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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 59

RIN 0937-AA11

Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services

AGENCY: Office of the Secretary, U.S. Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Office of Population Affairs (OPA), in the Office of the Assistant Secretary for Health, proposes to revise the rules issued on March 4, 2019, establishing standards for compliance by family planning services projects authorized by Title X of the Public Health Service Act. Those rules have undermined the public health of the population the program is meant to serve. The Department proposes to revise the 2019 rules by readopting the 2000 regulations, with several modifications needed to strengthen the program and ensure access to equitable, affordable, client-centered, quality family planning services for all clients, especially for low-income clients.

DATES: To ensure consideration, comments must be received by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Regulatory Information Number 0937-AA11, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Enter the above docket ID number in the "Enter Keyword or ID" field and click on "Search." On the next Web page, click on "Submit a Comment" and follow the instructions.

- *Mail or Hand Delivery [For paper, disk, or CD-ROM submissions] to*: Attn: Title X Rulemaking,

Office of Population Affairs, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C. 20201. Comments, including any personally identifiable or confidential businesses information, received prior to the close of the comment period will be posted without change to *http://www.regulations.gov*.

While the Department welcomes comments on any aspect of the regulations, we particularly welcome comments concerning how the current regulations have impacted the public's health or how this proposal to revise them will promote public health and aid in the program's fundamental mission to offer a broad range of effective family planning methods with priority given to clients from low-income families.

FOR FURTHER INFORMATION CONTACT: Alicia Richmond Scott, Office of Population Affairs, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Avenue, S.W. Washington, D.C. 20201; telephone: 240-453-2800; e-mail: Alicia.richmond@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Title X of the Public Health Service Act (PHS Act or the Act) (42 U.S.C. 300 through 300a–6) was enacted in 1970 by Public Law 91–572 as a means of "making comprehensive voluntary family planning services readily available to all persons desiring such services."[1] Section 1001 of the Act (42 U.S.C. 300(a)), as amended, authorizes the Secretary of Health and Human Services ''to make grants to

[1] Pub. L. 91-572 ("The Family Planning Services and Population Research Act of 1970"), section 2(1).

and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents).'' Section 1006 of the Act (42 U.S.C. 300a-4) ensures that priority of services is given to clients from low-income families and authorizes the Secretary to promulgate regulations governing the program.

Enacted as part of the original Title X legislation, Section 1008 of the Act (42 U.S.C. 300a-6) directs that "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." The Conference Report accompanying the legislation described the intent of this provision as follows:

> It is, and has been, the intent of both Houses that funds authorized under this legislation be used only to support preventive family planning services, population research, infertility services and other related medical, information, and educational activities. The conferees have adopted the language contained in section 1008, which prohibits the use of such funds for abortion, in order to make clear this intent.

H.R. Rep. No 91–1667, at 8–9 (1970) (Conf. Rep.). This requirement has been reiterated by later Congresses through annual appropriations provisos that state: "[A]mounts provided to said [voluntary family planning] projects under such title shall not be expended for abortions.'' *See, e.g.,* Consolidated Appropriations Act, 2021, Public Law 116-260, Div. H, 134 Stat 1182, 1570.

Since 1970 when Title X was first enacted, Congress has amended the law several times both through changes to the Title X statute itself and through yearly appropriations riders. For example, in 1975, Congress amended Title X to include "natural family planning methods" as part of the broad range of

family planning methods to be offered by Title X projects.[2] PHS Act 1001(a) (42 U.S.C. 300(a)). In 1978, Congress amended Title X to codify HHS past practice by specifically requiring that Title X projects include "services for adolescents."[3] PHS Act 1001(a) (42 U.S.C. 300(a)). The Act was again amended in 1981 to provide that ''[t]o the extent practicable, entities which receive grants or contracts under this subsection shall encourage family participation in projects under this subsection.''[4] PHS Act sec. 1001(a) (42 U.S.C. 300(a)).

Congress has also imposed additional requirements through annual appropriations riders. For example, since Fiscal Year (FY) 1996, the annual Title X appropriation includes the proviso that ''all pregnancy counseling shall be nondirective.''[5] *See, e.g.,* Consolidated Appropriations Act, 2021, Public Law 116-260, Div. H, 134 Stat 1182, 1570 (2021). Also since FY 1996, the Title X appropriation has directed that Title X funds ''shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.'' *Id.* Since FY 1998, Congress has included a rider in HHS's annual appropriations act that provides that ''[n]one of the funds appropriated in this Act may be made available to any entity under Title X of the PHS Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services.''[6] *See, e.g.,* Consolidated Appropriations Act, 2021, Public Law 116–260, Div. H, sec. 207, 134 Stat. 1182, 1590. The same appropriations rider also requires that such an applicant certify to the Secretary that it ''provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.'' *Id.* And, since FY 1999, in a separate rider, Congress has required that,

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[2] Pub. L. 94-63.
[3] Pub. L. 95-613. The amendment reflected Congress' intent to place "a special emphasis on preventing unwanted pregnancies among sexually active adolescents." S. Rep. No 822, 95th Cong, 2d sess. 24 (1978).
[4] Omnibus Budget Reconciliation Act of 1981, Public Law 97–35, sec. 931(b)(1), 95 Stat. 357, 570 (1981).
[5] Omnibus Consolidated Rescissions and Appropriations Act, 1996, Public Law 104–134, Title II, 110 Stat.1321, 1321–221 (1996).
[6] Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1998, Public Law 105–78, sec. 212, 111 Stat. 1467, 1495 (1997).

