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7 **UNITED STATES DISTRICT COURT**
EASTERN DISTRICT OF WASHINGTON
 8 **AT YAKIMA**

9 STATE OF WASHINGTON,

NO. 1:19-cv-3040

10 Plaintiff,

COMPLAINT FOR
 DECLARATORY AND
 INJUNCTIVE RELIEF

11 v.

12 ALEX M. AZAR II, in his official
 capacity as Secretary of the United
 13 States Department of Health and
 Human Services; and UNITED
 14 STATES DEPARTMENT OF
 HEALTH AND HUMAN SERVICES,
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Defendants.
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I. INTRODUCTION

1
2 1. The State of Washington seeks to enjoin and set aside the Federal
3 Government’s March 4, 2019 Final Rule that, should it become effective, will
4 cripple Washington’s Title X family planning network serving tens of thousands
5 of Washingtonians annually, to achieve ends unrelated to Congress’ Title X
6 program.

7 2. Congress enacted Title X in 1970 to equalize access to voluntary
8 family planning services. Title X sought to help low-income women reduce their
9 rate of unintended pregnancies and exercise control over their economic lives and
10 health by offering federally-funded access to effective contraception and
11 reproductive health care. Congress authorized the Department of Health and
12 Human Services (HHS or the Department) to award grants to public and
13 non-profit private entities to provide a “broad range of acceptable and effective
14 family planning methods and services” to patients in need. 42 U.S.C. § 300(a).

15 3. Every year since 1971, the State of Washington has competed for
16 and been a direct grantee of Title X funds. As a result, Washington has built a
17 family planning network that has been a remarkable success for the State and its
18 residents. In 2017 alone, it enabled over 18,000 women to avoid unintended
19 pregnancies and eliminated the need for over 6,000 abortions, and it saved the
20 State over \$113 million in health care costs. It now comprises 85 clinics providing
21 free or low-cost contraceptives and other reproductive health services to
22

1 low-income people in 32 of Washington’s 39 counties. If not curtailed because
2 of the Final Rule, it will serve 98,000 Washingtonians in 2019.

3 4. The Final Rule dramatically and unlawfully alters the longstanding
4 regulations governing Title X grants for family planning services. It is slated to
5 go into effect on May 3, 2019. The Final Rule will destroy Washington’s family
6 planning network, irreparably harming thousands of Washingtonians.

7 5. The Final Rule makes numerous changes that impose the
8 Administration’s views contrary to congressional will and five decades of
9 regulations, including the following:

10 a. **Coercive practices; denying patient access to medical**
11 **facts.** The Final Rule attempts to deprive pregnant patients of voluntary
12 decision-making about their health care. It eliminates the requirement that they
13 receive nondirective pregnancy counseling. It requires directive referrals to
14 prenatal care for all pregnant patients, while forbidding referrals for abortion care
15 even if requested by patients. The Final Rule permits Title X providers’ own
16 views to dictate the information a patient receives, by withholding factual
17 medical information and offering only biased information, regardless of the
18 patient’s wishes. These aspects of the rule violate Congress’s requirement that
19 Title X subsidizes only *voluntary* family planning services and its repeated
20 mandate that all pregnancy counseling in a Title X program “shall be
21 nondirective” (the Nondirective Mandate). These provisions also violate the
22 Patient Protection and Affordable Care Act (ACA), which prohibits HHS from

1 enacting any regulation that denies patients “full” information on their treatment
2 options and “full” disclosure of information relevant to their health care
3 decisions.

4 **b. The separation requirements.** The Final Rule denies Title X
5 funding to entities that provide comprehensive reproductive health care services
6 at the same clinical site, even though abortion care has *always* occurred outside
7 the scope of any Title X program without using federal funds. The Final Rule
8 establishes onerous and unnecessary “separation” requirements that obligate
9 providers to physically separate their facilities, staff, and materials and wastefully
10 duplicate their operations if they wish to provide abortion care or even referral.
11 These unworkable new requirements, along with the coercive and directive
12 practices mandated by the Final Rule, will disqualify almost 90% of
13 Washington’s Title X network providers—an outcome HHS ignores. The
14 separation provisions violate the ACA because they unreasonably interfere with
15 and impede timely access to care, and they violate Title X itself by making it
16 harder or impossible for the vast majority of people intended to benefit from the
17 program to use it.

18 **c. Other requirements.** Along with the coercive counseling
19 and separation provisions, the Final Rule imposes numerous additional new
20 requirements that further undermine the quality of medical care, interfere with
21 the provider–patient relationship, reduce access to services, and contravene
22 Title X’s purposes.

1 6. In addition to violating three distinct statutory mandates—the
2 Nondirective Mandate, the ACA, and Title X itself—the Final Rule is also
3 arbitrary and capricious for a host of reasons. It reverses longstanding policies
4 and agency interpretations of Title X with no rational explanation or evidentiary
5 support, backtracks from evidence-backed standards of care included in HHS’s
6 own Program Requirements and guidance, and adds unsupported, illogical, and
7 counterproductive new requirements, while ignoring contrary record evidence
8 and failing to consider the grave public health harms the new requirements will
9 cause. Furthermore, the Final Rule unconstitutionally conditions Title X funding
10 on the relinquishment of rights to free expression and association, violates
11 principles of federalism, and is unconstitutionally vague.

12 7. The Final Rule’s harmful effects will fall particularly hard on
13 uninsured patients and those in rural areas, especially in Eastern Washington,
14 who in some cases will have no other feasible option for obtaining family
15 planning services. Under the Final Rule, the number of counties in Eastern
16 Washington without a Title X provider will nearly triple. Across all of
17 Washington, the number of counties without a Title X provider will jump from 5
18 to 21. More than half of Washington’s counties will be without Title X care. As
19 a result, thousands of Washingtonians who rely on Title X for contraception and
20 other family planning services will lose access to those services, irreparably
21 harming the public health and increasing health care costs in Washington.
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1 8. The Final Rule harms the very people Title X was enacted to help.
2 To avert irreparable injury to the State and its residents, Washington brings this
3 suit to vacate and set aside the Final Rule.

4 **II. PARTIES**

5 9. Plaintiff the State of Washington is represented by its Attorney
6 General, who is the State's chief legal adviser. The powers and duties of the
7 Attorney General include acting in federal court on matters of public concern to
8 the State.

9 10. As a current recipient of Title X grant funds, Washington is directly
10 affected by the Final Rule. Washington brings this action to redress harms to its
11 sovereign, proprietary, and quasi-sovereign interests and its interests as *parens*
12 *patriae* in protecting the health and well-being of its residents. It is the public
13 policy of the State of Washington that every individual has the fundamental right
14 to choose or refuse birth control, to choose or refuse abortion, and to be free from
15 state interference in those decisions and from state discrimination against the
16 exercise of those rights. RCW 9.02.100, *et seq.*

17 11. Washington law recognizes that access to reproductive health care
18 is vitally important to individuals' health and well-being, no matter their income
19 level. The Washington Legislature declared that:

- 20 • Reproductive health care is the care necessary to support the
21 reproductive system, the capability to reproduce, and the
22 freedom and services necessary to decide if, when, and how
often to do so, which can include contraception, cancer and
disease screenings, abortion, preconception, maternity,

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prenatal, and postpartum care. This care is an essential part of primary care for women and teens, and often reproductive health issues are the primary reason they seek routine medical care;

- Neither a woman’s income level nor her type of insurance should prevent her from having access to a full range of reproductive health care, including contraception and abortion services;
- Restrictions and barriers to health coverage for reproductive health care have a disproportionate impact on low-income women, women of color, immigrant women, and young women, and these women are often already disadvantaged in their access to the resources, information, and services necessary to prevent an unintended pregnancy or to carry a healthy pregnancy to term;
- This state has a history of supporting and expanding timely access to comprehensive contraceptive access to prevent unintended pregnancy;
- Nearly half of pregnancies in both the United States and Washington are unintended. [. . .]
- Access to contraception has been directly connected to the economic success of women and the ability of women to participate in society equally.

Reproductive Parity Act, 2018 Wash. Legis. Serv. Ch. 119 (S.S.B. 6219).

12. Washington is a direct grantee of federal Title X funds. It administers a highly effective and successful statewide family planning program that will be devastated by the Final Rule. Washington is a regulated entity directly affected by the Final Rule, is directly injured by it, and the relief requested will redress the injury.

1 this action seeks relief against federal agencies and officials acting in their official
2 capacities. *See California v. Azar*, 911 F.3d 558, 569–70 (9th Cir. 2018).

3 IV. RELEVANT FACTS

4 A. Statutory and Regulatory Background

5 1. History, Text, and Purpose of Title X

6 a. Historical background

7 19. Title X originated as a response to the growing body of evidence in
8 the 1960s demonstrating adverse health and economic outcomes caused by
9 low-income individuals' unequal access to modern, effective contraception.
10 Low-income women had twice the rates of unwanted pregnancies compared to
11 more affluent women, and their more closely spaced pregnancies led to poor
12 health outcomes for themselves and their children. Unintended, mistimed, and
13 unwanted childbearing worsened poverty levels and educational attainment,
14 limiting women's control over their lives. At the same time, evidence showed
15 that newly available and highly effective contraceptive options, such as "the Pill,"
16 were unaffordable for too many. In light of these findings, there was bipartisan
17 agreement that the federal government should support voluntary family planning
18 programs as a means of equalizing access to modern, effective contraceptive
19 methods and improving public health outcomes.

20 20. The first presidential message on population in the United States
21 was delivered by President Nixon on July 18, 1969. His message to Congress
22 called for the establishment of a federal family planning program and proposed

1 “as a national goal the provision of adequate family planning services within the
2 next five years to all those who want them but cannot afford them.”¹

3 **b. Text and purpose of Title X**

4 21. In response to the growing national concerns regarding family
5 planning needs, Congress passed the Family Planning Services and Population
6 Research Act of 1970, 42 U.S.C. § 300 *et seq.*, which added Title X to the Public
7 Health Service Act. Title X provides for the HHS Secretary to award grants for
8 the “establishment and operation of voluntary family planning projects which
9 shall offer a broad range of acceptable and effective family planning methods and
10 services” 42 U.S.C. § 300(a). Grants are to be awarded based on four
11 criteria: “the number of patients to be served, the extent to which family planning
12 services are needed locally, the relative need of the applicant, and its capacity to
13 make rapid and effective use of such assistance.” *Id.* § 300(b). Grantees must
14 provide assurance that “priority will be given in [their] project or program to the
15 furnishing of such services to persons from low-income families.”
16 *Id.* § 300a-4(c)(1). Title X sought to fulfill President Nixon’s 1969 promise that
17 “no American woman should be denied access to family planning assistance
18 because of her economic condition.”

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21 ¹ Richard M. Nixon, Special Message to the Congress on Problems of Population
22 Growth (Jul. 18, 1969).

1 22. Developed and passed with strong bipartisan support, the goal of
2 Title X was to “assist in making comprehensive, voluntary family planning
3 services readily available to all persons desiring such services.” Pub. L. No.
4 91-572, § 2, 84 Stat. 1504 (1970). Congress’s concern was for the “medically
5 indigent”—individuals who, because of their economic condition, were “forced
6 to do without, or to rely heavily on the least effective nonmedical techniques for
7 fertility control” where public health or charitable services were not available.
8 S. Rep. No. 91-1004, at 9 (1970). Congress emphasized that the “problems of
9 excess fertility for the poor result to a large extent from the inaccessibility of
10 family planning information and services.” H.R. Rep. No. 91-1472, at 6 (1970).

11 23. Title X requires in two separate provisions that the acceptance of
12 family planning services “shall be voluntary” and must not be a condition for
13 receipt of any other public service or assistance. 42 U.S.C. §§ 300(a), 300a–5.
14 The requirement that Title X services be “voluntary” was important to Congress,
15 which emphasized that “explicit safeguards” were needed “to insure that the
16 acceptance of family planning services and information relating thereto must be
17 on a purely voluntary basis by the individuals involved[.]” S. Rep. No. 91-1004,
18 at 12.

19 24. Consistent with the goal of facilitating access to the most effective
20 forms of contraception and reducing rates of unintended pregnancy, Congress
21 provided that some Title X funding should be spent on “research in the
22 biomedical, contraceptive development, behavioral, and program

1 implementation fields related to family planning and population.” 42 U.S.C.
2 § 300a-2. Such funding has supported development of, access to, and voluntary
3 use of modern, evidence-backed, effective contraceptive methods and delivery of
4 family planning services.

5 25. Today, Title X funds a broad range of family planning health care
6 services. In addition to offering a broad range of effective and acceptable
7 contraceptive methods to patients on a voluntary and confidential basis,
8 Title X-funded service sites provide contraceptive education and counseling;
9 breast and cervical cancer screening; sexually transmitted infection (STI) and
10 human immunodeficiency virus (HIV) testing, treatment, referral, and prevention
11 education; and pregnancy diagnosis and counseling.² Title X’s primary goal
12 continues to be “to provide contraceptive supplies and information to all who
13 want and need them, with priority given to persons from low-income families.”³
14 It currently makes family planning services available for free or at low cost to
15 those with limited economic means throughout the United States, including in
16 Washington.

17 26. The State is the only direct grantee of Title X funds in Washington.
18 Its Department of Health (DOH) administers and co-funds a family planning

19 ² U.S. Office of Population Affairs, *Title X Family Planning Annual Report:*
20 *2017 National Summary* (Aug. 2018) (2017 FPAR), available at [https://www.hhs.gov/opa/](https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2017-national-summary.pdf)
21 [sites/default/files/title-x-fpar-2017-national-summary.pdf](https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2017-national-summary.pdf) (last accessed January 9, 2019).

22 ³ *Id.*

1 program comprised of public and nonprofit subgrantee organizations operating
2 an extensive network of clinics throughout the state. Title X facilities in
3 Washington offer a broad range of services, including contraceptive services
4 (such as insertions of long-acting reversible contraceptives (LARCs) and
5 provision of oral contraceptive pills onsite, among other services), pregnancy
6 testing and counseling on all options with regard to a confirmed pregnancy, and
7 referrals to other medical providers for health care needs outside the scope of the
8 Title X program. Some of these subgrantee organizations also provide abortion
9 care at their clinics independent of the Title X program. Consistent with section
10 1008 of Title X, abortion care is not provided within any Title X program and is
11 not provided using federal funding.

