a critically important precondition for the client's ability to make informed decisions. The techniques described in the recommendations have a well-established evidence base for increasing knowledge and satisfaction with services. This knowledge lays the foundation for further counseling steps that will increase the likelihood of correct and consistent use, and increased satisfaction will increase return visits to the service site, as needed. Four of seven EWG members agreed to this recommendation; three members did not express an opinion.

Contraceptive Services — Confirm Understanding

Recommendation: A check box or written statement should be available in the medical record that can be used to document that the client expressed understanding of the most important information about her/his chosen contraceptive method. The teach-back method may be used to get clients to express the most important points by repeating back messages about risks and benefits and appropriate method use and follow-up. Documentation of understanding using the teach-back method and a check box or written statement can be used in place of a written method-specific informed consent.

Quality of evidence: Two studies from outside the family planning literature (one cohort study and one controlled trial with unclear randomization) (*60,61*) and a strong recommendation by members of the Technical Panel on Counseling and Education were considered.

Potential consequences: More clients will make informed decisions, adherence to contraceptive and treatment plans will improve, and reproductive and other health conditions will be better controlled.

Rationale: Asking providers to document in the record that the client is making an informed decision will increase providers' attention to this task. This recommendation will replace a previous requirement that providers obtain method-specific informed consent from each client (in addition to a general consent form). Six of seven EWG members agreed to this recommendation.

Adolescent Services — Comprehensive Information

Recommendation: Providers should provide comprehensive information to adolescent clients about how to prevent pregnancy and STDs. This should include information about contraception and that avoiding sex (abstinence) is an effective way to prevent pregnancy and STDs.

Quality of evidence: A systematic review was not conducted because other recent reviews were available that have shown a substantial impact of comprehensive sexual health education on reduced adolescent risk behavior (*62–66*). The evidence for abstinence-only education was more limited: CDC's Community Guide concluded that there was insufficient evidence (*67*), but the Department of Health and Human Services' Office of Adolescent Health has identified two abstinence-based programs as having evidence of effectiveness (*68*).

Potential consequences: Teens will make more informed decisions and will delay initiation of sexual intercourse. The absence of harmful effects from comprehensive sexual health education was noted.

Rationale: The benefits of informing adolescents about all ways to prevent pregnancy are substantial. Ultimately, each adolescent should make an informed decision that meets her or his unique circumstances, based on the counseling provided by the provider. Six of seven EWG members agreed to this recommendation.

Adolescent Services — Use of Long-Acting Reversible Contraception

Recommendation: Education about contraceptive methods should include an explanation that long-acting reversible contraception is safe and effective for nulliparous women (women who have not been pregnant or given birth), including adolescents.

Quality of evidence: CDC guidelines on contraceptive use (*37*) provide evidence that long-acting reversible contraception is safe and effective for adolescents and nulliparous women.

Potential consequences: More providers will encourage adolescents to consider long-acting reversible contraception; more adolescents will choose long-acting reversible contraception, resulting in reduced rates of teen pregnancy, including rapid repeat pregnancy.

Rationale: Long-acting reversible contraception is safe for adolescents (*37*). As noted above, providers should inform clients about the most effective methods available. The potential increase in use of long-acting reversible contraception and other more effective methods by adolescents is substantial and is likely to lead to further reductions in teen pregnancy. Three EWG members agreed to this recommendation; two EWG members abstained.

Adolescent Services — Confidential Services

Recommendation: Confidential family planning services should be made available to adolescents, while observing state laws and any legal obligations for reporting.

Quality of evidence: Six descriptive studies documented one or more of the following: that confidentiality is important to adolescents; that many adolescents reported they will not use reproductive health services if confidentiality cannot be assured; and that adolescents might not be honest in discussing reproductive health with providers if confidentiality cannot be assured (*69–74*). One RCT showed a slight reduction in use of services after receiving conditional confidentiality, compared with complete confidentiality (*75*). One study showed a

positive association between confidentiality and intention to use services (*73*).

Potential consequences: Consequences might include an increased intention to use services, increased use of services, and reduced rates of teen pregnancy. However, explaining the need to report under certain circumstances (rape, child abuse) might deter some adolescent clients from using services. Further, some parents/guardians might not agree that adolescents should have access to confidential services.

Rationale: Minors' rights to confidential reproductive health services are consistent with state and federal law. The risks of not providing confidential services to adolescents are great and likely to result in an increased rate of teen pregnancies. Finally, this recommendation is consistent with the recommendations of three professional medical associations that endorse provision of confidential services to adolescents (*76–78*). All seven EWG members agreed to this recommendation.

Adolescent Services — Family-Child Communication

Recommendation: Providers should encourage and promote family-child communication about sexual and reproductive health.

Quality of evidence: From the family planning literature, 16 parental involvement programs (most using an RCT study design) were found to be positively associated with at least one short-term (13 of 16 studies) or medium-term (four of seven studies) outcome (*79–94*). However, only one of these studies was linked to clinical services (*80*); others were implemented in community settings.

Potential consequences: Consequences might include increased parental/guardian involvement and communication, improved knowledge/awareness, increased intentions to use contraceptives, and the adoption of more pro-social norms that support parent-child communication about sexual health.

Rationale: The literature provides strong evidence that increased communication between a child and her/his parent/guardian will lead to safer sexual behavior among teens, and numerous community-based programs have created an evidence base for how to strengthen parents/guardians' ability to hold those conversations. Although less is known about how to do so in a clinical setting, providers can refer their clients to programs in the community, and principles from the community-based approaches can be used to help providers develop appropriate approaches in the clinical setting. Research in this area will be monitored, and the recommendations will be revised, as needed. Four of five EWG members who provided input agreed to this recommendation; one member abstained.

Adolescent Services — Repeat Teen Pregnancy

Recommendation: Providers should refer pregnant and parenting adolescents to home visiting and other programs that have been shown to provide needed support and reduce rates of repeat teen pregnancy.

Quality of evidence: Three of four studies of clinic-based programs (using retrospective case-control cohort, ecological evaluation, and prospective cohort study designs) showed that comprehensive teen pregnancy prevention programs (programs with clinical, school, case management, and community components) were associated with both medium- and long-term outcomes (*95–98*). In addition, several randomized trials of community-based home visiting programs, and an existing systematic review of the home visiting literature, demonstrated a protective impact of these programs on preventing repeat teen pregnancy and other relevant outcomes (*99–103*).

Potential consequences: Consequences might include decreased rapid repeat pregnancy and abortion rates, and increased use of contraceptives.

Rationale: There is sufficient evidence to recommend that providers link pregnant and parenting teens to community and social services that might reduce rates of rapid repeat pregnancy. Three of seven EWG members agreed to an earlier version of this recommendation. Other members wanted to remove a clause about prioritizing the contraceptive needs of pregnant/parenting teens because they felt that all clients should be treated as priority clients. This suggestion was adopted, but the EWG did not have a chance to vote again on the modified recommendation.

Contraceptive Method Availability

Recommendation: Family planning programs should stock and offer a broad a range of FDA-approved contraceptive methods so that the needs of individual clients can be met. These methods are optimally available on-site, but strong referrals can serve to make methods not available on-site real options for clients.

Quality of evidence: No research was identified that explicitly addressed the question of whether having a broad range of methods was associated with short-, medium-, or long-term reproductive health outcomes. However, as noted above, three descriptive studies from the review of quality improvement literature identified contraceptive choice as an important aspect of quality care (*42–44*).

Potential consequences: Consequences might include increased use of contraception and increased use of reproductive

health services. It also was noted that there are sometimes high costs to stocking certain methods (e.g., intrauterine devices and contraceptive implants).

Rationale: Having a broad range of contraceptive methods is central to client-centered care, a core aspect of providing quality services. Individual clients need to have a choice so they can select a method that best fits their particular circumstances. This is likely to result in more correct and consistent use of the chosen methods. The benefits of this recommendation were weighed more heavily than the negative outcomes (e.g., additional cost). All five EWG members agreed to this recommendation.

Youth-Friendly Services

Recommendation: Family planning programs should take steps to make services "youth-friendly."

Quality of evidence: Of 20 studies that were identified, six looked at short-, medium-, or long-term outcomes with mixed designs (one group time series, one cross-sectional, three prospective cohort, and one nonrandomized trial); protective effects were found on long-term (two of three studies), medium-term (three of three), and short-term (three of three) outcomes (*29*,*30*,*104–107*). One of these six studies (*29*), plus 13 other descriptive studies (for a total of 14 studies), presented adolescents' or providers' views on facilitators for adolescent clients in using youth-friendly family planning services. Key factors described were confidentiality (13 of 14), accessibility (11 of 14), peer involvement (three of 14), parental or familial involvement (four of 14), and quality of provider interaction (11 of 14) (*105–121*). Four of these studies (*111*,*112*,*114*,*121*) plus one other descriptive study (*108*) described barriers to clinics adopting and implementing youth-friendly family planning services.

Potential consequences: Consequences might include increased use of reproductive health services by adolescents, improved contraceptive use, use of more effective methods, more consistent use of contraception, and reduced rates of teen pregnancy. It is also likely to lead to improved satisfaction with services and greater knowledge about pregnancy prevention among adolescents. It is possible that there will be higher costs, and some uncertainty regarding the benefits due to a relatively weak evidence base.

Rationale: Existing evidence has demonstrated the importance of specific characteristics to adolescents' attitudes and use of clinical services. The potential benefits of providing youth-friendly services outweigh the potential costs and weak evidence base. All five EWG members agreed to this recommendation. Some thought that it should be cast as an example of comprehensively client-centered care, rather than an end of its own.

Quality Improvement

Recommendation: Family planning programs should have a system for quality improvement, which is designed to review and strengthen the quality of services on an ongoing basis. Family planning programs should select, measure, and assess at least one outcome measure on an ongoing basis, for which the service site can be accountable.

Quality of evidence: A recent systematic review (*122*) was supplemented with 10 articles that provided information related to client and/or provider perspectives regarding what constitutes quality family planning services (*42–44*,*113*,*123–128*). These studies used a qualitative (k = 4) or cross-sectional (k = 6) study design. Ten descriptive studies identified client and provider perspectives on what constitutes quality family planning services, which include stigma and embarrassment reduction (n = 9), client access and convenience (n = 8); confidentiality (n = 3); efficiency and tailoring of services (n = 6); client autonomy and confidence (n = 5); contraceptive access and choice (n = 4); increased time of patient-provider interaction (n = 3); communication and relationship (n = 3); structure and facilities (n = 2); continuity of care (n = 2). Well-established frameworks for guiding quality improvement efforts were referenced (*122*,*129–132*).

Potential consequences: Consequences might include increased use by clients of more effective contraceptive methods, clients might be more likely to return for care, client satisfaction might improve, and there might be reduced rates of teen and unintended pregnancy, and improved spacing of births.

Rationale: Research, albeit limited, has demonstrated that quality services are associated with improved client experience with care and adoption of more protective contraceptive behavior. Further, these recommendations on quality improvement are consistent with those made by national leaders in the quality improvement field. Research is either under way or planned to validate a core set of performance measures, and the recommendations will be updated as new findings emerge. All five EWG members agreed to these recommendations.

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Appendix C

Principles for Providing Quality Counseling

Counseling is a process that enables clients to make and follow through on decisions. Education is an integral component of the counseling process that helps clients to make informed decisions. Providing quality counseling is an essential component of client-centered care.

Key principles of providing quality counseling are listed below and may be used when providing family planning services. The model was developed in consultation with the Technical Panel on Contraceptive Counseling and Education and reviewed by the Expert Work Group. Although developed specifically for providing contraceptive counseling, the principles are broad and can be applied to health counseling on other topics. Although the principles are listed here in a particular sequence, counseling is an iterative process, and at every point in the client encounter it is necessary to determine whether it is important to readdress and emphasize a given principle.

Principles of Quality Counseling

Principle 1. Establish and Maintain Rapport with the Client

Establishing and maintaining rapport with a client is vital to the encounter and achieving positive outcomes (*1*). This can begin by creating a welcoming environment and should continue through every stage of the client encounter, including follow-up. The contraceptive counseling literature indicates that counseling models that emphasized the quality of the interaction between client and provider have been associated with decreased teen pregnancy, increased contraceptive use, increased use of more effective methods, increased use of repeat or follow-up services, increased knowledge, and enhanced psychosocial determinants of contraceptive use (*2–5*) .

Principle 2. Assess the Client's Needs and Personalize Discussions Accordingly

Each visit should be tailored to the client's individual circumstances and needs. Clients come to family planning providers for various services and with varying needs. Standardized questions and assessment tools can help providers determine what services are most appropriate for a given visit (*6*). Contraceptive counseling studies that have incorporated standardized assessment tools during the counseling process have resulted in increased contraceptive use, increased correct use of contraceptives, and increased use of more effective methods (*2,7,8*). Contraceptive counseling studies that have personalized discussions to meet the individual needs of clients have been associated with increased contraceptive use, increased correct use of contraceptives, increased use of more effective methods, increased use of dual-method contraceptives to prevent both sexually transmitted diseases (STDs) and pregnancy, increased quality and satisfaction with services, increased knowledge, and enhanced psychosocial determinants of contraceptive use *(4,7,9–12)*.

Principle 3. Work with the Client Interactively to Establish a Plan

Working with a client interactively to establish a plan, including a plan for follow-up, is important. Establishing a plan should include setting goals, discussing possible difficulties with achieving goals, and developing action plans to deal with potential difficulties. The amount of time spent establishing a plan will differ depending on the client's purpose for the visit and health-care needs. A client plan that requires behavioral change should be made on the basis of the client's own goals, interests, and readiness for change (*13–15*). Use of computerized decision aids before the appointment can facilitate this process by providing a structured yet interactive framework for clients to analyze their available options systematically and to consider the personal importance of perceived advantages and disadvantages *(16,17)*. The contraceptive counseling literature indicates that counseling models that incorporated goal setting and development of action plans have been associated with increased contraceptive use, increased correct use of contraceptives, increased use of more effective methods, and increased knowledge *(2,9,18–20)*. Furthermore, contraceptive counseling models that incorporated follow-up contacts resulted in decreased teen pregnancy, increased contraceptive use, increased correct use of contraceptives, increased use of more effective methods, increased continuation of method use, increased use of dual-method contraceptives to prevent both STDs and pregnancy, increased use of repeat or follow-up services, increased knowledge, and enhanced psychosocial determinants of contraceptive use *(2,3,7,11,21,22)* . From the family planning education literature, computerized decision aids have helped clients formulate questions and have been associated with increased knowledge, selection of more effective methods, and increased continuation and compliance (*23–25*).

Principle 4. Provide Information That Can Be Understood and Retained by the Client

Clients need information that is medically accurate, balanced, and nonjudgmental to make informed decisions and follow through on developed plans. When speaking with clients or providing educational materials through any medium (e.g., written, audio/visual, or computer/web-based), the provider must present information in a manner that can be readily understood and retained by the client. Strategies for making information accessible to clients are provided (see Appendix D).

Principle 5. Confirm Client Understanding

It is important to ensure that clients have processed the information provided and discussed. One technique for confirming understanding is to have the client restate the most important messages in her or his own words. This teach-back method can increase the likelihood of the client and provider reaching a shared understanding, and has improved compliance with treatment plans and health outcomes *(26,27)*. Using the teach-back method early in the decision-making process will help ensure that a client has the opportunity to understand her or his options and is making informed choices (*28*).

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Appendix D

Contraceptive Effectiveness

Providers should counsel clients about the effectiveness of different contraceptive methods. Method effectiveness is measured as the percentage of women experiencing an unintended pregnancy during the first year of use, and is estimated for both typical and perfect use (Table).

TABLE. Percentage of women experiencing an unintended pregnancy during the first year of typical use* and the first year of perfect use† of contraception and the percentage continuing use at the end of the first year — United States

Method	% of women experiencing an unintended pregnancy within the first year of use		% of women continuing use at 1 year§
	Typical use	Perfect use	
No method¶	85.0	85.0	
Spermicides**	28.0	18.0	42.0
Fertility awareness-based methods	24.0		47.0
Standard days method††		5.0	
2-day method††		4.0	
Ovulation method††		3.0	
Symptothermal method		0.4	
Withdrawal	22.0	4.0	46.0
Sponge			36.0
Parous women	24.0	20.0	
Nulliparous women	12.0	9.0	
Condom§§			
Female	21.0	5.0	41.0
Male	18.0	2.0	43.0
Diaphragm¶¶	12.0	6.0	57.0
Combined pill and progestin-only pill	9.0	0.3	67.0
Evra patch	9.0	0.3	67.0
NuvaRing	9.0	0.3	67.0
Depo-Provera	6.0	0.2	56.0
Intrauterine contraceptives			
ParaGard (copper T)	0.8	0.6	78.0
Mirena (LNG)	0.2	0.2	80.0
Implanon	0.05	0.05	84.0
Female sterilization	0.5	0.5	100.0
Male sterilization	0.15	0.1	100.0

Emergency Contraceptives: Emergency contraceptive pills or insertion of a copper intrauterine contraceptive after unprotected intercourse substantially reduces the risk of pregnancy.***
Lactational Amenorrhea Method: LAM is a highly effective, temporary method of contraception.†††
Source: Adapted from Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M, eds. Contraceptive technology: 20th revised ed. New York, NY: Ardent Media; 2011.

* Among typical couples who initiate use of a method (not necessarily for the first time), the percentage of couples who experience an accidental pregnancy during the first year if they do not stop use for any other reason. Estimates of the probability of pregnancy during the first year of typical use for spermicides and the diaphragm are taken from the 1995 National Survey of Family Growth corrected for underreporting of abortion; estimates for fertility awareness-based methods, withdrawal, the male condom, the pill, and Depo-Provera are taken from the 1995 and 2002 National Survey of Family Growth corrected for underreporting of abortion. See the text for the derivation of estimates for the other methods.

† Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage of couples who experience an accidental pregnancy during the first year if they do not stop use for any other reason. See the text for the derivation of the estimate for each method.

§ Among couples attempting to avoid pregnancy, the percentage of couples who continue to use a method for 1 year.

¶ The percentages becoming pregnant in columns labeled "typical use" and "perfect use" are based on data from populations in which contraception is not used and from women who cease using contraception to become pregnant. Among such populations, approximately 89% become pregnant within 1 year. This estimate was lowered slightly (to 85%) to represent the percentage of women who would become pregnant within 1 year among women now relying on reversible methods of contraception if they abandoned contraception altogether.

** Foams, creams, gels, vaginal suppositories, and vaginal film.

†† The Ovulation and 2-day methods are based on evaluation of cervical mucus. The Standard Days method avoids intercourse on cycle days 8 through 19. The Symptothermal method is a double-check method based on evaluation of cervical mucus to determine the first fertile day and evaluation of cervical mucus and temperature to determine the last fertile day.

§§ Without spermicides.

¶¶ With spermicidal cream or jelly.

*** Ella, Plan B One-Step, and Next Choice are the only dedicated products specifically marketed for emergency contraception. The label for Plan B One-Step (1 dose is 1 white pill) says to take the pill within 72 hours after unprotected intercourse. Research has indicated that all of the brands listed here are effective when used within 120 hours after unprotected intercourse. The label for Next Choice (1 dose is 1 peach pill) says to take one pill within 72 hours after unprotected intercourse and another pill 12 hours later. Research has indicated that that both pills can be taken at the same time with no decrease in efficacy or increase in side effects and that they are effective when used within 120 hours after unprotected intercourse. The Food and Drug Administration has in addition declared the following 19 brands of oral contraceptives to be safe and effective for emergency contraception: Ogestrel (1 dose is 2 white pills), Nordette (1 dose is 4 light-orange pills), Cryselle, Levora, Low-Ogestrel, Lo/Ovral, or Quasence (1 dose is 4 white pills), Jolessa, Portia, Seasonale or Trivora (1 dose is 4 pink pills), Seasonique (1 dose is 4 light-blue-green pills), Enpresse (1 dose is 4 orange pills), Lessina (1 dose is 5 pink pills), Aviane or LoSeasonique (one dose is 5 orange pills), Lutera or Sronyx (1 dose is 5 white pills), and Lybrel (1 dose is 6 yellow pills).

††† However, for effective protection against pregnancy to be maintained, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeds is reduced, bottle feeds are introduced, or the baby reaches age 6 months.

Appendix E

Strategies for Providing Information to Clients

The client should receive and understand the information she or he needs to make informed decisions and follow treatment plans. This requires careful attention to how information is communicated. The following strategies can make information more readily comprehensible to clients:

Strategies for Providing Information to Clients

Educational materials should be provided that are clear and easy to understand. Educational materials delivered through any one of a variety of media (for example, written, audio/visual, computer/web-based) need to be presented in a format that is clear and easy to interpret by clients with a 4th to 6th grade reading level (*1–3*). Many adults have only a basic ability to obtain, process, and understand health information necessary to make decisions about their health (*4*). Making easy-to-access materials enhances informed decision-making (*1–3*). Test all educational materials with the intended audiences for clarity and comprehension before wide-scale use.

The following evidence-based tools provide recommendations for increasing the accessibility of materials through careful consideration of content, organization, formatting, and writing style:

- Health Literacy Universal Precautions Toolkit, provided by the Agency for Healthcare Research and Quality (available at http://www.ahrq.gov/qual/literacy),
- Toolkit for Making Written Material Clear and Effective, provided by the Centers for Medicare and Medicaid Services (available at http://www.cms.gov/WrittenMaterialsToolkit), and
- Health Literacy Online, provided by the Office of Disease Prevention and Health Promotion (available at http://www.health.gov/healthliteracyonline).

Information should be delivered in a manner that is culturally and linguistically appropriate. In presenting information it is important to be sensitive to the client's cultural and linguistic preferences (*5*,*6*). Ideally information should be presented in the client's primary language, but translations and interpretation services should be available when necessary. Information presented must also be culturally appropriate, reflecting the client's beliefs, ethnic background, and cultural practices. Tools for addressing cultural and linguistic differences and preferences include

- Health Literacy Universal Precautions Toolkit, provided by the Agency for Healthcare Research and Quality (available at http://www.ahrq.gov/qual/literacy), and
- Toolkit for Making Written Material Clear and Effective, Part 11; Understanding and using the "Toolkit Guidelines for Culturally Appropriate Translation," provided by the Centers for Medicare and Medicaid Services (available at http://www.cms.gov/outreach-and-education/outreach/writtenmaterialstoolkit/downloads/toolkitpart11.pdf).

The amount of information presented should be limited and emphasize essential points. Providers should focus on needs and knowledge gaps identified during the assessment. Many clients immediately forget or remember incorrectly much of the information provided. This problem is exacerbated as more information is presented (*7–9*). Limiting the amount of information presented and highlighting important facts by presenting them first improves comprehension (*10–14*).