‘‘[n]otwithstanding any other provision of law, no provider of services under Title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.’’[7] *See, e.g.*, Consolidated Appropriations Act, 2021, Public Law 116–260, Div. H, sec. 208, 134 Stat. 1182, 1590 (2021).

II. Regulatory and Litigation Background

The Department first promulgated regulations for the Title X program in 1971 but did not directly address section 1008. 36 FR 18465 (Sept. 15, 1971). With experience, the Department interpreted section 1008 to prohibit grantees[8] from promoting or encouraging abortion as a method of family planning in any way and to require that Title X activities be separate and distinct from any abortion activities. 53 FR 2922, 2923 (Feb. 2, 1988) (describing the Department’s interpretation in the early years of the program). In 1981, the Department built upon this experience and issued guidelines directing grantees to provide “nondirective counseling” to pregnant clients “upon request” including: (1) prenatal care and delivery; (2) infant care, foster care, or adoption; and (3) pregnancy termination. Counseling included “referral upon request.” OPA, Program Guidelines for Project Grants for Family Planning Services at 13 (1981).

In 1988, reacting in large part to a directive from President Reagan, the Department changed course. 53 FR 2922 (Feb. 2, 1988). Regulations promulgated then - commonly called the “gag rule” - prohibited the discussion of or referral for abortion. The regulations also required grantees to maintain strict physical and financial separation between Title X projects and abortion related activities, to be determined by the “facts and circumstances” of each grantee. Additionally, the regulations prohibited lobbying, education, dues-paying, or any other activities which could be interpreted to encourage or promote abortion as a method of family planning.

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[7] Department of Health and Human Services Appropriations Act, 1999, Public Law 105-277, Title II, sec. 219, 112 Stat. 2681, 2681-363 (1998).

[8] For purposes of this notice of proposed rulemaking, the terms “grantee” and “recipient” are used interchangeably.

The 1988 regulations were immediately subject to multiple lawsuits and ultimately upheld by the Supreme Court in *Rust v. Sullivan*, 500 U.S. 173 (1991). In *Rust,* the Supreme Court held that section 1008 was "ambiguous" and "at no time did Congress directly address the issues of abortion counseling, referral or advocacy." *Id* at 185. The Court was nearly unanimous on this point. *Blackmun dissenting* at 207; O'Connor Dissenting at 223.[9] Given the lack of clarity regarding section 1008, the Court deferred to the Secretary's construction of the statute as "reasonable" under *Chevron U.S.A v. NRDC*, 467 U.S. 837 (1984).

The Court also upheld the regulations against constitutional attack under the Fifth and First Amendments. Following recent precedent, the Court held that the Government could constitutionally subsidize some activities over others and that plaintiffs were still free to pursue abortion related activities and speech "when they are not acting under the auspices of the Title X project." *Id.* at 199.

On November 5, 1991, responding to widespread concerns over the regulation's overreach into the doctor-patient relationship, President Bush issued a directive to the Department to allow for open communications between doctors and patients for all aspects of their medical condition. *See Nat'l Family Planning & Reprod. Health Ass'n v. Sullivan*, 979 F.2d 227 (D.C. Cir 1992). However, the Department did not engage in rulemaking to carry out the directive, as required by the Administrative Procedure Act. Therefore, the D.C. Court of Appeals upheld a lower court injunction prohibiting the directives from taking effect. *Id.*

Almost immediately after taking office, President Clinton issued a memorandum to the Secretary of HHS, directing suspension of the "gag rule" and commencement of new rulemaking regarding the Title X program. 58 FR 7455 (Feb. 5, 1993). The Department suspended the 1988 regulations and adopted compliance standards predating the 1988 rules on an interim basis. 58 FR 7462 (Feb. 5, 1993). The Department also sought comment on adopting as final the rules and guidance in effect prior to the 1988

[9] Justice Stevens, the only Justice to find the §1008 unambiguous, believed it "plainly" foreclosed the Secretary's regulations. Stevens dissent at 221.

rules. 58 FR 7464 (Feb. 5, 1993). In response to this proposed rulemaking, the Department received 146 comments, and finalized new Title X rules in July of 2000. 65 FR 41270 (July 3, 2000). On that same day, the Department published interpretations relating to the statutory requirement that no funds appropriated under Title X of the Public Health Service Act be used in programs in which abortion is a method of family planning. 65 FR 41281 (July 3, 2000).