12 **c. Section 1008**

13 27. Title X funds have never been permitted to be used to perform
14 abortions as a method of family planning. Section 1008 of Title X, entitled
15 “Prohibition of Abortion,” provides that “[n]one of the funds appropriated under
16 this subchapter shall be used in programs where abortion is a method of family
17 planning.” 42 U.S.C. § 300a-6.

18 28. Washington’s Title X program has always ensured that each
19 subrecipient maintains the required financial separation between Title X funds
20 and any abortion care they may provide.

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1 **2. Five Decades of Title X Regulations**

2 29. Title X provides that grants will be made “in accordance with such
3 regulations as the Secretary [of HHS] may promulgate.” *Id.* § 300a–4(a). From
4 the 1970s onward, the Secretary’s regulations have implemented Title X by
5 establishing specific requirements for grantees’ provision of a broad range of
6 effective contraception and other medically approved family planning and related
7 services, including nondirective pregnancy counseling and referrals for
8 out-of-program medical care. Aside from the Final Rule, there has been one
9 anomaly in Title X’s nearly 50-year history: the 1988 “gag rule,” which limited
10 Title X providers’ ability to provide counseling and referral to their patients. The
11 1988 rule was swiftly enjoined, and was never fully implemented due to ongoing
12 litigation and bipartisan concern over its invasion of the medical provider–patient
13 relationship. It was formally suspended after being on the books for four years.

14 30. The Final Rule imposes even stricter restrictions than the 1988 gag
15 rule, and erects even higher barriers impeding patients’ access to wanted and
16 needed care. In numerous respects, it is a significant departure from decades’
17 worth of regulations and from the Title X statute itself.

18 **a. Early Title X regulations require nondirective pregnancy**
19 **counseling**

20 31. In 1971, the Department issued its first regulations implementing
21 Title X. They required each grantee of Title X funds to provide assurances that,
22 *inter alia*, priority will be given to low-income individuals, services will be

1 provided “solely on a voluntary basis” and “in such a manner as to protect the
2 dignity of the individual,” and the “project will not provide abortions as a method
3 of family planning.” 36 Fed. Reg. 18,465, 18,466 (1971), *codified at* 42 C.F.R.
4 § 59.5(9) (1972). Each program was to provide “medical services related to
5 family planning including physician’s consultation, examination, prescription,
6 continuing supervision, contraceptive supplies, and necessary referral to other
7 medical facilities when medically indicated” and include “[p]rovision for the
8 effective usage of contraceptive devices and practices.” *Id.*

9 32. In 1980, HHS promulgated new regulations that retained many of
10 the same provisions as the 1971 regulations, including those discussed above.
11 45 Fed. Reg. 37,433, 37,437 (1980), *codified at* 42 C.F.R. § 59.5(5) (1980). The
12 following year, the Department issued “Program Guidelines” “to assist current
13 and prospective grantees in understanding and utilizing the Title X family
14 planning services grants program.” These guidelines provided that Title X
15 projects were to provide nondirective pregnancy counseling, including on the
16 option of abortion if a patient wanted such counseling.

17 **b. The anomalous 1988 gag rule**

18 33. In 1988, the Reagan Administration promulgated extensive new
19 regulations related primarily to section 1008. The 1988 regulations provided for
20 the first time that Title X covers “preconceptional” services only. 53 Fed. Reg.
21 2922 § 59.2 (Feb. 2, 1988).

22

1 34. The 1988 regulations established a broad prohibition on abortion
2 counseling and referral, including a “gag rule” applicable to all Title X project
3 personnel that prohibited them from providing “counseling concerning the use of
4 abortion as a method of family planning” and “referral for abortion as a method
5 of family planning.” *Id.* § 59.8. The 1988 regulations also imposed a new
6 requirement that a “Title X project must be organized so that it is physically and
7 financially separate” from abortion-related services. *Id.* § 59.9. Whether adequate
8 separation existed was based on a set of factors including the degree of separation
9 between treatment, consultation, examination, and waiting rooms and separate
10 personnel. *See id.*

11 35. The Supreme Court upheld the 1988 regulations in *Rust v. Sullivan*,
12 500 U.S. 173 (1991), on the record before it in that case. At that time, the Court
13 viewed Congress’ directives on Title X pregnancy counseling as ambiguous and
14 the agency’s 1988 gag rule a permissible construction of section 1008’s
15 “ambiguous” requirement in that regard.

16 36. As detailed below, the 1988 regulations generated enormous
17 controversy and were never fully implemented. Congress subsequently removed
18 any ambiguity from section 1008 through superseding legislation.

19 **c. Rebuffing limits on medical counseling after *Rust v.***
20 ***Sullivan***

21 37. On November 5, 1991, responding to widespread concerns (both
22 before and after *Rust*) that the 1988 gag rule unduly interfered in the medical

1 provider–patient relationship, President George H.W. Bush issued a
2 memorandum to the Secretary of HHS. President Bush urged that the
3 “confidentiality” of the doctor–patient relationship be preserved and that
4 operation of the Title X program be “compatible with free speech and the highest
5 standards of medical care.”⁴ To accomplish this result, President Bush directed
6 that the implementation of the regulations adhere to four principles:

- 7 1) Nothing in these regulations is to prevent a woman from
8 receiving complete medical information about her condition
9 from a physician.
- 10 2) Title X projects are to provide necessary referrals to
11 appropriate health care facilities where medically indicated.
- 12 3) If a woman is found to be pregnant and to have a medical
13 problem, she should be referred for complete medical care,
14 even if the ultimate result may be termination of her
15 pregnancy.
- 16 4) Referrals may be made by Title X programs to full-service
17 health care providers that perform abortions, but not to
18 providers whose principal activity is providing abortion
19 services.⁵

20 38. President Bush’s memorandum and HHS’s implementing
21 directives, however, had not followed required administrative processes, nor had
22 they gone far enough in correcting the counterproductive aspects of the 1988

⁴ George H.W. Bush, Message to the Senate Returning Without Approval the Family
Planning Amendments Act of 1992 (Sept. 25, 1992).

⁵ *Nat’l Family Planning & Reproductive Health Ass’n, Inc. v. Sullivan*, 979 F.2d 227,
230 (D.C. Cir. 1992).

1 regulations. The Bush actions were promptly enjoined in *National Family*
2 *Planning and Reproductive Health Ass'n v. Sullivan*, 929 F.2d 227 (D.C. Cir.
3 1992), because they were issued without notice and comment and did not resolve
4 the errors in the still-extant 1988 regulations.

5 39. Because of the ongoing litigation, the 1988 regulations were never
6 implemented on a nationwide basis. In early 1993, the HHS Secretary suspended
7 the 1988 regulations and issued a proposed rule that would revoke the gag rule
8 and reinstate the policies and interpretations that had been in effect prior to the
9 1988 regulations. 58 Fed. Reg. 7464 (Feb. 5, 1993).

10 **d. The Current Regulations restore the status quo**

11 40. The 1993 regulations were finalized in 2000, memorializing the
12 same regulatory approaches as had governed since Title X's inception, and have
13 been in place ever since. 65 Fed. Reg. 41270 (Jul. 3, 2000), *codified at* 42 C.F.R.
14 Part 59. (Current Regulations). The Current Regulations formally reinstated the
15 requirement of providing nondirective pregnancy counseling, in which the
16 provider covers all options about which a pregnant patient wishes to receive
17 information, including referral for abortion upon request; required referrals for
18 out-of-program care when "medically indicated"; and required financial, but not
19 physical, separation of Title X-eligible and non-Title X-eligible activities and
20 services. *Id.*

21 41. Under the Current Regulations, each Title X project must "[p]rovide
22 a broad range of acceptable and effective medically approved family planning

1 methods (including natural family planning methods) and services (including
2 infertility services and services for adolescents)”; offer services “solely on a
3 voluntary basis” and “without subjecting individuals to any coercion”; and give
4 “priority in the provision of services” to “persons from low-income families.”
5 42 C.F.R. § 59.5. Projects must provide for “medical services related to family
6 planning” and “necessary referral to other medical facilities when medically
7 indicated[.]” *Id.* Consistent with section 1008 of Title X, the Current Regulations
8 provide that Title X projects must “[n]ot provide abortion as a method of family
9 planning” and require that “[a]ny funds granted under this subpart shall be
10 expended solely for the purpose for which the funds were granted in accordance
11 with . . . the regulations of this subpart” *Id.* §§ 59.5, 59.9.

12 42. The Current Regulations state that the nondirective pregnancy
13 counseling requirement means providers must offer neutral information about all
14 pregnancy options and referral (including referral for abortion) if desired by the
15 patient. Each Title X project must “[o]ffer pregnant women the opportunity to be
16 provided information and counseling regarding each of the following options:”

- 17 (A) prenatal care and delivery;
18 (B) infant care, foster care, and adoption; and
19 (C) termination of pregnancy.

20 42 C.F.R. § 59.5. “If requested to provide such information and counseling” as
21 to the options listed above, the project is to “provide neutral, factual information
22 and nondirective counseling on each of the options, and referral upon request,

1 except with respect to any option(s) about which the pregnant woman indicates
2 she does not wish to receive such information and counseling.” *Id.* These
3 patient-focused requirements ensure that every patient at a Title X facility
4 receives the information she wants and needs when a pregnancy is confirmed.

5 43. In promulgating the Current Regulations, the HHS Secretary noted
6 that “the requirement for nondirective options counseling has existed in the Title
7 X program for many years, and, with the exception of the period 1988–1992, it
8 has always been considered to be a necessary and basic health service of Title X
9 projects.” 65 Fed. Reg. 41273 (Jul. 3, 2000). “Indeed, pregnancy testing is a
10 common and frequent reason for women coming to visit a Title X clinic” and
11 nondirective counseling for pregnant patients is “consistent with the prevailing
12 medical standards recommended by national medical groups such as the
13 American College of Obstetricians and Gynecologists and the American Medical
14 Association.” *Id.*

15 44. In addition to the Current Regulations, HHS has established
16 Program Requirements that summarize Title X as follows:

17 The program is designed to provide contraceptive supplies and
18 information to all who want and need them, with priority given to
19 persons from low-income families. All Title X-funded projects are
20 required to offer a broad range of acceptable and effective medically
21 (U.S. Food and Drug Administration (FDA)) approved
22 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

1 (HIV) prevention education, testing, and referral; and pregnancy
2 diagnosis and counseling.⁶

3 45. Title X grantees are also required to follow the “QFP”—a 2014
4 publication entitled “Providing Quality Family Planning Services:
5 Recommendations of CDC and the U.S. Office of Population Affairs”⁷ that is
6 incorporated into the Program Requirements. The QFP, prepared by the Centers
7 for Disease Control and Prevention (CDC) and the Office of Population Affairs
8 (OPA), both of which are housed within HHS, is a careful, extensive,
9 evidence-based description of the best practices for providing family planning
10 services in the United States. Its recommendations were “developed jointly under
11 the auspices of CDC’s Division of Reproductive Health (DRH) and the Office of
12 Population Affairs (OPA), in consultation with a wide range of experts and key
13 stakeholders,” which included a “multistage process that drew on established
14 procedures for using clinical guidelines” developed by “family planning clinical
15 providers, program administrators, representatives from relevant federal

16 ⁶ “Program Requirements for Title X Funded Family Planning Projects,” Office of
17 Population Affairs (April 2014), *available at*
18 <https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf> (last
19 accessed February 20, 2019).

20 ⁷ “Providing Quality Family Planning Services: Recommendations of CDC and the
21 U.S. Office of Population Affairs,” *Morbidity and Mortality Weekly Report* Vol. 63, No. 4
22 (April 25, 2014), *available at* <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf> (last accessed
January 2, 2019) (the QFP).

1 agencies, and representatives from professional medical organizations.”⁸ This
2 process included “[s]ystematic reviews of the published literature from January
3 1985 through December 2010,”⁹ and the report itself (exclusive of appendices)
4 contains over 150 citations to scholarly publications in the endnotes.¹⁰

5 46. The QFP requires that for pregnant patients, “[o]ptions counseling
6 should be provided in accordance with recommendations from professional
7 medical associations, such as ACOG [the American College of Obstetricians and
8 Gynecologists] and AAP [the American Academy of Pediatrics].”¹¹ ACOG and
9 AAP’s *Guidelines for Perinatal Care* state that providers should “[a]ssess all
10 patients’ desire for pregnancy. If the patient indicates that the pregnancy is
11 unwanted, she should be fully informed in a balanced manner about all options,
12 including raising the child herself, placing the child for adoption, and abortion.”¹²

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18 ⁸ QFP, *supra* n.7, p. 30 (Appendix A).

19 ⁹ *Id.*

20 ¹⁰ *Id.*, pp. 25–29.

21 ¹¹ *Id.* at 14.

22 ¹² American Academy of Pediatrics & The American College of Obstetricians &
Gynecologists, *Guidelines for Perinatal Care*, p. 127 (7th ed. 2016).

1 47. On December 22, 2017, the CDC published an update to the QFP
2 (QFP Update),¹³ which stated that after a thorough review, “CDC and the Office
3 of Population Affairs determined that none of the newly published
4 recommendations [since 2014] marked a substantial shift in how family planning
5 care should be provided” as set forth in the QFP.¹⁴ That is, as of December 2017,
6 no new evidence supported any significant changes to the QFP.

7 **3. Statutes Requiring Nondirective Pregnancy Counseling and**
8 **Limiting Government Interference with Health Care**

9 48. In its annual appropriations acts, Congress has consistently required
10 that all pregnancy counseling in Title X programs must be nondirective. In
11 addition, Congress has broadly forbidden the Secretary of HHS from
12 promulgating “any” regulation that interferes with provider–patient
13 communications or patients’ access to information, that requires providers to
14 violate medical ethics requirements, or that impedes patients’ timely access to
15 health care.

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19 ¹³ “Update: Providing Quality Family Planning Services – Recommendations from
20 CDC and the U.S. Office of Population Affairs, 2017,” *Morbidity and Mortality Weekly*
21 *Report* Vol. 66, No. 50 (December 22, 2017), available at [https://www.cdc.gov/mmwr/
22 volumes/66/wr/pdfs/mm6650a4-H.pdf](https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6650a4-H.pdf) (last accessed January 2, 2019) (the QFP Update).