Numeric quantities should be communicated in a way that is easily understood. Whenever possible, providers should use natural frequencies and common denominators (for example, 85 of 100 sexually active women are likely to get pregnant within 1 year using no contraceptive, as compared with 1 in 100 using an IUD or implant), and display quantities in graphs and visuals. Providers also should avoid using verbal descriptors without numeric quantities (for example, sexually active women using an IUD or implant almost never become pregnant). Finally, they should quantify risk in absolute rather than relative terms (for example, "the chance of unintended pregnancy is reduced from 8 in 100 to 1 in 100 by switching from oral contraceptives to an IUD" versus the chance of unintended pregnancy is reduced by 87%). Numeracy is more highly correlated with health outcomes than the ability to read or listen effectively (*15*). The strategies listed above can help clients interpret numeric quantities correctly (*16–28*).

Balanced information on risks and benefits should be presented and messages framed positively. In addition to discussing risks, contraindications, and warnings, providers should discuss the advantages and benefits of contraception. In presenting this information, providers should express risks and benefits in a common format (for example, do not present risks in relative terms and benefits in absolute terms), and frame messages in positive terms (for example "99 out of 100 women find this a safe method with no side effects," versus "1 out of 100 women experience noticeable side effects"). Many clients prefer to receive a balance of information on risks and benefits (*29*), and using a common format avoids bias in presentation of information (*18*,*22*,*26*,*30*). Framing messages positively increases acceptance and comprehension (*18*,*22*,*31*,*32*).

Active client engagement should be encouraged. Providers should use educational materials that encourage active information processing (e.g., questions, quizzes, fill-in-the-blank, web-based games, and activities). In addition, they should be sure the client has an opportunity to discuss the information provided, and when speaking with a client, providers should engage her or him actively. Research has indicated that interactive materials improve knowledge of contraceptive risks, benefits, and correct method use (*33*–*35*). Clients also value spoken information (*29*,*36*); and educational materials, when delivered by a provider, more effectively increase knowledge (*10*,*37*). In particular, presenting information in a question and answer format is more effective than simply presenting the information (*10*,*15*,*37*–*41*).

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Appendix F

Screening Services For Which Evidence Does Not Support Screening

The following services have been given a D recommendation from the U.S. Preventive Services Task Force (USPSTF), which indicates that the potential harms of routine screening outweigh the benefits. Providers should not perform these screening services.

The USPSTF has recommended against offering the following services to women and men:

- **Asymptomatic bacteriuria:** USPSTF recommends against screening for asymptomatic bacteriuria in men and nonpregnant women (*1*).
- **Gonorrhea:** USPSTF recommends against routine screening for gonorrhea infection in men and women who are at low risk of infection (*2*).
- **Hepatitis B:** USPSTF recommends against routinely screening the general asymptomatic population for chronic hepatitis B virus infection (*3*).
- **Herpes simplex virus (HSV):** USPSTF recommends against routine serological screening for HSV in asymptomatic adolescents and adults (*4*).
- **Syphilis:** USPSTF recommends against screening of asymptomatic persons who are not at increased risk of syphilis infection (*5*).

The USPSTF has recommended against offering the following services to women:

- **BRCA mutation testing for breast and ovarian cancer susceptibility:** USPSTF recommends against routine referral for genetic counseling or routine breast cancer susceptibility gene (BRCA) testing for women whose family history is not associated with an increased risk of deleterious mutations in breast cancer susceptibility gene 1 (BRCA1) or breast cancer susceptibility gene 2 (BRCA2) (*6*). However, USPSTF continues to recommend that women whose family history is associated with an increased risk of deleterious mutations in BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing.
- **Breast self-examination:** USPSTF recommends against teaching breast self-examination (*7*).
- **Cervical cytology:** USPSTF recommends against routine screening for cervical cancer with cytology (Pap smear) in the following groups: women aged <21 years, women aged >65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer, women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia grade 2 or 3) or cervical cancer. USPSTF recommends against screening for cervical cancer with HPV testing, alone or in combination with cytology, in women aged <30 years (*8*).
- **Ovarian cancer:** USPSTF recommends against routine screening for ovarian cancer (*9*).

The USPSTF has recommended against offering the following services to men:

- **Prostate cancer:** USPSTF recommends against prostate-specific antigen (PSA)-based screening for prostate cancer (*10*).
- **Testicular cancer:** USPSTF recommends against screening for testicular cancer in adolescent or adult males (*11*).

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Competing interests for the development of these guidelines were not assessed.

*These persons made important contributions to a discussion about community outreach and participation. A decision was made to narrow the focus of this report to clinical services, so recommendations informed by the input of these persons will be published separately.

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

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, et al.,

Defendants.

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

Plaintiffs,

v.

ALEX M. AZAR II, et al.,

Defendants.

No. 1:19-cv-03040-SAB

DECLARATION OF DR. KATHRYN KOST IN SUPPORT OF NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION'S MOTION FOR A PRELIMINARY INJUNCTION

I, Kathryn Kost, declare as follows:

1. I am the Acting Vice President of Domestic Research at the Guttmacher Institute, where I have worked in a full-time or consulting capacity since 1989.

2. I hold a B.A. in sociology from Reed College and a Ph.D. in sociology, specializing in demography, from Princeton University.

3. The Guttmacher Institute is a private, independent, nonprofit, nonpartisan corporation that advances sexual and reproductive health and rights through an interrelated program of research, policy analysis, and public education. The Institute's overarching goal is to ensure quality sexual and reproductive health for all people worldwide by conducting research according to the highest standards of methodological rigor and promoting evidence-based policies. It produces a wide range of resources on topics pertaining to sexual and reproductive health and publishes two peer-reviewed journals.

4. The information and analysis Guttmacher generates on reproductive health and rights issues are widely used and cited by researchers, policymakers, the media and advocates across the ideological spectrum. Guttmacher began as the Center for Family Planning Development in the late 1960s and contributed research to Congress in its creation of Title X. In the early 2010s, Guttmacher experts were among those selected to participate in the Centers for Disease Control and Prevention (CDC) and the Office of Population Affairs' (OPA) development of the national standards of care for family planning services. The Department of Health and Human Services (HHS) frequently invokes Guttmacher research, including in the context of Title X.[1,2]

5. Over the course of more than 30 years, I have designed, executed, analyzed, and supervised numerous quantitative and qualitative research studies in the field of reproductive health care, including those on contraceptive use and failure, unintended pregnancy, maternal and child health, and analysis of trends in key demographic and reproductive health measures. My peer-reviewed research has been published in dozens of articles, including first-authored work in *Demography*, *Perspectives on Sexual and Reproductive Health*, *Contraception*, *Family Planning Perspectives*, *Studies in Family Planning* and other public health, medical and demographic journals. My education, training, responsibilities and publications are set forth in greater detail in my curriculum vitae, a true and correct copy of which is attached as Exhibit A. I submit this declaration as an expert on reproductive health care, family planning, and unintended pregnancy, and the impact on individuals, families, and public health from access to contraception and related care, or interference with that care, in the United States.

6. I understand that this lawsuit involves a challenge to the federal government's newly issued regulations regarding the Title X family planning program (the "New Rule," published at 84 Fed. Reg. 7714). In addition to my own expertise on family planning topics, including for example, on demographic trends in unintended pregnancy and disparities in its incidence, and on contraception, including access to it as well as its use, efficacy, and importance for the prevention of unintended pregnancy, in my role as Acting Vice President of Domestic Research at Guttmacher, I lead a team of researchers whose specialties include publicly funded family planning programs.

7. As discussed in more detail below, research over many decades establishes that Title X projects have been extremely effective in expanding access to modern contraceptive technologies, including the most effective methods, for patients with limited economic means. As a result, Title X projects have helped significantly diminish the rate of unintended pregnancies in the United States. Research also shows that Title X providers are especially effective in gaining patients' trust, treating particularly marginalized populations, offering a broad range of effective options for patients' personal, voluntary decision-making, and helping individuals take control of their own reproductive plans and lives. Since its inception, the Title X program has provided high-quality family planning care to low-income individuals, improved public health, and saved public expense at all levels of government.

8. In my expert opinion, the New Rule, if implemented, would force the Title X program in counterproductive directions that are contrary to evidence-based family planning research and that would significantly undermine the individual and public health benefits of Title X in multiple ways.

9. The New Rule would immediately harm the quality of care provided in Title X-funded health centers; deprive patients of non-directive pregnancy options counseling, including referrals; compromise Title X patients' ability to obtain timely, acceptable and effective contraceptive methods; and increase (rather than continue to help diminish) individuals' risk of unintended pregnancy.

10. In addition, many of the high-quality, experienced providers that have been the hallmark of Title X care for years would be pushed from the program. The

departure of these providers from the network, without similarly effective providers to take their place, would result in a reduction in patients served and further hamstring the Title X program.

11. Ultimately, the New Rule would fundamentally subvert the Title X program's purpose of helping to close the gap in contraceptive access between individuals and couples with more resources and those with less, ensuring that low-income individuals can count on receiving the highest standard of family planning care. The evidence-based clinical recommendations that guide the delivery of Title X set the bar for what high-quality family planning care should look like: services that are comprehensive, timely, affordable, voluntary, confidential and respectful of all who seek them. The New Rule would effectively transform Title X from the gold standard of family planning care to a program that prioritizes providers' religious or moral beliefs over patient-centered care—with the government's imprimatur. This would erode the nearly 50-year legacy of Title X–funded sites serving as trusted providers of evidenced-based, high-quality, ethical medical care.

12. The negative consequences of the New Rule would impact not only current and future patients, but also their children and families, public health, government budgets, and the nation's health care infrastructure.

I. THE TITLE X PROGRAM REDUCES SYSTEMIC GAPS IN ACCESS TO HIGH-QUALITY FAMILY PLANNING SERVICES.

A. Title X Expands Access to Wanted Family Planning Services Among Low-Income Individuals

13. The Title X Family Planning Program is the nation's only federal program devoted exclusively to providing family planning services.[3]

14. At President Richard Nixon's urging and with strong bipartisan support, Congress established the Title X program in 1970 to make modern contraceptive options and the clinical care they required just as accessible to low-income women as they were to more affluent women.[4] Studies in the 1960s showed that women with low incomes wanted the same number of children as more affluent women, yet had more children than they desired because they lacked access to modern contraceptives.[5]

15. Title X helps low-income individuals maintain reproductive health; avoid pregnancies they do not want; and determine the number, timing, and spacing of their children, all of which contribute to the health and social and economic well-being of patients, their families and communities. In addition to providing access to the most advanced contraceptive methods, comprehensive counseling and information, and related medical services, Title X providers also offer basic clinical infertility services (infertility counseling and screening), as well as pregnancy testing and nondirective counseling on all pregnancy options, including referral upon request regarding prenatal care, adoption, and abortion.[6] Title X funding can also support clinical services addressing other aspects of patients' sexual and reproductive health, including STI testing, counseling and treatment,

cervical and breast cancer screening and prevention, and screening for high blood pressure, diabetes and depression, or other preconception issues.[7,8]

16. For any health services outside a provider's scope of care, Title X program regulations and guidelines require referrals to and coordination with other health care providers, social service agencies, and other resources, including but not limited to those that are publicly funded.[9,10]

17. Since the program's inception, Title X funds have been prohibited from use in programs where abortion is a method of family planning.[11] Title X providers, however, are explicitly required to offer patients who are pregnant factual, nondirective information and counseling, including referrals, on all pregnancy options, including abortion, that the patient wishes to consider.[12,13]

B. The Title X Program Requires the Provision of High-Quality Family Planning Care

18. The principles of high-quality, ethical care defined in the Title X statute, regulations and program guidelines apply to all women, men and adolescents served by a Title X project.[14]

19. A central tenet of Title X family planning care is that it is voluntary and non-coercive. This is critical, because history has shown that family planning programs can and have been abused as a tool of social control: Deliberate campaigns have been waged, for example, to limit the fertility of women of color, low-income women, incarcerated women, and women with disabilities.[15]

20. Title X's authorizing statute requires that projects offer clients a broad range of contraceptive methods from which they can choose. This protection helps

ensure that individuals seeking contraceptive care are not coerced into using any method they do not want, and to help ensure individuals can in fact obtain the methods that will work best for them. The statute also expressly prohibits conditioning individuals' participation in other publicly funded programs on the acceptance of family planning services.[16]

21. Voluntary decision-making necessarily depends on access to information. Title X standards promote informed decision-making by offering neutral and complete factual counseling, with regard to contraceptives, pregnancy, and other Title X clinical care.

22. In addition to this foundational principle, Title X care is also governed by standards published by OPA, which administers the Title X program, and the CDC, under the title: "Providing Quality Family Planning Services" ("the QFP").[17] The QFP resulted from an exhaustive, multi-year process involving numerous panels of experts from around the country. They were tasked with developing national, evidence-based clinical recommendations intended to serve as the national standard of care for all providers of family planning services, whether publicly funded or not.[18] The QFP is periodically updated by CDC and OPA, including as recently as December 2017.

23. The Title X Family Planning Guidelines, through which HHS implements the Title X program, require Title X grantees to adhere to the QFP.[19]

24. The QFP recommends offering a full range of Food and Drug Administration (FDA)-approved contraceptive methods and counseling that highlights methods' effectiveness in helping to prevent pregnancy, further

explaining that: "Contraceptive counseling is … a process that enables clients to make and follow through on decisions about their contraceptive use."[20] The selected contraceptive method(s) are preferably provided to the patient onsite and in multiple cycles (if applicable), the patient should be able to start their chosen methods immediately (unless medically contraindicated), and clinicians should assist patients in their decision-making through patient-centered planning and counseling discussions.[21]

25. The QFP also sets the standard of care for pregnancy testing and counseling, which are core family planning services supported by Title X. Indeed, 100% of Title X sites offer pregnancy testing.[22] The QFP specifically instructs that "[positive pregnancy] test results should be presented to the client, followed by a discussion of options and appropriate referrals. Options counseling should be provided in accordance with the recommendations from professional medical associations, such as ACOG and AAP."[23] Both ACOG and AAP are explicit in their recommendations that all pregnant individuals, including adolescents, be provided with factual, nondirective pregnancy options counseling that includes information on and timely referral for abortion services.[2425]

26. Leading professional medical associations, including those referenced by the QFP, state unequivocally that it is unethical to withhold relevant information about options from patients or mislead patients as to their options, when patients indicate a desire for information.[26,27]

27. The QFP further stresses that "every effort should be made to expedite" referrals for pregnant patients and that initial prenatal counseling is to be provided only for "clients who are considering or choose to continue the pregnancy."[28]

28. Taken together, these provisions of the QFP ensure that patients are able to make informed decisions about and truly consent to their own health care.[29]

C. Title X Patients Reflect the Program's Priorities

29. In 2017, Title X-funded providers served approximately 4.0 million individual family planning patients, providing 6.6 million family planning visits.[30] These numbers demonstrate that many patients visit their Title X provider multiple times in a given year.

30. Consistent with the program's prioritization of low-income individuals, in 2017, 90% (3.6 million) of Title X patients had household incomes that qualified them for either free or reduced-cost services under Title X:[31] Sixty-seven percent (2.7 million) had family incomes at or below 100% of the federal poverty level, and 23% (932,000) had incomes ranging from 101% to 250% of that threshold.[32] In 2017, the federal poverty level was $12,060 for a single-person household, and $20,420 for a household of three.[33]

31. In 2017, 42% (1.7 million) of Title X patients were uninsured, 38% (1.5 million) had some form of public health insurance (reflecting household incomes low enough to qualify for public coverage), and 19% (760,000) had private health insurance.[34] Although increases in health insurance coverage in recent years suggest somewhat greater overall access to health care for Title X patients, the proportion of uninsured Title X patients is still more than triple the national

proportion among all women of reproductive age (12%).[35] Furthermore, some 17% of insured patients are not in a position to use their insurance to pay for the clinic visit.[36] The most common reasons given by insured clients for not using their coverage were that the services they were going to receive were not covered under their plan (31%) or that someone might find out about their visit if they did so (28%).[37]

32. In 2017, 47% of Title X patients (1.9 million) were aged 20 to 29, 35% (1.4 million) were 30 or older, and 17% (693,724) were younger than 20.[38] This shows that while the greatest proportion of Title X patients are young adults in their 20s, Title X providers serve individuals of all reproductive ages.

33. In 2017, 31% (1.2 million) of Title X patients self-identified with at least one of the Office of Management and Budget's nonwhite race categories: Black or African American, Asian, Native Hawaiian or Pacific Islander, American Indian or Alaska Native, or more than one race. Thirty-three percent (1.3 million) of Title X patients identified as Hispanic or Latino.[39]

34. In 2017, 14% (553,241) of Title X patients reported having limited English language proficiency.[40]

II. TITLE X-SUPPORTED SERVICES YIELD ENORMOUS BENEFITS TO INDIVIDUALS, FAMILIES AND PUBLIC HEALTH

A. Title X-Supported Contraceptive Care Helps Individuals Avoid Pregnancies They Do Not Want, and Time and Space Wanted Pregnancies

35. In 2015, the most recent year for which these numbers are available, the contraceptive care delivered by Title X-supported providers helped women avoid

an estimated 822,000 unintended pregnancies, which would have resulted in an estimated 387,000 births and 278,000 abortions.[41,42] Without the contraceptive care provided by these Title X-funded health centers that year, the U.S. rates of unintended pregnancy and abortion would have been 31% higher, and the adolescent unintended pregnancy rate would have been 44% higher.[43]

36. This impact comes from Title X's expansion of low-income individuals' ability to freely choose from among a broad range of acceptable and effective contraceptive methods, along with related counseling and clinical services.[44]

37. The ability to obtain contraceptive methods that best meet an individual's needs helps that person feel satisfied with their chosen methods, and women who are satisfied with their current contraceptive methods are more likely to use them consistently and correctly.[45] For example, only 35% of satisfied oral contraceptive users have skipped at least one pill in the past three months, compared with 48% of dissatisfied users.[46]

38. Consistent and correct contraceptive use increases individuals' likelihood of successfully avoiding unintended pregnancies: The women at risk for unintended pregnancy (those who are sexually active and able to become pregnant but are not pregnant and do not want to become pregnant) who consistently and correctly use a contraceptive method account for only 5% of unintended pregnancies.[47]

39. True choice in contraceptive methods is also important because U.S. women and couples rely on a broad mix of contraceptive methods and sometimes use two or more methods at once.[48,49] Furthermore, most individual women rely

on multiple methods over the course of their reproductive lives, with 86% having used three or more methods by their early 40s.[50]

40. The ability to make an informed choice from a broad range of method options is also important to ensuring individuals can obtain and use the contraceptive methods that best fulfill their own needs and priorities, which may include not only preventing pregnancy, but also managing potential side effects, drug or hormonal interactions, perceived risk of HIV and other STIs, and many other considerations.[51]

41. Offering patients a wide choice of contraceptive methods—or the choice to use no method at all—is also essential to guarding against reproductive coercion, and requires considerable resources and provider expertise, which Title X expressly facilitates.[52]

42. Title X sites facilitate choice by providing a greater number of contraceptive method options to their patients, as compared to other publicly funded health centers that do not receive Title X support and provide contraceptive care to at least 10 women each year[53] —70% of which are operated by federally qualified health centers (FQHCs).[54] *See infra*, Section D. Seventy-two percent of Title X sites offer a full range of FDA-approved reversible contraceptive methods, compared to 49% of non-Title X sites.[55] Title X-supported centers offer a choice of 12 methods, on average, and 85% offer at least one long-acting reversible method, such as the IUD or contraceptive implant.[56]

43. Title X-supported centers are also more likely than non-Title X providers to offer contraceptives on site rather than give a prescription that women must fill

at a pharmacy or a referral to another provider for insertion of an IUD or implant. Seventy-two percent of Title X–funded centers provide oral contraceptive supplies and refills on site, compared with only 40% of sites not funded by the program.[57] Similarly, among Title X sites, 41% offer same-day insertion of IUDs or implants, compared to 27% of non-Title X sites.[58] Minimizing the number of trips a woman must make to obtain her contraceptive methods makes it easier for her to successfully use those methods, especially for those who juggle the demands of school, family and work, or who rely on public or perhaps a borrowed mode of transportation—all common complicating factors in patients' lives.