The new rules rescinded the 1988 rules prohibiting counseling and referral for abortion. They also eliminated the provisions requiring strict physical and financial separation between Title X projects and abortion related activities, while still requiring that abortion and Title X activities are separated by more than "mere bookkeeping." 65 FR 41270, 41271. Section 59.10 concerning lobbying restrictions was also repealed, while still adhering to long established interpretations of the statute forbidding promotion of abortion through advocacy activities. *Id.* at 41277. Finally, the Department codified the 1981 guidance requiring, upon request of the pregnant patient, nondirective counseling and referral, regarding any option requested: "(1) prenatal care and delivery; (2) infant care, foster care, or adoption; and (3) pregnancy termination." *Id.* at 41279 [42 CFR 59.5(a)(5) (2000 reg)].

In promulgating the 2000 regulations, the Department concluded that revoking the 1988 regulations was within its administrative discretion and that there was no evidence the "gag rule" would – or could - work in practice. The Department concluded experience had taught that the rules and policies previous to the 1988 regulations had been accepted by grantees and enabled the program to operate successfully during virtually its entire history. Additionally, the Department relied on the direction from Congress in appropriations riders beginning in 1996 (Pub. L. 104–134), requiring that "all pregnancy counseling be nondirective," believing any referral to a prenatal or other provider when not requested would raise real questions of coercion. The rule also incorporated referrals as a "logical and appropriate outcome" of nondirective counseling and consistent with the requirement that the project provide referrals for any medical services not provided by the project [42 CFR 59.5(b)(1)]. *Id.* 41274. For two decades after these rules were finalized (and nearly three decades after they had been in place following the 1988

rule's suspension in 1993), Title X faced no litigation or controversy over these regulations. [10]

In 2018, under a new Administration, the Department proposed new rules again. 83 FR 25502 (June 1, 2018). These rules largely mirrored the 1988 regulations and were finalized in 2019. 84 FR 7714 (March 24, 2019). The Department promulgated the 2019 rules because of its stated view, at that time, that they represented the best interpretation of the statute and provided the most appropriate guidance for compliance with the statutory provisions, including section 1008. While pointing to no direct violations of Title X, associated laws, or the 2000 regulations, the Department believed the 2000 regulations "fostered an environment of ambiguity surrounding appropriate Title X activities." *Id.* at 7721. Therefore, "bright line rules" would ameliorate any confusion by grantees and the public.

The Department also cited several conscience protection laws enacted by Congress to support the changes to the 2000 regulations. These laws prohibit public health service grantees from requiring individuals to assist in the performance of health service activities against their religious beliefs or convictions, 42 U.S.C. 300a-7(d), and prohibit discrimination against both individual and institutional providers for their refusal to provide, cover, or refer for abortions. Consolidated Appropriations Act, 2021, Public Law 116-260, Div. H, sec. 507(d) (2020), Consolidated Appropriations Act, 2021, Public Law 116-260, Div. H, sec. 507(d) (2020). The Department concluded in 2019 that the 2000 regulations, if enforced against objecting grantees, would be inconsistent with these statutory protections and dissuade otherwise qualified providers from applying for Title X funds.

The 2019 rules also re-imposed the physical separation provisions of the 1988 rule, as well re-codifying the lobbying restrictions. Additionally, the rule added requirements on grantees and subrecipients regarding compliance with state reporting laws, as well as expanded application and record-keeping requirements. And, with respect to minors, the 2019 rule required providers to document what specific

[10] As discussed below, the 2000 rule also fully recognized the statutory conscience right of individual providers to object to counseling and referral for abortions. *Id.* At 41274, 41275.

actions were taken to encourage family participation.

As to nondirective counseling and referral for abortion, in recognition of the Congressional direction for nondirective counseling on abortion in yearly appropriations riders, the 2019 rule allowed, but did not require, counseling by grantees, limited to physicians and advanced care providers. *Id.* at 7744. However, the Department believed that the abortion referral requirement was inconsistent with section 1008 and that, though permissible for nearly the entire history of the program, such referrals must be prohibited. *Id.*

Litigation over the 2019 rule immediately ensued. The Department was sued by 23 states, every major medical organization, Title X grantee organizations, and individual grantees. The suits were lodged in multiple district courts and alleged a variety of claims under the Administrative Procedure Act, the Affordable Care Act, and the Constitution. The rule was ultimately upheld by an *en banc* Court of Appeals for the Ninth Circuit and enjoined (only as to the state of Maryland) by a district court in Maryland in a decision upheld by the *en banc* Court of Appeals for the Fourth Circuit. Both court of appeals decisions were issued over substantial dissents.