¹⁴ *Id.*

1 **a. The Nondirective Mandate**

2 49. Since 1996, Congress has passed annual legislation requiring that all
3 pregnancy counseling within a Title X program *must* be nondirective (the
4 “Nondirective Mandate”). Specifically, the Department of Health and Human
5 Services Appropriations Act, 2019, states that, with respect to the amounts
6 appropriated “for carrying out the program under title X of the [Public Health
7 Service] Act to provide for voluntary family planning projects, . . . all pregnancy
8 counseling shall be nondirective[.]” Pub. L. No. 115-245 (Sept. 28, 2018). The
9 Nondirective Mandate has been included in every appropriations act since
10 1996.¹⁵

11 50. In issuing the proposed rule that preceded the Final Rule, the
12 Secretary acknowledged that “nondirective counseling is the provision of
13 information on all available options without promoting, advocating, or
14 encouraging one option over another.”¹⁶

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17 ¹⁵ Pub. L. No. 115-31; Pub. L. No. 115-141; Pub. L. No. 114-113; Pub. L. No.
18 113-76; Pub. L. No. 113-235; Pub. L. No. 112-74; Pub. L. No. 111-117; Pub. L. No. 111-8;
19 Pub. L. No. 111-322; Pub. L. No. 110-161; Pub. L. No. 109-149; Pub. L. No. 108-199; Pub.
20 L. No. 108-7; Pub. L. No. 108-447; Pub. L. No. 107-116; Pub. L. No. 106-554; Pub. L. No.
21 106-113; Pub. L. No. 105-78; Pub. L. No. 105-277; Pub. L. No. 104-134; Pub. L. No.
22 104-208.

¹⁶ 83 Fed. Reg. 25512, n.41 (Jun. 1, 2018).

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b. Section 1554 of the Affordable Care Act

51. In 2010, Congress passed the Patient Protection and Affordable Care Act (ACA), which includes section 1554 (“Access to therapies”). That section provides that the Secretary of HHS “shall not promulgate any regulation” that, *inter alia*:

- 1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
- 2) impedes timely access to health care services;
- 3) interferes with communications regarding a full range of treatment options between the patient and the provider;
- 4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; or
- 5) violates the principles of informed consent and the ethical standards of health care professionals.

42 U.S.C. § 18114.

4. Impact of Title X

52. The bipartisan concerns that led to Title X’s passage in 1970 are just as salient today: an article cited in the QFP Update in December 2017 recognizes that unintended pregnancy “can result in negative health consequences for women and children and an enormous financial burden to the health care system,”

1 as well as creating “undue financial burdens in many families.”¹⁷ Title X has been
2 extremely successful in addressing these problems in a win-win
3 fashion—generating cost savings while empowering women and families and
4 improving health outcomes.

5 53. Title X’s positive impact on the reproductive health of low-income
6 Americans cannot be overstated. Title X clinics serve more than four million
7 women, men, and young people every year. In 2017, Title X clinics served 2.8
8 million patients seeking contraception, and Title X funds helped provide over
9 4 million STI tests for chlamydia, gonorrhea, and syphilis, 1.2 million
10 confidential HIV tests, and over 1.5 million screenings for cervical and breast
11 cancer. More than two thirds of people who received preventive care through the
12 Title X program in 2017 were living in poverty, and 90% had incomes at or below
13 250% of the federal poverty level.¹⁸

14 54. Title X clinics typically provide significantly better access to
15 contraceptive care than any other type of safety-net provider. A study published
16 by HHS administrators within the Office of Population Affairs in 2016 showed
17 that Title X clinics do a better job overall than non-Title X clinics in providing
18 safety-net reproductive health care that is consistent with current, evidence-based

19 ¹⁷ [https://journals.lww.com/greenjournal/fulltext/2016/02000/Committee_Opinion_](https://journals.lww.com/greenjournal/fulltext/2016/02000/Committee_Opinion_No_654_Reproductive_Life.53.aspx)
20 [No_654_Reproductive_Life.53.aspx](https://journals.lww.com/greenjournal/fulltext/2016/02000/Committee_Opinion_No_654_Reproductive_Life.53.aspx) (cited in QFP Update) (last accessed
21 March 4, 2019).

22 ¹⁸ 2017 FPAR, *supra* n.2.

1 clinical guidelines.¹⁹ As just one example, Title X sites are more likely to offer
2 intra-uterine devices (IUDs) and contraceptive implants onsite.²⁰ Those methods,
3 often grouped under the umbrella term “long-acting reversible contraceptives”
4 (LARCs), are by far the most effective non-permanent contraceptive methods.

5 55. Title X’s impact on public health is significant, even beyond its
6 central role in helping women avoid unintended pregnancies. Title X providers
7 are critical in identifying and treating STIs—for example, screening for
8 chlamydia and treating it early to prevent infertility from an untreated infection.
9 Title X sites are more likely than other public non-Title X providers and private
10 providers to follow chlamydia screening guidelines for testing those most at risk
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13 ¹⁹ Carter, *et al.*, *Four aspects of the scope and quality of family planning services in*
14 *US publicly funded health centers: Results from a survey of health center administrators*,
15 94 J. Contraception 340 (2016), <http://dx.doi.org/10.1016/j.contraception.2016.04.009> (last
16 accessed March 4, 2019).

17 ²⁰ See, e.g., Bocanegra, *et al.*, *Onsite Provision of Specialized Contraceptive Services:*
18 *Does Title X Funding Enhance Access?*, J. Women’s Health (May 2014),
19 <https://www.liebertpub.com/doi/full/10.1089/jwh.2013.4511> (last accessed March 4, 2019)
20 (finding IUD availability at 90% of Title X clinics, as opposed to 51% of public non-Title X
21 clinics and 38% of private clinics; and finding onsite contraceptive implant availability at
22 58% of Title X clinics, as opposed to 19% of public non-Title X clinics and 7% of private
clinics).

1 for chlamydia.²¹ In addition to STI testing, Title X providers perform hundreds
 2 of thousands of screenings for breast, cervical, and testicular cancer each year,
 3 facilitating early diagnosis and treatment that can be lifesaving.

4 56. Title X's role within the broader health care system is distinctly
 5 important because many women seek out reproductive health specialists for their
 6 family planning needs. Studies have shown that, even where women have
 7 primary care options available, they prefer to get reproductive health and family
 8 planning care from clinicians who specialize in those areas—as most Title X
 9 providers do. As one study explained, “[l]arge majorities of women ... said that
 10 they chose the family planning clinic because the staff is knowledgeable
 11 about—or easy to talk to about—sexual and reproductive issues or because the
 12 clinic makes it easy for them to get the contraceptive method they want, and to
 13 do so directly, without having to make a separate trip to a pharmacy to have a
 14 prescription filled.”²² Because healthy women of child-bearing age tend to seek
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16 ²¹ Chow, *et al.*, *Comparison of adherence to chlamydia screening guidelines among*
 17 *Title X providers and non-Title X providers in the California Family Planning, Access, Care,*
 18 *and Treatment Program*, J. Women's Health Vol. 21, No. 8 (Aug. 2012),
 19 <https://www.ncbi.nlm.nih.gov/pubmed/22694761> (last accessed March 4, 2019).

20 ²² *E.g.*, Frost, *et al.*, *Specialized Family Planning Clinics in the United States: Why*
 21 *Women Choose Them and Their Role in Meeting Women's Health Care Needs*, 22 *Women's*
 22 *Health Issues* 519 (2012), <https://doi.org/10.1016/j.whi.2012.09.002> (last accessed
 March 4, 2019).

1 out such specialized care, Title X health centers serve a critical role in fostering
2 trust and encouraging women to seek and receive needed and wanted health care.

3 57. The Title X program’s impact is particularly significant in rural
4 areas, and for communities of color. Of the 4 million patients across the country
5 who were served by Title X health centers in 2017, 31% self-identified with at
6 least one nonwhite race category and 33% self-identified as Hispanic or Latino.²³
7 And in rural areas, Title X health centers are often the only provider of
8 reproductive health services for low-income individuals. In one out of five
9 counties in America, a Title X clinic is the only family planning center for people
10 without the means to see a private physician.

11 58. The Final Rule, which fundamentally alters the regulatory
12 requirements that have been in place for decades and contradicts evidence-backed
13 standards of care and principles of medical ethics, threatens to reverse Title X’s
14 exceptional success by dismantling provider networks and dramatically reducing
15 patients’ access to needed services—including in Washington.

16 **B. Washington’s Title X Program**

17 59. The Washington State Department of Health (DOH) is the sole
18 grantee of Title X funds in Washington and runs the statewide Title X program,
19 which is jointly funded by federal and state dollars. The Washington Legislature
20 has directed the Secretary of DOH to “[e]nter into contracts and enter into and
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22 ²³ 2017 FPAR, *supra* n.2.

1 distribute grants on behalf of the department,” and through this authority the
2 Secretary operates the state-administered Title X family planning program.
3 RCW 43.70.040(5).

4 60. Washington’s Title X program serves as an umbrella organization
5 for 16 subrecipients of Title X funding that operate 85 clinics throughout the
6 state: Washington’s Title X network. DOH anticipates that, absent disruption
7 caused by the Final Rule, the Title X program would serve approximately 98,000
8 individual Washingtonians from April 1, 2019 through March 31, 2020.

9 61. In 2017, the total expenditure for Washington’s Title X program was
10 approximately \$13 million. The federally funded amount was approximately
11 \$4 million, and the state-funded amount was approximately \$9 million.

12 62. For the current Title X funding period, DOH initially received a
13 grant for a three-year period, which began on April 1, 2017. Partway through that
14 period, DOH received a letter from HHS shortening the project period to one
15 year, ending March 31, 2018. HHS did not announce a new funding opportunity
16 in time to make awards for the next project period before March 31, 2018, so
17 DOH was granted an extension of the grant period to August 31, 2018. DOH
18 applied for and received a grant in the amount of \$2,783,000 for the period of
19 September 1, 2018 to March 31, 2019.

20 63. On January 10, 2019, DOH submitted an application for a new
21 three-year Title X grant, to begin on April 1, 2019.

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1 64. Washington's Title X program served 91,285 patients in 2017, with
2 128,409 patient visits. Fifty-six percent of Title X program clients in 2017 had
3 annual incomes at or below the federal poverty level,²⁴ and 81% had incomes
4 below 200% of the federal poverty level. Seventeen percent of clients were
5 women of color; of those, 58% were at or below the federal poverty level, and
6 80% had incomes below 200% of the federal poverty level. Nine percent of
7 clients were under the age of 18. DOH estimates that services provided through
8 Washington's Title X project in 2017 helped women avoid over 18,000 unwanted
9 pregnancies. The resulting net savings created by services provided through the
10 program (including contraceptive services, STI testing, and cancer screening)
11 was over \$113 million.

12 65. Title X is a competitive program, and DOH spends a tremendous
13 amount of time preparing its application for a Title X grant. Washington's
14 application is prepared by the staff of DOH's Office of Family and Community
15 Health Improvement, and it is subjected to three levels of review within DOH.
16 For DOH's most recent application, it spent over 300 hours of staff time
17 preparing the application, gathering the required materials, and ensuring
18 accuracy.

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21 ²⁴ The federal poverty level for 2018 was \$12,140 for a single-person household and
22 \$20,780 for a three-person household.

1 66. Of the 16 subrecipients of Title X funds in Washington, five operate
2 clinics that offer abortion care independently of the Title X project. These clinics
3 provided 89% of all Title X patient visits in 2017. Consistent with the Current
4 Regulations and medical standards of care, all subrecipients' clinics provide
5 referrals for out-of-program abortion care if desired by the patient.

6 67. A number of counties in Washington have only one Title X provider
7 or subrecipient each: Adams, Benton, Clallam, Cowlitz, Grays Harbor, Klickitat,
8 San Juan, Wahkiakum, Lewis, Thurston, Jefferson, Whatcom, Skagit,
9 Snohomish, Clark, Skamania, Kittitas, Chelan, Ferry, Stevens, Pend Oreille,
10 Franklin, Whitman, and Walla Walla. The following counties currently have no
11 Title X provider: Island, Lincoln, Columbia, Garfield, and Asotin.

12 68. DOH selects subrecipients using robust criteria to ensure their
13 capacity to provide large numbers of patients with a broad range of high-quality
14 family planning services in a voluntary, noncoercive, client-directed manner that
15 respects and is appropriate to the populations in their communities. Abortion care
16 is not provided as part of Washington's Title X project. Subrecipients' written
17 policies must state clearly and unequivocally that no Title X funds will be used
18 for abortion services. DOH's contract with each subrecipient in its network
19 affirms that the subrecipient does "not provide abortion as a method of family
20 planning within the Title X Project (42 CFR 59.5(5))."

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1 **C. HHS’s 2018 Final Rule**

2 69. On June 1, 2018, HHS issued a proposed rule²⁵ that would overhaul
3 the longstanding Title X regulations in numerous respects. HHS received over
4 500,000 public comments opposing the proposed rule—including extensive
5 comments from major medical associations, major Title X providers and policy
6 and research organizations, nearly 200 members of Congress, and several states,
7 including Washington.

8 70. On March 4, 2019, HHS published a final rule entitled “Compliance
9 with Statutory Program Integrity Requirements,” 84 Fed. Reg. 7714 (the Final
10 Rule) (attached as Exhibit A). Despite the outpouring of opposition through
11 public comments, the Final Rule retains key provisions of the proposed rule,
12 significantly altering HHS’s previous interpretation of Title X. The Final Rule
13 introduces numerous changes to the Title X regulations that have been in place
14 for decades, including those discussed below.

15 **1. The Coercive and Misleading Counseling Requirements**

16 71. The Final Rule restricts communications within the medical
17 provider–patient relationship. It broadly prohibits Title X providers from
18 referring pregnant patients for abortion, and strikes the Current Regulations’

19 ²⁵ Compliance With Statutory Program Integrity Requirements (Proposed rule), 83
20 Fed. Reg. 25,502 (Jun. 1, 2018), *available at* [https://www.federalregister.gov/documents/
21 2018/06/01/2018-11673/ compliance-with-statutory-program-integrity-requirements](https://www.federalregister.gov/documents/2018/06/01/2018-11673/compliance-with-statutory-program-integrity-requirements) (last
22 accessed March 4, 2019).

1 provision for referral for out-of-program care if requested by the patient. It also
2 forbids Title X projects to “promote, refer for, or support abortion as a method of
3 family planning” or “take any other affirmative action to assist a patient to secure
4 such an abortion.” Final Rule § 59.14(a); *see also id.* § 59.5(a)(5).