44. Among the 3.1 million sexually active female patients at risk of unintended pregnancy who visited a Title X site in 2017, 70% (2.2 million) left their last visit with a contraceptive method deemed either most or moderately effective at preventing pregnancy.[59] This is unsurprising, given that an important feature for most individuals seeking contraceptive care is how well a method works to prevent pregnancy.[60] "Most effective" methods include vasectomy, female sterilization, implant, or IUD, and "moderately effective" methods include injectable contraception, vaginal ring, contraceptive patch, pills, diaphragm, or cervical cap.[61] These methods require a prescription or services provided by a medical professional. In contrast, the contraceptive methods that can be purchased over the counter at a neighborhood drugstore for a comparatively low cost—male condoms and spermicide—are far less effective at preventing pregnancy than methods that require a prescription or a visit to a health care provider, which have higher up-front and ongoing costs.[62]

45. While long-acting reversible contraceptives ("LARC"), such as implants and IUDs are very effective, they are also costly.[63] Without any third-party payer to help defray the expense, the total cost to the patient of initiating one of these methods generally exceeds $1,000.[64] Oral contraceptives, which are nearly twice as effective as condoms in practice, require a prescription and have ongoing monthly costs.[65] Many methods would cost a patient at least $50 per month, or upwards of $600 per year.[66]

46. Title X providers work hard to ensure that women are able to start their method at the same time that they request it. For example, Title X–supported centers are particularly likely to use the so-called "quick start" protocol (87% of them did so in 2015, as compared to only 66% of all publicly funded health centers delivering contraceptive care not supported by Title X), under which clients who choose to use oral contraceptives begin taking them immediately, rather than waiting until a certain point in their menstrual cycles, as some providers require.[67]

47. Title X–supported centers are also particularly likely to prescribe contraception without requiring a pelvic exam (88%, as compared to only 76% of non-Title X supported clinics),[68] a practice in line with evidence-based guidelines issued by the World Health Organization[69] and the American College of Obstetricians and Gynecologists.[70]

48. Title X support also helps clinicians to obtain the necessary training and spend the needed time during a patient visit to provide in-depth contraceptive counseling and explore options with clients.[71] On the whole, clinicians at Title X-

supported sites spend more time with patients during initial contraceptive visits than do clinicians at non-Title X sites—especially those clients with specific needs, such as those who are younger, have limited English proficiency or have other complex medical or personal issues.[72]

B. Title X-Supported Care Helps Prevent Preterm or Low-Birth-Weight Births and Other Negative Health Outcomes

49. The contraceptive services provided at Title X family planning visits also help prevent poor birth outcomes. In 2010 (the most recent year for which these estimates are available), the contraceptive services provided by Title X-supported providers helped individuals and couples to avert an estimated 87,000 preterm or low-birth-weight births.[73,74]

50. Contraceptive use enables women to plan their pregnancies, and women who plan generally recognize their pregnancies earlier on, in turn allowing women more time to engage in behaviors that promote healthy pregnancies, such as taking prenatal vitamins, and reducing or stopping smoking and drinking.[75]

51. Moreover, by enabling women to plan their pregnancies, contraceptive use can decrease individuals' risk for pregnancy-related morbidity and mortality.[76] The risk of such adverse outcomes is particularly high for individuals who are near the end of their reproductive years and for those with medical conditions that may be exacerbated by pregnancy.[77] Although reversible contraceptives—like virtually all medications and medical devices—are not without risk, the likelihood of serious health risks is lower than that for pregnancy or childbirth, which can be an important consideration for individual patients.[7879]

C. Title X-Supported Services Contribute to the Prevention, Early Detection and Treatment of STIs

52. Title X-supported STI testing and screening also yields considerable benefits for individuals' and their partners' sexual and reproductive health. Testing for chlamydia, gonorrhea and/or HIV are conducted routinely as part of family planning visits.[80] Chlamydia and gonorrhea testing can help prevent additional health problems, such as pelvic inflammatory disease, ectopic pregnancy and infertility.[81,82,83] Testing can do so directly, by detecting an infection early and facilitating treatment, and indirectly, because treating an infection prevents its spread to a client's current sexual partners and to any future partners they may have.[84]

53. Similarly, HIV testing and early detection help facilitate treatment and reduce transmission of the virus to partners, because they may lead to less risky behavior after a positive test result and to reduced infectivity after entry into treatment.[85]

54. In 2017, Title X providers tested 61% (939,300) of female patients under age 25 for chlamydia, and they performed 2.4 million gonorrhea tests (6.1 tests per 10 patients), 1.2 million confidential HIV tests (3.0 tests per 10 patients), and 709,000 syphilis tests (1.8 tests per 10 patients).[86] Of the confidential HIV tests performed, 2,200 (1.8 per 1,000 tests performed) were positive.[87]

55. In 2010 (the most recent year for which these data are available), the STI testing, screening and related services provided by Title X-supported providers helped to avert an estimated 63,000 STIs.[88]

D. Title X-Supported Services Contribute to the Prevention and Early Detection of Cervical Cancer

56. Title X funding and services also support the provision of services intended to aid in the prevention and early detection of cervical cancer as part of routine family planning care, namely Pap tests, human papillomavirus (HPV) testing and HPV vaccinations.[89] Pap tests—now often performed in conjunction with HPV tests in accordance with clinical recommendations—help to detect abnormal cervical cells and cases of precancer, which allows for early treatment that prevents cervical cancer cases and deaths.[90,91] HPV vaccinations help protect clients against the viral strains of HPV most commonly linked to cervical cancer; they also provide some protection against HPV-attributable cancers of the vulva, vagina, anus, rectum, and oropharynx.[92,93]

57. In 2017, Title X-supported sites provided Pap tests to screen for cervical cancer to 18% (649,300) of female patients. Fourteen percent of those Pap tests yielded indeterminate or abnormal results, prompting further evaluation and possible treatment.[94]

58. In 2010 (the most recent year for which these data are available), the cervical cancer prevention services provided by Title X-supported providers helped to prevent an estimated 2,000 cases of cervical cancer.[95]

E. Title X Provides A Gateway To Health Coverage and Care

59. For 60% of Title X patients, that Title X-supported provider was their sole source of medical care in the last year, making these providers critical sources of care in their own right.[96] However, Title X providers have also long served as entry points to the broader health care system for many individuals, as the high-

quality, low-cost, confidential services they offer enable many people to walk through Title X providers' doors when they would not be willing or able to walk through others.[97]

60. Title X sites have long engaged in outreach and enrollment assistance efforts helping eligible people obtain comprehensive health insurance coverage, particularly since the ACA's implementation.[98]

61. Title X providers' referral relationships help ensure that individuals who need them can obtain services and supports outside their family planning visit. Ninety-nine percent of sites have formal or informal referral relationships with other providers; 97% refer to other public providers, including FQHCs and other community clinics offering primary care, and 90% refer to private providers, including ob-gyns and private physicians or group practices.[99] Sixty-two percent of Title X sites refer patients to social service agencies, and nearly half to home visiting programs or services.

F. Title X-Supported Services Help Individuals to Achieve Their Educational, Workforce and Economic Goals

62. By enabling individuals and couples to more reliably time and space pregnancies, the Title X program promotes individuals' continued educational and professional advancement, contributing to the enhanced economic stability of individuals and their families. In a 2011 national survey of more than 2,000 women obtaining family planning care from Title X sites focused on reproductive health care, women reported that over the course of their lives, contraception had enabled them to take better care of themselves or their families (63%), support

themselves financially (56%), complete their education (51%), or get or keep a job (50%).[100]

63. When asked why they were seeking contraceptive services at that moment, women provided similar answers, including not being able to afford to care for a baby or another baby at that time (65%), not being ready to have children (63%), feeling that contraception gives them better control over their life (60%) and wanting to wait to have a baby until life is more stable (60%).[101]

64. Economic analyses have found positive associations between women's ability to obtain and use oral contraceptives and their ability to obtain higher levels of education, participate in the labor force and obtain higher-paying jobs, in turn contributing to a narrowing of the gender-based wage gap.[102]

65. Given its connections to so many central aspects of people's lives, it makes sense that the ability to determine for oneself whether and when to have children is also related to an individual's mental health and happiness. Individuals and couples who experience an unintended pregnancy that ends in birth are particularly likely to experience depression, anxiety and a decreased perception of happiness.[103]

G. Title X Investment Yields Considerable Public Savings

66. In addition to promoting positive health and other outcomes for individuals, couples and families, and the broader public, Title X-supported services also yield considerable savings of government expenditures. Title X-supported services—including contraceptive care, STI testing, and cervical cancer testing and prevention—save approximately $7 for every public dollar invested.[104]

This amounted to an estimated $8.1 billion in gross federal and state government savings in 2010 (the most recent year for which these data are available), by avoiding public expenditures that would have otherwise been made for medical care associated with unintended pregnancies, STIs and cervical cancer. The federal and state governments realized an estimated $7 billion in net savings that year, after subtracting the cost of delivering Title X-supported services.[105]

III. TITLE X FUNDS SUPPORT A NATIONWIDE NETWORK OF HEALTH CENTERS THAT ARE CRITICAL, TRUSTED SOURCES OF HIGH-QUALITY CARE FOR THEIR PATIENTS

67. The Title X program's ability to serve four million patients each year[106] and advance the extensive individual, familial and societal benefits articulated above depends on the participation of health care providers with the expertise, staff and resources necessary to deliver a truly broad range of contraceptive options and counseling, and related clinical services, to considerable numbers of patients.

68. In 2017, Title X funds supported a network of over 1,000 provider organizations, including both non-profit and public entities, which operated 3,858 service sites.[107]

69. In 2015, among Title X-supported centers, sites operated by Planned Parenthood represented 13% of sites and served 41% of all contraceptive patients; those operated by state or local health departments represented 48% of sites and served 28% of patients; sites operated by federally qualified health centers (FQHCs) accounted for 26% of sites and served 19% of patients; and other

independent agencies operated 9% of all sites and served 7% of patients.[108] Seventy-two percent of Title X sites focus on the provision of reproductive health services,[109] including all of those operated by Planned Parenthood affiliates, and a majority of those operated by public health departments (81%), hospitals (70%), and other independent providers (86%).[110]

70. Reproductive health-focused sites serve a considerable majority of Title X patients. These sites provide contraceptive care to an estimated 2.7 million women each year, or seven in 10 who rely on Title X for such services.[111] (Patients served by the small number of reproductive health–focused sites that FQHCs report operating are not included in this estimate.)

71. Many women prefer to obtain contraceptive services from reproductive health–focused health centers over primary care–focused sites in their communities: Six in 10 women obtaining services at a reproductive health-focused provider report having made a visit to another provider in the last year, but chose the specialized provider for their contraceptive care; the remaining four in 10 of these women report that the reproductive health–focused provider was their only source of care in the last year, despite having other options in their communities.[112]

72. Leading reasons patients provided for preferring to visit reproductive–health focused sites over other, non-specialized sites include: “The staff here treat me respectfully” (84%), “Services here are confidential” (82%), and “The staff here know about women’s health” (80%).[113]

IV. THE NEW RULE WOULD IMMEDIATELY HARM PATIENTS AND PUBLIC HEALTH BY IMPOSING SUBSTANDARD CARE AND DISRUPTING THE TITLE X SAFETY NET OF PROVIDERS

73. The New Rule would immediately impose substandard care on those who rely on Title X-funded providers by eliminating the requirement that Title X sites all offer nondirective pregnancy options counseling to patients who are pregnant and forbidding abortion referrals except in the case of medical emergency. This change deprives patients of information and referrals regarding all options, including abortion, if they are pregnant and is contrary to the QFP and medical ethics. Additionally, the New Rule would allow providers to deprive patients of full information or provide them with misleading information, inhibit informed decision-making, and delay patients from obtaining the care they may desire.

74. In addition, the New Rule would require that all pregnant patients be referred for prenatal care, regardless of their wishes. Furthermore, while not mandatory, clinicians would be allowed to provide information on "maintaining the health of the mother and unborn child," even when it is not requested by the patient, in direct violation of Title X's central tenet that all services are voluntarily received and free from coercion.

75. The New Rule would also curtail contraceptive options for Title X clients by deemphasizing the provision of modern, medically approved contraceptive methods, diverting funds away from core family planning services, and encouraging a shift toward "non-traditional" providers that are permitted to offer a single or limited method(s) of contraception.

76. In addition to the direct, immediate impacts on patient care and public health, the New Rule would also create a massive disruption in the Title X network of providers that would compound the harms to patient and public health. The New Rule would put Title X grantees and the providers now participating in the Title X program in the untenable bind of choosing between two bad options: Either (1) agreeing to provide care that does not adhere to medical or ethical standards, because they want to continue providing at least some Title X–supported services for their low-income patients, or (2) deciding that they must exit the program because they are unwilling to comply with the New Rule's requirements for substandard care, and do so mid-grant, when the New Rule goes into effect. Title X grantees and providers may also be forced to exit the program because the New Rule would impose significant new costs and hurdles that are not tenable and would interfere with Title X's effectiveness even if they could be feasibly implemented—including new "financial and physical" separation requirements that also impose considerable limits on providers' use of funding for infrastructure.

77. Many current providers would feel compelled to choose the second option and leave the Title X program in the middle of the current funding cycle. The New Rule erroneously assumes that there would be sufficient available capacity and willingness among other health care providers—particularly, among primary care providers, such as FQHCs—to take their place. The inevitable result would be a considerable disruption in the current Title X network and gaps in capacity.

78. The departure of providers would be acutely felt in areas of the country that do not have another safety-net family planning center. Twenty-one percent of Title X sites are in counties that do not have another safety-net family planning center.[114] Moreover, in one-fifth of all 3,142 U.S. counties, a Title X site is the only safety-net family planning center. If any of these sites were to no longer participate in Title X as a consequence of this rule, it would make it exceedingly difficult for low-income individuals in those areas to obtain high-quality, affordable family planning care.

79. Furthermore, the New Rule does not address the inevitable difficulty OPA would face in finding new, comparably qualified providers to fill this gap during its next funding cycle. HHS offers only a single letter submitted in response to the Proposed Rule as evidence of the existence of providers that might be able to fill the gap.[115] The letter and, in turn, HHS rely on 2009 and 2011 online surveys of "faith-based medical professionals" to suggest individual practitioners would increasingly participate in Title X under the New Rule, helping to fill the gap in service delivery. However, the evidence presented in the letter does not support HHS' conclusion. These surveys asked health care providers broadly about the importance of "conscience protections" to their ability to practice medicine, but did not assess providers' interest in participating in Title X or delivering family planning services specifically. Moreover, the letter and HHS offer no estimates of how many providers might newly participate, or their capacity to serve large numbers of contraceptive patients—critical considerations in contemplating the loss of current Title X providers that each serve thousands of patients each year.

In fact, the letter suggests that faith-based organizations are unlikely to seek federal funding without extensive grants training and restructuring of the grants process, activities that are not part of the new rule and that would take many years to implement, leaving huge gaps in service delivery for many years to come. The comment letter further asserts that FQHCs could fill the gap in Title X service delivery, an unrealistic suggestion addressed extensively in Section D, below.

80. Even if some new resources or new providers could be found, there would still be significant short-term and potentially long-term harms as patients are inevitably left without the high-quality, affordable Title X–supported care they rely on for months or longer.

81. The New Rule, if implemented, would thus trigger a downward spiral within the Title X program that harms patients, providers, grantees and public health right away and in a growing fashion from the effective date, and that current data and conditions indicate would be very hard to stop or reverse. Some patients would be effectively excluded from the program and others would receive inadequate care.

82. Taken together, and without any intervention, these changes would inevitably increase some people's risks for unintended pregnancy, undetected and untreated STIs, and cervical cancer, among other health effects.

83. Moreover, as soon as the New Rule takes effect, all current Title X grantees, sub-recipients and individual providers would be forced to choose between compromising national standards of care and central ethical requirements, or exiting the Title X program.

A. The New Rule Would Involve Providers in and Subject Patients to Directive, Involuntary Pregnancy Counseling that Misleads and Denies Wanted Abortion Referral

84. If the New Rule is allowed to take effect as planned, patients would immediately be treated with substandard care following positive pregnancy tests, in the form of falsely limited pregnancy options counseling, misleading responses or outright denials to requests for abortion referrals, and forced referrals for prenatal care, regardless of the patient's wishes or medical needs. Pregnant patients could only be referred for abortion services in the event of a medical emergency, and would be denied referral if abortion was "only" medically indicated.

85. The New Rule would eliminate the long-standing guarantee that all pregnant patients at Title X-funded sites be offered unbiased, factual, and comprehensive counseling—including referrals upon request. Such nondirective counseling is necessary to ensuring patients are able to make informed, voluntary decisions about their own health care. These changes not only violate congressional directives,[116] but also the federal government's own standard of care as articulated in the QFP, described above.[117] Moreover, they also ignore bedrock principles of medical ethics.[118,119,120,121]

86. The New Rule would also unnecessarily limit pregnancy options counseling to physicians and "advanced practice providers" with "at least a graduate level degree." This definition excludes highly trained providers who also play an important role in delivering counseling in Title X settings, such as registered nurses, public health nurses, health educators and clinical social

workers.[122] Although Guttmacher does not have data specific to clinicians offering pregnancy options counseling, data from 2010 show that 65% of Title X sites and 64% of all safety-net family planning centers focused on reproductive health rely on trained health educators, registered nurses and other qualified providers (excluding physicians and advanced practice clinicians) to counsel patients in selecting contraceptive methods.[123] Given the critical role these clinicians play in contraceptive counseling, needlessly excluding them from pregnancy options counseling stands to harm patients' experiences and service delivery.

87. Regarding the substance of permissible pregnancy options counseling, the New Rule would allow physicians and advance practice practitioners to deliver counseling that excludes information on abortion, rendering that counseling far from "nondirective." Even more directive, those clinicians would be forced to provide information about prenatal care, even when the patient does not request or actively does not want such information, and required to discuss a prenatal or adoption option with a patient that only wishes to discuss abortion.

88. The New Rule would effectively require clinicians to deny abortion referrals entirely. Providers would have the option of offering pregnant patients an intentionally misleading provider list that must include only "licensed, qualified comprehensive primary health care providers (including providers of prenatal care)." At best, that list would provide incomplete and confusing information as "some, but not the majority" of sites could also offer abortion, though neither the list nor clinic staff would be permitted to identify those sites as abortion providers. At worst, patients requesting abortion could be given a referral list without any

abortion providers, without the patient's knowledge or understanding that the referral list was in no way responsive to their request.

89. Additionally, there is also no guarantee that any comprehensive primary care sites offering abortion would be available in patients' communities to even include on the list, and the rule bars clinicians from telling patients about other, specialized abortion providers. For example, in 2018, in eight states (Kentucky, Louisiana, Mississippi, Missouri, South Dakota, North Dakota, West Virginia and Wyoming), the only providers known to offer abortions in the state are specialized abortion providers, including Planned Parenthood clinics and independent providers.[124] There are no comprehensive primary care sites that are known to offer abortion services in these states, making it effectively impossible to put any abortion providers on the misleading referral list permissible under the New Rule. Moreover, there are likely similar situations in many areas of many other states, because there are no known primary care providers that also offer abortion, or perhaps only private practice physicians who offer abortion care only to their established patients. As a result, under the New Rule, Title X patients in these states and areas would not even be able to obtain obscured referral information from their Title X provider.

90. All of these restrictive options would harm and confuse all patients, but may be particularly problematic for adolescents, those with limited English proficiency, or other especially marginalized populations.

91. Beyond denying abortion referrals to patients who request them, the New Rule mandates that all pregnant patients at Title X sites be referred for prenatal

care, regardless of the patient's wishes. Moreover, though not required, pregnant patients may be provided prenatal counseling, may be referred to social services or adoption agencies, and may be given "information about maintaining the health of the mother and unborn child"—again, all regardless of the patient's wishes. These provisions are coercive not only in requiring or allowing for services to be provided even for women who do not want them, but also because they force all patients toward the particular pregnancy outcome of childbirth, regardless of the patient's own wishes and in violation of the voluntary, patient-centered foundations of Title X care.[125,126,127,128]

92. Restricting pregnancy options counseling, including abortion referrals, and directing pregnant patients only toward childbirth would ultimately threaten their health and well-being in a number of ways. First, limiting information and referrals only to those related to carrying a pregnancy to term would misleadingly deprive patients of broader information about relative risks and suggests that pregnancy and childbirth are a woman's safest options. In fact, pregnancy and delivery pose decidedly greater medical and health risks than abortion.[129]

93. Second, denying a woman information about and access to her full range of options once she knows that she is pregnant would interfere with her ability to obtain additional services in a timely manner. For women who choose to terminate a pregnancy, abortion is particularly safe when obtained in the first trimester of pregnancy and risks increase with any delay.[130] Moreover, it often becomes more difficult for a woman to obtain an abortion as pregnancy progresses due to a lack of providers and increased cost.[131,132,133]

94. Third, denying Title X patients' access to information concerning their ability to obtain abortions would especially jeopardize the health and well-being of patients with certain medical conditions. Multiple professional medical associations have asserted that the inability to make a fully informed decision on how to proceed with a pregnancy would be especially harmful for women with severe diabetes, heart conditions, HIV/AIDS and estrogen-dependent tumors—all conditions that could be exacerbated by continuing a pregnancy.[134] Yet the New Rule would forbid direct referrals to abortion providers for a patient with these types of conditions, even if the patient so desires.

95. Finally, forcing clinicians to deny patients the full scope of information and referral would interfere in the provider-patient relationship and reinforce what experts have described as "the historical imbalance of power in gender relations and in the physician-patient relationship…and the intersection of gender bias with race and class bias" that are particularly present in obstetrics and gynecology, and in reproductive health care broadly.[135] Forcing providers to sabotage rapport they have built with patients may cause those patients to retreat from seeking health care; this may be particularly true for women of color, low-income women and others who have historically experienced coercive treatment in the context of reproductive health care.[136,137]

B. The New Rule Would Diminish Contraceptive Choice and Access for Title X Patients

96. Another way in which the New Rule would directly impede patient care is by curtailing contraceptive options for Title X clients by: (1) deemphasizing the

provision of modern, medically approved contraceptive methods; and (2) reshaping the Title X network to favor "diverse" providers, including those that offer only a single method or limited methods of contraception.

97. The New Rule deemphasizes the provision of modern methods of contraception in several ways. First, it would remove the requirement that the range of family planning methods offered by a Title X project must be "medically approved" methods. As stated above, in 2017, 70% (2.2 million) of the 3.1 million sexually active female Title X patients at risk of unintended pregnancy left their last visit with a method deemed either most or moderately effective at preventing pregnancy, all of which require a prescription or services provided by a medical professional.[138] Notably, just 15,300 female Title X patients (less than 0.5%) chose some fertility awareness-based method in 2017.[139]

98. Second, the New Rule would also distort the long-standing interpretation of the statutory requirement that Title X projects provide a "broad range of acceptable and effective family planning methods and services." Historically, this requirement has meant that projects must provide a broad range of contraceptive options, in addition to other care or services. Now, a Title X project could apparently satisfy this requirement by providing only a limited choice of modern contraceptive care so long as they offer a seemingly broad range of "methods and services" overall. For instance, it appears that the rule would allow a Title X project to include abstinence-only-until-marriage counseling, and natural family planning or other fertility awareness–based methods together with just a few other contraceptive options, to represent a "broad range" of "methods and services."

99. Third, the New Rule would open the door for Title X funds to go to entities that commonly do not have any medical staff and are not able or willing to provide many or all modern methods of contraception; such sites would not be required to provide information or referrals about other methods. Entities such as antiabortion counseling centers and abstinence-only programs approach "family planning" in a way that would undermine Title X's core tenets of ensuring patients' contraceptive choices are broad, voluntary and free from coercion. Shifting Title X dollars to such entities would harm patients and jeopardize the documented benefits of Title X as identified above.

100. Moreover, the administration twists what it means to ensure patients have a meaningfully broad range of contraceptive options. Individuals' ability to obtain the methods that are best for them and successfully avoid pregnancy depends not just on having a provider nearby, but also on the range of options available at those sites. Seventy-four percent of reproductive health–focused providers offer a full range of contraceptive methods onsite;[140] directing Title X funds away from such providers and toward ideologically motivated single-method sites would sharply diminish patients' access to a broad range of options. And while the rule clarifies that contraceptive methods are expected to be provided as part of a Title X project, a project may stretch across an entire state and dozens of widely separated sites.

101. Collectively, the provisions of the New Rule would interfere with Title X patients' ability to learn about, obtain and use their preferred method of contraception. This would fundamentally undermine the program's long history as

the gold standard of family planning care, and its congressionally defined purpose: "to assist in making comprehensive voluntary family planning services readily available to all persons desiring such services."[141] Without intervention, the New Rule would result in some individuals' increased risk of unintended pregnancy and the consequent harms that follow, as described above.

C. The New Rule's Additional, More Onerous Separation Requirements, And Other Mandates Would Also Force Many Providers Out of the Program, and Create Dislocation and Disruption That Would Start Immediately and Build

102. The New Rule would modify the long-standing requirement that Title X funds be used solely for Title X purposes and separately accounted for in detail by all Title X projects by imposing a series of additional, more onerous, "financial and physical" separation requirements. These separation requirements would create new, significant obstacles for many current Title X providers to remain in the program. This includes not only the approximately one in 10 sites that offer abortions outside their Title X projects and using non–Title X funds,[142] but also any provider engaging in any of the wide range of services that fall under the administration's construct of prohibited abortion-related activities, including abortion referral. These providers would be forced to either exit the program, alter the scope of services they provide in their communities, or incur substantial new costs in an attempt to separate their services in a manner that HHS deems acceptable.

103. The latter scenario would require providers to lease or purchase new office space, find and hire new staff, procure exam tables, medical equipment, and

office systems. In light of the New Rule's infrastructure spending prohibitions, it is not clear whether any or how much of a provider's Title X's funds could be used to satisfy the separation requirements. These costs would have to come directly out of providers' coffers and would leave ever fewer dollars available for actually providing family planning care. The costs to completely separate one health center into two standalone clinics, with different staff and systems, are costs that could quickly swamp providers and make their participation in Title X financially irrational and practically infeasible.