In *California v. Azar*, 950 F.3d 1067 (9th Cir. 2020), the Ninth Circuit relied heavily on *Rust* in upholding the rule. A majority of the *en banc* panel found that the Department "could" interpret section 1008 as it did in the 2019 rule, and nothing in subsequent legislation prevented this reading. *Id.* at 1085. The Ninth Circuit upheld the rule against an arbitrary and capricious challenge, stating, "that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better." *Id.* at 1097 (emphasis in original). Conversely, a majority of the Fourth Circuit found the Department's 2019 rule arbitrary and capricious. *Mayor of Baltimore v. Azar*, 973 F.3d 258 (4th Cir. 2020). The Fourth Circuit also held the 2019 rule violated the non-directive mandate.[11]

[11] Both the Ninth and Fourth Circuits also came to opposite results on the validity of the rule under section 1554 of the Affordable Care Act [42 U.S.C. 18114].

Losing parties in both cases sought review from the Supreme Court in October of 2020. The Court granted certiorari on February 22, 2021, consolidating the cases. No. 20-429. On March 12, 2021, the parties stipulated to dismiss the cases under Supreme Court Rule 46.1.

III. Public Health Impact as a Result of the 2019 Rules and Reason for this Proposal

The 2019 rule split courts and judges on its approach, its reasonableness, and the interpretation of subsequent legislative provisions. Still, no court questioned the Supreme Court's fundamental holding in *Rust* that section 1008 is "ambiguous." And, while section 1008 may be ambiguous, the public health consequences of the previous Administration's interpretation of the statute are not. The following outlines the effects of the 2019 rule:

- **The number of family planning services grantees has dropped precipitously, resulting in an adverse impact on the number of clients served.** After the implementation of the 2019 Title X Final Rule, 19 Title X grantees out of 90 total grantees, 231 subrecipients, and 945 service sites immediately withdrew from the Title X program. Overall, the Title X program lost more than 1,000 service sites. Those service sites represented approximately one quarter of all Title X-funded sites in 2019. Title X services are not currently available at all in six states (HI, ME, OR, UT, VT, and WA) and are only available on a very limited basis in six additional states (AK, CT, MA, MN, NH, and NY). California, the single-largest Title X project in the nation (before the 2019 Final Rule) had 128, or 36 percent, of its Title X service sites withdraw from the program, leaving more than 700,000 patients without access to Title X-funded care. Similarly, in New York, the number of Title X-funded service sites dropped from 174 to just two, leaving more than 328,000 patients without Title X-funded care. All Planned Parenthood affiliates—which in 2015 had served 41 percent of all clients at Title X service sites—withdrew from Title X due to the 2019 Final Rule.[12] The withdrawal of numerous grantees, subrecipients, and service sites adversely impacted the number of clients served under the Title X program. With the 2019 Final

[12] (Kaiser Family Foundation, 2020). Current Status of the Title X Network and the Path Forward.

Rule only being in place for five and a half months, the remaining 71 Title X grantees served 844,083 fewer clients as compared to the previous year, prior to the change in the regulations. Specifically, 3,939,749 clients were served in 2018; 3,095,666 clients were served in 2019, an approximately 22 percent decrease. [13]

- **Low-income, uninsured, and racial and ethnic minorities' access to Title X family planning services has decreased, thereby contributing to the increase in health inequities and unmet health needs within these populations.** Compared to 2018 Family Planning Annual Report (FPAR) data prior to the implementation of the 2019 Final Rule, in 2019, 573,650 fewer clients under 100 percent of the Federal poverty level (FPL); 139,801 fewer clients between 101 percent to 150 percent FPL; 65,735 fewer clients between 151 percent and 200 percent FPL; and, 30,194 fewer clients between 201 percent to 250 percent FPL received Title X services. This contradicts the purpose and intent of the Title X program, which is to prioritize and increase family planning services to low-income clients. Additionally, 324,776 fewer uninsured clients were served in 2019 compared to 2018. FPAR data also demonstrate that in 2019 compared to 2018, 128,882 fewer African Americans; 50,039 fewer Asians; 6,724 fewer American Indians/Alaska Natives; 7,218 fewer Native Hawaiians/Pacific Islanders; and, 269,569 fewer Hispanics/Latinos received Title X services.[14]

- **Provision of critical family planning and related preventive health services has decreased dramatically[15].** The impact of the 2019 Final Rule has been devastating to the hundreds of thousands of Title X clients who have lost access to critical family planning and related preventive health services due to service delivery gaps created by the 2019 Final Rule. More specifically, compared to 2018, 225,688 fewer clients received oral contraceptives; 49,803 fewer

[13] (OPA, 2020). Family Planning Annual Report: 2019 National Summary Report. Accessed on March 9, 2021 from https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf
[14] (OPA, 2020). Family Planning Annual Report: 2019 National Summary Report. Accessed on March 9, 2021 from https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf
[15] Ibid

clients received hormonal implants; and 86,008 fewer clients received IUDs. Additionally, 90,386 and 188,920 fewer Papanicolaou (Pap) tests and clinical breast exams respectively were performed in 2019 compared to 2018. Confidential human immunodeficiency virus (HIV) tests decreased by 276,109. Sexually transmitted infection (STI) testing decreased by 256,523 for chlamydia, by 625,802 for gonorrhea, and by 77,524 for syphilis. Furthermore, 71,145 fewer individuals who were pregnant or sought pregnancy were served. As a result of the dramatic decline in Title X services provided, the 2019 Final Rule undermined the mission of the Title X program by helping fewer individuals in planning and spacing births, providing fewer preventive health services, and delivering fewer screenings for STIs. Adolescent services were also adversely affected. In 2019, 151,375 fewer adolescent clients received family planning services and 256,523 fewer women under the age of twenty-five were tested for chlamydia.[16]