5 72. The Final Rule provides that all patients with a confirmed pregnancy
6 “shall” be referred to a health care provider for “prenatal health care”—regardless
7 of whether the patient wants to continue the pregnancy, and regardless of the Title
8 X provider’s medical judgment as informed by the patient’s individual
9 circumstances. *Id.* § 59.14(b). Despite the statutory requirement that services be
10 “voluntary,” the Final Rule strikes the Current Regulations’ requirement that a
11 project refrain from providing information when the patient “indicates she does
12 not wish to receive” that information. The mandatory referral is directive, since
13 it pushes patients toward a certain type of care regardless of their wishes.

14 73. Citing no medical evidence or authority, HHS deems prenatal health
15 care to be “medically necessary” for *all* pregnant patients. *Id.* § 59.14(d);
16 *see also, e.g.*, Supplementary Information, 84 Fed. Reg. 7761 (“Prenatal care is
17 medically necessary for any patient who is pregnant[.]”); *id.* at 7728, 7730, 7747
18 & n.75, 7748. This is arbitrary and irrational, as there is typically no medical
19 reason for a patient whose pregnancy will be terminated to receive prenatal care.
20 HHS’s assertion is based on an unsupported and erroneous assumption that if a
21 certain type of care is “medically necessary” for purposes of Medicaid coverage,
22

1 all patients must receive that type of care. *See id.* at 7762. HHS failed to give the
2 public an opportunity to comment on this rationale for the mandatory referral.

3 74. The Final Rule eliminates the longstanding requirement that
4 pregnant patients be offered nondirective counseling in response to a pregnancy.
5 Instead, in addition to providing the mandatory prenatal care referral, providers
6 may choose to provide pregnant patients with the following “counseling and/or
7 information”: (1) Nondirective pregnancy counseling, if provided by a physician
8 or “advanced practice provider”; (2) a list of “comprehensive primary health care
9 providers (including providers of prenatal care)”; (3) referral to “social services
10 or adoption agencies”; and/or (4) information about “maintaining the health of
11 the mother and unborn child during pregnancy.” *Id.* § 59.14(b)(1)–(4). Thus,
12 although doctors and “advanced practice providers” may choose to provide what
13 the Final Rule refers to as “nondirective” pregnancy counseling (along with the
14 directive referral for prenatal care), a provider or clinic may alternatively choose
15 to provide only biased, one-sided information about carrying the pregnancy to
16 term, or they may choose to provide no information other than the directive
17 prenatal care referral. Yet HHS acknowledges elsewhere that offering
18 information about only one option is directive and therefore impermissible.
19 *See* Supplementary Information, 84 Fed. Reg. 7747.

20 75. HHS’s new definition of “advanced practice provider” excludes
21 registered nurses and others who may lack a “graduate level degree” and a
22 “license to diagnose, treat, *and* counsel” patients. Final Rule § 59.2 (emphasis

1 added). The Final Rule prohibits individuals who are not physicians or “advanced
2 practice providers” from providing so-called “nondirective” pregnancy
3 counseling to patients—though the same prohibition does not apply to the
4 directive counseling permitted by the Final Rule. *See id.* § 59.14(b)(1)–(4). HHS
5 fails to rationally explain why it has limited the ability of qualified professionals
6 and trained staff to provide “nondirective” pregnancy counseling as part of a Title
7 X program, or why the same limitation does not apply to directive pregnancy
8 counseling.

9 76. The list of “comprehensive primary health care providers (including
10 providers of prenatal care)” permitted by section 59.14(b)(2) “may” (but need
11 not) include some providers who “also provide abortion as part of their
12 comprehensive health care services.” Final Rule § 59.14(c)(2). Such providers
13 must not be identified as such and must not comprise a majority of the list. *Id.* A
14 Title X provider’s theoretical ability to include providers of abortion on this
15 obfuscated list is illusory: in Washington, there are *no* publicly known primary
16 health care providers that offer abortion care.

17 77. Limiting medical referrals to “primary health care providers” delays
18 patients’ access to care—whether abortion care or any other type of care that
19 primary health care providers do not offer. As to abortion in particular, even if
20 there were providers who could be included on the referral list (which is not the
21 case in Washington), the required obfuscation and misdirection would delay or
22 obstruct patients’ access to care, putting them at greater risk of the complications

1 associated with abortions later in pregnancy. Although abortion is very safe and
2 much safer than childbirth,²⁶ the risk increases with each week of delay. HHS
3 failed to acknowledge or address these concerns.

4 78. The Current Regulations require that all patients be referred for
5 “medically indicated” out-of-program care, including medically indicated
6 abortion. Current Regulations § 59.5(b)(1). The Final Rule strikes this
7 requirement and *prohibits* referrals for abortion in all circumstances except
8 “cases in which emergency care is required[.]” *Id.* § 59.14(b). The Final Rule
9 prohibits referrals for abortion (or to reproductive health specialists generally)
10 even in cases where carrying a pregnancy to term will endanger the patient’s life
11 or health but there is no acute medical “emergency,” in cases of rape or incest,²⁷

12 ²⁶ Studies show that abortion is “markedly safer than childbirth.”
13 <https://www.ncbi.nlm.nih.gov/pubmed/22270271> (last accessed March 4, 2019); *see also*,
14 *e.g.*, *Whole Woman’s Health v. Hellerstedt*, 136 S. Ct. 2292, 2311 (2016) (reviewing
15 evidence that “abortion in Texas was extremely safe with particularly low rates of serious
16 complications and virtually no deaths occurring on account of the procedure”).

17 ²⁷ A footnote in the Supplementary Information accompanying the Final Rule states
18 that “in cases involving rape and/or incest, it would not be considered a violation of the
19 prohibition on referral for abortion as a method of family planning if a patient is provided a
20 referral to a licensed, qualified, comprehensive health service provider who also provides
21 abortion, provided that the Title X provider has complied with any applicable State and/or
22 local laws requiring reporting to, or notification of, law enforcement or other authorities and
such reporting or notification is documented in the patient’s record.” Supplementary

1 and in cases where a patient is concerned about the inherent dangers of
2 childbirth.²⁸

3 79. Subsection 59.5(b)(1)'s general requirement that Title X projects
4 provide "referral to other medical facilities when medically necessary" is made
5 subject to subsection 59.14(a)'s "[p]rohibition on referral for abortion." *Id.*
6 § 59.5(b)(1). In addition, this provision now uses the term "medically necessary"
7 instead of "medically indicated." *Compare* Final Rule § 59.5(b)(1) *with* Current
8 Regulations § 59.5(b)(1). This change in terminology appears to limit the
9 circumstances in which referral for out-of-program medical care is required. HHS
10 offers no explanation for this change. *See* Supplementary Information, 84 Fed.
11 Reg. 7752.

12 Information, 84 Fed. Reg. 7747 n.76. Not only are these unique provisions for "cases
13 involving rape and/or incest" found nowhere in the Final Rule itself, but HHS offers no
14 explanation or support for them.

15 ²⁸ Maternal mortality (i.e., death related to pregnancy or birth) has been rising in the
16 United States, as shown in a recent, widely cited study analyzing maternal mortality data
17 from all U.S. states. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5001799/> (last accessed
18 March 4, 2019) ("[T]he maternal mortality rate for 48 states and Washington D.C. from
19 2000-2014 was higher than previously reported, is increasing, and places the U.S. far behind
20 other industrialized nations."). The United States has the highest maternal mortality rate
21 compared to 40 other countries in the developed world, with the risks being "especially high"
22 for women of color. <https://www.worldcat.org/title/deadly-delivery-the-maternal-health-care-crisis-in-the-usa/oclc/694184792> (last accessed March 4, 2019).

1 80. These provisions endanger patients’ lives and health by interfering
2 in the provider–patient relationship, and unreasonably restrict patients’ timely
3 access to wanted and needed information and medical care. They contradict
4 HHS’s own evidence-based assessment of the importance of nondirective
5 counseling and medically appropriate referrals as reflected in the QFP, which
6 HHS reaffirmed in the December 2017 QFP Update. HHS offers no new evidence
7 to support this departure from the extensively evidence-backed QFP standards,
8 and never mentions the QFP in the Supplementary Information accompanying
9 the Final Rule.

10 81. The Final Rule defies patients’ expectations that their medical care
11 providers—regardless of their funding source—will offer complete, medically
12 accurate, and nondirective information in a candid, confidential, and respectful
13 manner. These expectations are enshrined in principles of medical ethics and
14 providers’ fiduciary duties to their patients, as well as federal law. HHS does not
15 meaningfully address this, myopically asserting that these expectations and
16 principles are not part of the “purpose of Title X,” even though Title X inherently
17 involves medical care. Supplementary Information, 84 Fed. Reg. 7746.

18 82. Doctors, physicians’ assistants, and nurses all have affirmative
19 ethical duties to give patients complete information about all care options and to
20 make medically appropriate referrals. For example, the American Medical
21 Association (AMA) advises that patients have a right to “receive information
22 from their physicians and to have an opportunity to discuss the benefits, risks,

1 and costs of appropriate treatment alternatives[.]”²⁹ ACOG specifically advises
 2 that after a pregnancy is confirmed, “[t]he patient should be fully informed in a
 3 balanced manner about all options, including raising the child herself, placing the
 4 child for adoption and abortion.”³⁰ When the care that patients seek is beyond the
 5 scope of clinicians’ practice, clinicians fulfill their obligations to patients through
 6 referral to other professionals who have the appropriate skills and expertise to
 7 address the situations.³¹

8 83. Numerous public comments, including from members of the
 9 medical community, overwhelmingly oppose the Final Rule based on these and
 10 other ethical and legal concerns, providing extensive detail and support. HHS
 11 dismisses such concerns without directly addressing any of the specific ethical or
 12 legal problems created by the Final Rule.

13 ²⁹ AMA Code of Medical Ethics Opinions on Patient–Physician Relationships § 1.1.3
 14 (citing AMA Principles of Medical Ethics: I, IV, V, VIII, IX).

15 ³⁰ American College of Obstetricians and Gynecologists (ACOG), Guidelines for
 16 Women’s Health Care: A Resource Manual, 719-20 (4th ed. 2014).

17 ³¹ See, e.g., AMA Code of Medical Ethics Opinions on Patient–Physician
 18 Relationships, *supra* n.27, § 1.2.3 (“Physicians’ fiduciary obligation to promote patients’ best
 19 interest and welfare can include ... referring patients to other professionals to provide care.”)
 20 (citing AMA Principles of Medical Ethics IV, V, VI); World Medical Association,
 21 *International Code of Medical Ethics* (2018) (“Whenever an examination or treatment is
 22 beyond the physician’s capacity, he/she should consult with or refer to another physician who
 has the necessary ability.”).

1 84. The Final Rule will damage patients’ trust in Title X providers and
2 the health care system more broadly, by misdirecting patients who want abortions
3 to providers that do not perform them, and by referring patients for prenatal care
4 they may not want or need. Far from treating patients with “dignity,” as required
5 by the regulations, these unethical practices shame and humiliate them. This
6 reduces the likelihood that patients will seek Title X or other health care services
7 in the future, leading to poorer health outcomes.

8 85. HHS fails to rationally explain why referrals for abortion care are
9 the *only* prohibited referrals, whereas referrals for all other types of
10 out-of-program care are permitted (and in some cases, required). *See* Final Rule
11 § 59.5(b)(1) (requiring referral for “medically necessary” out-of-program care,
12 except abortion care); § 59.14(b) (requiring referral for out-of-program prenatal
13 care).

14 86. As a primary justification for the coercive counseling and related
15 provisions, HHS cites federal “conscience” statutes that in certain circumstances
16 absolve medical care providers from being required to care for patients in a
17 manner that is inconsistent with the provider’s own conscience. Supplementary
18 Information, 84 Fed. Reg. 7716–17, 7719, 7746–47. Contrary to HHS’s assertion,
19 these statutes do not justify prohibiting *all* providers from offering referrals for
20 medically appropriate care. The gag rule would affirmatively require many
21 providers to violate their own consciences, to the extent their consciences are
22 consistent with the ethical standards discussed above. Moreover, HHS’s rationale

1 | improperly shifts Title X’s focus from patients in need of reproductive health
2 | care to providers who have objections to reproductive health care without
3 | adequate justification.

4 | 87. The Final Rule will impose a Hobson’s choice on existing Title X
5 | providers: comply with the coercive counseling and related provisions, or comply
6 | with their ethical and legal obligations to patients. These new provisions, and/or
7 | others such as the onerous separation requirements discussed below, will drive
8 | most (if not all) providers and clinics out of Washington’s Title X network
9 | entirely. Four Planned Parenthood affiliates and the entity that operates the Cedar
10 | River Clinics—five subrecipients that represent 89% of Title X network coverage
11 | in the state—have announced that they are unable to continue participating in
12 | Washington’s Title X program subject to the Final Rule. The Final Rule’s impact
13 | on Washington’s network will deprive a great many patients of access to a Title X
14 | provider.

15 | 88. Studies show that when specialized family planning clinics such as
16 | Planned Parenthood are excluded from statewide networks, patients lose access
17 | to care because clinics close, reduce their hours, offer fewer services and
18 | contraceptive options, see fewer patients, require longer wait times for
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1 | appointments, and raise their fees, while clinics that remain in the network are
2 | unable to fill the gaps even when the program is adequately funded.³²

3 | 89. HHS disregards the Final Rule’s effect on providers as established
4 | in the administrative record, and asserts with no evidence that it “does not believe
5 | that the rule will limit the ability of individuals to access affordable health care[.]”
6 | Supplementary Information, 84 Fed. Reg. 7725; *see also id.* at 7766, 7775, 7785.