104. Incurring such extensive costs would be impractical for many Title X providers whose resources are already stretched thin trying to meet the demand for services in their communities. Title X providers must accept all patients, regardless of their ability to pay, and sites routinely struggle with inadequate reimbursement from public and private third-party payers. For instance, a 2016 Guttmacher Institute analysis found that Medicaid reimbursement for family planning services provided by Title X clinics typically covers less than half the actual cost of delivering these services.[143] This makes Title X grants themselves a main source of funding that safety-net providers would rely on for the type of infrastructure investments necessary under the New Rule's separation requirements. Plus, Title X funding nationwide is already insufficient because it has been flat for years.[144]

105. The proposed restrictions on "activities that encourage, promote or advocate for abortion"—which include providing speakers or educators, attending conferences, paying membership dues, and developing or disseminating

materials—are also subject to the separation requirements, as are any activities that may assist patients in obtaining abortions, including referral. Separating these activities to meet HHS's requirements may further constrain providers' willingness and ability to participate in Title X, as many may determine that participation would either too significantly limit their activities or impose too great a financial burden.

106. Moreover, given the extensive degree to which separation between Title X–funded activities and the wide range of prohibited abortion-related activities would be required, the rule might impose onerous separation requirements not just to individual health centers offering abortion or abortion-related services, but also to agencies operating multiple health centers where only a subset of sites do so. As such, entire agencies may determine the New Rule's demands would compromise their services or their finances too significantly to remain in the program, demonstrating the rule's potential to impact the Title X provider network as a whole.

107. Notably, to justify its extensive financial and physical separation requirements, HHS leans heavily on Guttmacher publications on Title X as supposed proof that Title X funds support the physical "infrastructure" of sites that also provide abortions—and thereby fund abortions themselves.[145] This framing is inaccurate and misleading. The cited Guttmacher analyses unambiguously refer to the basic and underlying infrastructure of the family planning safety net—the systems and activities directly necessary to providers' ability to deliver high-quality family planning services to those who need them.

Such expenditures are wholly appropriate uses of Title X funds, as detailed by a 2009 panel convened by the Institute of Medicine to provide an independent evaluation of the Title X program, and fund the Title X project–nothing else.[146,147]

108. Additionally, the rule's impact would extend beyond sites that offer abortion or engage in any of the New Rule's prohibited abortion-related activities. For instance, the rule's restrictions on abortion referral and requirement of prenatal care referral regardless of the patient's wishes are antithetical to ethical and professional standards on voluntary decision-making and would harm the patient-provider relationship. Many current providers consider these requirements unethical, and may therefore feel compelled to leave the Title X network.

109. Already, at least four states with Title X grants and all Planned Parenthood grantees or sub-recipients have made clear to HHS that they would be forced by the New Rule to exit the Title X program, if they should go into effect.[148]

110. Planned Parenthood health centers serve 41% of women who rely on Title X sites for contraceptive care.[149] In order to serve all the women who currently obtain contraceptive care at Title X–supported Planned Parenthood health centers nationwide, Guttmacher analyses estimate that other Title X sites—if they were to stay in the program, which the rule's expected impact indicates many may not—would have to increase their client caseloads by 70%, on average.[150] The impact would also be more severe in some locations: without Title X–supported Planned Parenthood sites, other providers in 13 states would have to at least double their contraceptive client caseloads to maintain the program's current reach in their

states. Furthermore, Planned Parenthood is the only Title X provider in 38 counties in the country, out of the 415 counties in which the organization operates.

111. Finally, findings from a nationally representative 2016 survey of women obtaining services at Title X–funded health centers reinforce the gap that would be left by Planned Parenthood's exit: Twenty-six percent of clients at Planned Parenthood sites reported that it was the only place they could get the services they need.[151]

112. All of these scenarios would result in considerable disruptions to the Title X provider network, and there is no evidence that the remaining providers would be able to compensate for these losses. Indeed, available evidence only underscores the challenges that remaining providers would face in accommodating massive increases in their contraceptive patient populations. *See infra*, Section D. Therefore, if the New Rule goes into effect and providers are forced to leave the network, it would lead to significant, broad-based harm because it would be more difficult for the patients who rely on Title X to obtain any, much less high-quality, family planning care.

D. Primary Care–Focused Sites Would Not Be Able to Absorb the Displaced Patient Population

113. While primary care–focused sites and federally qualified health centers (FQHCs) specifically have become an increasingly integral part of the Title X provider network in some areas,[152] these providers could not serve the entire existing Title X population. As discussed above, reproductive health-focused sites

serve a considerable majority of Title X patients—seven in 10 women who rely on Title X for contraceptive care.[153]

114. FQHCs currently account for the majority (52%) of primary care–focused sites in the Title X network.[154] If FQHCs that offer contraceptive care were asked to serve all of the women who rely on many different types of providers for Title X–supported contraceptive care, these FQHCs would have to at least double their contraceptive client caseloads in 41 states, and at least triple them in 27 states.[155,156] Nationwide, this would add up to an additional 3.1 million contraceptive clients that FQHCs would need to serve. FQHCs themselves report they could not handle large increases to their client caseloads; only 6% said they could sustain a caseload increase of 50% or greater, and the majority said they could increase their caseloads by at most 24%.[157] That is far below what Guttmacher's analysis projects those FQHCs would have to do in most states, if they were to take the entire Title X client load.

115. Additionally, in 33% of the just over 2,000 counties that have a Title X provider, there is no FQHC site providing contraceptive services.[158] In another 47% of counties with a Title X site, the FQHC sites that offer contraceptive care would have to at least double their contraceptive client caseloads in order to serve all of those currently served by other Title X sites. In 24% of all counties with a Title X site, FQHCs would have to serve at least six times their current number of contraceptive clients. Put another way, 2.8 million (91%) of the contraceptive clients currently served by Title X–supported centers that are not FQHCs are in

the 1,625 counties where FQHC sites would have to at least double their capacity, or where there is *no* FQHC site providing contraceptive care.

116. The inability of FQHCs to absorb the volume of displaced patients from even any short-term disruption to the Title X network is salient because the New Rule would attempt to shift the program's emphasis away from centers focused on reproductive health and toward FQHCs and other primary care–focused providers. Specifically, the New Rule would require that Title X providers "offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site."

117. Not only would the rule seek to shift patients' contraceptive care to providers that cannot realistically be expected to serve huge influxes of Title X patients, but it would also deny many Title X patients access to the reproductive health–focused providers they trust. Reproductive health-focused providers are particularly likely to offer their patients a broad range of contraceptive methods in a timely manner, and to implement protocols that help patients start their chosen methods quickly.[159] As a consequence, the primary care provider provision of the rule would make it more difficult for marginalized patient populations to obtain high-quality, low-cost family planning care, if they can access care at all, given capacity constraints and areas without such a provider.

118. Finally, the New Rule is unnecessary to promote referral and linkages between Title X and primary care. Existing Title X regulations require Title X projects to "provide for coordination and use of referral arrangements with other

providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs."[160] Moreover, Title X providers screen for numerous health issues (such as high blood pressure, diabetes and depression) and customarily establish referral arrangements both to and from other providers.[161] According to a recent Guttmacher Institute analysis, 99% of Title X–funded providers reported making referrals of some kind to other providers: 97% reported referring patients to other public providers and 90% reported referring patients to private providers.[162]

E. Data From State-Administered Programs Show Excluding Providers Offering Abortion-Related Services Has Reduced Family Planning Patients Served and Highlights Some of the Harms That Would Result from Provider Network Disruption

119. Policies enacted in Texas and Iowa demonstrate the impact of excluding providers that directly offer abortion or are affiliated with abortion providers from publicly funded programs. In order to exclude abortion providers and affiliates, including Planned Parenthood health centers and others, from their respective programs, both states opted to forgo federal Medicaid funding to cover family planning services for people otherwise ineligible for Medicaid (a "Medicaid family planning expansion") in favor of entirely state-administered family planning programs. Excluding providers that offer abortion or are affiliated with a site that does from these publicly funded programs mirror what the New Rule, in part, would do to Title X. Officials in both Texas and Iowa suggested that other providers would replace those excluded, and that residents' care would not be affected.[163,164] However, these changes resulted in widespread disruption of their

programs' provider networks, leading to diminished access to contraceptive services and ongoing difficulty for individuals finding alternative providers.

120. After Texas made a series of changes to its family planning program starting in 2011—which included disqualifying agencies providing abortion—the reach and effectiveness of the state's program drastically declined. The state reported a nearly 15% decrease in enrollees statewide between 2011 and 2015.[165] The state further reported that claims and prescriptions for contraceptive methods declined 41% over the same four-year period.[166,167]

121. Analyses conducted by the Austin-based Center for Public Policy Priorities (CPPP) offer a more comprehensive view: Between 2011 and 2016, program enrollment declined by 26% and the proportion of women getting health care services in the program declined by nearly 40%.[168] CPPP further reports substantial declines (41%) in the number of women accessing contraceptives through the program, as well as in utilization of highly effective contraceptive methods, including long acting reversible contraception (35% reduction) and injectable contraception (31% reduction).[169]

122. In 2017, then-governor of Iowa Terry Branstad signed an appropriations bill that imposed similar restrictions on the state's Medicaid family planning expansion.[170] Recent data provided by the state showed the new, state-administered program covered a total of only 970 family planning services from April through June of 2018, a 73% decline from the 3,637 services covered in April through June of 2017, the last three months of the previous family planning program, when abortion providers and affiliates were still included in the

program.[171] Furthermore, the number of patients enrolled in the program fell by more than half, with enrollment dropping from 8,570 in June 2017, the last month of the previous program, to 4,177 in June 2018.[172]

F. Summary of the New Rule's Negative Impacts on Patients, Public Health and Government Costs

123. If the New Rule is allowed to take effect, Title X patients would face substandard care and a compromised network of providers. The rule would diminish access to modern, medically approved family planning services and counseling, and unbiased, comprehensive information on the full range of pregnancy options for low-income individuals. For current and prospective Title X patients who would be given fewer contraceptive choices or deterred from seeking Title X–supported care, this would mean an increased risk of unintended pregnancies, low-birth-weight or preterm births, STIs and cervical cancer. For the pregnant patients who decide on or want information about abortion, this would mean an increased risk of delayed care and medical complications. As risks increase for individual patients, on aggregate the Title X population at large would experience these harms and public health would suffer.

124. The New Rule would also likely push a number of high-quality health care providers dedicated to the provision of a full package of family planning services out of Title X, because of mandated compromises to providers' professional and ethical standards, and untenable operational requirements. Title X funds would instead be made available to entities focusing on efforts that deviate from the program's core purpose. This disruption of a well-established

program would further compromise the considerable benefits to individuals and overall public health that Title X–supported providers have demonstrably delivered for decades.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on March 20, 2019 in Washington D.C.

Dr. Kathryn Kost

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among all patients receiving contraceptive care. This is compared to the number of pregnancies that would occur among a hypothetical group of similar women who do not have access to publicly funded services. This methodology relies on updated information on contraceptive failure rates for different methods, use of national survey data to construct the hypothetical cohort, and a number of adjustments that align the results with actual numbers of pregnancies occurring to women using contraceptive methods. For more detailed methodology, see: Frost JJ et al., *Contraceptive Needs and Services, 2010: Methodological Appendix,* New York: Guttmacher Institute, 2013, https://www.guttmacher.org/sites/default/files/report_downloads/contraceptive-needs-methodology_0.pdf; Frost JJ et al., Return on investment: a fuller assessment of the benefits and cost savings of the US publicly funded family planning program, *Milbank Quarterly*, 2014, 92(4):667–720, https://onlinelibrary.wiley.com/doi/epdf/10.1111/1468-0009.12080.

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(e.g., federal, state or local funding though programs such as Title X, Medicaid or the federally qualified health center program) to provide free or reduced-fee services to at least some clients. Sites must serve at least 10 contraceptive clients per year to be counted among this group. These sites are operated by a diverse range of provider agencies, including public health departments, Planned Parenthood affiliates, hospitals, federally qualified health centers and other independent organizations.

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[166] Ibid.
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DECLARATION OF SERVICE

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

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

/s/ *Emily Chiang*
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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON
AT YAKIMA

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, et al.,

Defendants.

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

Plaintiffs,

v.

ALEX M. AZAR II, et al.,

Defendants.

No. 1:19-cv-03040-SAB

DECLARATION OF CONNIE CANTRELL IN SUPPORT OF NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION'S MOTION FOR A PRELIMINARY INJUNCTION

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Connie Cantrell declares and states as follows:

1. I am the Executive Director of the Feminist Women's Health Center (FWHC), doing business as Cedar River Clinics. FWHC is a plaintiff in this action and one of 16 sub-recipients of the grant awarded to the Washington State Department of Health ("WA DOH") Family Planning Program for federally-funded Title X family planning services. Plaintiff FWHC is also a member of the National Family Planning & Reproductive Health Association ("NFPRHA"), the first named plaintiff.

2. As the Executive Director of FWHC, I am responsible for overseeing all aspects of our Title X program, in conjunction with the numerous clinical and other staff who implement this resource-intensive program for FWHC on a day-to-day basis. I provide this declaration on behalf of FWHC, based on my personal knowledge, experience, and access to our business records.

3. I have worked in the health care field for over 30 years. Prior to becoming FWHC's Executive Director in 2014, I was the Director of Operations & Quality Assurance Risk Management (QARM) for almost eight years. Before that, I served as Clinic Manager at one of FWHC's family planning clinics for almost 13 years. Prior to my 26 years at FWHC, I worked in home care for medically fragile children and at a skilled nursing facility. During my career, I have often expanded my knowledge and skillset through course work in health care

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administration, patient advocacy, reproductive health, and family planning services.

4. I am familiar with the key provisions of the new Title X regulations ("New Rule"). If the New Rule were to take effect, it would cause significant and immediate harm to FWHC, our providers, and the patients we serve, as well as to the other approximately 4 million low-income clients around the country who depend on the Title X program for access to critical, high-quality family planning care each year.

Background on FWHC

5. FWHC is a 501(c)(3), nonprofit organization, founded in Yakima in 1979 as an independent, reproductive health care provider. We are guided by the mission to ensure that individuals have local access to unbiased reproductive health services and education in order to achieve reproductive freedom and determine their own destinies.

6. FWHC operates three health center sites in Seattle, Tacoma, and Renton. Our corporate headquarters office, which handles administrative operations for all of our locations, is located in Yakima. In the 1980s, we were able to purchase our building in Yakima, which became a key piece of the financial foundation for our organization. In 2000, we purchased a second building in Tacoma. We lease property in multi-tenant, medical office space for the health

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centers in Renton and Seattle. FWHC has been certified to provide Ambulatory Office Based Health Care by the Accreditation Association for Ambulatory Health Care. All of our clinics are located on major bus routes for easy access to public transportation.

7. For 37 years, FWHC has dedicated itself to the health care needs of the communities it serves and has experienced continuous growth in its family planning program. In 2004, we were invited to join the WA DOH's Family Planning Leadership Team. In that same year we officially began doing business as Cedar River Clinics to provide greater community awareness of our three clinics as one entity. In addition to our family planning care, FWHC also provides abortion care at each of our clinics.

8. In 2012, due to patient and staff requests, we examined LGBTQ health care in our communities. We discovered that LGBTQ individuals face challenges and intolerance when seeking health care and are underserved. In 2013, we launched our LGBTQ Wellness Services, including family planning services, and our clinics have subsequently been nationally recognized as a "Leader in LGBTQ Healthcare Equality" by the Human Rights Campaign Foundation.

9. Also in 2012, we expanded our relationship with the University of Washington medical school ("UW") and were selected to participate in the creation of the UW's first Family Planning Fellowship training program. Working under

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the guidance of Dr. Sarah Prager, we continue that relationship with the UW and have created a learning model that is being used in physician and other clinical training programs nationwide. In addition, FWHC frequently hosts nursing and medical assistant students for internships.

10. Around the beginning of 2015, Washington State approached FWHC and asked us to consider applying to become part of its Title X project. As I describe further below, FWHC successfully applied to become a Title X sub-recipient in December 2016 and has received Title X funds since April 1, 2017.

11. FWHC employs a staff of 55 people, including nine employees in our corporate office in Yakima, which handles payroll, accounting, and reporting responsibilities, among others. All health services are provided by Physicians, Advanced Practice Clinicians, Registered Nurses, and Registered and Certified Medical Assistants. Our staff members' demographics represent the communities they live and work in, representing many different cultures and speaking several different languages: Spanish, Hindi, Punjabi, Romanian, Mien, Cantonese, and Mandarin.

12. In addition to other clinical needs, there is a critical need for access to testing, education, and prevention for sexually transmitted infections (STIs) in our state. According to Center for Disease Control data, from 2013 to 2017, rates of chlamydia, gonorrhea, and syphilis have all risen in Washington State.

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13. FWHC's health centers offer all FDA-approved contraceptive options, including natural family planning, and provide counseling regarding all of these options. Contraceptive supplies are stocked regularly to ensure all patients can receive the method of their choice the same day of their visit. We also provide pregnancy testing and counseling; testing, treatment, and prevention for STIs, including HIV; and treatment of minor gynecologic problems (such as vaginitis and urinary tract infections); cervical and breast cancer screenings, and basic infertility advice and screening.

14. FWHC also participates in various public education efforts, including outreach at health fairs and community events, and provides speakers to schools and organizations relating to reproductive health and family planning.

15. FWHC is an organizational NFPRHA member, along with WA DOH and the other sub-recipients of its Title X grant. I also have an individual NFPRHA membership. In addition, FWHC pays dues from its Yakima headquarters to the Abortion Care Network, the Feminist Abortion Network, and the National Abortion Federation.

Applying for Title X Funding

16. Four and a half years ago, WA DOH approached us about applying for Title X funds, as we had already been providing high-quality family planning care, including for low-income, uninsured, or underinsured patients, in conjunction

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with the Department of Health for almost 40 years. With our ongoing sources of income at that time, including some support from the WA DOH, we could not offer all the low-income patients who needed it completely free family planning care, including free access to their contraceptive method of choice.

17. Not all of FWHC's patients qualify for Medicaid or have other insurance sufficient to cover the costs of their family planning care. Therefore, prior to FWHC becoming a Title X sub-recipient, even though we were committed to doing everything we could to offer subsidized contraceptive care and help any low-income patients, FWHC's financial constraints sometimes interfered. At times, for example, we could only offer clients birth control pills instead of an intrauterine device (IUD), even though the patient requested the more effective and more costly IUD.

18. With Title X, we could ensure that each patient could choose which contraceptive method was best for them and adopt that method, rather than only having access to the method(s) they (or FWHC subsidizing their contraceptive care) could afford. In addition, the Title X funding would help us ensure that we could provide access to contraceptives and contraceptive counseling at no or reduced cost to qualifying patients right after we saw patients in our separate abortion practice, a particularly important time for offering care to those women to effectively help them achieve their goal of avoiding unintended pregnancies.

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19. For more than a year we researched Title X's requirements, weighed carefully the decision to apply, and ultimately proceeded to do so, because FWHC is committed to making affordable contraceptive care accessible to all, especially those with limited economic resources. The process of applying for Title X sub-recipient funding proved very time-consuming and challenging. We established a four-person team to put together the application, including myself and three others. We invested considerable resources into learning the structure of Title X, how to comply with all of the Title X rules and regulations, and how to establish a successful Title X-funded program.

Establishing Our Title X Program

20. We submitted a twenty-page narrative proposal and dozens of other pages of financial, clinical, and administrative information to the WA DOH in August 2016. We found out in December 2016 that our application to become a Title X sub-recipient had been successful and that we had until April 1, 2017 to be fully ready to serve in that role. We then had to train and educate our staff, help them learn the new reporting and recordkeeping requirements, and adopt new protocols. We had to change our accounting and payroll practices, and take many other steps required by Title X, all before we started receiving federal funds.

21. All existing staff had to complete the following trainings prior to providing Title X care, and we have required the same of new employees that

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FWHC hired after joining Title X: Mandated Child Abuse Reporting Law, Counseling Adolescents about Sexual Coercion and Abuse, Human Trafficking, Family Planning Basics, and Quality Contraceptive Counseling and Education. We also mandate that employees review the QFP ("Providing Quality Family Planning Services: Recommendations of CDC and Office of Population Affairs") and the Program Requirements for Title X Funded Family Planning Projects, and employees must sign acknowledgement forms that they have done so.

22. In order to keep current with best clinical practices, FWHC implemented an electronic health records (EHR) system for all of its health center sites in 2012. It was a huge and costly undertaking. FWHC uses the NextGen Enterprise Practice Management/Electronic Medical Records system; it is the only health records and practice management system FWHC has. The NextGen system holds all patient medical records, regardless of the clinic site or reason for any visits, which ensures that clinicians always have access to our patients' full medical information and history, and that their ongoing care is based on that complete record. NextGen also includes coding to describe the care provided, and for Medicaid and private billing purposes, so that we can manage our business based on the specifics of the care we provide.

23. When we joined the Title X program, FWHC established separate NextGen templates within our single EHR system for Title X and abortion

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respectively. That allows FWHC staff to chart and code Title X visits on one template, and chart and code abortion visits on the separate abortion template, but both are housed within the same NextGen system. A patient's full medical records are available to any clinician, which is the essential purpose of integrated electronic health records, just as all billing information on NextGen is available to our administrative personnel.

24. Our experience with EHR is that even small adjustments to the system are very costly and can easily run over $10,000 per change; that was the case when we had to make adjustments to facilitate client visit reporting for the federal Family Planning Annual Report ("FPAR") to WA DOH, as we ramped up our Title X program. When we first purchased and installed the EHR system, our costs were over $100,000.

25. FWHC also must track staff time for Title X family planning care and pay staff for that care out of our family planning project funds, while we pay staff for abortion-related care out of separate funds. FWHC created a new department in its payroll system to do so, and we keep ongoing records of actual staff utilization that then determine payments to staff from the two different payroll departments and budgets.

26. Establishing the Title X practices and procedures at FWHC led to more complicated administrative and record-keeping tasks for our clinical staff.

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We lost two nurse practitioners during the summer and fall of 2017 because of these new burdens and administrative rules. Those clinicians did not like the new record-keeping requirements and other administrative tasks that added to their patient care responsibilities, and wanted instead to spend more of their time providing that care.

27. It has been difficult to replace those nurse practitioners. We have since hired one full-time replacement, but otherwise are relying on coverage from temporary staffing services or extra help from our existing staff. The market for qualified non-physician clinician candidates is very tight, and we seek not only clinicians who provide quality care but also those that are willing to accommodate the current Title X record-keeping and administrative tasks in order to serve low-income clients and advance the purposes of Title X.

28. FWHC had its first administrative audit as a Title X provider in January 2018 and its first clinical site review in February 2018. Both of these reviews went well. There were no issues noted during the January 2018 fiscal monitoring review and the WA DOH observed that our "books and records are in very good order." And during the February on-site review, the Department noted that FWHC is "administered and maintained exceptionally well by qualified, caring staff" and recognized us as "true leaders in the forefront of family planning services, which include LGBTQ wellness services."

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29. As a sub-recipient of the Washington State grantee, FWHC received approximately $195,000 in federal Title X funds for fiscal year 2018, which ran from October 1, 2017, to September 30, 2018. Our Title X sub-recipient funding continues at approximately the same level this fiscal year.