The true impact of the 2019 Final Rule in terms of long-term sexual and reproductive health negative sequelae in the lives of hundreds of thousands of low-income clients and clients of color is difficult to quantify. As a result of the decrease in clients able to receive Title X services, it is estimated that the 2019 Final Rule may have led to up to 181,477 unintended pregnancies.[17]

Unintended pregnancies increase the risk for poor maternal and infant outcomes. Individuals having a birth following an unintended pregnancy are less likely to have benefitted from preconception care, to have optimal spacing between births, and to have been aware of their pregnancy early on, which in turn makes it less likely that they would have received prenatal

[16] (OPA, 2020). Family Planning Annual Report: 2019 National Summary Report. Accessed on March 9, 2021 from https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf

[17] Estimating that of the 844,083 fewer clients served by Title X in 2019 compared to 2018, 21.5% of those clients could have experienced an unintended pregnancy as a result of not receiving services. Formula taken from Guttmacher Institute (2017). Unintended pregnancies prevented by publicly funded family planning services: Summary of results and estimation formula. Accessed on March 8, 2021 from https://www.guttmacher.org/sites/default/files/pdfs/pubs/Guttmacher-Memo-on-Estimation-of-Unintended-Pregnancies-Prevented-June-2017.pdf.

care early in pregnancy.[18,19] The 2019 Final Rule likely also resulted in additional costs to taxpayers as a result of an increase in unintended pregnancies, preterm and low-birthweight births, STIs, infertility, and cervical cancer.[20]

- **OPA has been unable to secure new Title X grantees and service sites to meet the unmet need for family planning services.** To meet the unmet need for family planning services nationwide, in Fiscal Year 2019 OPA issued a competitive supplemental funding announcement to existing grantees. Fifty existing grantees were awarded $33.7 million to expand Title X services. However, only 7 states (CO, DE, KY, ND, NM, NV, TX) had a meaningful increase in the number of Title X clinics in their states.

  In addition, OPA has been unable to find new grantees to fill most of the gaps the 2019 Final Rule created, including in the six states that lost all Title X-funded services. To address gaps in the Title X service network and increase coverage, a new competitive funding announcement was issued in Fiscal Year 2020 to provide services in unserved or underserved states and communities. The number of applications received was so low (8 eligible applications received) that the resulting grant awards were for less than the total amount of funding available (grant awards for $8.5 million with $20 million available), and were only able to provide services in three states with no or limited Title X services at the time. This demonstrated the negative effects of the 2019 Title X Final Rule on client access to needed family planning and related preventive health services, especially for the priority low-income populations that Title X is mandated to

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[18] Jessica D. Gipson, Michael A. Koenig, and Michelle J. Hindin. "The Effects of Unintended Pregnancy on Infant, Child, and Parental Health: A Review of the Literature." Studies in family planning 39.1 (2008): 18–38. Web.
[19] Power to Decide. Maternal and Infant Health and the Benefits of Birth Control in America. Accessed on March 8, 2020 from https://powertodecide.org/sites/default/files/resources/supporting-materials/getting-the-facts-straight-chapter-3-maternal-infant-health.pdf.
[20] Kaiser Family Foundation. https://www.kff.org/womens-health-policy/issue-brief/data-note-impact-of-new-title-x-regulations-on-network-participation/

serve.

The realization of a greater pool of grantees, as predicted by the 2019 rule, has not transpired over the course of two grant cycles. As discussed above, OPA was unable to meaningfully expand services nor was it able to find new grantees to fill existing gaps. In fact, the 2019 Final Rule did not increase the pool of grantees and was unable to generate interest in providing Title X services from organizations who had not previously been Title X grantees. This, coupled with the exodus of otherwise qualified grantees, subrecipients and service sites that left the network due to their opposition to the 2019 Final Rule, led to great difficulty in awarding appropriated funds as intended by Congress.

- **The 2019 Final Rule is contrary to the CDC and OPA's Quality Family Planning (QFP) Guidelines.** In April 2014 (with updates in 2015 and 2017), *Providing Quality Family Planning Services: Recommendations from Centers for Disease Control and Prevention and the US Office of Population Affairs* (QFP),[21] was published as a CDC Morbidity and Mortality Weekly Report (MMWR) Recommendations and Reports. The QFP, developed jointly by the Centers for Disease Control and Prevention (CDC) and the HHS Office of Population Affairs (OPA), provides recommendations for use by all reproductive health and primary care providers with patients who are in need of services related to preventing or for achieving pregnancy. The QFP are scientific and evidence-based recommendations that integrate and fill gaps in existing guidelines for the family planning settings. QFP recommendations are based on a rigorous, systematic, transparent review of the evidence and with input from a broad range of clinical experts, OPA, and CDC. The QFP references numerous other clinical guidelines that are published by Federal agencies, as well as guidelines released by professional medical

[21] CDC. Providing Quality Family Planning Services – Recommendations from CDC and the U.S. Office of Population Affairs. Accessed on March 8, 2021 from https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/quality-family-planning.

associations.