7 | 2. The “Separation” Requirements

8 | 90. The Final Rule requires that Title X projects be “physically and
9 | financially separate” from abortion care and referral, and from various expressive
10 | and associational activities related to abortion that are outside the Title X

11 |
12 | ³² See Kari White et al., *The Impact of Reproductive Health Legislation on Family*
13 | *Planning Clinic Services in Texas*, 105 Am. J. of Public Health 851 (May 2015); Center for
14 | Reproductive Rights & National Latina Institute for Reproductive Health, *Nuestra Voz,*
15 | *Nuestra Salud, Nuestro Texas: The Fight for Women’s Reproductive Health in the Rio*
16 | *Grande Valley* 6 (Nov. 2013), [http://www.nuestrotexas.org/wp-content/uploads/2015/03/NT-](http://www.nuestrotexas.org/wp-content/uploads/2015/03/NT-executive-summary-EN1.pdf)
17 | [executive-summary-EN1.pdf](http://www.nuestrotexas.org/wp-content/uploads/2015/03/NT-executive-summary-EN1.pdf) (last accessed March 4, 2019); Amanda J. Stevenson et al.,
18 | *Effect of Removal of Planned Parenthood from the Texas Women’s Health Program*, 374
19 | *New Eng. J. of Med.* 853 (2016); Tony Leys and Barbara Rodriguez, *State family planning*
20 | *services decline 73 percent in fiscal year as \$2.5M goes unspent*, Des Moines Register (Oct.
21 | 18, 2018), *available at*
22 | [https://www.desmoinesregister.com/story/news/health/2018/10/18/iowa-health-care-family-](https://www.desmoinesregister.com/story/news/health/2018/10/18/iowa-health-care-family-planning-contraception-services-planned-parenthood-abortion-medicaid/1660873002/)
[planning-contraception-services-planned-parenthood-abortion-medicaid/ 1660873002/](https://www.desmoinesregister.com/story/news/health/2018/10/18/iowa-health-care-family-planning-contraception-services-planned-parenthood-abortion-medicaid/1660873002/) (last
accessed March 4, 2019).

1 project's scope. Final Rule § 59.15. These new separation requirements go far
2 beyond the financial separation required by section 1008 and are a drastic
3 departure from decades of Title X regulations.

4 91. "Factors relevant to" adequate separation include whether Title X
5 and non-Title X facilities have separate treatment, consultation, examination and
6 waiting rooms; separate office entrances and exits; separate phone numbers and
7 email addresses; separate websites; separate educational services; separate
8 personnel; separate workstations; and separate health care records. *Id.* An
9 additional factor is the "extent to which" any "signs and material referencing or
10 promoting abortion are absent" from Title X facilities. *Id.* The Final Rule does
11 not indicate what degree of separation is required for each factor, or how the
12 "factors" will be evaluated or balanced in assessing compliance. *See id.*

13 92. The separation requirements reverse HHS's longstanding regulatory
14 position (reflected in the Current Regulations) that while provision of abortion
15 care must be separate and distinct from a Title X project, physical separation of
16 facilities, staff, and non-Title X activities is not required. The Current
17 Regulations are consistent with the fact that a Title X "project" is not a grantee,
18 a subrecipient, or a physical location, but rather "a plan or sequence of activities"
19 to provide family planning services "that satisfy the requirements of the grant
20 within a service area." Final Rule § 59.2. A grantee or subrecipient of Title X
21 funds must remain free to provide services that are not covered by Title X, as
22 long as its Title X project complies with federal requirements.

1 93. Many Title X grantees and subrecipients, including the State of
2 Washington, have extensive experience and a demonstrated ability to comply
3 with section 1008 of Title X, and there is no evidence of compliance problems
4 that warrant a change in the regulations.

5 94. The separation requirements do not apply only to abortion
6 care—they also apply to newly prohibited activities such as referrals for abortion,
7 as well as a grantee’s expressive and associational activities that are independent
8 of Title X funding. *See* Final Rule § 59.15 (requiring separation for “activities
9 which are prohibited under section 1008 of the Act *and* §§ 59.13, 5.14, and
10 59.16” of the Final Rule (emphasis added)). For example, even Title X providers
11 that do not provide abortion care, but that do offer pregnant patients referrals for
12 abortion or other specialized reproductive health care, must comply with the
13 separation requirements to qualify for Title X funding. Like the coercive
14 counseling and related provisions, the separation requirements present such
15 clinics with a Hobson’s choice: breach their ethical and legal duties to their
16 patients in exchange for federal funding, or attempt to separate their facilities and
17 operations at enormous cost. Both options prevent clinics from providing the
18 same care to their Title X patients that is available to patients with more financial
19 resources.

20 95. Despite the Final Rule’s statement that Title X projects must have
21 “an objective integrity and independence” that goes beyond financial separation,
22 the new separation requirements do not establish clear, objective criteria. They

1 introduce significant uncertainty as to what degree of separation is sufficient for
2 compliance, and vest the Secretary with broad discretion to balance the various
3 “factors” and decide when the “extent” of separation is not sufficient.

4 96. The lack of clear standards is particularly problematic in light of the
5 Final Rule’s new requirement that applications for Title X funds will not even be
6 *considered* in the competitive review process unless they “clearly address how
7 the proposal will satisfy” the separation and other requirements. Final Rule
8 § 59.7(b). If an application does not describe the project’s “plans for affirmative
9 compliance with each provision,” the application “shall be deemed ineligible for
10 funding” at the outset. *Id.* The State of Washington, with its broad network of
11 clinics operated by numerous subrecipients, cannot determine based on the Final
12 Rule what degree of separation to require for all subrecipient clinic sites to ensure
13 compliance. Nor can it determine what degree of separation DOH itself must
14 maintain between its administration of Washington’s Title X program and its
15 abortion-related activities having nothing to do with Title X. Because no similar
16 requirements have ever been fully implemented in the nearly 50 years in which
17 Title X has been in effect, there is no precedent indicating how the “factors” test
18 is likely to be applied. There is no guarantee that HHS would apply it in a fair
19 and objective manner.

20 97. The physical separation requirements at a minimum would require
21 substantial investment in needless facility changes. For all or almost all current
22 subrecipients that provide abortion care or referral in addition to Title X services,

1 this would be cost-prohibitive. Creating physically separate “treatment,
2 consultation, examination and waiting rooms,” as well as separate “office
3 entrances and exits,” would require clinics to incur significant construction costs.
4 Where construction on existing facilities is not possible, clinics would have to
5 locate, rent or purchase, and renovate or build on new property to create
6 physically separate facilities. The “separate personnel” factor would require
7 clinics to hire separate staff to perform the same functions in parallel. Grantees
8 and subrecipients would have to separate their operations to such an extent that
9 they could not even discuss their services on the same website, and must establish
10 separate phone numbers and email addresses related to different services.

11 98. The true costs of complete physical separation would well exceed
12 HHS’s unsupported estimate of \$30,000 per affected clinic on average, or
13 \$36 million in total nationwide. *See* Supplementary Information, 84 Fed. Reg.
14 7718, 7782. Planned Parenthood, whose clinics comprise the majority of
15 Washington’s Title X network, estimates an average cost of nearly \$625,000 per
16 service site, as reflected in its public comments on the proposed rule. For the
17 Washington Title X clinics that currently offer abortion care, this amounts to over
18 \$21.8 million in Washington alone. For those properties where a renovation of
19 an existing facility is not possible and an entirely new location would be needed,
20 Planned Parenthood estimates the cost to be between \$1.3 and \$1.5 million per
21 site. Planned Parenthood estimates that for its clinics, building and renovation
22 costs alone would total \$1.2 billion in the first year after the Final Rule goes into

1 effect—over 33 times HHS’s estimate. Architecture professor Lori Brown
2 commented that, even aside from renovation and acquisition costs (the largest
3 parts of the costs of separation), a single clinic’s site selection, architectural, and
4 interior design costs alone would be a minimum of \$65,000—over twice HHS’s
5 estimate for the *total* cost of separation. The National Family Planning and
6 Reproductive Health Association (NFPRHA) commented that the costs
7 associated with electronic health record separation alone could easily reach
8 \$10,000 to \$30,000 per entity.

9 99. In Washington, the clinics that receive Title X funds and provide
10 abortion care independent of the Title X program have been designed to maximize
11 efficiency to serve the most patients with available staff resources, while providing
12 the full spectrum of reproductive health care that patients need. These clinics
13 currently have one reception area and one check-in station each, meaning that they
14 would not satisfy the Final Rule’s separation requirements. They would have to
15 undergo massive remodeling to comply with the new requirements, but that is not
16 financially or logistically feasible. Construction costs for health care facilities are
17 very high, and it is difficult to find available contractors due to current demand for
18 construction workers. At a minimum, meeting the physical separation requirements
19 would take significant resources and time, including time when the clinics would
20 have to be closed. Clinic closure further reduces access to care, exacerbating poor
21 public health outcomes.

22

1 100. HHS downplays the costs of separation by ignoring the steps clinics
2 would have to take in reality to achieve compliance. For example, HHS suggests
3 that clinics could simply “shift their abortion services, and potentially other
4 services not financed by Title X, to distinct facilities, a change which likely
5 entails only minor costs.” Supplementary Information, 84 Fed. Reg. 7781. This
6 suggestion assumes, with no support, that there are adequate “distinct facilities”
7 already available and waiting to be utilized.

8 101. In addition to being costly—often prohibitively so—the separation
9 requirements will take significant time to implement. Many clinics could not
10 achieve the required separation within the one-year timeframe established by the
11 Final Rule. HHS rejects the numerous comments discussing the difficulty (if not
12 impossibility) for many clinics of meeting the compliance deadline, stating that it
13 “believes one year is an ample and generous amount of time for an entity to
14 rearrange locations, find new locations, comply with related State requirements, or
15 even make changes to a facility to physically separate Title X services from
16 abortion services.” *Id.* at 7774. HHS ignores the practical realities of “mak[ing]
17 changes to a facility” or locating, renting or purchasing, and renovating or
18 building on separate property.

19 102. HHS states that the separation requirements are necessary to avoid
20 (1) “potential” use of Title X funds for impermissible purposes or commingling
21 of funds, and (2) a “risk for public confusion” over whether Title X funds are
22 used for “abortion-related purposes.” *Id.* at 7715. HHS fails to provide any

1 evidence that impermissible use of funds or public confusion are actual as
2 opposed to speculative or manufactured problems, irrationally rejects less
3 restrictive means of addressing such problems if they exist, and fails to
4 acknowledge or address the compliance mechanisms that are already in
5 place—including the extensive oversight already exercised by HHS’s Office of
6 Population Affairs. And HHS does not explain why concerns about potential
7 misuse of funds and public confusion apply only to abortion care and referral, but
8 not to other types of out-of-program care that may be provided by Title X
9 grantees and subrecipients, such as prenatal care.

10 103. Like other experienced Title X grantees, Washington has always
11 ensured that each subrecipient in its Title X program complies with section 1008.
12 DOH manages the program and monitors compliance with all statutory
13 requirements, including section 1008, as detailed in its funding applications. Each
14 Washington subrecipient is required to sign a contract affirming their
15 compliance, and each must have a written policy clearly indicating that no Title X
16 funds will be used in programs where abortion is a method of family planning.
17 DOH regularly monitors compliance through several levels of review, including
18 reviewing subrecipient policies and medical records; interviewing clinic staff and
19 medical care providers; and ensuring that any subrecipients that offer abortion
20 care maintain clear funding separation. DOH’s monitoring also includes on-site
21 reviews and desk reviews of clinics, which involve examining their financial
22 systems and their Title X revenue and expenditure reports. Review teams include

1 a financial consultant from DOH's fiscal monitoring section and may also include
2 outside review experts such as certified public accountants.

3 104. There is no medical reason to enforce physical separation between
4 Title X and non-Title X services. In fact, the separation requirements inhibit
5 continuity of care, jeopardizing patients' health and safety. For example, the Final
6 Rule's requirement that grantees maintain separate sets of medical records for
7 Title X services and non-Title X services provided to the same patient introduces
8 a likelihood of errors in patient care, since two separate sets of records would
9 need to be consulted to obtain a complete medical history. HHS disregards
10 federal standards that emphasize the importance of integrated health records to
11 reduce health care costs resulting from "inefficiency, medical errors,
12 inappropriate care, duplicative care, and incomplete information" and to facilitate
13 informed medical decision-making and coordination of care. 42 U.S.C.
14 § 300jj-11. This aspect of "separation" would force some clinics to dismantle
15 their fully integrated medical records systems, undoing financially costly efforts
16 to integrate their medical records which they undertook precisely to enable all
17 providers to understand the full scope of a patient's health challenges and
18 treatment plans, promote cost-efficient treatment, and protect patient health and
19 safety.

20 105. The separation requirements restrict Title X providers from
21 truthfully disclosing the terms under which health care services are provided,
22 including by restricting their ability to post signs and material "referencing"

1 | abortion. For example, a Title X clinic could not post a sign truthfully stating that
2 | the clinic does not provide referrals for abortion care.

3 | 106. The separation requirements apply not only to abortion care and
4 | referral, but also to expressive and associational activities that “encourage,
5 | promote, or advocate abortion as a method of family planning” as provided in
6 | section 59.16. *See* Final Rule §§ 59.15, 59.16. This means that even if a grantee
7 | or subrecipient engages in protected activities without using Title X funding, it
8 | must incur the costs of physically separating those activities from any Title X
9 | activities.

10 | 107. The separation requirements unduly burden Washington’s
11 | out-of-program expressive and associational activities, and substantially interfere
12 | with its ability to administer a Title X program at all. DOH administers the State’s
13 | Title X program primarily from its headquarters at a government building in
14 | Olympia, Washington. DOH also administers a host of other programs and
15 | exercises its other state governmental functions from the same location, some of
16 | which may relate to abortion. Some DOH personnel, particularly those at higher
17 | levels, are involved in the administration of both the Title X program and other
18 | programs and activities. DOH’s activities can include legislative efforts and
19 | litigation related to reproductive rights and health policy, supporting reproductive
20 | health education and outreach, associating with organizations that provide public
21 | health support, and other activities consistent with Washington’s public policy
22 | and commitment to protecting the health and welfare of its residents. By requiring

1 that these activities having nothing to do with Title X be physically separated
2 from the Title X program itself, even at the highest administrative level, the Final
3 Rule vastly exceeds HHS's authority, interferes with Washington's expressive
4 and associational rights, and places enormous burdens on the State.

5 108. The Final Rule's new separation requirements are contrary to law,
6 unjustified, and vastly disproportionate to address the concerns HHS identifies.
7 HHS downplays and does not meaningfully address the true financial costs of the
8 separation requirements or their negative impacts on patient health and safety,
9 continuity of care, or medical ethics. HHS's assertion that it "does not believe
10 that the rule will limit the availability of individuals to access affordable health
11 care," Supplementary Information, 84 Fed. Reg. 7725, is unsupported and
12 contradicts the evidence before the agency.

13 3. Removal of the "Medically Approved" Requirement

14 109. The Final Rule eliminates the Current Regulations' requirement that
15 family planning methods must be "medically approved." *Compare* Final Rule
16 § 59.5(a)(1) *with* Current Regulations § 59.5(a)(1). This reversal undermines
17 Title X's purpose and conflicts with HHS's Program Requirements and the QFP.