30. In 2018, we provided approximately 3,100 Title X visits in our three clinics. During that year, we provided contraceptive care to approximately 2,400 Title X patients. We also provided pregnancy testing and counseling to 535 Title X patients in 2018.

31. Under the standards set by the federal government, almost all of the clients served through FWHC's Title X project qualify for free or reduced cost services based on their income level. Thirty-five percent of our Title X patients have incomes at or below 100% of the federal poverty level—which was $12,140 for a single-person household and $20,780 for a household of three in 2018. These clients are entitled to services free of charge through the Title X program. Another 59% have incomes at or below 250% of the poverty level and receive care based on a sliding scale.

32. Thirteen percent of our clients are Hispanic and 23% are Black. We serve primarily young adults; 52% of our project's clients are between 20 and 29 and an additional 33% are between 30 and 39. Approximately 3% of our project's clients are under 18.

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33. Under current Title X regulations, FWHC is able to provide contraception on the same day as an abortion service, as a separate, second consecutive appointment for the patient. Our abortion patients often cannot afford contraception and they do not wish to be pregnant. Providing both family planning care and abortion care on the same date at the same health center site saves patients the need for a second appointment, which could be difficult to accomplish for the patient or otherwise be delayed, and reduces the risk of another unintended pregnancy. The Title X contraceptive services and abortion services are provided and funded separately, based on Title X requirements, but received efficiently on the same day by the patients who desire that follow-on contraceptive counseling and access to contraceptives, including IUDs.

34. In addition, FWHC also schedules designated family planning clinic times to serve Title X patients who make appointments or walk in for family planning care. Those clinics take place at the same three health centers, but at different times than abortion care is scheduled.

The Impending Harms from the New Title X Regulations

35. The New Rule would immediately harm FWHC, our mission, our clinicians, our patients, and the communities we serve in numerous ways.

36. As described below, should the New Rule be allowed to take effect, it would force many Title X providers, including FWHC, to leave the program,

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which would prevent FWHC and others from providing the care their patients need. In Washington State, almost 90% of all Title X patients are served by organizations that provide abortion and that are committed to pregnant patients' access to full information and referrals about their options, including abortion. In addition to FWHC, as an independent abortion provider, that includes Planned Parenthood health centers. Planned Parenthood has already made clear that its clinics would not be able to continue providing care under the terms of the New Rule. If FWHC and the Washington State Planned Parenthood clinics are pushed out of Title X, no other Title X providers in the state have the capacity to suddenly care for all of these patients, which would create huge service gaps and harm an already underserved population. Moreover, all of those lost Title X provider organizations would lose the Title X funds they have relied upon, and have fewer funds to provide family planning care to those in need of such services.

37. The New Rule would have this disruptive effect, *first*, because it distorts routine, standard-of-care pregnancy counseling. The New Rule would interfere with clinician-patient communications, prevent FWHC from providing abortion referrals, and require our clinicians to compromise ethical principles and professional standards. In keeping with the current Title X regulations, our policies and procedures regarding pregnancy counseling ensure that the information provided is unbiased and factual. Our staff responds to patient cues

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and preferences, and provides information about all options unless the patient wishes otherwise: carrying the pregnancy to term, adoption or infant/foster care, and pregnancy termination. The New Rule would unreasonably limit provider speech, forbidding referral upon request for one option only, abortion, while requiring prenatal referral even when not desired.

38. This is not an approach that FWHC could use with its patients. The organization strongly believes in providing patients with unbiased information so that they have the freedom to make their own reproductive decisions and control their own destiny.

39. The New Rule singles out abortion as the only out-of-Title X program care for which FWHC would not be able to directly or indirectly refer Title X patients. At the same time, the New Rule requires us to refer to all other types of out-of-program health care in any instance where "medically necessary," as well as to provide for coordination and use of referral arrangements to help patients in any other way.

40. Again, FWHC could not agree to arbitrarily cut off our Title X patients from referrals to abortion care in this fashion. That would require our clinicians to pretend that they had no knowledge of FWHC's other practice areas, though those are separate from the Title X program, and require our staff to silently

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and misleadingly turn away patients from any referral to a type of care they themselves might provide, at FWHC but outside Title X.

41. Moreover, the New Rule not only requires that our providers withhold information, but also mandates FWHC to refer all pregnant patients for prenatal and/or social services related to carrying their pregnancy to term, even if the patient does not wish to receive that type of care. Additionally, the New Rule only allows doctors and advanced practice clinicians with a graduate level degree to conduct pregnancy counseling. This would strain FWHC resources if we were to try to comply. Pregnancy counseling is often conducted at our clinics by providers who may not have a graduate level degree but do have the relevant training and expertise. Plus, for those clinicians who are allowed to provide pregnancy counseling, the New Rule requires them to discuss carrying the pregnancy to term even if the patient is only interested in discussing abortion. These coercive, newly required steps would contradict a central aspect of Title X care to which FWHC is deeply committed—that patients freely make voluntary choices about the counseling or other care they receive.

42. *Second*, the New Rule also imposes physical facility, electronic system, and staff separation requirements that would force abortion providers like FWHC out of the Title X program because it would not be financially possible or rational to comply.

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43. FWHC, for example, could not finance the cost of installing a second, completely separate EHR system. Its cost would immediately eat up more than half of the annual federal funds we receive to provide Title X care, and make it not cost effective to be in the Title X program. Indeed, we would apparently not even be able to attempt to fund such major "infrastructure" with federal monies, but would have to find those large sums elsewhere, because the New Rule imposes new limits on funding for infrastructure versus "direct implementation" (or "direct services") purposes. Moreover, we already have a fully functional integrated system, consistent with current best practices, and creating two different ones would complicate medical care and increase risks for patients, because providers would not have integrated access to their complete medical records. FWHC could not set back our medical standards in this way.

44. It is also not feasible or logical to have to hire two completely different staffs, or obtain and equip duplicate workspaces. As I noted above, FWHC confronts difficulty in hiring qualified staff, particularly non-physician clinicians, and requiring us to end our use of staff part-time for Title X care and part-time for abortion care would harm our ability to care for Title X patients. Staff and real estate are two of our highest expenses. We have invested in our own buildings and rented other health center space in locations accessible to our Title X clients. Requiring us to undertake complete physical separation of any abortion

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care or administrative services, or activities that support access to abortion, on the one hand, and any Title X services and administration on the other, would swamp the amount of Title X funds we receive, and not make any financial sense.

45. If we were to try to comply with the New Rule, our patients may have difficulty even finding us and/or scheduling appointments because we would have to establish separate sites, phone numbers, email addresses, and websites.

46. Separation would also severely disrupt the current continuum of care that we provide our patients. If FWHC were to completely separate into duplicate physical locations, we would no longer be able to offer Title X contraceptive care right after abortion procedures. Any abortion patients seeking Title X services would instead have to make a second appointment at a different location, rather than having the ability to get an IUD or another effective contraceptive option at no or low cost under Title X immediately. As a practical matter, patients might not be able to take additional time away from work, family, and other obligations to make a separate visit anytime soon, and would again be at risk for unintended pregnancy.

47. But as described above, the separation requirements are cost prohibitive and contrary to our high standards of care, and FWHC could not undertake them, just as we could not have our staff providing ethically compromised pregnancy counseling. In addition, the New Rule also imposes even

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more elaborate record-keeping and reporting requirements that would add to the staff burden and cost of providing Title X care. The New Rule, if allowed to take effect, would push FWHC from the Title X program, and we would have to cease being a sub-recipient of funds.

48. If forced to lose our federal Title X funding, our annual budget for contraceptive and other family planning care would suddenly have a hole of approximately $200,000. We would not be able to maintain the same number of dedicated clinic hours for family planning care at our health centers, nor would we be able to serve as many patients with family planning services. We would especially not be able to accommodate as many low-income patients at low or no cost to them, particularly for expensive services such as IUD insertion.

49. If the New Rule becomes operative, and pushes FWHC from Title X, that setback would make our mission more difficult to accomplish, and reverse the benefits that Title X has provided for our patients. FWHC serves especially vulnerable populations that need Title X services, including the women we see for abortions who have already experienced an unintended pregnancy and the LGBTQ patients we have so effectively reached. FWHC's loss of federal resources would mean fewer resources to provide family planning care to these and other needy patients.

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50. FWHC dedicated significant resources over several years to applying for, learning the details of, and implementing Title X-funded and -regulated care. We expended resources to do so, because we saw the benefits for our patients and the expanded family planning care that Title X funds would allow us to provide.

51. The New Rule presents a much different equation—it tells health care organizations to adopt unethical, deceptive approaches to counseling and to implement counterproductive, prohibitively costly separation of records, staff, and facilities. The New Rule's provisions would harm, rather than help, Title X care and the many patient and public health benefits it brings. And it would drive dedicated providers such as FWHC from the Title X program. In Washington State, the Title X network would suffer a particularly devastating blow as providers serving almost 90% of all current Title X patients exit. For our state's sake, I hope that day never comes.

52. I submit this declaration to emphasize these great impending harms to FWHC, other Title X provider organizations, and our patients, and in support of a preliminary injunction against implementation of the New Rule. The current Title X regulations should remain in effect while NFPRHA, FWHC, and our co-plaintiffs argue the legal claims against the New Rule.

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I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on March 19, 2019 in Yakima, Washington.

Connie Cantrell

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DECLARATION OF SERVICE

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

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

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

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

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, et al.,

Defendants.

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

Plaintiffs,

v.

ALEX M. AZAR II, et al.,

Defendants.

No. 1:19-cv-03040-SAB

DECLARATION OF KRISTIN A. ADAMS, PH.D, IN SUPPORT OF NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION'S MOTION FOR A PRELIMINARY INJUNCTION

AMERICAN CIVIL LIBERTIES UNION
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I, Kristin A. Adams, Ph.D., declare and state as follows:

1. I am the President and CEO of the Indiana Family Health Council ("IFHC"), the sole Title X grantee in Indiana.

2. I hold a Ph.D. in Health Education and am a Certified Health Education Specialist. I have worked in public health and health education for 25 years. I have been in my current role since 2014.

3. As the President and CEO of IFHC, I am responsible for overseeing all aspects of IFHC's Title X program, including managing the program's network and distributing funds to our 11 subrecipients, which operate 28 Title X health clinic sites.

4. I provide this declaration on behalf of IFHC and its Title X project to describe the harms that will result if the regulations recently finalized by the Department of Health and Human Services ("HHS") and published at 84 Fed. Reg. 7714 (Mar. 4, 2019) ("New Rule") are allowed to take effect. This declaration is based on my personal knowledge and experience.

5. As the facts set forth below demonstrate, that New Rule will drastically interfere with IFHC's mission, the functioning of our Title X project, and the ability of low-income Indiana residents to access Title X family planning care. It will throw into disarray our network of experienced family planning providers that IFHC has built up through decades. The New Rule will create huge gaps in the provision of Title X services and leaves no viable means for replacing ousted providers or maintaining quality care for many thousands of Title X patients.

Background on IFHC

6. IFHC is a 501(c)(3) non-profit organization. The organization was founded in May 1975 with the specific purpose of taking over as the Title X grantee and grant administrator for the state. Indiana University had previously been the Title X grantee here, but as the family planning project grew, stakeholders decided that the Title X project would function better with a dedicated grant administrator. "Family planning councils" like IFHC were founded in numerous states as the Title X program grew. They remain Title X grantees in many places.

7. IFHC's mission is to "promote[] and facilitate[] family planning and reproductive health services for those in need."

8. IFHC is a member of the National Family Planning & Reproductive Health Association ("NFPRHA"). We pay dues to NFPRHA each year to secure membership not only for IFHC, but also for each of our Title X subrecipients. Because of our NFPRHA membership, IFHC and its staff, and our subrecipients and their staffs, can access important training and compliance resources, keep up to date on requirements and best practices for Title X projects, attend NFPRHA conferences to learn from and share with other Title X providers, and benefit from other NFPRHA services. In many ways, NFPRHA functions as a "professional trade association" for Title X grantees and subrecipients.

9. The Title X project that we oversee and administer accounts for approximately 95% of IFHC's own organizational budget, and roughly the same percentage of our IFHC staff's time. IFHC employs several full-time staff members to administer and oversee the Title X project, including a Chief

Financial/Chief Operating Officer, a Performance and Evaluation Director, an Accountant, a Clinical Program Manager, an Advanced Practice Nurse, and a contracted Medical Director.

10. IFHC is located in a single building in Indianapolis. All of IFHC's operations are there. IFHC does not currently provide direct family planning services, but it has in the past and may again in the future. We selected this location because it is accessible to low-income Title X patients. The building is in downtown Indianapolis, across from the courthouse, with a public bus stop directly outside. We currently have 4 years remaining on a long-term lease.

IFHC's Title X Project for the State of Indiana

11. IFHC's Title X project has a budget of over $9,000,000 each year. IFHC's Title X federal grant has, for the last several years, totaled just over $5,000,000. Other government monies include Medicaid reimbursement and other funds from the State of Indiana, some private insurance payments, a small amount of patient fees, and some in-kind contributions. These sources make up the difference between the Title X grant amount and the overall budget of IFHC's Title X project.

12. The Title X grant is essential to operate IFHC's family planning project. It funds necessary training, administrative, compliance, reporting, infrastructure (including physical space, electronic systems, and equipment), clinical oversight, and patient care expenses that the project and its providers could not otherwise afford. Medicaid, for example, does not come close to reimbursing the actual costs of a patient's family planning care in Indiana. The Title X grant

also allows all of our subrecipients to take advantage of a program that enables them to purchase drugs and other contraceptive supplies for much less than those supplies would otherwise cost—often at 1/3 the price.

13. In addition, Title X is essential for enforcing the family planning practice standards required by its governing laws, regulations, and HHS guidance, as well as the national clinical standards set out in *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs* ("QFP"). Title X ensures that low-income patients receive family planning services without any financial or other barriers. And the program's uniform rules and quality standards enable us to guarantee accessible, state-of-the-art care by all subrecipients and clinicians in our project.

14. As the grantee for and administrator of Indiana's Title X project, IFHC applies for the federal grant, solicits and secures subrecipients, maximizes the project's reach to low-income patients, plans and balances the project's budget, and distributes and documents its use of funds. IFHC also creates and distributes to subrecipients operation manuals and protocols for every aspect of the Title X grant administration and clinical practice, including compliance with the QFP. IFHC conducts trainings, answers questions, and provides any help subrecipients need if they face unforeseen obstacles (such as broken equipment, building code compliance, or other regulatory requirements beyond Title X). To ensure program integrity, we also conduct audits, site reviews, and other oversight functions. IFHC also oversees patient visit reporting for the federal "Family Planning Annual Report" ("FPAR"), and other Title X reporting requirements.

15. As this list makes clear, IFHC is a jack-of-all-trades. I am sure that I have left off some IFHC duties and responsibilities. Our financial, medical, and administrative staff work tirelessly and do whatever they can to create and maintain the best possible Title X project and reach as many low-income patients as we can.

16. IFHC's Title X project includes 11 subrecipients, operating 28 different service sites. Our subrecipients include a Planned Parenthood affiliate, two other non-profit family planning specialist organizations, a large urban hospital system, a small rural hospital, a county health department, two community action centers, one university-operated clinic, and two federally qualified health centers ("FQHCs") that operate standalone Title X clinics.

17. IFHC has built up this steady network of providers, spread across 21 Indiana counties, through concerted effort over many years. We have worked hard to construct a network that reaches low-income patients where they need family planning care.

18. Twelve of our Title X project's health center sites are located in Indiana counties where there is no other health care center offering safety-net care of *any* kind. There are no FQHCs or community health centers in those counties. Low-income patients in those counties can look only to our Title X sites for family planning health care—and as an entry point into the health care system.

19. IFHC continues to try to expand our Title X project's network, but it is very difficult to recruit new health care organizations. The challenge in enlisting additional providers and expanding project sites arises from Title X's

administrative burdens and added costs to medical care—from reporting, record-keeping, and oversight, to required free services and necessary staff training and monitoring. Plus, Indiana, like many parts of the country, faces a general shortage of health care providers.

20. IFHC recently issued a Request for Applications ("RFA") seeking applications for new Title X providers to open sites in any or all of ten medically-underserved Indiana counties. Even though there are FQHCs in or near a few of those counties, not a single one stepped up to apply to be a Title X provider. IFHC received only two applications: one from an existing subrecipient hoping to expand geographically, and another from a new non-profit organization attempting to help address Indiana's care shortage.

21. Our tremendous difficulty recruiting new providers to Title X does not arise from any reluctance of health care professionals to follow standards of care (including, for example, providing patient-centered counseling and appropriate referrals)—contrary to what HHS seems to suggest in the New Rule. In my decades of experience in family planning and health education, I have found that virtually all health care professionals strive to meet those standards and follow principles of medical ethics.

22. The difficulty in finding new Title X providers comes, instead, from financial constraints, the shortage of medical personnel, and the practical challenges of running a Title X subrecipient organization and service sites. These facts underscore why IFHC is so concerned about network disruption and other harms that the New Rule will cause for our current providers.

23. These challenges notwithstanding, IFHC's Title X project has been a public health success story. In 2017, the 28 health center sites in the IFHC Title X network provided services to 23,887 patients. Ninety-four percent of our patients had incomes at or below 250% of the federal poverty level; 62% had incomes at the federal poverty level or below. Fifty-three percent of our patients had no public or private insurance coverage. Among patients at risk of unintended pregnancy, 85% departed their family planning service visits having chosen a "moderately effective" or "most effective" contraceptive method. Our Title X sites conducted 8,778 HIV tests and performed 17,160 chlamydia/gonorrhea tests. In 2016, IFHC's clinics identified 6.1% of all chlamydia cases and 5% of all gonorrhea cases in Indiana.

24. The family planning care provided by the IFHC Title X network has played a pivotal role in helping patients avoid unintended pregnancies, detect and treat infections, learn and better understand their medical options (including when they unexpectedly find themselves pregnant), and take control of their own care.

25. For example, the teen pregnancy rate in Indiana declined 53% between 1988 and 2013. IFHC's Title X providers' education, counseling, and contraceptive care have contributed significantly to teenagers' avoiding unintended pregnancies. Access to family planning care not only allows our patients to better control their reproductive lives, but also saves public dollars. In 2015 alone, for example, the declining teen pregnancy and birth rates in Indiana saved $58 million in public expenses.

26. Even with all these advances, the need for family planning health care remains critically high. In 2016, for example, there were over 135,000 women in Indiana from age 20 to 44 whose income fell below the federal poverty level. IFHC structures its project as cost-effectively as possible, but Title X care remains strapped for funds, struggling to serve our existing patients and also to attempt to expand access to care in the state.

The Harms That the New Title X Rule Causes

27. IFHC exists for the sole purpose of facilitating Title X care in Indiana. Because that is our mission, IFHC will make every effort to stay in the program despite the many patient and provider harms that the New Rule will cause. The fate of our Title X project depends, however, on both the continued participation of our subrecipients and medical professionals, and IFHC's somehow surviving the New Rule's fundamental alterations to grant criteria.

28. If the New Rule takes effect, it will immediately and seriously destabilize our network of subrecipients and clinicians, and subject patients at the project's remaining service sites to pregnancy counseling that does not meet national standards. The New Rule's impacts will continue from there—destroying the provider network and access to quality family planning care that IFHC has worked so hard to build for Indiana. I fear our organization will suffer irreparable reputational damage as a result of these fundamental disruptions to our network. I do not know how we could rebound from this.

A. New Mandatory Limits on Pregnancy Counseling Will Cause Immediate Provider Exits

29. The New Rule's constraints on pregnancy counseling include its: (1) bar on abortion referrals; (2) mandatory prenatal referral for all patients, regardless of their wishes; and (3) prohibition on providers conducting patient-centered pregnancy counseling—under the New Rule, if the provider even mentions abortion, she must also discuss, regardless of patients' wishes, continuing the pregnancy to term and/or adoption.

30. Beyond that, the New Rule abandons any semblance of Title X's longstanding requirement that all pregnancy counseling be nondirective. The New Rule gives objecting providers free reign to omit abortion information from pregnancy counseling altogether, even when patients specifically request information about abortion. These objecting providers can engage in coercive counseling exclusively about protecting the health of the unborn child, even against patients' wishes and over their objections.

31. These aspects of the New Rule violate national clinical standards of care and medical ethics (established by the American College of Obstetricians and Gynecologists ("ACOG") and other medical associations) and contravene IFHC's medical standards and protocols.

32. The New Rule requires us to implement the ban on abortion referrals by May 3, 2019 and the remainder of these new counseling restrictions shortly thereafter (by July 2, 2019).

33. IFHC knows that the New Rule's ban on abortion referrals will immediately force one of its two largest subrecipients to leave the Title X program. We also know that this aspect of the New Rule will jeopardize the continued participation of IFHC's other subrecipients, as well as the individual clinicians who comprise their staff.

34. Planned Parenthood of Indiana and Kentucky ("PPINK") is one of IFHC's two largest providers; it operates five locations in the IFHC Title X project and serves over 5,000 patients annually with Title X care. Planned Parenthood advised HHS during the comment period that *all* of its affiliates "would be forced to discontinue their participation in Title X" if the New Rule's ban on abortion referrals took effect. *See* Planned Parenthood Federation of America Comments at 15.

35. Thus, on May 3, 2019, one of our largest providers and its 5 sites will have to withdraw from IFHC's network. Three of those PPINK Title X service sites are the only safety net health care providers in the counties in which they operate.

36. All of my interactions with IFHC's subrecipients and my experience in overseeing their high-quality family planning programs and clinical work lead me to believe that PPINK's will not be the only departure. The New Rule will force each individual clinician and subrecipient to decide between two harmful choices: (1) subject any pregnant Title X patient to substandard pregnancy counseling, withhold information, and refuse to respond professionally to questions

about or requests for abortion referral; or (2) exit the Title X program and cease providing free and reduced-cost care to low-income patients who depend on it.

37. For example, another one of our subrecipients, Indiana University Fort Wayne ("IUFW"), operates the Lafayette Street Family Health Clinic as an initiative of the College of Health and Human Services. The college includes a leading nursing school and other programs that teach and train future health care professionals. Management, administrative staff, and student instruction overlap between the College and the Lafayette Street location. IUFW will likely be unable to carry out the New Rule's compromised pregnancy counseling because it cannot, as a teaching institution, conduct medical instruction through the provision of patient care that contravenes medical ethics and national standards of care.

38. IFHC's Medical Director—who is board-certified in obstetrics and gynecology and holds a doctorate in epidemiology—is a prominent academic, researcher, and practicing clinician outside of his Title X responsibilities. He will face a similar dilemma because he provides clinical instruction in his other roles and currently works with IFHC to ensure our compliance with governing standards of care across our network. I responsibly fear we will lose our Medical Director if the New Rule takes effect. How could he suddenly work to ensure compliance with substandard and unethical care requirements?

39. At each and every subrecipient site, medical directors (who provide clinical oversight), physicians, and clinicians will face this dilemma. I am gravely concerned that we will lose many of them.