These guidelines were developed over a three-year period through the CDC's Division of Reproductive Health (DRH) and OPA, in consultation with a wide range of experts and key stakeholders. These guidelines have been the undisputed standard in reproductive healthcare ever since. QFP recommendations support all providers in delivering quality family planning services and define family planning services within a broader context of preventive services, to improve health outcomes for women, men, and their (future) children.

The client centered approach adopted in the QFP requires pregnancy tests to be "followed by a discussion of options and appropriate referrals." *Id.* at 14 Further, counseling and referral are to be provided, "at the request of the client," in accordance with recommendations from professional medical organizations. Though formally adopted as a QFP recommendation in 2014, appropriate referrals with nondirective counseling have been the practice and implicit standard of care in Title X programs for essentially its entire history, including in early guidelines and later when expressly incorporated in the 2000 regulations.

The 2019 rule abandoned this client centered approach over the objection of every major medical organization without any countervailing public health rationale. Moreover, the 2019 rule required prenatal referral even over the objection of the patient. For the reasons discussed above, that approach cannot be squared with well-accepted public health principles.

- **The 2019 Final Rule increased compliance and oversight costs, with no discernible benefit.** The 1988 rules requiring strict physical and financial separation requirements, were based, in part, on two governmental reports finding minor compliance issues with grantees and recommended only more specific guidance, not a substantial reworking of the regulations**.** *See,*

e.g., Comp. Gen. Rep. No GAO/HARD-HRD-82-106 (1982), at 14-15; 65 FR 41270, 41272. While those reports found some confusion among grantees around section 1008, "GAO found no evidence that Title X funds had been used for abortions or to advise clients to have abortions." More importantly, in the decades between 1993 and the 2019 rule, and as evidenced by the silence of the 2019 final rule on this issue, legally required audits, regular site visits, and other oversight of grantees have found no diversion of grant funds that would justify the greatly increased compliance and oversight costs the 2019 rule required.

The 2019 rule's separation requirements also claimed to be addressing questions of "fungibility" and a concern that Title X funds might be "intentionally or unintentionally" co-mingling with activities not allowed under the statute. 84 FR at 7716. As noted, close oversight for decades under the 2000 rules uncovered no misallocation of Title X funds by grantees. Moreover, courts have long since held that governments cannot restrict access to funds for one activity simply because it may "free up" funds for another activity. *See Planned Parenthood of Cent. & N. Arizona v. Arizona,* 718 F.2d 938, 945 (9th Cir 1983) (concluding "as a matter of law, the freeing-up theory cannot justify withdrawing all state funds from otherwise eligible entities merely because they engage in abortion-related activities disfavored by the state"); *see also Agency for Int'l Dev. v. Alliance for Open Soc'y Int'l, Inc*., 570 U.S. 205, 220 (2013) ("[I]f the Government's argument [that fungibility is sufficient for prohibition] were correct, *League of Women Voters* would have come out differently, and much of the reasoning of *Regan* and *Rust* would have been beside the point"). Because of the 2019 rule, appropriations that would otherwise be used to carry out the purposes of the Title X program, providing a broad range of family planning services to individuals (including confidential services to minors), are now being diverted to increased infrastructure costs resulting from the separation requirement as well as the micro-level monitoring and reporting now required of grantees. None of these burdensome additional requirements provide discernible compliance benefits, particularly not to public

health. As many commenters and at least one court emphasized, the 2019 rule was a solution in search of a problem, a solution whose severe public health consequences caused much greater problems.

The Department also recognizes Congress has passed several laws protecting the conscience rights of providers, particularly in the area of abortion. For example, in promulgating the 2000 Title X rules, the Department affirmed: "under 42 U.S.C. 300a-7(d), grantees may not require individual employees who have such objections [to abortion] to provide such counseling." 65 FR 41270, 41274 (July 3, 2000). Since 2005 Congress has also annually enacted an appropriations rider which extends non-discrimination protections to other "health care entities" who refuse to counsel or refer for abortion. *See, e.g.*, Consolidated Appropriations Act, 2021, Pub. L. 116-260, Div. H, section 507(d) (2020). Under these statutes, objecting providers or Title X grantees are not required to counsel or refer for abortions.[22] However, such protections for objecting providers and grantees should not prohibit willing providers and grantees from providing information in accordance with the ethical codes of major medical organizations.