18 110. Medically approved family planning methods and services are
19 evidence-based and demonstrably "effective," as required by Title X. 42 U.S.C.
20 § 300(a). For example, the QFP provides that family planning providers should
21 offer "a full range of Food and Drug Administration (FDA)-approved
22 contraceptive methods," which include a variety of methods from the most

1 effective (e.g., IUDs and implants) to the least effective (e.g., fertility-awareness
2 based methods, condoms, and withdrawal).³³

3 111. HHS states that it removed the “medically approved” requirement
4 from the Title X regulations because the term “risked creating confusion about
5 what kind of approval is required for a method to be deemed ‘medically
6 approved.’” Supplementary Information, 84 Fed. Reg. 7741. HHS fails to
7 explain why the asserted risk of “confusion” justifies removing this longstanding
8 requirement entirely. HHS provides no reason why Title X projects should offer
9 methods that are *not* “medically approved,” and fails to identify any family
10 planning method or service that it contends should be offered by Title X projects
11 that is not already included in the QFP.

12 112. While eliminating the “medically approved” requirement, the Final
13 Rule places new emphasis on “diverse” Title X providers (without defining this
14 term). Final Rule § 59.7(c)(2). “Diverse” providers (presumably, providers that
15 are not currently part of the Title X program and that offer differing varieties of
16 care and services as opposed to the “broad range of acceptable and effective
17 family planning methods and services” required by the statute) are less likely to
18 have experience with providing Title X services; are less likely to be equipped to
19 handle high volumes of patients; are less likely to offer the broadest possible
20 range of effective contraceptive methods; and are more likely to offer methods

21 _____
22 ³³ QFP, *supra* n.7, pp. 2, 10 (Fig. 3).

1 and services that are not “medically approved,” as newly permitted by the Final
2 Rule. Such providers may offer services that have minimal or no demonstrable
3 effect on fertility.

4 113. These new provisions will shift Title X funds away from effective,
5 evidence-based, FDA-approved family planning methods offered by qualified
6 providers and towards funding programs that emphasize the least effective
7 methods for preventing unintended pregnancies, such as abstinence-only
8 counseling. The Final Rule does not require that family planning services have
9 *any* medical basis, so “diverse” Title X providers may include those whose staff
10 have no medical training or qualifications. Some “diverse” clinics may
11 emphasize or exclusively offer a more limited range of less effective family
12 planning services, contrary to Title X’s intent to equalize access to the most
13 effective forms of contraception.

14 **4. Extra-Statutory Primary Health Services Requirement**

15 114. The Final Rule adds a new provision that Title X providers “should”
16 either offer “comprehensive primary health services onsite” or “have a robust
17 referral linkage with primary health providers who are in close physical
18 proximity to the Title X site[.]” Final Rule § 59.5(a)(12).

19 115. Many, but not necessarily all, Title X providers already have referral
20 relationships with primary health care providers. It is unclear whether or to what
21 extent the “should” language renders this new provision mandatory.

22

1 116. Requiring Title X clinics to offer “comprehensive primary health
2 services” is beyond the scope of Title X, which specifically and exclusively
3 concerns “family planning” services. The disconnect between the “primary
4 health services” requirement and the statute is underscored by HHS’s assertion
5 in the Supplementary Information accompanying the Final Rule that Title X
6 clinics should use funds from other sources—not Title X funds—to offer primary
7 health services. Supplementary Information, 84 Fed. Reg. 7750. HHS offers no
8 indication of where such funding would come from, nor any analysis of the
9 financial burdens the new provision would impose on grantees and subrecipients.

10 117. Further, the Final Rule does not define “comprehensive primary
11 health services,” “robust,” or “close physical proximity.” Clinics without an
12 on-site comprehensive primary health services provider will not know based on
13 the Final Rule whether their current referral sources are physically close or
14 “robust” enough to be compliant.

15 118. HHS fails to explain or resolve the contradiction in requiring
16 “comprehensive” primary health services while limiting Title X providers’ ability
17 to refer patients for medically appropriate care. A core function of primary care
18 is to serve as a first point of contact with the health care system, assess a patient’s
19 condition and treat it if possible, and provide any appropriate referrals for more
20 specialized care. A provider who cannot perform these functions is not providing
21 “comprehensive” primary care.

22

1 119. HHS failed to meaningfully consider the financial costs of the
2 requirement that Title X clinics either provide “comprehensive primary health
3 services onsite” or refer patients to providers within “close proximity” for such
4 services. The new requirement will disqualify many clinics that are not already
5 in compliance—particularly those in rural areas—since they would have to either
6 move their physical location or hire primary care providers and acquire the
7 infrastructure and other resources they would need to care for patients, either of
8 which may be cost-prohibitive or at least unduly burdensome.

9 120. HHS also failed to consider the impact of de-funding Title X clinics
10 that are not in “close proximity” to a comprehensive primary health services
11 provider, which could deprive patients in that area of *all* options for basic medical
12 care. Even for clinics that are currently in “close proximity” to a primary care
13 provider to which they could refer patients, the clinic would have to ensure that
14 that provider does not perform abortions; otherwise, the clinic would be in
15 violation of the Final Rule’s referral prohibition.

16 **5. Changes Subjecting Adolescents to More Coercive Practices**

17 121. Approximately 9% of the patients served by Washington Title X
18 programs in 2017 were under the age of 18. Title X specifically requires that
19 programs offer family planning services to adolescents, without any suggestion
20 that adolescents are not entitled to the same confidential, individualized,
21 noncoercive, dignified care as adults.

22

1 122. The Final Rule redefines “low income” so as to subject
2 unemancipated minors seeking no-cost care based on their own individual
3 resources to a different standard than minors with the ability to self-pay. If a
4 minor wishes to be considered on the basis of her or his own resources, the
5 provider must “document[] in the minor’s medical records the specific actions
6 taken by the provider to involve her/his family (including her/his parents or
7 guardian) in her/his decision to seek family planning services[.]” Final Rule §
8 59.2. The only exception is if the provider suspects that the minor is “the victim
9 of child abuse or incest” and has made and documented a report to state or local
10 authorities. *Id.*

11 123. While HHS acknowledges that Title X only requires the
12 encouragement of family participation “[t]o the extent practicable,” HHS fails to
13 explain or justify its determination that encouragement is required in every
14 circumstance unless there is reportable “child abuse or incest,” or its infringement
15 on providers’ ability to assess patients’ needs on an individualized basis.
16 *See* Supplementary Information, 84 Fed. Reg. 7752. HHS also fails to offer any
17 coherent rationale for subjecting low-income minors to a different standard than
18 minors with the ability to self-pay.

19 124. The Final Rule requires providers to document in *every* adolescent
20 patient’s private medical record the “specific actions taken” to “encourage family
21 participation” in the patient’s medical care “(or the specific reason why such
22 family participation was not encouraged),” so that HHS can monitor compliance

1 with the Final Rule by reviewing these sensitive and personal records. Final Rule
2 § 59.5(a)(14).

3 125. HHS fails to meaningfully address multiple comments to the effect
4 that removing providers' ability to exercise their judgment in deciding when and
5 how to encourage family participation in minors' family planning decisions, and
6 requiring "specific" documentation in medical records of their conversations,
7 will compromise patients' confidentiality and may jeopardize their safety, will
8 discourage minors from seeking services, and violates the principles of dignified,
9 patient-centered care.

10 **6. New Grant Eligibility Hurdles**

11 126. The Final Rule imposes extensive new requirements for grant
12 applications that incorporate substantive requirements found nowhere else in the
13 regulations, and that create new hurdles for applicants to even qualify for
14 consideration as Title X grantees.

15 127. The Final Rule provides for an initial application review phase in
16 which grant applications are disqualified from being considered unless they
17 "clearly address" how the Title X project proposal will "satisfy the requirements
18 of this regulation"; if an application fails to do so, the project "shall be deemed
19 ineligible for funding" at the outset. Final Rule § 59.7(b).

20 128. Many of the Final Rule's "requirements" are undefined, vague,
21 and/or based on the "extent to which" various "factors" are met, making it
22 difficult for applicants to know whether they are eligible for consideration or not.

1 This vagueness leaves considerable room for HHS to exclude applicants at its
2 discretion and based on impermissible and arbitrary factors, rather than
3 evaluating them based on objective standards. HHS dismisses these concerns
4 without meaningfully responding to them.

5 129. The initial hurdle to be eligible for consideration interferes with the
6 right to apply guaranteed by Title X: “Local and regional entities shall be assured
7 the right to apply for direct grants and contracts under this section, and the
8 Secretary shall by regulation fully provide for and protect such right.” 42 U.S.C.
9 § 300(b). An applicant that fails to clear the initial hurdle for reasons that may be
10 unclear has no recourse.

11 130. If a proposal clears the initial hurdle to be eligible for consideration,
12 applicants will be evaluated based on the “degree to which” their Title X project
13 (1) “adheres to the Title X statutory purpose and goals”; (2) is in need of federal
14 funds and “shows capacity” to make “rapid and effective” use of grant funds,
15 “including its ability to procure a broad range of diverse subrecipients”;
16 (3) accounts for the number of patients to be served and targets areas where
17 adequate services are not available; and (4) proposes “innovative” ways to
18 provide services to unserved or underserved communities. Final Rule §§ 59.7,
19 59.10.

20 131. These four new criteria replace the seven application review criteria
21 reflected in the Current Regulations, which have been in place since the 1970s
22 and are clear, capable of objective evaluation, and connected to Title X’s text and

1 purpose. HHS has not provided any reasoned explanation for replacing the seven
2 longstanding criteria with the four new ones.

3 132. The second and fourth criteria incorporate new requirements related
4 to “diverse” subrecipients and “innovative” methods, but HHS does not define
5 these terms or otherwise provide meaningful guidance to applicants or
6 explanation for their inclusion. These undefined terms suggest an emphasis on
7 providers and clinics that do not have a demonstrated ability to efficiently and
8 effectively provide core Title X services, including a broad range of effective and
9 medically approved contraception, to a large number of patients. Further, the
10 second and fourth criteria are not found among the Final Rule’s substantive
11 “requirements,” *see* Final Rule § 59.5, but are only incorporated into the grant
12 eligibility criteria, making their meaning and applicability even more unclear.

13 7. New Limitations on Use of Federal Funds

14 133. Title X provides that federal grants are to be used “to assist in the
15 establishment and operation of” family planning projects. 42 U.S.C. § 300.

16 134. The Final Rule requires that Title X grantees “must use the majority
17 of grant funds to provide direct services to clients[.]” Final Rule § 59.18(a). HHS
18 does not define “direct services,” and this provision introduces uncertainty about
19 what family planning services or support the funds may or may not be used for.
20 For example, in the Supplementary Information accompanying the Final Rule,
21 HHS suggests that Title X funds should not be used for community outreach or
22 other efforts to inform individuals of the availability of Title X resources. *See*

1 Supplementary Information, 84 Fed. Reg. 7774. Education about the availability
2 of Title X resources is critical to improving health outcomes and is an integral
3 part of the delivery of family planning services to those in need. Indeed, an entire
4 subsection of the Title X statute is dedicated to funding the development and
5 dissemination of “Informational and Educational Materials.” 42 U.S.C. § 300a-3.
6 HHS fails to reconcile the new restrictions with the statute itself or otherwise
7 provide an adequate rationale for them.

8 **8. The Final Rule’s Unlawful Purpose and Effect**

9 135. All of the above provisions of the Final Rule further its true and
10 unlawful purpose and effect: to expel Planned Parenthood and other
11 comprehensive reproductive health care providers from the Title X program, and
12 divert Title X funds toward directive programs that do not support patients’
13 access to complete and unbiased medical information about their reproductive
14 health care options.

15 136. As Donald Trump stated during his campaign for the presidency,
16 “We’re not going to allow, and we’re not going to fund, as long as you have the
17 abortion going on at Planned Parenthood.”³⁴ On the day the proposed rule leading
18 up to the Final Rule was unveiled, President Trump inaccurately stated in a

19 ³⁴ Danielle Paquette, “Donald Trump’s Incredibly Bizarre Relationship with Planned
20 Parenthood,” *Washington Post* (Mar. 2, 2016), [https://www.washingtonpost.com/news/wonk/
21 wp/2016/03/02/donald-trumps-incredibly-bizarre-relationship-with-planned-parenthood/?utm
22 _term=.db131f627e96](https://www.washingtonpost.com/news/wonk/wp/2016/03/02/donald-trumps-incredibly-bizarre-relationship-with-planned-parenthood/?utm_term=.db131f627e96) (last accessed July 13, 2018).

1 | speech to an anti-abortion group: “For decades American taxpayers have been
2 | wrongfully forced to subsidize the abortion industry through Title X federal
3 | funding so today, we have kept another promise. My administration has proposed
4 | a new rule to prohibit Title X funding from going to any clinic that performs
5 | abortions.”³⁵

6 | 137. In fact, there is no evidence that Title X funds have been used for
7 | abortions, and Title X-funded family planning services have *prevented* millions
8 | of abortions since the statute went into effect.³⁶

9 | 138. Organizations that provide abortion care independent of their Title
10 | X projects have received Title X funding since the program’s inception, and are
11 | an integral part of Washington’s existing Title X network. Their exclusion is
12 | contrary to law, arbitrary and capricious, and unconstitutional, and will cause
13 | significant harm to Washington and its residents.

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16 | ³⁵ [https://www.whitehouse.gov/briefings-statements/remarks-president-trump-susan-
17 | b-anthony-list-11th-annual-campaign-life-gala/](https://www.whitehouse.gov/briefings-statements/remarks-president-trump-susan-b-anthony-list-11th-annual-campaign-life-gala/) (last accessed March 4, 2019).

18 | ³⁶ In 2015 alone, contraceptive care delivered by Title X-funded providers helped
19 | women avoid 822,000 unintended pregnancies, which would have resulted in 387,000
20 | unplanned births and 278,000 abortions. Frost J.J., et al., *Publicly Funded Contraceptive
21 | Services at U.S. Clinics*, 2015, New York: Guttmacher Institute, 2017,
22 | <https://www.guttmacher.org/report/publicly-funded-contraceptive-services-us-clinics-2015>
(last accessed March 4, 2019).