40. IFHC's and its subrecipients' medical directors get paid a very small amount by the Title X project compared to their other professional commitments, and they assist the project because of their commitment to its purpose. But if participating in Title X suddenly requires these medical professionals to set aside ethical principles and sign off on misleading and directive pregnancy counseling, I know that we will see defections. For these same reasons, finding any suitable replacements will be extremely difficult.

41. Meanwhile, the New Rule will mandate that each pregnant patient receives substandard counseling and quality of care. Pregnant patients will be unable to obtain any clear information about or a referral for abortion care, even if they have already decided to terminate the pregnancy. The New Rule will cause those patients delay and confusion, and it will subject them to dignitary harm in the form of latent or obvious disapproval of their choices.

42. If that is the kind of care that patients will receive at IFHC-participating health center sites, I fear that our reputation—as an organization whose purpose is facilitating the provision of high-quality care to low-income patients—will be tarnished. I also worry that the New Rule will cause us to lose patients and stymie our ongoing outreach efforts. How will patients come to trust our health center sites again?

B. Unworkable Separation Provisions Will Lead to More Departures

43. The new pregnancy counseling requirements are not the only parts of the New Rule that will make retaining subrecipients and clinicians extremely

difficult. Each of IFHC's subrecipients and service sites will also have to contend with the New Rule's excessive separation requirements and other "compliance" measures, including new limitations on infrastructure spending. These aspects of the New Rule will interfere with subrecipients' missions and may render their continued participation in Title X practically impossible.

44. For example, the other one of our two largest subrecipient providers is the Eskenazi Health System, a division of the Health and Hospital Corporation of Marion County. Eskenazi operates 5 Title X sites and serves over 5,000 Title X patients per year. Eskenazi also partners with Indiana University School of Medicine to operate its major teaching hospital. It is one of the largest public health systems in the country.

45. The New Rule's fundamental changes to pregnancy counseling could well cause Eskenazi to exit the Title X program. But if those changes do not, several other aspects of the New Rule will likely make it impossible for Eskenazi to remain in the program.

46. The New Rule's separation requirements will likely make compliance impossible, given Eskenazi's integrated, state-of-the-art health care system. Eskenazi operates an ambulatory care center that provides abortions, and its health facilities are used in medical and residency training programs, including for abortion care. Eskenazi also houses a full-service obstetrics and gynecology ("ob/gyn") practice, which routinely counsels pregnant women about all of their options—including information about and referrals for abortion care. And Eskenazi has a single, integrated health record system throughout all of its medical

practices, including the Title X health centers, ob/gyn practices, and units offering abortion care. There are also shared administrative and communication functions at Eskenazi, like its email and accounting systems, that cover these practice areas.

47. Eskenazi is one of our longest-standing and most dedicated Title X providers. But the New Rule's requirement that Title X projects have no physical, staff, or systems overlap with abortion care or abortion referrals will likely make it impossible for Eskenazi to remain in the Title X program.

48. Eskenazi's forced departure will cause IFHC to lose its other major subrecipient provider (in addition to PPINK, described above). These two losses alone will hobble our Title X project and be a major setback to serving Indiana patients. IFHC's reputation and support in the community will suffer, and our mission will be greatly compromised.

49. But the New Rule threatens to do even more. Its separation requirements will also interfere with the ability of our two FQHC subrecipients, HealthNet and OpenDoor, to continue providing Title X care.

50. HealthNet operates a Title X project service site within the same physical facility as a full-service health clinic with an ob/gyn practice. The Title X project and ob/gyn practice share not only physical space, but also systems and some personnel. Open Door operates a separate Title X service site, but it shares systems and some personnel, including financial and communications staff, with the full-service health clinic (including an ob/gyn practice). The New Rule thus leaves each provider unable to continue with this care.

51. Even if each of these FQHCs attempted to separate completely and set up different physical spaces, with different staff and different systems, to comply with the New Rule, their expenditures would quickly outstrip the amount of Title X funds these entities receive annually. As a result, it makes no financial sense for them to continue in the program. (Strangely, the New Rule's separation requirements would push these FQHCs to attempt to separate from the Title X projects, at the same time as other aspects of the New Rule, discussed below, seek more Title X projects that are co-located with comprehensive primary care.)

52. I am not attempting to catalogue all aspects of the New Rule that will push existing provider entities and clinicians from the IFHC program. But the facts above show that the rule will trigger immediate and ongoing difficulties in maintaining IFHC's network of provider entities.

53. As a grantee, IFHC is supposed to get HHS's permission before *any* service sites in our Title X project close, but HHS's own regulation will trigger widespread disruption to our subrecipients and will end numerous Title X service sites. It is therefore unclear to me how IFHC can remain in compliance with its grant terms if the New Rule ever takes effect.

54. HHS is requiring entities like IFHC to overhaul all of their protocols, retrain subrecipients and staff, and comply with onerous requirements. But it does not explain how we are supposed to undertake this effort while the New Rule pushes our project's clinicians and subrecipients from the program. Title X networks across the country will be in disarray, with no time to find replacement

providers, get approval from HHS to shutter sites, or advise patients how their family planning access will be interrupted.

55. This chaos will not only complicate our Title X project's service delivery immensely, but also jeopardize IFHC's ongoing receipt of Title X funds and those funding amounts. As mentioned above, HHS could attempt to end our grant for losing numerous service sites in our network without pre-approval.

56. In addition, the New Rule forbids IFHC and other grantees from drawing further from their federal *current* grant without representing to HHS—and demonstrating with documentary evidence upon the Secretary's request—strict compliance throughout the project with each of the new pregnancy counseling, infrastructure, separation, and abortion-related activity restrictions as those take effect. *See* Section 59.13-.16, 59.18.

57. But providing that assurance will be practically impossible. For example, Section 59.18's new Title X funding limitations do not set clear guidelines for IFHC or other grantees. The New Rule does not clarify how a grantee like IFHC can effectuate the program's new focus on "direct implementation," or its novel requirement that a majority of grant funds "provide direct services to clients." How is an existing grantee like IFHC supposed to understand how these constraints impact our current budgets and grants? For example, our Title X project budget—like that of many grantees—is divided into categories like personnel costs, electronic health records fees (which we handle for our small subrecipients), contraceptives and HIV testing kits (which we purchase in bulk for our providers), rent, and others. Because it is entirely unclear how

Section 59.18's new requirements map onto our existing budget, I am concerned that this new provision alone will jeopardize IFHC's existing grant.

58. If our Title X funds end or are drastically diminished, IFHC will be in danger of ruin. Our entire mission and reputation for service to the community will be at risk, and we may have to close our doors.

59. The Title X program is the central piece of what we do. Without our Title X role, IFHC would not be able to continue to effectively advance our mission. We would have to immediately cut staff and, at minimum, would need to redirect the organization's future efforts.

C. New Referral Rules Will Harm Title X Referral Relationships and Limit Care Networks

60. The major disruption and difficulties discussed above are not the only harms the New Rule will trigger. The New Rule also demands, under Section 59.5(a)(12), that Title X service providers "should offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity, to the Title X site."

61. IFHC and its Title X project participants already have extensive relationships with primary care providers, and can refer any Title X patient who needs primary health care to a useful resource. But those referrals are not necessarily "in close physical proximity" to the Title X sites, as this New Rule mandates.

62. For example, providers at our Title X sites in 12 counties can point to no other safety net primary care provider that might treat our Title X patients

anywhere in the county. Indeed, we have often worked with our subrecipients to locate our Title X project sites in the middle of so-called "donut" county arrays, so that the Title X site is in the middle of an area drastically underserved by other resources, including primary care.

63. Section 59.5(a)(12), however, would render non-compliant these Title X sites—the only health care resources anywhere nearby. If IFHC may no longer use such locations, it will harm our patients and their communities by contracting the services IFHC is able to offer. Moreover, our subrecipients could not afford to build and staff primary care clinics just to maintain these Title X service sites.

D. New Application and Grant-Making Rules Will Jeopardize IFHC's Role in Title X and Cause IFHC to Adopt the Most Extreme Interpretations of the New Rule

64. The New Rule also introduces a new eligibility standard for Title X grant applications. This standard will require IFHC to read the New Rule in the most restrictive way possible, in order to get our Title X application considered.

65. The New Rule's Section 59.7(b) states that HHS will refuse to consider "any grant applications that do not clearly address how the proposal will satisfy the requirements" of the New Rule. To that end, the New Rule requires the applicant to "describe its plans for affirmative compliance with each requirement" of every single Title X regulation. The HHS Secretary has complete, unfettered authority to deem an application noncompliant and not even consider it for a grant. The New Rule provides no recourse for entities thus summarily deemed noncompliant. This is deeply concerning to IFHC—after all, our sole mission is

to operate Indiana's Title X project.

66. A number of important parts of the New Rule are vague and provide uncertain targets for explaining IFHC's affirmative compliance with them. Those include Sections 59.5(a)(12), (13), 59.15, 59.16, and 59.18, among others. To preserve any chance to even be considered for a Title X grant, IFHC will have to interpret these provisions as restrictively as possible (and require all of our subrecipients to do the same), to describe affirmative compliance in a way that has the best chance of clearing HHS's opaque eligibility threshold. Unless we do so, the merits of our application may never even reach consideration for a grant.

67. Attempting to implement the most extreme possible interpretation of the New Rule would mean, for example: decreasing important infrastructure spending in favor of what might be seen as more "direct implementation" (Section 59.18); closing isolated service sites that cannot show they "provide seamless care" with primary care providers in close proximity (Section 59.5(a)(12)); forbidding any referrals for medical care or social services of any kind that could be interpreted as an "indirect means of encouraging abortion" (Section 59.14(c)); requiring all sites to remove any material merely referencing abortion in any way (Section 59.15(d)); ending IFHC's payment of dues to NFPRHA or other organizations that support the continued availability of abortion care, and forbidding subrecipients from paying any such dues from the same location (or with the same staff) as their Title X work (Section 59.16).

68. All of these steps would undermine the standards of patient care, reduce the success of the IFHC Title X network, harm IFHC's mission, damage

IFHC's reputation, and contravene the central aim of the Title X program. Nevertheless, the New Rule renders these kinds of changes necessary so that IFHC can remain in the program.

69. Even if IFHC somehow manages to preserve its current grant and reaches competitive evaluation for its next application, we will face additional unclear provisions of the New Rule. The grant-making criteria in Section 59.7(c) are vague and appear internally inconsistent. As a result, it will be extremely difficult to write responsive grant applications, highlighting IFHC's longstanding, successful program.

70. The new threshold eligibility requirement and the confusing criteria of Section 59.7 will continue to disrupt the Title X network of providers, limit providers' effectiveness, and further expand the New Rule's harms.

E. Once These Rapid Harms Start Unfolding, They Will Spread Beyond IFHC

71. My greatest concern is for Indiana's Title X patients, both current and future. The New Rule seriously undermines the standards and ethics of care, compromises the number of accessible health center sites, and shrinks other critical resources. At a time when IFHC and other Title X grantees like it around the country are working hard to address family planning provider shortages and ongoing public health crises (like HIV, the opioid epidemic, and the increasing need for contraceptive services), the New Rule will disable the Title X program.

72. The New Rule's impact will expose more Title X patients and their partners to STIs, increase the rate of unintended pregnancy, and delay cancer care.

It will increase public outlays for medical costs and set public health back tremendously.

73. Once the number of Title X health centers decreases, their staffs disperse, and their patients are left to fend for themselves, it will be nearly impossible to recreate current levels of care. Individual and public health harms—and the accompanying harm to IFHC's mission, reputation, and funding—will be irreparable.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on 3/20/19 in Indianapolis, Indiana.

Kristin A. Adams, Ph.D.

DECLARATION OF SERVICE

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

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

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

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

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, et al.,

Defendants.

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

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ALEX M. AZAR II, et al.,

Defendants.

No. 1:19-cv-03040-SAB

DECLARATION OF J. ELISABETH KRUSE, M.S., C.N.M., A.R.N.P., IN SUPPORT OF NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION'S MOTION FOR A PRELIMINARY INJUNCTION

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J. Elisabeth Kruse, M.S., C.N.M., A.R.N.P., declares and states as follows:

1. I am an Advanced Registered Nurse Practitioner (ARNP) and Certified Nurse Midwife (CNM). I serve as the Lead Clinician for Sexual and Reproductive Health and Family Planning at the Public Health Department for Seattle and King County ("Public Health–Seattle & King County"). I submit this declaration in support of Plaintiffs' motion for a preliminary injunction.

2. I came to Title X family planning work because of its focus on caring for underserved and low-income patients with limited access to health care. I am deeply committed to making sure that all people, regardless of their income level, can determine their own reproductive destiny. I fear that the new Title X regulations ("New Rule") will cause serious harm to Title X patients, Title X programs (including those of local government entities like Public Health–Seattle & King County), and Title X clinicians, unless this Court grants a preliminary injunction. The New Rule will unreasonably limit the ability of non-physician clinicians to provide care to Title X patients. It will also eliminate non-directive pregnancy counseling and referrals to appropriate providers, which is contrary to medical ethics and national standards of care (including those issued by the federal government).

3. Since 2012, I have worked full-time at Public Health–Seattle & King County. I currently work exclusively in the County's Title X program. In my capacity as Lead Clinician for the Family Planning Program, I not only provide direct care to patients, but also participate in hiring, develop and run new clinician orientation and trainings for all licensed Title X staff, and conduct cross-program

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trainings for the County's Public Health Nurses. I also participate in quality management and develop and maintain clinical guidance for the Family Planning Program.

4. I have been a nurse since 1982. I hold a nursing degree from Oregon Health Sciences University and a Master's degree in Nurse-Midwifery from the Intercampus Graduate Studies Program of the University of California, San Francisco, and the University of California, San Diego. I have been on staff with the midwifery practice at Virginia Mason Hospital in Seattle, and have provided comprehensive family planning and sexual and reproductive health care in other settings in Seattle (Aradia Women's Health Center and Aurora Medical Services). I have extensive experience with preventive and screening exams; diagnosis and treatment of common gynecological disorders; sexually transmitted infections (STI) risk-reduction counseling, diagnosis and treatment; contraceptive counseling and management (including intrauterine and subcutaneous device insertion and removal); and early pregnancy diagnosis, counseling, and management. In these settings, I have also been involved in the training and supervision of medical assistants and in the development of patient education and staff training materials. I have been on the faculty of numerous professional conferences, and co-authored the chapter on quality care in the textbook *Management of Abnormal and Unintended Pregnancy* (Wiley-Blackwell, 2009).

5. At Public Health–Seattle & King County, in my capacity as a clinical ARNP, I personally conduct between 15 - 45 appointments per week with adolescent and adult Title X patients. This care includes counseling for and

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provision of all outpatient family planning methods; pregnancy testing and counseling; STI prevention, screening, diagnosis and management; and well-patient gynecological care and cancer screenings.

6. Ninety-eight percent of the patients we see in Public Health–Seattle & King County's Title X project are at or below 250% of the federal poverty line. We also provide care to a substantial number of homeless individuals. Many of our patients are refugees or immigrants; in fact, 27% of our population has limited English ability or requires an interpreter. We also serve a high number of adolescent patients, both independently and through established connections with local schools and our school-based clinics. Because of the demographics of our patient population, we are often patients' only professional health care.

7. Many of our patients return time and again—some are successive generations, or family members of other patients. Our patients come to us specifically because they trust us with highly sensitive medical concerns. We work hard to earn that trust, and to keep it, by providing a safe, nonjudgmental space for our patients on an ongoing basis.

8. Many of our patients have a history of adverse childhood experiences and other trauma, including sexual abuse, assault, and coercion. Throughout Public Health–Seattle & King County, employees at all levels are deeply committed to fostering a protective and safe environment for the patients we see who have experienced highly stressful, emotionally painful, and potentially traumatic circumstances.

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9. In my capacity as Lead Clinician for our Title X project, I maintain our Clinical Practice Guidelines for Quality Family Planning Services (CPGs), updating them to ensure that they are evidence-based, consistent with nationally recognized best practices, and reflective of standards of care and medical ethics—including those promulgated by the Institute of Medicine (IOM) and the American College of Obstetricians and Gynecologists (ACOG), among others.

10. The Department of Health and Human Services published a 2014 document, setting national family planning standards, entitled "Providing Quality Family Planning Services: Recommendations of CDC and the US Office of Population Affairs" (QFP). The QFP's Recommendations serve as a foundational document governing Public-Health Seattle & King County's CPGs.

11. Complying with medical ethics and standards of care is a baseline expectation for all medical and nursing professionals. To that end, the County's CPGs provide that "clinicians are responsible for practicing in accordance with recognized national guidelines for sexual health . . . as described in [the QFP]."

12. The code of ethics for the American College of Nurse-Midwives (ACNM) states that midwives in all aspects of their practice will "develop a partnership with the woman, in which each shares relevant information that leads to informed decision-making" and will "promote just distribution of resources and equity in access to quality health services."[i]

13. Similarly, the code of ethics for the American Nursing Association (ANA) provides that "[p]atients have the moral and legal right to . . . be given accurate, complete, and understandable information in a manner that facilitates an

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informed decision."[ii] And it further states that patients "have the right to accept, refuse, or terminate treatment without deceit, undue influence, duress, coercion, or prejudice."[iii]

14. Additionally, pregnancy counseling training materials from the Family Planning National Training Center, which works in collaboration with OPA to address the needs of Title X providers, state that Title X "[s]taff providing counseling must demonstrate a consistent ability to discuss all options and resources in an unbiased, neutral and supportive manner."[iv] The materials remind the provider, "You do need to be able to clearly separate your personal values from your professional role."

15. As Lead Clinician for the Family Planning Program, I have a role in ensuring that all of our ARNPs and Certified Medical Assistants (CMAs) provide a standard of quality care consistent with the QFP and our CPGs. We have eight ARNPs on staff and an additional four ARNPs on-call to provide backup as needed. There are seven CMAs. Approximately half of our staff has been with the program for at least 10 years.

16. Both the QFP and our CPGs emphasize the importance of informed decision-making. The goal in family planning care—indeed, a principle across all health care—is to give patients the information they need to make their own decisions, to obtain the care and follow-up they need, and to facilitate that process and that care. Sharing accurate information in a useful and approachable manner is especially critical for the population Title X serves.

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17. The New Rule prohibits any referral for abortion, even where specifically requested by a patient. Not only that, but this New Rule also requires that we actively provide counseling information about prenatal care and/or adoption, even if the patient has already decided that she does not want to continue with the pregnancy and seeks only information about abortion. The *most* we can do for a patient who wants an abortion or information about where to obtain one is to provide the patient a list of "comprehensive primary health care providers," some of which, but not the majority of which, may provide abortion. *See* New Rule Section 59.14(b)(1)(ii). But we are not even allowed to identify for the patient which providers actually offer the services she seeks.

18. Even more coercive, the New Rule requires that we give all pregnant patients a referral for "medically necessary prenatal care." *See* New Rule Section 59.14(b)(1). But, of course, such care is *not* medically necessary for someone who wishes to terminate her pregnancy.

19. Selectively withholding certain information and referrals, while at the same time forcing other information and care upon our patients is deceptive and contradicts ethical standards. This approach is completely inappropriate for any patient interaction. It would also present particular challenges to Title X patients.

20. In Public Health–Seattle & King County in general, and in our Title X program in particular, we see a very diverse range of patients. Consistent with national, state, and county standards of care, we endeavor to establish a trusting, open, and nonjudgmental patient-provider relationship with everyone who comes through our doors.

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21. We encourage our patients to lead the conversation. We ask all of our patients seeking family planning care whether or not they would like to be pregnant or become a parent anytime in the next year, so that we can provide the type of counseling that will be helpful to them. Some may say "yes"; others, "no"; some indicate that they are "not sure"; and others say they are "fine either way."

22. When a patient has indicated that she would like to be pregnant, and she then receives a positive pregnancy test result, the ensuing appointment is almost always a happy one. Under these circumstances, pregnancy counseling consists of providing support, talking through next steps, offering guidance on immediate self-care, and supplying written resources and referrals for accessing medical insurance coverage, maternity support services, and high-quality prenatal care.

23. For a patient who has indicated that she either does not want to be pregnant at all, or at least not at the time, a positive pregnancy test result will mean something very different. Patients in such circumstances often express disbelief and distress—sometimes extreme distress—at the test result. They may say, "This can't be true, this can't be happening," or, "I can't do this right now, I just can't." Patients often cry. They sometimes describe feeling trapped or desperate by the news that they are pregnant when the circumstances of their lives are such that they cannot imagine continuing a pregnancy. In these circumstances, pregnancy counseling *also* consists of providing support, talking through next steps, offering guidance on immediate self-care, and supplying written resources and referrals for accessing medical insurance coverage and other support services.

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24. When a patient is upset about being pregnant, pregnancy counseling is very delicate. Accordingly, the QFP, our CPGs, and opinions and guidance by ACOG, ACNM and other professional organizations provide for neutral, non-directive counseling.

25. As described in our CPGs, our staff will "share both the [pregnancy] test results and accurate information about the available options for pregnancy; specifically, either abortion or continuation/childbirth; with further options for either relinquishing for foster care/adoption, or parenting." The QFP similarly instructs that Title X providers give "appropriate referrals" to patients in the course of "[c]lient-centered" pregnancy counseling.[v]

26. Above all, it is most important to let patients guide the conversation with reactions and questions. Patients frequently need to process the news and talk through their options with a trained medical professional who has complete information about all options. It is essential that counseling remain nondirective and nonjudgmental, and center on communicating to uncertain or distressed patients that they are not trapped. They have choices.

27. That's why, consistent with my training and experience as an ARNP, I always encourage patients to express their thoughts and feelings—positive, negative, or ambivalent. I offer support by affirming the validity of patients' feelings, and when they indicate they are ready, I offer to give further information about any and all options in which they express interest.

28. If a patient with a positive pregnancy test says she does not want to be pregnant, I first explain that she does not have to remain pregnant. Abortion is a

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safe, locally accessible, and legal option. I assure her that she will have support and resources available no matter what she decides. I ask her about people in her life who will support her emotionally, regardless of what she decides. I then ask her which options she'd like to hear more about. If she's interested in more information about abortion (regarding the types of abortion available, or other anticipatory guidance), we'll go into more depth about pros and cons, risks and benefits of different methods, and any other information. If she affirms that she wants to be referred for abortion care, I provide that. If she wants to talk about options for continuing the pregnancy, we'll discuss the pros and cons of that option (also safe, locally accessible, and legal), along with available resources and support (medical coverage, maternity support services, housing and food programs, and any other relevant information). If the patient is interested, we can discuss the options of temporary foster placement or adoption and arrange for a referral for prenatal care or other appropriate services.

29. The New Rule bans that basic level of care by forbidding providers from providing referrals for abortion or clearly indicating where a patient can obtain abortion care. What's more, it requires providers to force information about, discussion of, and referral for prenatal care on patients *regardless* of those patients' wishes. I would have to provide that information even if the patient asked me to stop or said she didn't want to hear anymore because it was upsetting her. I would have to continue even through her tears. And I would need to help facilitate an appointment for prenatal care that is a direct affront to what she has expressed

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she wants and needs. As I see it, this would constitute verbal and emotional abuse; it would be the antithesis of trauma-informed care.