Ultimately, continued enforcement of the 2019 rule raises the possibility of a two-tiered healthcare system in which those with insurance and full access to healthcare receive full medical information and referrals, while low-income populations with fewer opportunities for care are relegated to inferior access. Given that so many individuals depend on the Title X program as their primary source of healthcare, this situation creates a widespread public health concern. The 2019 rule is not in the best interest of public health.

IV. Proposed Rules

[22] This has been the consistent position of the Department since 2000. See 65 FR at 41274 (in response to comments on individual objections to providing abortion counseling or referral, Department stating: "under 42 U.S.C. 300a-7(d), grantees may not require individual employees who have such objections to provide such counseling.").

For nearly 50 years without interruption, Title X program grants have been administered against the backdrop of counseling and referral for appropriate medical care, including referral for abortion. Family planning is widely considered one of the most important public health achievements of the 20th Century.[23] As the only Federal program exclusively dedicated to providing contraceptive services, Title X has been imperative to that success.

For five decades, Title X family planning clinics have played a critical role in ensuring access to a broad range of family planning and related preventive health services for millions of low-income or uninsured individuals and others.[24] Over the 50 years of the Title X program, Title X clinics have served more than 190 million clients: 182.2 million women, 8.1 million men, comprising 139.5 million adults and 50.8 million adolescents, across 50 states, the District of Columbia, and eight U.S. territories and freely associated states. Title X providers offered clients a broad range of effective and medically safe contraceptive methods approved by the U.S. Food and Drug Administration. Title X-funded sexually transmitted infection (STI) and human immunodeficiency virus (HIV) screening services prevented transmission and adverse health consequences. Over the 50 years of the Title X program, Title X clinics also performed 34.1 million chlamydia tests, 18.3 million HIV tests, 37 million Papanicolaou tests, and 42 million clinical breast exams.

Given the previous success of the program, the large negative public health consequences of maintaining the 2019 rules, the substantial compliance costs for grantees, and the lack of tangible benefits, the Department proposes revoking the 2019 Title X regulations. As has been clearly borne out by case law and history, the Department has the discretion to make this determination and it is in the interest of public health.

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[23] Centers. for Disease Control & Prevention, *Achievements in Public Health, 1900-1999: Family Planning*, 48 Morbidity & Mortality Weekly Reports No. 47, 1073–80 (Dec. 3, 1999), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4847a1.htm.
[24] OPA. Title X: Celebrating 50 Years of Title X Service Delivery. Accessed on March 8, 2021 from https://opa.hhs.gov/sites/default/files/2020-11/title-x-50-years-infographic.pdf.

The Department is also concerned that some state policies restricting eligible subrecipients unnecessarily interfere with beneficiaries' access to the most accessible and qualified providers. These state restrictions are not always related to the subrecipients' ability to effectively deliver Title X services, but rather are sometimes based either on the non-Title X activities of the providers or because they are a certain type of provider. However, providers with a reproductive health focus often provide a broader range of contraceptive methods on-site and therefore may reduce additional barriers to accessing services. Moreover, denying participation by family planning providers that can provide effective services has resulted in populations in certain geographic areas being left without Title X providers for an extended period of time.[25] And, while many otherwise qualified providers are willing and can provide effective Title X services, some lack the administrative capacity to directly apply for and manage a Title X grant.

The Department believes that these state restrictions on subrecipient eligibility unrelated to the ability to deliver Title X services undermine the mission of the program to ensure widely available access to services by the most qualified providers. Therefore, the Department invites comment on ways in which it can ensure that Title X projects do not undermine the program's mission by excluding otherwise qualified providers as subrecipients.

In place of the 2019 Title X regulations, the Department proposes to largely readopt the 2000 regulations (65 FR 41270) with several revisions aimed at ensuring access to equitable, affordable, client-centered, quality family planning services. Advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent

[25] Carter, M.W., Gavin, L., Zapata, L.B., Bornstein, M., Mautone-Smith, N., & Moskosky, S.B. (2016). Four aspects of the scope and quality of family planning services in US publicly funded health centers: Results from a survey of health center administrators. Contraception. doi:10.1016/j.contraception.2016.04.009.

poverty and inequality, is a priority for OPA and the Title X program. By focusing on advancing equity in the Title X program, we can create opportunities for the improvement of communities that have been historically underserved, which benefits everyone. Additionally, given the success of the *Providing Quality Family Planning Services* guidelines published in 2014,[26] the Department is proposing to incorporate into regulations several of the QFP's recommendations. Based on experience, the Department is also proposing some provisions it believes will make the program function more effectively, efficiently and consistently for all.

The Department proposes revising the 2019 Title X Final Rule through notice and comment rulemaking, by readopting the 2000 regulations with revisions that will enhance the Title X program and its family planning services, including family planning services provided using telemedicine, for the future. This will remove the 2019 Final Rule requirements for strict physical and financial separation, allow Title X providers to provide nondirective options counseling, and allow Title X providers to refer their patients for all family planning related services desired by the client, including abortion services. In addition, this will allow for several revisions that are needed to strengthen the program and ensure access to equitable, affordable, client-centered, trauma-informed quality family planning services for all clients, especially for low-income clients. At the same time, the proposed rule will retain the longstanding prohibition on directly promoting or performing abortion that follows from Section 1008's text and subsequent appropriations enactments. And as indicated above, individuals and grantees with conscience objections will not be required to follow the proposed rule's requirements regarding abortion counseling and referral.