1 **D. Injuries to the State of Washington and Its Residents**

2 139. The Final Rule frustrates and contradicts the purposes of Title X by
3 disqualifying the vast majority of Title X clinics in Washington from receiving
4 federal funds, destroying Washington's integrated family planning services
5 network, and preventing DOH from continuing to administer a statewide Title X
6 program. This will leave many patients in need with diminished or no access to
7 family planning services, exacerbating the negative health and economic
8 outcomes that Title X was meant to address. The dire consequences for
9 Washingtonians and the State itself can never be fully remedied if the Final Rule
10 goes into effect.

11 140. The Final Rule will leave many counties in Washington without any
12 Title X provider at all. Because the Final Rule will undermine the quality of
13 health care provided through Title X programs, prevent providers from fulfilling
14 their duties to patients and acting in patients' best interests, and impose extremely
15 burdensome and counterproductive separation and reporting requirements, many
16 providers in Washington will be unable to comply. The Final Rule's negative
17 effects will fall particularly hard on uninsured patients and those in rural areas,
18 who in some cases will have no other feasible option for obtaining family
19 planning services. As a result of the Final Rule, thousands of people who rely on
20 Title X providers for contraception and other family planning services will lose
21 access to those services.

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1 141. Title X providers and clinics in the State of Washington have built
2 their practices and business models in accordance with the understanding that
3 federal funding would not be conditioned on violating ethical and legal
4 requirements or medical standards of care. The State of Washington itself has
5 relied on being able to operate an integrated program in which state and federal
6 funds are used to provide voluntary family planning services consistent with such
7 requirements to all Washingtonians who want and need them. This program will
8 be upended if the Final Rule goes into effect and destroys the statewide network.

9 142. Under any possible scenario, the Final Rule will injure the State of
10 Washington and its residents by dismantling the State's current system for
11 delivering family planning services and significantly impeding patients' access
12 to services.

13 **1. The Final Rule will expel providers representing 89% of**
14 **Washington's Title X network**

15 143. As Washington explained in its public comments, the Final Rule
16 will dismantle the vast majority of the State's current family planning services
17 network. Five subrecipients of Title X grant funds in Washington have informed
18 DOH that they will be unable to continue participating in the Title X program
19 because they cannot meet the Final Rule's new requirements. As soon as the Final
20 Rule goes into effect, this will immediately remove 35 clinics from the statewide
21 Title X network. In 2017, these clinics provided family planning services to
22 approximately 89% of all Title X patients served in Washington.

1 144. In 16 of Washington’s 39 counties, the only Title X provider is a
2 clinic operated by one of these five subrecipients. If the Final Rule goes into
3 effect, over half of the counties in Washington will have no Title X provider.
4 Seven counties in Eastern Washington will lose their Title X providers, leaving
5 11 counties with no Title X provider at all. Nine counties in Western Washington
6 will lose their Title X providers, leaving 10 counties with no Title X provider at
7 all—including six of the 10 most populous counties in the state.

8 145. If the Final Rule goes into effect, Title X patients in these counties
9 would either need to travel hundreds of miles to Title X clinics in distant counties
10 or forego the benefits of the Title X program altogether. In some counties, even
11 where a Title X provider remains, the loss of one of the 35 clinics discussed above
12 will overburden any remaining providers in that county.

13 146. The Final Rule will not just force out subrecipients that offer
14 abortion services independent of the Title X Project. The coercive counseling
15 provisions and other costly requirements will force other providers from the Title
16 X program as well, or at least prevent them from providing services at current
17 levels. For example, the Public Health Service of King County—a subrecipient
18 that does not provide abortion services but does provide referrals for
19 abortion—has expressed that if the Final Rule were to take effect, it would not
20 be able to maintain its current level of family planning service. In 2017, King
21 County served 5,489 Title X clients.

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1 147. The harmful consequences of the Final Rule will especially impact
2 rural and uninsured patients. In four largely rural Washington counties, one
3 quarter or more of Title X patients are uninsured, and the only Title X clinics in
4 those counties have indicated that the Final Rule would preclude them from
5 continuing in the Title X Project. These counties are San Juan (30% of Title X
6 patients were uninsured in 2017), Skagit (29%), Douglas (28%), and Whitman
7 (27%). These counties would lose their Title X providers entirely, and do not
8 have local health jurisdictions providing family planning services that could help
9 to fill the gap.

10 148. In five other counties in rural Washington, patients are served by
11 small Title X clinics that have indicated they cannot comply with the Final Rule.
12 These clinics are in Ellensburg (in Kittitas County), Walla Walla (in Walla Walla
13 County), Wenatchee (in Chelan County), Pullman (in Whitman County), and
14 Moses Lake (in Grant County). Some of these clinics may not survive the loss of
15 federal funds and would have to close their doors. Even if some current Title X
16 providers in other counties remain in the program, the distance patients would
17 have to travel to reach them is impracticable.

18 149. Absent Title X funding, the clinics most at risk of closing are those in
19 rural communities that are already underserved, as it is more difficult to create,
20 fund, and staff medical clinics in rural areas. Given that, and the lack of alternative
21 resources, these areas are likely to have some of the worst public health outcomes
22 due to lack of access to family planning services. In particular, the clinics most at

1 risk of closing are located in the cities of Sunnyside, Pasco, Moses Lake, and
2 Wenatchee. There are already provider shortages in those areas, and clinic closure
3 or service reduction will leave more patients without needed care, exacerbating
4 poor public health outcomes in those communities.

5 150. Students will also be especially hurt by the Final Rule. Many
6 students lack adequate insurance, and many do not have a steady source of income
7 that would enable them to self-pay for family planning services. Title X health
8 centers in Ellensburg, Pullman, Walla Walla, and Spokane, in particular, serve
9 student populations that rely on the departing subrecipients' participation in the
10 Title X program to obtain family planning services. As a result of the loss of the
11 five subrecipients from Washington's Title X network, there will no longer be
12 any Title X providers near Central Washington University, Eastern Washington
13 University, Western Washington University, Washington State University,
14 Yakima Valley Community College, Columbia Basin College, and Big Bend
15 Community College. In Spokane, Gonzaga University does not offer any
16 reproductive health services to its students, making the Title X-funded Spokane
17 health center near the Gonzaga campus a critical resource for students. This clinic
18 has announced that it will be forced by the Final Rule to depart the Title X program.
19 These losses will jeopardize the ability of the students served at these clinics to
20 remain healthy and complete their education.

21 151. Further, the remaining subrecipients representing 11% of
22 Washington's Title X network cannot fill the gap created by the loss of the five

1 subrecipients, even in the unlikely event they all remain in the program (and are
2 able to maintain the same number of clinicians on their staff) despite the
3 Hobson’s choice posed by the Final Rule. For example, Federally Qualified
4 Health Centers (FQHCs) in Washington do not have the infrastructure nor the
5 financial means to provide services to the 81,000 patients currently served by the
6 five subrecipients. For FQHCs to adequately serve the patients who otherwise
7 would have received care from one of the five subrecipients’ clinics, they would
8 need several years and significant additional funding to prepare—neither of
9 which has been provided. FQHCs and other safety-net providers in underserved
10 areas will be disproportionately impacted because the Final Rule is more likely
11 to force existing Title X clinics in those areas to close down, forcing their patients
12 to seek care from other parts of the safety net.

13 152. HHS provides no evidentiary basis for its assertion that it
14 “anticipates other, new entities will apply for funds, or seek to participate as
15 subrecipients, as a result of the final rule,” or that it “anticipates that the net
16 impact on those seeking services from current grantees will be zero[.]”

17 Supplementary Information, 84 Fed. Reg. 7782.

18 153. If Washington were to lose the Title X subrecipients that served 89%
19 of individual clients in 2017, HHS in all likelihood would not fund the remaining
20 skeletal network at anywhere near the existing level. Washington currently
21 receives several million dollars in federal funds to support a statewide network
22 serving nearly a hundred thousand patients. But with a network that omits the

1 number of counties—particularly rural, underserved counties—described above,
2 and is capable of serving far fewer patients statewide, Washington’s Title X grant
3 would probably be significantly reduced. Due to network shrinkage, HHS may
4 reduce the current grant, decline to disperse the remainder of the grant, or even
5 cancel the grant entirely in the middle of the cycle, compounding the chaos
6 caused by the Final Rule. Moreover, with a crippled network, Washington’s
7 Title X program would be far less competitive in future grant cycles.

8 **2. A DOH program that complied with the restrictions of the Final**
9 **Rule would be contrary to Washington law**

10 154. DOH cannot comply with the Final Rule without violating
11 Washington’s Reproductive Privacy Act and Article I, section 5 of the
12 Washington Constitution.

13 155. Washington’s Reproductive Privacy Act, approved by Washington
14 voters in 1991, provides that “it is the public policy of the state of Washington”
15 that:

- 16 i. Every individual has the fundamental right to choose or refuse birth
17 control;
- 18 ii. Every woman has the fundamental right to choose or refuse to have
19 an abortion [except as limited by the act];
- 20 iii. Except as [permitted by the act], the state shall not deny or interfere
21 with a woman’s fundamental right to choose or refuse to have an
22 abortion; and
- iv. The state shall not discriminate against the exercise of these rights
in the regulation or provision of benefits, facilities, services, or
information.

1 Reproductive Privacy Act, RCW 9.02.100. Under this statute, the State may not
2 “interfere with a woman's right to choose to have an abortion prior to viability of
3 the fetus.” RCW 9.02.110. Further, if the State provides “maternity care benefits,
4 services, or information to women” through any state-funded or
5 state-administered program, the State “shall also provide women otherwise
6 eligible for any such program with substantially equivalent benefits, services, or
7 information to permit them to voluntarily terminate their pregnancies.”
8 RCW 9.02.160.

9 156. Article I, section 5 of the Washington Constitution provides more
10 expansive protections than the First Amendment, and protects freedom of speech
11 within the medical provider–patient relationship.

12 157. For these reasons and more, the State would be unable to lawfully
13 participate in a Title X program subject to the Final Rule’s new requirements.
14 The Final Rule interferes with speech in the provider–patient relationship,
15 discriminates against women who are interested in terminating their pregnancies,
16 erects barriers to access to care, and would inhibit the State’s ability to provide
17 substantially equivalent benefits, services, or information to all pregnant women
18 who participate in the program.

19 158. Even if the State could somehow continue its participation in a
20 Title X program subject to the Final Rule without violating Washington law, that
21 program would offer substandard care that would jeopardize patients’ health,
22 safety, and well-being and increase health care costs in Washington. Despite

1 HHS’s assertion that the referral prohibition and directive counseling provisions
2 would entail “no costs,” Supplementary Information, 84 Fed. Reg. 7719, the
3 reality is that these provisions will impede patients’ access to medical care,
4 resulting in more unintended pregnancies and other issues, and the enormous
5 health consequences and economic costs associated with them.

6 **3. The loss of Title X funds Would Irreparably Harm Washington**
7 **and Its Most Vulnerable Residents**

8 **a. Reducing the effectiveness of Washington’s family**
9 **planning program**

10 159. If federal Title X funds disappeared, Washington’s Family Planning
11 Program would lose approximately one third of its funding. DOH would have
12 less funding to allocate to grant recipients, which would result in fewer patients
13 receiving services, causing negative health consequences for patients and
14 increasing costs to the State. If services are reduced, the incidence of unintended
15 pregnancies and reproductive health-related illnesses and disease within
16 Washington is likely to increase, leading to worse long-term health and economic
17 outcomes, as well as more abortions.

18 160. Currently, approximately one third of Washington’s Title X
19 program is funded with federal dollars. DOH projects that, if it lost this federal
20 funding, at the very least it would not have the funds to continue to serve patients
21 whose incomes are anywhere above the federal poverty level; it would not be
22 able to continue to serve underinsured (as opposed to entirely uninsured) patients;

1 and it may otherwise have to restrict the population of patients eligible for
2 subsidized family planning services.

3 161. In 2017, Washington’s Title X program served 40,041 people with
4 incomes above 100% of the federal poverty level, and 72,989 people with some
5 public or private insurance. If these individuals could not afford to pay on their
6 own—or could not travel to a clinic that offers these services at a level that is
7 affordable—they would lose access to family planning services entirely.

8 162. Counties with high numbers of low-income, underinsured people
9 who want and need family planning services would be the most adversely
10 impacted by the disappearance of federal funds.

11 163. Some college and university students who currently receive family
12 planning services would lose access to them.

13 164. DOH would be unable to provide continuing education for clinicians
14 and staff at current levels. DOH would also likely have to limit educational and
15 outreach activities, decreasing awareness that subsidized family planning
16 services are available and exacerbating poor health outcomes associated with
17 lack of access. Other services like STI testing and treatment would likely be
18 eliminated.

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1 165. Analyses show that nationally, every \$1 spent on family planning
2 services results in over \$7 of cost savings.³⁷ HHS asserts that the Office of
3 Management and Budget determined that the Final Rule is not “economically
4 significant,” Supplementary Information, 84 Fed. Reg. 7776, but this disregards
5 the Final Rule’s true financial impact. In fact, the economic impacts will be
6 highly significant: a study of data from 2010 shows that Title X family planning
7 services resulted in net savings of almost \$7 *billion* nationwide. The Final Rule
8 will slash these savings when it slashes the services.

9 166. In Washington alone, Title X services saved multiple millions of
10 dollars in 2017 that otherwise would have been spent on addressing health issues
11 that could have been prevented. The costs imposed by the Final Rule on the State
12 of Washington would be well over \$100 million. In the first year after the Final
13 Rule goes into effect, if not enjoined, Washington will lose more than \$28 million
14 in savings due to the loss of federal dollars.

15 167. The Final Rule puts the health of Washington’s most vulnerable
16 populations at even greater risk, and jeopardizes public health as a whole. If
17 Washington’s network is destroyed, many patients will lose access to

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19 ³⁷ See Jennifer J. Frost, *Return on Investment: A fuller Assessment of a Benefits and*
20 *Cost Savings of the US Publicly Funded Family Planning Program*, Milbank Quarterly,
21 Vol. 92, No. 4, p. 668 (2014), available at
22 [https://www.guttmacher.org/sites/default/files/article_files/frost_et_al-2014-
milbank_quarterly.pdf](https://www.guttmacher.org/sites/default/files/article_files/frost_et_al-2014-milbank_quarterly.pdf) (last accessed March 4, 2019).