30. Providing an inappropriate and unwanted referral is unprofessional, unethical, and harmful. It risks misleading patients about the kind of care they will receive from the follow-up provider, and misleading the referral providers as to the type of service that a patient needs or wants. For example, staff (and other patients) at prenatal care clinics may quite logically assume that any new patient is there because she wishes to continue her pregnancy. When she is forced to correct their assumptions, she becomes vulnerable to the potential disapproval of strangers who cannot know her situation.

31. If my patients were to be subjected to the experience of forced counseling, they would very likely interpret the barrage of information about continuing the pregnancy, as well as the referral for prenatal care, as judgment: clearly, they would assume that their provider thinks they should or must continue the pregnancy. This will never happen in my exam room. If my words and actions were to cause a patient to think I was judging her, or that she was somehow wrong, or bad, or immoral, I would be contravening my own professional ethics and standards of care.

32. The New Rule's ban on referrals for abortion care is especially dangerous in the context of Title X because nearly all of our patients are low-income, and many also have low literacy and/or low health literacy. Many patients, especially (but not only) those from immigrant or refugee communities, may not know that abortion is legal in the United States. They may have no idea

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that affordable, high-quality abortion care is locally accessible. Our homeless patients, as well as patients with mental or behavioral health challenges, may lack any means to access care without assistance. Adolescent patients may also find it especially challenging to figure out where and how to access abortion, particularly if they are concerned about confidentiality. This will also be true for victims of abuse, assault, incest or reproductive coercion, of any age.

33. Health care providers are expected routinely to provide referrals where patient needs and conditions are outside of their particular scope of practice. Our patients receive referrals not only for prenatal or abortion care, but also for a wide range of other services, such as diagnostic imaging for a breast mass (identified during a wellness visit), cervical biopsy (following an abnormal Pap smear), or diagnosis and management of common chronic health conditions such as hypertension, diabetes or heart disease; the list is long.

34. As noted above, the New Rule narrowly permits certain providers to provide a list of "comprehensive primary health care providers," some, "but not the majority of which," may also provide abortion. *See* New Rule Section 59.14(c)(2). But it is well known that the overwhelming majority of abortion services throughout the United States (including in King County) are available at health centers that specialize in gynecology, and do not offer obstetrical care or "comprehensive primary health care." (There are instances when an obstetrician, midwife, or family practice clinician may offer abortion care in addition to prenatal care, but this is normally in the context of caring for a current patient in their practice.) Practically speaking, Public Health–Seattle & King County would be

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unable to offer patients any sort of choice of providers who offer both prenatal and abortion services (in keeping with the New Rule's mandate).

35. Without referrals or other information about follow-up care, the patient populations we serve will meet numerous, sometimes insurmountable, barriers in accessing safe, affordable abortion services.

36. As discussed above, our patients often have no other health care professionals to whom they can turn. Challenges include significant literacy and language barriers, as well as financial difficulties. These obstacles mean that patients are unlikely to independently obtain information about health care providers, including referrals. The fact that the New Rule's discussion suggests that information about abortion is readily available "on the internet" betrays a complete lack of understanding of the realities of our Title X patient population, or the relative sophistication needed to navigate the web safely. From many years of experience in this work, I know that the information or referral I provide is often a patient's only viable way to access additional health care—because of language, literacy (including health literacy and electronic literacy), or economic barriers.

37. As a result, I am very concerned that if we cannot provide our patients with complete information about their options—including where they can obtain care if they so choose—it will forestall or foreclose access to those services.

38. I believe in the core message of the American College of Midwives with all my heart: "Listen to Women." The New Rule's coercive requirements would force me to disrespect, contradict, and patronize my patient, and violate her trust, compounding her feelings of isolation and vulnerability.

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39. The New Rule's ban on referral for and information about obtaining abortion care is not only unethical, but also cruel and dangerous. It will delay or prevent patients from obtaining the care they want and need. It will make patients distrust me, my colleagues, our clinic, and health care providers in general. Forcing any unwanted and directive information on patients is unethical and inconsistent with national standards of care for, including, but certainly not limited to, the QFP. It will destroy the delicate trust at the heart of the patient-provider relationship. It goes against the basic medical and ethical obligations of CNMs, ARNPs, and of all health care providers.

40. I am a highly competent professional with more than 36 years of experience in the field of sexual and reproductive health; and the prospect of being required to withhold referrals and information that is responsive to my patients' needs, and to disrespect, mislead and confuse my patients, is untenable. As a result, I will be forced to choose to leave the Title X program if the rules take effect.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on 20 March 2019 in Seattle, Washington.

J. Elisabeth Kruse, M.S.,
C.N.M., A.R.N.P.

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[i] *See* Code of Ethics, American College of Nurse Midwives, http://www.midwife.org/ACNM/files/ACNMLibraryData/UPLOADFILENAME/000000000048/Code-of-Ethics.pdf.

[ii] ANA, Code of Ethics, at 2 (2015), https://www.nursingworld.org/practice-policy/nursing-excellence/ethics/code-of-ethics-for-nurses/ (Provision 1.4).

[iii] *Id.*

[iv] *See* "Exploring All Options: Pregnancy Counseling Without Bias" Discussion Guide, https://www.fpntc.org/sites/default/files/resources/2017-10/fpntc_expl_all_options2016.pdf.

[v] Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs ("QFP"), 63 Recommendations & Reports 4, 14 (2014), https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf.

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DECLARATION OF SERVICE

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

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

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

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

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, et al.,

Defendants.

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

Plaintiffs,

v.

ALEX M. AZAR II, et al.,

Defendants.

No. 1:19-cv-03040-SAB

DECLARATION OF HEATHER MAISEN IN SUPPORT OF NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION'S MOTION FOR A PRELIMINARY INJUNCTION

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I, Heather Maisen, declare and state as follows:

1. I am the Manager of the Family Planning Program in the Public Health Department for Seattle and King County, Washington ("Public Health-Seattle & King County"). I hold Master of Public Health and Master of Social Work degrees from the University of Washington. I have led Public Health-Seattle & King County's Family Planning Program for over nine years and been employed in that program for 13 years. I submit this declaration in support of National Family Planning & Reproductive Health Association's motion for a preliminary injunction.

2. Public Health-Seattle & King County's mission is to achieve and sustain healthy people and healthy communities throughout King County by providing public health services that promote health and prevent disease. Public Health-Seattle & King County is one of 16 subrecipients of the Title X grant awarded to the Washington State Department of Health. Our Family Planning Program has been providing Title X services since the inception of Title X almost five decades ago.

3. As the Family Planning Program Manager, I am responsible for overseeing all aspects of our Title X program, including supervising our Lead Clinician and other program staff; establishing and monitoring program policies, data reporting, and budgets; implementing periodic quality improvement and

strategic planning initiatives; hiring; and compliance with all Title X requirements.

4. Public Health-Seattle & King County's Family Planning Program operates four family planning clinics and supports family planning services in four school-based health centers.

5. Public Health-Seattle & King County is a member of the National Family Planning & Reproductive Health Association ("NFPRHA"). I also serve on the Board of Directors of NFPRHA, and served on the former Washington State Family Planning Leadership Committee, an entity convened by the Washington State Department of Health and composed of representatives from different types of Title X providers to provide guidance and feedback on Washington's Title X program.

6. Public Health-Seattle & King County will fight hard to avoid leaving the Title X program, but the new Title X rule ("New Rule") forces recipients like us and our clinical staff into having to choose among bad options, all of which would be harmful to our patients and the public health.

7. Although Public Health-Seattle & King County could apply to become a grantee even if the Washington State Department of Health is forced to exit the Title X program, the New Rule will stand in the way of our doing so for all the reasons discussed in more detail below: The rules would seriously interfere with our ability to staff such a project, house such a project, or otherwise continue

in the Title X program.

8. Moreover, the New Rule mandates incomplete, substandard pregnancy counseling and onerous separation requirements that would undermine the quality and impact of our program. If we were to maintain Title X funding, this mandate would harm our patients and force our providers to compromise important medical care principles. If the New Rule instead forces us to leave the Title X program, family planning in King County will also be harmed, because we will have fewer resources to serve our very vulnerable patients, and will therefore be faced with reducing clinic hours, laying off staff, or even closing one or more locations—all of which mean serving fewer patients.

9. As described below, if the New Rule takes effect, it will cause immediate, significant, and irreparable harm to Public Health-Seattle & King County, our mission and the patients we serve, as well as to the other approximately 4 million low-income patients around the country who depend on the Title X program for access to critical, high-quality family planning care each year.

A. Background on Public Health-Seattle & King County's Family Planning Program

10. In 1964, Public Health-Seattle & King County opened the White Center Public Health clinic, our first clinic providing family planning services for low-income women; the clinic predated the federal Title X program by nearly 7

years.

11. Congress approved Title X in 1970, and Public Health-Seattle & King County has received Title X funding from the time of the first grants until the present. With the help of Title X dollars, Public Health-Seattle & King County has greatly expanded its service locations and today operates family planning clinics in Auburn, Eastgate, Federal Way, and Kent, and supports family planning care in school-based health centers in Cleveland, Rainier Beach, Ingraham, and Kent Phoenix Academy high schools.

12. The primary goal of the Family Planning Program is to provide no or low cost clinical services to the most vulnerable in our community in order to decrease the rate of unintended (unplanned) pregnancy and improve the reproductive and sexual health of all King County residents.

13. In 2017, our family planning clinics served 5,489 clients during 9,300 clinic visits.

14. Our family planning clinics and the school-based health centers we help support provide a comprehensive range of family planning services. We offer all FDA-approved contraceptive options and provide counseling regarding all of these options. Contraceptive supplies are stocked regularly to ensure all patients can receive the method of their choice the same day of their visit, including long acting reversible contraceptives ("LARCs") like implants and intra-uterine devices.

We adhere to the "Quick Start" method under which clients can begin taking certain types of contraception—oral and hormonal contraceptives—immediately, rather than waiting until a certain point in their menstrual cycles.

15. We also provide pregnancy testing and counseling, testing and treatment for STIs and minor gynecologic problems (such as vaginitis and urinary tract infections) as well as HIV testing, cervical and breast cancer screenings, preconception care and basic infertility counseling and screening.

16. For pregnant patients, all eight sites provide non-directive pregnancy counseling. This includes information about and referral for abortion, if that is an option that the patient is considering. In our four family planning clinics, we provide clinical abortion referral packets containing information about the cost of an abortion, local clinicians that provide abortion care, how late into pregnancy people can obtain an abortion in Washington, the availability of birth control after an abortion, how to contact emotional support centers, and taking care of yourself after an abortion. Neither the Family Planning Program nor Public Health-Seattle & King County provides abortions.

17. Title X also supports the FLASH sexual health curriculum. FLASH has been adopted by all of the public schools in King County. The curriculum is developed by Public Health-Seattle & King County and designed to prevent teen pregnancy, sexually transmitted diseases, and sexual violence. Title X funds help

pay for the educators that train teachers on the FLASH curriculum as well as the educators that teach the curriculum in schools.

18. The FLASH high school curriculum has 15 lessons; Lesson #3 on pregnancy contains pregnancy options and abortion information. One of the key learning objectives of Lesson #3 is to ensure that students are able to access medically accurate information about pregnancy, pregnancy options, and prenatal care services. Teachers are to provide a Sexual Health Resource Sheet for all students in the course of that lesson. All care providers included on that list must provide for or refer for prenatal care, adoption, and abortion care. This lesson is aligned with National Sexuality Education Standards, which requires information about pregnancy options.

19. In 2017, our services prevented an estimated 1,030 unintended pregnancies, 490 unplanned births, and 350 abortions resulting in net savings of over $6.5 million associated with maternal and birth-related care, miscarriages, ectopic pregnancies, and abortions averted. An estimated 84% of female clients of reproductive age served in 2017 left with some form of “moderately effective” or “most effective” contraceptive method.

20. Public Health-Seattle & King County has shown our extraordinary dedication to the Title X program since its inception, and as further described below, we have worked hard to build an exemplary Title X program. Our Eastgate

Public Health Center Family Planning Clinic achieved the highest-level National Center for Quality Assurance rating, Patient Centered Specialty Practice Recognition Level 3. We have long-standing patients who value and rely on the care we provide. In qualitative reviews of the clinics, one patient described coming to our clinic "for 20 years … [because she] ha[s] always been treated with respect." Another prizes the fact that "[e]veryone from the nurse to the client services specialist was extremely helpful and their knowledge was very comforting which made a wonderful experience." Another appreciated that "[e]verything felt safe and confidential."

B. The Family Planning Program's Especially Vulnerable Patient Base

21. Our program works with particularly vulnerable patient populations, even in the context of Title X's national low-income focus. Ninety-seven percent of our clients have incomes at or below 250% of the federal poverty line and 71% are at or below 100% of the poverty line. Both of these numbers are higher than the national average for Title X providers. This reflects our hard work to provide outreach to the most needy, and to make sure that they are aware the Family Planning Program exists.

22. Similarly, forty-seven percent of our clients are uninsured. Sixty-three percent of our clients are Latino/a and another 12% of our patients identify as Black or African American, Asian, Native Hawaiian or Pacific Islander, American

Indian or Alaska Native, or more than one race. Over 25% of our clients are under 20 years old. Our clients face not only poverty, but also other vulnerabilities and challenges in accessing health care. Many have little English or limited English proficiency ("LEP"). To most effectively deliver care to our patient populations, we have bilingual staff and robust interpretation and translation services available. Our brochures are available in English, Spanish, and Vietnamese; those materials are translated based on the languages most represented among the clinics' patient population. All written materials are developed using health literacy principles and target a 6th grade reading level to ensure readability. After one recent Department of Health site visit, one of the reviewers commented that we "shine[] in [our] LEP [(Limited English Proficiency)] services, and offer[] a variety of languages and resources to accommodate [our] clients."

C. The Family Planning Program's Careful Efforts To Best Locate Our Clinical Care Sites

23. To best reach low-income patients in need of family planning care, we have also worked hard to locate our clinics in strategic and easily accessible locations. As a result, our clinical care sites are located in communities with notable health disparities and fewer health care provider options, such as south King County. The four standalone family planning clinics either have a bus stop or a transit hub right in front of our clinic doors (as is the case for one clinic) or are within a five-minute walk of bus stops; there are parking lots available as well. All

clinics are ADA accessible.

24. The four standalone family planning clinics are open five days a week, between 8AM to 5PM or 9AM to 6PM depending on the day of the week. We routinely conduct community surveys about ease of access to our facilities, and include questions about ideal days and hours of operation to ensure that we are meeting the needs of the communities we serve.

25. Similarly, the Family Planning Program selected our school-based health centers because of the needs for contraceptive and other care in the teen population. We focused our initial efforts on south Seattle and south King County because of their disproportionately high teen pregnancy rates: Three of our four school-based health centers are located in these areas. After selecting our school-based family planning locations, our staff worked closely with the pre-existing health center's personnel to have the family planning services operate in an integrated and unobtrusive manner. As a result, the school-based health centers are seen as very accessible, while still preserving teens' confidentiality.

D. The Physical Layout of Public Health-Seattle & King County's Administrative Offices

26. The administrative offices of Public Health-Seattle & King County are located in a government-owned building in Seattle, Washington. The Family Planning Program shares the building with a number of different program offices including First Steps, which provides maternity support services and infant case

management up to age two; the Women, Infants, and Children program (WIC), which provides healthy foods, breastfeeding support, and nutrition information to eligible pregnant women and caregivers with a child under five years old; Access and Outreach, which is primarily responsible for enrolling eligible individuals in Apple Health and other Medicaid programs; and a Primary Care program which supports primary care health centers in King County. First Steps, WIC, Access and Outreach, and the Primary Care programs are all outside the Title X program and all provide information and referrals for abortion. In fact, they use the abortion referral packets developed in our Title X program to do so.

27. Our Title X program offices are located on the same floor as two call centers that assist the community in obtaining medical care. Public Health-Seattle & King County operates both of those call centers. The Family Planning Program helps support one of those call centers. The call center we support helps patients learn about our family planning services, maternity services, dental services, and the Special Supplemental Nutrition Program for WIC. For patients interested in family planning services, this call center helps find the closest family planning service site for them, schedule appointments, provide patients with detailed information on how to get to the clinics, and, if necessary, obtain referrals for other health care resources. The other call center, Community Health Access Program (CHAP), provides more general community health care access information and

serves a Medicaid enrollment function. Currently, if a caller calls the call center we help support and requests information about abortion services, the call center operator would refer them to either our family planning clinics or the CHAP phone line for more information.

E. The New Rule's Physical Separation Requirements Will Be Impossible To Implement Within The Current Structure of Our Program

28. The New Rule's separation requirements demand that Title X projects be physically separated from the provision of any information on abortion or referral for abortion, even if that information is provided by others outside the Title X project. All of the clinics within our Family Planning Program and the school-based health centers that we support provide women with neutral abortion counseling—which includes information and referral. If our Family Planning Program wishes to keep providing neutral abortion counseling and comply with the separation requirements of the New Rule, we would have to establish new, duplicative facilities somewhere outside each of our existing sites in order to offer that information— which as discussed below is not feasible for us to do. Additionally, Title X patients could not be referred to or otherwise informed about such a duplicative facility.

29. For example, the high schools we serve are housed in a single building or small campus, each with a single health center facility. There is no other separate physical location on the high school property that could be used for

Title X care and effectively reach teen patients. Similarly, our clinics are strategically located in county-owned buildings or leased spaces, which we do not want to vacate and that could not feasibly be duplicated. The same problem arises within our program offices and the call center we support. To separate abortion service information and referral from within the call center, we would have to establish a separate phone number to provide abortion service information and referral, hire an entirely separate call center staff, and physically separate that call center from our existing call center. Doing so would not only be a financial impossibility, but it would undermine the very premise of the call center, which is to connect patients to the family planning care they need.

30. Even if we chose to stop providing neutral abortion counseling in order to comply with the New Rule so that we might have a chance to stay in the Title X program, some of our sites and our Title X administrative offices would nonetheless *still* have to undergo separation simply because they are now co-located with non-Title X programs that provide information about and referral for abortion care.

31. For example, the separation requirement would be impossible to implement within the four school-based health centers because the clinicians in those centers provide a full range of non-family planning care in addition to family planning services, the former of which includes as-needed information about and

referral for abortion care. As a result, to comply with the separation requirement, we would still have to create two physically separate, duplicative health centers per school campus: one for the provision of Title X care, and one for the provision of other, general health care services as well as neutral abortion information and referral. But as explained above, there is no physical location that could accommodate such duplication on our high school campuses.

32. Separation would similarly be required for two of our standalone family planning clinics that are housed under the same roof as a primary care facility, even if we were willing to alter our own services to comply with the New Rule. This separation too would be impossible because as discussed above, our clinics are strategically located and could not feasibly be moved elsewhere, nor could we move the primary care program elsewhere.

33. Same with our program offices and our call center. Our Family Planning Program offices and our call center are on the same floor as the CHAP call center; they share administrative systems and functions with the First Steps, WIC, Access and Outreach, and the Primary Care programs. All of these other programs provide abortion information and referrals. To comply with the separation requirement we would have to physically separate from these programs. However, there is no capacity within our county-owned office building or way to rearrange it to permit physical separation from all these other county initiatives. It

would be impossible to separate our program offices and our call center from these other programs.

34. In sum, to attempt to comply with the separation requirement we would have to uproot our existing programs and find entirely new locations. That would be an incredibly costly endeavor, exacerbated by the fact that moving out of the schools or county-owned buildings and hiring new staff to comply with the separation requirement would mean absorbing the entirety of those new operational costs ourselves. It would also mean abandoning the locations we have strategically selected and that our patients are used to visiting. Our family planning program does not have anything approaching an adequate budget to do this, nor would it serve our mission to do so.

F. The New Rule Fails to Take Into Account Unitary Local Government Systems

35. In addition, there are other unitary county systems that we could not "separate." For example, under the New Rule, we would have to set up a separate electronic health records system for the Title X program because non-Title X health centers on the existing system provide nondirective pregnancy counseling and referrals for abortion. Our electronic health records system is implemented countywide to protect patients from medical errors, to ensure fully informed care, and to facilitate the county's administrative and billing requirements. We would not be authorized (or have the funding) to use a different system for a subset of

county patients.

36. Likewise, as discussed above, we only have one administrative office, within a county building, for our Title X program. We share part of certain staff that also serve other Public Health-Seattle & King County programs, including those where abortion might be discussed, to allow us to optimize our limited resources and focus those as much as possible on providing family planning. All of our Title X funding, including this use of shared administrative staff, is carefully accounted for and documented in compliance with current Title X rules.

37. Public Health-Seattle & King County has extensive experience in planning and administering major regional and national programs and proudly holds an excellent track record of managing complex grants. In 2014 alone, Public Health-Seattle & King County managed 70 federal grants totaling $49 million as well as a contract with the Washington State Department of Health that provided $11 million for 36 programs. None of Public Health-Seattle & King County's other federal funding streams require us to artificially and physically completely separate federally funded activity from other government efforts, or mandate the waste of funds that would be necessitated by such complete physical separation requirements. The targeted use of federal funds is instead accomplished through our careful, exclusive use for and documentation of serving the federal purposes for each grant, according to the strict, general federal grants management

requirements.

G. The New Rule Will Drive Clinicians Away From Serving Our Health Centers

38. Just as we have spent considerable time, resources, and effort to locate our family planning sites where patients need them, we have made similar investment in recruiting committed, high quality family planning staff. However, five of our sites have only one clinician. If any of those clinicians call in sick on a given day, we generally have only one on-call clinician who can substitute in.[1] As a result, in recent years, we have frequently had to shut sites down during days in which we had no clinicians who were available to provide services.

39. Furthermore, at certain points in recent years, our family planning sites have been faced with a number of vacancies, primarily due to retirements, and we know that the market for these types of non-physician family planning clinicians—the backbone of our program—is very tight.

40. If the New Rule takes effect, the counseling requirements would mandate that we provide incomplete, misleading, and coercive pregnancy counseling which violates the ethical and professional standards of clinicians. For example, for those patients who present as pregnant and make clear that they are only interested in abortion counseling, our providers would nonetheless have to

[1] While we do have two additional on-call clinicians on staff, they are both only available one day per week.

provide them counseling on prenatal care and/or adoption. For those patients who explicitly request abortion referrals, the New Rule prohibits clinicians from providing those patients with any responsive information, frustrating and delaying patients' access to wanted medical care. The New Rule would also mandate that our providers refer patients for prenatal care, even if the patient does not wish to receive that type of care.

41. These coercive and confusing new counseling steps contradict a key aspect of Title X care to which Public Health-Seattle & King County is deeply committed—that patients receive all the information they need to freely make choices about the counseling and other care they receive. The New Rule's intrusions on the clinician-patient relationship run counter to best practices, violate HHS's own national standards of care for family planning services, and will erode the trust between vulnerable patient populations and their health care professionals. The New Rule's counseling requirements will also simply confuse and mislead patients, requiring the opposite of the informative, supportive, and affirming care the Family Planning Program seeks to provide.