1 contraceptive care, including access to the most effective forms of contraception,
2 as well as other essential preventative services like STI testing and cancer
3 screening. This disruption will have profound short- and long-term consequences
4 for patients, their families, and the public in general, including a rise in
5 unintended pregnancies.

6 168. Women who experience an unintended pregnancy are more likely to
7 receive inadequate or delayed prenatal care, resulting in poor health outcomes
8 such as preterm births, low-birth-weight babies, and still births. Unintended
9 pregnancies are associated with increases in maternal and child morbidity.
10 An increase in the number of pregnancies also means that more women will die.³⁸
11 Unwanted childbearing also tends to result in negative psychological outcomes
12 for both women and children. And an increase in the number of unintended
13 pregnancies will increase the number of abortions, contrary to the Final Rule's
14 stated goal. *See* Final Rule § 59.2. In addition, undiagnosed and untreated STIs
15 would create poor health and reproductive outcomes, and cancers that go
16 undetected at a stage when they are treatable will exacerbate healthcare costs and
17 cause deaths that could have been prevented.

18 **b. Financial harm to State Medicaid and related programs**

19 169. The Final Rule will cause financial harm to the Washington Health
20 Care Authority, which administers state public health care programs including
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22 ³⁸ *See supra* n.27 (noting rising maternal mortality in the United States).

1 Washington's Medicaid program, called Apple Health. It also will undermine the
2 health benefits the Health Care Authority achieves in administering its public
3 health programs for Washingtonians, which will increase health care costs in the
4 long term.

5 170. The Health Care Authority relies on the high-quality services
6 provided at Title X-funded clinics to achieve performance measures related to
7 reductions in unintended pregnancies, improved pregnancy outcomes, cancer and
8 STI screenings, and treatment of various conditions to maintain healthy
9 reproductive functioning. These benefits will be compromised by the Final Rule,
10 which will force many qualified Title X providers out of the program and reduce
11 access to family planning services.

12 171. Some individuals who lose access to contraception through
13 Title X-funded programs as a result of the Final Rule will no longer be able to
14 afford their current form of contraception or will not be able to access effective
15 contraception at all. The result will be an increase in the number of unintended
16 pregnancies.

17 172. The costs of these unintended pregnancies will be borne by the
18 Health Care Authority. The Health Care Authority currently funds nearly 50% of
19 all births in Washington State, a figure that is likely to increase if the number of
20 unintended pregnancies among low-income patients increases. Further, 81% of
21 Washington's Title X clients have incomes below 200% of the federal poverty
22 level. These Title X clients either already have Apple Health or will become

1 eligible for Apple Health because of the higher eligibility income criteria during
2 pregnancy. If these clients lose access to Title X services and experience an
3 unintended pregnancy as a result, Apple Health will pay for their care.

4 173. Some Title X clients will be forced to stop working or reduce their
5 hours if they lose access to Title X services and experience an unintended
6 pregnancy. This will change some families' income, causing these families to
7 become eligible for Apple Health. The change in family size due to the birth of a
8 child also could cause these families to become eligible for Apple Health. This
9 will result in an increase in state expenditures related to pregnancy, delivery,
10 newborn, and child health services. Other support services will be impacted as
11 well, as an increase in the number of families eligible for Apple Health will
12 increase costs to the State for transportation, home visiting, and case
13 management.

14 174. Currently, Title X clinics in Washington serve some patients who
15 pay on a sliding scale, because they are not eligible for Apple Health, free Title
16 X care, or other programs offering free services. Title X permits patients who do
17 not qualify for free family planning services to pay on a sliding scale to
18 accommodate their financial limitations. The 16,082 current Title X clients who
19 pay on a sliding scale will suffer financial hardship to maintain their
20 contraception if they lose access to a Title X clinic. Some will not be able to find
21 a different nearby clinic that offers sliding scale pricing. The Health Care
22 Authority will not be able to absorb these clients if they do not qualify for Apple

1 Health or other state programs. As a result, these clients would not receive
2 adequate services, and the Health Care Authority will see increased costs due to
3 more unintended pregnancies.

4 175. The shift of Title X clients from a departing Title X subrecipient to
5 an FQHC also will increase costs for the Health Care Authority. This is because
6 the Health Care Authority pays FQHCs for services they provide to covered
7 clients, and FQHCs are typically entitled to a higher reimbursement per visit than
8 non-FQHCs.

9 176. Overall, the Final Rule is not designed to further the purposes of
10 Title X. Rather, it is designed to punish health care providers who provide
11 abortion care and referral—and by extension, impede their patients’ access to
12 abortion—even when Title X funds are not used to provide abortion care. The
13 Final Rule also appears to be designed to limit patients’ access to modern,
14 effective, medically approved contraception, and to introduce providers who
15 emphasize the least effective family planning methods and services into the
16 federally funded program. HHS fundamentally fails to grapple with the
17 real-world consequences of the Final Rule’s drastic and politically motivated
18 changes.

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V. CLAIMS FOR RELIEF

Count I

**Violation of the Administrative Procedure Act
Agency Action Not in Accordance with Law—Nondirective Mandate**

177. The State realleges and reincorporates by reference the allegations set forth in each of the preceding paragraphs.

178. The APA requires that agency action that is “not in accordance with law” be held unlawful and set aside. 5 U.S.C. § 706(2).

179. The Final Rule violates the Nondirective Mandate established by the Department of Health and Human Services Appropriations Act, 2019, and every annual appropriations act since 1996, by eliminating the Current Regulations’ nondirective pregnancy counseling requirement, permitting providers to offer only biased, one-sided information about “maintaining the health of the mother and unborn child during pregnancy,” and affirmatively requiring directive referral for one option (carrying the pregnancy to term) while broadly prohibiting referral for another option (abortion).

180. Absent injunctive and declaratory relief vacating the Final Rule and prohibiting it from going into effect, Washington and its residents will be immediately, continuously, and irreparably harmed by Defendants’ illegal actions.

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1 **Count II**
2 **Violation of the Administrative Procedure Act**
3 **Agency Action Not in Accordance with Law—ACA Section 1554**

4 181. The State realleges and reincorporates by reference the allegations
5 set forth in each of the preceding paragraphs.

6 182. The APA requires that agency action that is “not in accordance with
7 law” be held unlawful and set aside. 5 U.S.C. § 706(2).

8 183. Section 1554 of the ACA provides that the HHS Secretary “shall not
9 promulgate any regulation” that “creates any unreasonable barriers to the ability
10 of individuals to obtain appropriate medical care”; “impedes timely access to
11 health care services”; “interferes with communications regarding a full range of
12 treatment options between the patient and the provider”; “restricts the ability of
13 health care providers to provide full disclosure of all relevant information to
14 patients making health care decisions”; or “violates the principles of informed
15 consent and the ethical standards of health care professionals.” 42 U.S.C.
16 § 18114.

17 184. The Final Rule violates section 1554 in numerous ways, including
18 the following:

- 19 a. The Final Rule “creates . . . unreasonable barriers to the
20 ability of individuals to obtain appropriate medical care” in a number of
21 ways, including by preventing Title X patients from receiving referrals for
22 choice-based, medically indicated, and medically necessary abortions, and

1 imposing wasteful, excessive, and unnecessary physical and financial
2 separation and other requirements that will disqualify the vast majority of
3 current Title X providers in Washington, reduce patients’ access to
4 reproductive health care, inhibit continuity of care, artificially separate the
5 provision of related health services, and require clinics to divert resources
6 from caring for patients.

7 b. The Final Rule “impedes timely access to health care
8 services,” including by broadly prohibiting Title X patients from receiving
9 referrals for choice-based, medically indicated, and medically necessary
10 abortions (subject to an illusory exception that is meaningless in
11 Washington), leaving most patients to attempt to find a provider of the
12 desired care on their own. Timely access is important in this context
13 because abortion is safest when performed early in a pregnancy. The
14 coercive counseling provisions and the wasteful, excessive, and
15 unnecessary physical and financial separation requirements also impede
16 timely access to care because they will disqualify the providers that
17 constitute the vast majority of Washington’s Title X network, forcing
18 many patients to travel long distances for Title X care, and will prevent
19 patients from receiving comprehensive reproductive health care at a single
20 location.

21 c. The Final Rule “interferes with communications regarding a
22 full range of treatment options between the patient and the provider,”

1 including by imposing a gag rule that broadly prohibits Title X providers
2 from referring patients for choice-based, medically indicated, and
3 medically necessary abortions, while affirmatively requiring Title X
4 providers to direct their patients to the government’s preferred option,
5 regardless of the patient’s wishes and the provider’s medical judgment.

6 d. The Final Rule “restricts the ability of health care providers
7 to provide full disclosure of all relevant information to patients making
8 health care decisions,” including by imposing a gag rule that broadly
9 prohibits Title X providers from referring patients for choice-based,
10 medically indicated, and medically necessary abortions, while
11 affirmatively requiring Title X providers to direct their patients to the
12 government’s preferred option, regardless of the patient’s wishes and the
13 provider’s medical judgment.

14 e. The Final Rule “violates the principles of informed consent
15 and the ethical standards of health care professionals,” including by
16 preventing Title X patients from receiving referrals for choice-based,
17 medically indicated, and medically necessary abortions, and by requiring
18 Title X providers to direct their patients to the government’s preferred
19 medical treatment, regardless of the patient’s wishes and the provider’s
20 medical judgment. In addition, the Final Rule imposes medically
21 unnecessary physical separation requirements that interfere with
22 continuity of care and needlessly jeopardize patients’ health and safety.

1 These provisions require medical professionals in Title X programs to
2 withhold medically relevant information and violate medical ethical
3 standards and other duties to their patients recognized by leading medical
4 authorities.

5 185. Absent injunctive and declaratory relief vacating the Final Rule and
6 prohibiting it from going into effect, Washington and its residents will be
7 immediately, continuously, and irreparably harmed by Defendants’ illegal
8 actions.

9 **Count III**
10 **Violation of the Administrative Procedure Act**
11 **Agency Action in Violation of Law and Excess of Statutory Authority**

12 186. The State realleges and reincorporates by reference the allegations
13 set forth in each of the preceding paragraphs.

14 187. The APA requires that agency action that is “not in accordance with
15 law” or “in excess of statutory jurisdiction, authority, or limitations, or short of
16 statutory right” be held unlawful and set aside. 5 U.S.C. § 706(2).

17 188. The Final Rule violates various provisions of Title X—including
18 that Title X services must be “voluntary,” among others—and exceeds HHS’s
19 delegated rulemaking authority in multiple respects, as detailed above. It is also
20 fundamentally inconsistent with Title X’s purpose of expanding and equalizing
21 access to a broad range of acceptable and effective family planning methods and
22 services regardless of income, because it imposes unjustified requirements that
will have the effect of reducing such access.

1 189. Absent injunctive and declaratory relief vacating the Final Rule and
2 prohibiting it from going into effect, Washington and its residents will be
3 immediately, continuously, and irreparably harmed by Defendants' illegal
4 actions.

5 **Count IV**
6 **Violation of the Administrative Procedure Act**
7 **Arbitrary and Capricious Agency Action**

8 190. The State realleges and reincorporates by reference the allegations
9 set forth in each of the preceding paragraphs.

10 191. The Final Rule is arbitrary and capricious in numerous respects. It
11 reverses the Department's longstanding policies and interpretations of Title X
12 with no evidentiary basis or cogent rationale, requires deviation from
13 evidence-backed standards of care and medical ethical and fiduciary obligations,
14 needlessly jeopardizes patients' lives, health, and well-being, disregards and/or
15 is contrary to evidence before the agency, ignores many important aspects of the
16 problem and the significant new problems it will create, relies on factors
17 Congress did not intend the agency to consider, and is illogical and
18 counterproductive. HHS also adds a new, unsupported and illogical rationale for
19 the Final Rule's mandatory prenatal care referral requirement without having
20 given the public notice or an opportunity to comment on this new rationale.

21 192. One or more of these problems affects virtually every new provision
22 of the Final Rule, rendering the Final Rule arbitrary and capricious in its entirety.

1 activities related to reproductive rights and public health—including separate
2 physical facilities, separate personnel, separate contact information, and separate
3 websites—the Final Rule places substantial burdens on the State of Washington’s
4 expressive and associational rights to “encourage, promote, or advocate for”
5 access to legal abortion.

6 199. Absent injunctive and declaratory relief vacating the Final Rule and
7 prohibiting it from going into effect, Washington and its residents will be
8 immediately, continuously, and irreparably harmed by Defendants’ illegal
9 actions.

10 **Count VI**
11 **Fifth Amendment—Unconstitutional Vagueness**

12 200. The State realleges and reincorporates by reference the allegations
13 set forth in each of the preceding paragraphs.

14 201. The APA requires that agency action that is “contrary to
15 constitutional right” be held unlawful and set aside. 5 U.S.C. § 706(2).

16 202. The Final Rule violates the Due Process Clause of the Fifth
17 Amendment because it is unconstitutionally vague in numerous respects and
18 vests the Secretary with discretion to make grant awards in an arbitrary,
19 inconsistent, and/or biased manner. It fails to provide adequate guidance as to
20 how the State can satisfy various unclear, undefined, vague, and subjective new
21 provisions of the Rule in order to qualify for a Title X grant. The lack of clear
22 standards permits the Secretary to unfairly and arbitrarily decide whether the

1 State's application even qualifies for consideration, and if so, whether and how
2 much Title X funding should be granted to the State. There is no compelling
3 government interest in imposing these vague requirements, and the Final Rule is
4 not appropriately tailored to achieve any such interest.

5 203. Absent injunctive and declaratory relief vacating the Final Rule and
6 prohibiting it from going into effect, Washington and its residents will be
7 immediately, continuously, and irreparably harmed by Defendants' illegal
8 actions.

9 VI. PRAYER FOR RELIEF

10 Wherefore, the State of Washington prays that the Court:

11 a. Declare that the Final Rule is unauthorized by and contrary to the
12 Constitution and laws of the United States;

13 b. Declare that the Final Rule is invalid and without force of law and
14 vacate the Final Rule in full;

15 c. Issue preliminary and permanent injunctions prohibiting Defendants
16 from implementing or enforcing the Final Rule;

17 d. Award the State of Washington its costs and reasonable attorneys'
18 fees; and

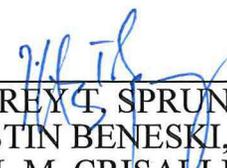
19 e. Award such other and further relief as the interests of justice may
20 require.

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Respectfully submitted this 5th day of March, 2019.

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