42. I know that the New Rule's highly flawed counseling approach is not acceptable to a number of our providers, from our meetings and planning for the future. They have indicated that they would leave the program if these rules were imposed on them, and I feel confident that they would easily be able to find

clinical positions elsewhere. In addition, it would be extraordinarily difficult for me to recruit replacement providers, because of course they would be subject to the same New Rule that is not acceptable to many clinicians. Thus, it is by no means certain that we could even staff any, much less all, of the existing clinics, if we attempted to maintain federal funding under the conditions imposed by the New Rule.

H. The Limited Funding for the Family Planning Program

43. As described above, the New Rule will create vast new challenges for Public Health-Seattle & King County to stay in the Title X program. It is far from clear that we could find the clinicians, locations, and administrative solutions to do so. Public Health-Seattle & King County has a deep commitment to its Title X patients, but also a deep devotion to the highest standards of care, and so the New Rule may end up forcing us to decide to leave the program. If that occurs, various other harms will flow from the lost Title X funding. Either way, Public Health-Seattle & King County and its patients lose under these new regulations: we will either have a newly-constrained and hobbling Title X program, or we will have significantly fewer dollars with which to try to maintain a non-Title X funded family planning effort.

44. We receive over $340,000 in Title X federal funds annually. Our Title X project is also funded by state family planning funds which are available to

us as long as we remain Title X recipients. The sum of these two funding source is approximately $1,300,000. In addition, we collect other government funding along with some client direct payment for services and reimbursement from third-party payers, such as Medicaid.

45. For several years, both Title X funding and state family planning funding have been flat. There is no certainty that, should the Title X funding disappear, Public Health-Seattle & King County could fill that significant gap, with ongoing funds.

46. Recent history shows that fiscal pressure can come from all directions. Washington State enacted new revenue caps at the same time as the cost of providing family planning and other health care was increasing. Public Health-Seattle & King County suffered a structural gap in its finances. This meant that we had to close three family planning clinics at the end of 2014, and we were at risk of having to shut down the whole family planning program. Any loss of the Title X dollars will similarly cause serious financial problems for our program.

47. If the New Rule pushes Public Health-Seattle & King County out of the Title X program, and we thus lose over $1,300,000 annually, we will have to implement staff reductions, operational-hours reductions, and other budget-tightening measures to accommodate the significant shortfall. These changes will harm our patients and their access to care. Just as when financial disruptions hit us

in the recent past, we may well be faced with closing some family planning sites altogether.

48. Despite our experience and comparative success in obtaining grant funding and running a very strategic, high-quality family planning program, we are under constant financial pressure. There is no way that our program will be as successful and treat as many patients as well if we lose our Title X funding. This loss will harm our mission of protecting the public health of those in King County, including through access to vital family planning clinical care.

49. In the wake of the 2014 clinic closures, some of our patients were effectively turned away from obtaining care at other publicly-funded health care providers in the area because the providers could not accommodate the sudden influx of patients. Other patients who could make sacrifices and cope with new, more challenging logistics to stay within our Family Planning Program took two to three buses, traveling out of the city in which they reside, to come to one of our other family planning clinics in a different part of the county.

50. We know that not all of our low-income patients have the time and resources to navigate the loss of current locations and find a new provider elsewhere. As one of our patients explained, in some cases, our clinics are their "only option for any health care" and are "important part[s] of the community." In our qualitative review, this patient emphasized that, "We all hope that it stays open

[as an] available option for low income families to get help and advice." If we let those patients down, leave the program and have to reduce services, or if we implement the mandatory, directive pregnancy counseling and other harmful aspects of the New Rule, our reputation in the community and patients' trust will suffer either way.

******

51. The New Rule would force us to choose between no good outcomes. We will either be staying in the Title X program and providing substandard care, or leaving the program and losing serious resources, which would reduce critical patient care. Neither outcome is consistent with our almost five decades-long commitment to providing vulnerable members of our community access to Title X's quality care, which we have done since the program's inception.

52. For all these reasons, Public Health-Seattle & King County supports NFPRHA's request for an injunction barring implementation of the new Title X regulations. The current Title X regulations should remain in effect to effectively govern the program, as they have for many years, in order to avoid these myriad harms.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on 3-21-19 in Seattle, Washington.

Heather Maisen

DECLARATION OF SERVICE

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

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

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

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

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, et al.,

Defendants.

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

Plaintiffs,

v.

ALEX M. AZAR II, et al.,

Defendants.

No. 1:19-cv-03040-SAB

DECLARATION OF SARAH PRAGER, M.D., M.A.S., IN SUPPORT OF NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION'S MOTION FOR A PRELIMINARY INJUNCTION

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Sarah Prager, M.D., M.A.S., states as follows:

1. I am a Professor of Obstetrics and Gynecology at the University of Washington, where I serve as the Director of the Family Planning Division and Family Planning Fellowship. I also serve as the Title X Director of the Feminist Women's Health Center (doing business as Cedar River Clinics) ("FWHC"). FWHC has participated in Title X since 2017. FWHC decided to become a Title X provider out of a deep commitment to reaching as many patients as possible with full, quality family planning care. I submit this declaration in support of Plaintiffs' motion for a preliminary injunction.

2. I earned a B.A. *summa cum laude* from Princeton University. I then obtained my M.D. degree from the University of Texas Southwestern Medical School in 2000, and I completed an internship and residency at the University of Vermont. Thereafter, I earned a master's degree from the University of California at San Francisco, where I also completed a fellowship in family planning. I have been board certified in Obstetrics & Gynecology since 2005. My curriculum vitae, which sets out my professional qualifications and experiences in greater detail, is attached as Exhibit A.

3. Plaintiff Dr. Deborah Oyer is my colleague and serves as Medical Director of FWHC's Cedar River Clinics. She has provided family planning and

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other reproductive health care in Washington for more than 25 years and is a graduate of Harvard Medical School.

4. In my capacity as Title X Director, and in partnership with Dr. Oyer, we oversee the provision of medical services to FWHC's Title X patients, including pregnancy counseling and contraceptive care. Dr. Oyer and I ensure that FWHC's Title X program meets the directives set forth in "Providing Quality Family Planning Services" ("QFP"), the national clinical standards of care for family planning developed by the Centers for Disease Control and Prevention ("CDC") and the HHS Office of Population Affairs ("OPA"). A central part of our mission is to give Title X patients the same, high-quality care as better-resourced patients.

5. I personally treat approximately 425 Title X patients per year at FWHC.

6. Dr. Oyer and I also provide abortions at Cedar River Clinics outside the Title X program and unsupported by Title X funds.

7. I provide the full spectrum of general obstetrics and gynecologic care, with a special clinical focus on family planning. I strive to help women navigate their needs around contraception, abortion, and miscarriage. I also conduct research on miscarriage management, contraceptive use, and pregnancy termination, including second trimester surgical abortion. I have been published in

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numerous medical journals on these topics and others. In my various professional roles, I interact with other Title X health care providers and family planning researchers around the country. I am typical of the doctors who serve as Title X medical directors across the country. Many of us are practitioners and academics who do Title X work part-time to ensure the quality of the Title X program.

8. I am familiar with the key provisions of the new Title X regulations ("New Rule"). If the New Rule were to take effect, as I explain below, I would no longer be able to serve as Title X Medical Director or to provide Title X care, and FWHC would be forced to exit the program. Having to leave Title X would significantly harm FWHC's ability to provide high quality, affordable family planning care to our low-income patients. In my expert opinion, this would create new health risks and harms for our patient population.

The New Title X Regulations

9. The New Rule would cause immediate harm to patients, physicians, and Title X providers in the form of coercive pregnancy counseling. The New Rule requires withholding information from pregnant patients by preventing referral for all available options for their pregnancy, while at the same time, forcing certain information on patients regardless of their wishes.

10. The New Rule would also cause cascading other harms, as it disrupts the provision of care, including contraceptive care, in the Title X network.

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The New Rule's Coercive Pregnancy Counseling Requirement Would Harm Patients and Providers

11. Patients that come to FWHC for pregnancy testing have a range of experiences: some hope that they are pregnant; others fear that they are; and some do not know exactly how the news would make them feel. As a result, when a pregnancy test comes back positive, a patient's emotions are often very intense.

12. If the patient has been trying to conceive, she may be elated and will want to talk through and obtain referrals for prenatal care. In that case, consistent with protocols, our pregnancy counseling focuses on appropriate next prenatal steps.

13. If a patient's pregnancy is unplanned, she is often surprised and overwhelmed. Sometimes she is very distressed. Such patients often do not know what they will do, and they look to us to discuss their options.

14. As Title X Director, I ensure that FWHC non-physician clinicians—who are highly trained and best positioned to provide pregnancy counseling—create an open dialogue with patients. It is critical that clinicians form a relationship with patients based on sensitivity, candor, and, above all, trust.

15. FWHC aims to give patients facing unplanned pregnancies space to discuss their options and to weigh their concerns. This is one of the most sensitive areas of medical practice, so providers must be especially attentive to the feelings and needs of their individual patients.

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16. Nondirective pregnancy counseling is consistent with the relevant standards of care and medical ethics.

17. The American College of Obstetricians and Gynecologists ("ACOG") provides that, following a pregnancy diagnosis, "[t]he patient should be fully informed in a balanced manner about all options, including raising the child herself, placing the child for adoption and abortion."[i]

18. The American Medical Association ("AMA") Code of Medical Ethics similarly advises providers that "withholding information without the patient's knowledge or consent is ethically unacceptable."[ii]

19. And the American Academy of Pediatrics ("AAP") directs that "[w]hen consulted by a pregnant adolescent, pediatricians should be able to make a timely diagnosis and to help the adolescent understand her options and act on her decision to continue or terminate her pregnancy."[iii]

20. The QFP standards also state that pregnancy testing should be "followed by a discussion of options," consistent with the recommendations of professional medical associations, such as ACOG and the AAP.[iv] The QFP is clear that providers must be "respectful of, and responsive to, individual client preferences, needs, and values," ensuring that "client values guide all clinical decisions."[v]

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21. However, in contrast to the previously longstanding Title X regulations, the New Rule does not require clinicians to discuss all options with women seeking such counseling. The New Rule also requires a Title X provider to have a graduate level degree to be able to conduct nondirective pregnancy counseling. These are unnecessary and harmful limitations.

The New Rule Curtails Necessary Referrals & Misleads Patients

22. When patients seek services beyond the scope of clinicians' practice, ACOG directs that clinicians "fulfill their obligations to patients through referral to other professionals who have the appropriate skills and expertise to address the situation."[vi]

23. The AMA similarly instructs that in cases where the patient seeks treatment beyond their practice, physicians should "consult or refer the patient to … health care professionals who have appropriate knowledge and skills and are licensed to provide the services needed."[vii]

24. The QFP directs that Title X providers supply "appropriate referrals" in the course of nondirective, patient-driven pregnancy counseling.[viii]

25. Under the New Rule, however, even when a patient requests referral for abortion care, providers are prohibited from providing clear information about how to get that care. Title X clinicians are permitted only to furnish a list of "licensed, qualified, comprehensive primary health care providers (including

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providers of prenatal care), some, but not the majority, of which also provide abortion as part of their comprehensive health care services," but the provider may not "identify which providers on the list perform abortion." 84 Fed. Reg. 7714, 7789.

26. This bar on referral for abortion—even when a patient requests such information—would confuse patients. Patients may reasonably but incorrectly assume that the list includes only abortion providers—that is, after all, the information they sought. In direct violation of the standards of care and medical ethics, patients would be left to discover on their own where and how abortion care is available.

27. As both an academic and a doctor, I am committed to making available the full array of ob/gyn care to patients regardless of income and ensuring that they have access to the most complete information about treatment and options. It would be completely incongruous not to provide referral information about abortion to the patients within Title X that seek that care. Complying with the new regulations would force me to shame patients about abortion and steer them to certain types of care, which I simply cannot do.

28. In many areas there may well be *no* abortion providers who satisfy the rules' criteria to appear on the list of follow-up providers. This is because the New Rule permits listing only "comprehensive primary health care providers … which

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also provide abortion as part of their comprehensive health care services." In reality, in many parts of the country, including where I practice, abortion care is not generally available in such settings and is limited to more specialized health centers and clinics. This means that the New Rule would require especially misleading and unethical care, because Title X providers would, in some cases, be forced not only to supply referrals to prenatal care, but also could offer only a written list that excludes any option, even a hidden one, for abortion services or abortion information in response to patients' explicit requests for help in finding abortion care. This would misdirect and shame patients, pushing them toward prenatal care they do not want.

29. Preventing providers from clearly communicating where and how patients can access abortion care—even when patients have expressed that they want to access abortion—creates significant obstacles for patients, who are left to discover that information on their own. In contravention of standards of care and medical ethics, the New Rule places enormous burdens on patients.

30. These burdens would likely delay access to abortion care. While abortion in the U.S. is very safe, every week of delay increases the risks associated with the procedure.[ix]

31. Because many Title X patients have linguistic, educational, informational, and financial barriers to accessing healthcare, the impediments

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introduced by the New Rule may prevent such patients from accessing abortion altogether.

The New Rule Directs Providers to Coerce Patients

32. ACOG directs that "[i]t is never acceptable for [providers] to attempt to influence patients toward a clinical decision using coercion."[x] Similarly, the AMA Code of Medical Ethics provides that patients must "make an independent, voluntary decision" about care.[xi] Providing medical information to patients against their articulated interests or their will is unethical and dangerous.

33. But the New Rule forces providers to refer all pregnant patients for prenatal care or related social services, regardless of patients' wishes—and even when patients have already decided to have an abortion.

34. Having this referral forced on them may be severely upsetting to patients who are considering abortion. The prenatal referral (and refusal to provide an abortion referral) may also cause patients to mistakenly conclude that they must discount abortion as an option for medical reasons.

35. I cannot imagine directing a patient to a prenatal appointment and withholding information about care that I provide when they have expressed interest in possibly obtaining an abortion. If a patient asks me if I can provide them with abortion care, the New Rule prevents me from answering or requires me to lie.

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36. As an academic, researcher, and clinical ob/gyn who provides abortion care outside the Title X project, it would be antithetical to my medical practice, contrary to my work, and damaging to my reputation to provide care in this manner or to allow those I supervise to provide pregnancy counseling that misleadingly omits information about abortion care. I cannot—in one part of my practice, with patients who have the means to pay—provide the full scope of care and—in another part of my practice, with patients of limited means—withhold information and coerce patients to receive certain types of care. This would be seriously harmful to my practice and reputation as both a physician and an academic.

The New Rule Unreasonably Limits Provision of Care

37. Clinicians and counselors typically conduct pregnancy counseling at FWHC and other Title X sites. These providers possess relevant training and expertise.

38. But the New Rule states that only physicians and advanced practice clinicians with a graduate level degree may conduct nondirective pregnancy counseling.

39. Limiting pregnancy counseling to physicians and advanced practice clinicians would constrain FWHC's ability to treat pregnant patients.

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The New Rule Would Interrupt Patients' Access to Contraception

40. The New Rule also imposes stringent requirements that force Title X projects to completely separate from any abortion-related activity or care. Aside from their practical difficulty or impossibility, these separation requirements would introduce new barriers and health complications for women who seek contraception.

41. In overseeing counseling for patients who seek abortion care outside of the FWHC Title X project, I ensure that clinicians and counselors discuss contraceptive methods with these patients to avoid future unplanned pregnancies.

42. Discussing contraceptive care and delivering a chosen contraceptive method at the time of an unplanned pregnancy or an abortion is, consistent with clinical recommendations by the Society of Family Planning, "an optimal time to initiate use of effective contraceptives" because it removes logistical hurdles, including travel, time, and cost.[xii] It also provides a unique opportunity to talk with patients about pregnancy prevention when they may be particularly focused and motivated to "avoid a subsequent pregnancy and to leave the abortion appointment with a contraceptive method."[xiii] Especially relevant for the Title X population, the Society of Family Planning makes clear that "[f]or women who do not regularly seek or have access to gynecologic or preventive health services, the

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abortion visit may be one of their only interactions with the health care system and an important opportunity to discuss contraception."[xiv]

43. The new separation requirements would disrupt continuity of care for patients as they would have to make multiple appointments to access contraceptive counseling and care that could be accomplished on a single date, in a single location.

44. Barriers to access for low-income patients—such as requiring patients to make multiple appointments and trips, to take additional time off work, and perhaps to find childcare on multiple occasions—have been shown to decrease contraceptive use, and increase instances of unplanned pregnancy, abortion rates, and harmful outcomes.[xv]

45. Moreover, if patients choose an intrauterine device ("IUD")—one of the most effective forms of contraception—a particularly safe and easy time to insert the device is immediately after a surgical abortion because the cervix is already dilated.[xvi] However, under the new separation requirements, the patient would have to travel to a separate site and see a different team of clinicians for IUD insertion. Therefore, the New Rule's complete separation requirement creates a new barrier to patients electing an IUD.

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The New Rule Would Force Title X Providers like Me out of the Program

46. The New Rule would harm not only high-need Title X patients, who would receive substandard and misleading care under its dictates, but also their physicians: The New Rule forces providers to adopt a highly unprofessional and unethical approach to patient care.

47. Each clinician and physician who currently serves Title X patients would be forced to choose between, on the one hand, continuing to serve Title X patients but with mandated substandard and unethical care; or, on the other, ceasing to offer family planning care to high-risk, high-need patients.

48. For me, because of the New Rule, I would be forced to leave the program. As I stated above, I cannot provide the full spectrum of care to a subset of my patients (i.e., those who can afford comprehensive family planning care without public support), while offering substandard care to the most vulnerable patients by shaming them about abortion and coercing them into receiving prenatal care. It is inconceivable to me to provide differing standards of care depending on a patient's means, especially in a manner that is so flagrantly inconsistent with my approach to medical practice and my academic research. As a result, I could no longer be a Title X provider or serve as FWHC's Title X Medical Director.

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I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on March 20, 2019 in Seattle, Washington.

Sarah Prager, M.D., M.A.S.

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[i] American College of Obstetricians & Gynecologists ("ACOG"), *Guidelines for Women's Health Care: A Resource Manual* 719-20 (4th ed. 2014).

[ii] American Medical Association ("AMA") Code of Medical Ethics § 2.1.3.

[iii] American Academy of Pediatrics ("AAP"), Policy Statement: Counseling the Adolescent About Pregnancy Options, *Pediatrics* (Vol. 101, Issue 5, May 1998) at 938; reaffirmed Jan. 2006.

[iv] *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs* ("QFP"), 63 Recommendations & Reports 1, 14 (2014), https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf.

[v] *Id.* at 4.

[vi] ACOG, *Guidelines for Women's Health Care: A Resource Manual* at 100-01.

[vii] AMA Code of Medical Ethics § 1.2.3.

[viii] QFP at 14.

[ix] U.D. Upadhyay, et al. *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175-83 (2015).

[x] ACOG, *Committee Opinion No. 664: Refusal of Medically Recommended Treatment During Pregnancy*, 127 Obstetrics & Gynecology 175-82 (2016).

[xi] AMA Code of Medical Ethics, § 2.1.1(a).

[xii] Andrea Hsu Roe & Deborah Bartz, *Society of Family Planning Clinical Recommendations: Contraception after Surgical Abortion*, 99 Contraception 2, 2 (2019) (citations omitted); *cf.* QFP at 14 (explaining that a "negative pregnancy test" where the pregnancy was unplanned "also provides an opportunity to discuss the value of making a reproductive life plan" and providing that "[i]deally, these services will be offered in the same visit as the pregnancy test because clients might not return at a later time for contraceptive services").

[xiii] Roe & Bartz, *Society of Family Planning Clinical* at 2.

[xiv] *Id.*

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[xv] *See, e.g.*, Gina M. Secura et al, The Contraceptive CHOICE Project, 203 Am. J. of Obstetrics & Gynecology e1 (2010) (reducing access and information barriers increases long-acting reversible contraception usage and decreases unintended pregnancies); M. Antonia Biggs et al, *Did Increasing Use of Highly Effective Contraception Contributing to Declining Abortions in Iowa?* 91 Contraception 167 (2015) (abortion rate decline); Paul D. Blumenthal et al, *Strategies to Prevent Unintended Pregnancy*, 17 Human Reproduction Update 121 (2011) (unintended pregnancy increases risks of, *inter alia*, low birthweight babies, adverse behaviors, and physical violence by partners).

[xvi] *See* Elizabeth Micks & Sarah Prager, *Plan A: Postabortion Contraception*, 57 Clinical Obstetrics & Gynecology 751 (2014).

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DECLARATION OF SERVICE

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

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

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

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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, Plaintiff, v. ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants. ——————————— NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION, FEMINIST WOMEN'S HEALTH CENTER, DEBORAH OYER, M.D., and TERESA GALL, F.N.P., Plaintiffs, v. ALEX M. AZAR II, in his official capacity as Secretary of the United States	No. 1:19-cv-03040-SAB **ORDER DENYING DEFENDANTS' MOTION TO STAY PROCEEDINGS PENDING APPEAL**

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

Defendants.

Before the Court is Defendant's Motion to Stay Proceedings Pending Appeal, ECF No. 79. The motion was heard without oral argument.

Defendants ask the Court to stay further proceedings in these consolidated cases pending final resolution of Defendants' appeal from this Court's Order granting Plaintiffs' motions for preliminary injunction.

Motion Standard

This Court "has broad discretion to stay proceedings as an incident to its power to control its own docket" in promoting judicial economy. *Clinton v. Jones*, 520 U.S. 681, 706 (1997). In the Ninth Circuit, district courts are instructed to not grant stays that delay trial preparation while waiting an interim ruling on a preliminary injunction. *California v. Azar*, 911 F.3d 558, 583 (9th Cir. 2018); *see also Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012) (approving how the district court "expedited the case and moved with appropriate speed toward final disposition"). The Circuit has long cautioned against staying a case while a motion for preliminary injunction is being appealed, being "persuaded that in some cases, parties appeal orders granting or denying motions for preliminary injunctions in order to ascertain the view of the appellate court on the merits of the litigation." *SportsForm, Inc. v. United press Int'l, Inc.*, 686 F.2d 750, 753 (9th Cir. 1982).

Analysis

The Court takes heed of the Ninth Circuit's admonishments and declines to stay the proceedings. Judicial economy and the interest of justice will be met by the production and review of the Administrative Record as this case moves toward resolution on the merits. Defendants have not shown how they will be harmed if the stay was not imposed.

Accordingly, **IT IS HEREBY ORDERED**:

1. Defendants' Motion to Stay Proceedings Pending Appeal, ECF No. 79, is **DENIED**.

2. Defendants' Unopposed Motion for Extension of Time to Respond to Complaints, ECF No. 80, is **GRANTED**. The deadline for responding to Plaintiffs' complaints will be set after the August 1 telephonic status conference.

IT IS SO ORDERED. The Clerk of Court is directed to enter this Order and forward copies to counsel.

DATED this 14th day of June 2019.

Stanley A. Bastian
United States District Judge