For all the above reasons, the Department proposes to revise the regulations that govern the Title X family planning services program by readopting the 2000 regulations (65 FR 41270), with several

[26] CDC. Providing Quality Family Planning Services – Recommendations from CDC and the U.S. Office of Population Affairs. Accessed on March 8, 2021 from https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/quality-family-planning.

modifications. The proposed revisions to the 2000 regulations and rationale for each are listed below:

A. Section 59.2 Definitions

The Department proposes to revise §59.2 to include a modified definition of family planning. The definition of family planning services included in the 2019 Final Rule did not align with the widely accepted definition. The definition of family planning services should be consistent with the Title X statutory requirements and reflect the widely-recognized definition that is included in *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*,[27] which has been used historically by OPA when implementing the program prior to 2019. Under the proposed regulations, "family planning services" are defined as including a broad range of medically approved contraceptive services, which includes FDA-approved contraceptive services and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services.

The Department also proposes to add definitions for terms used throughout the revised regulations to provide clarity. The newly proposed definitions include adolescent-friendly health services,[28] client-centered care,[29] health equity,[30] inclusivity,[31] quality[32] healthcare, service site,

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[27] CDC. Providing Quality Family Planning Services – Recommendations from CDC and the U.S. Office of Population Affairs. Accessed on March 8, 2021 from https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/quality-family-planning.
[28] World Health Organization. Quality Assessment Guidebook. A guide to assessing health services for adolescent clients. Geneva, World Health Organization, 2009. Accessed on March 8, 2021 from https://apps.who.int/iris/handle/10665/44240.
[29] CDC. Providing Quality Family Planning Services – Recommendations from CDC and the U.S. Office of Population Affairs. Accessed on March 8, 2021 from https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/quality-family-planning.
[30] CDC. Health Equity. Accessed on March 12, 2021 from https://www.cdc.gov/chronicdisease/healthequity/index.htm.
[31] White House. Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Accessed on March 8, 2021 from https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.
[32] Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Accessed on March 8, 2021 from https://www.ncbi.nlm.nih.gov/books/NBK222274/.

and trauma-informed.[33]

The proposed definition for "service site" is adapted from previous Title X Family Planning Guidelines that implemented the 2000 regulations, the 2014 *Program Requirements for Title X Funded Family Planning Projects* (hereafter "2014 Title X Program Requirements").[34] "Service site" is defined as a clinic or other location where Title X services are provided to clients. The Title X grantees and/or their subrecipients may have services sites. The proposed definition of service site will assist Title X grantees in more accurately reporting data on their subrecipient and service sites and will eliminate confusion in the OPA Title X clinic locator database.

All other proposed definitions are used by Federal Government agencies or major medical associations, and include:

Adolescent-friendly health services are services that are accessible, acceptable, equitable, appropriate and effective for adolescents.[35]

Client-centered care is respectful of, and responsive to, individual client preferences, needs, and values; client values guide all clinical decisions.[36]

Culturally and linguistically appropriate services are respectful of and responsive to the health beliefs, practices and needs of diverse patients.[37]

Health equity is achieved when every person has the opportunity to attain their full health potential and no one is disadvantaged from achieving this potential because of social position or

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[33] SAMHSA. SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach. Accessed on March 8, 2021 from https://ncsacw.samhsa.gov/userfiles/files/SAMHSA_Trauma.pdf.

[34] OPA. 2014 Program Requirements for Title X Funded Family Planning Projects. Accessed on March 8, 2021 from https://www.nationalfamilyplanning.org/document.doc?id=1462.

[35] World Health Organization. Quality Assessment Guidebook. A guide to assessing health services for adolescent clients. Geneva, World Health Organization, 2009. Accessed on March 8, 2021 from https://apps.who.int/iris/handle/10665/44240.

[36] CDC. Providing Quality Family Planning Services – Recommendations from CDC and the U.S. Office of Population Affairs. Accessed on March 8, 2021 from https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/quality-family-planning.

[37] Office of Minority Health. What is Cultural and Linguistic Competence? Accessed on March 8, 2021 from https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=1&lvlid=6.

other socially determined circumstances.[38]

Inclusivity ensures that all people are fully included and can actively participate in and benefit from family planning, including, but not limited to, individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.[39]

Quality healthcare is safe, effective, client-centered, timely, efficient, and equitable.[40]

Trauma-informed is a program, organization, or system that realizes the widespread impact of trauma and understands potential paths for recovery; recognizes the signs and symptoms of trauma in clients, families, staff, and others involved with the system; and responds by fully integrating knowledge about trauma into policies, procedures, and practices, and seeks to actively resist re-traumatization.[41]

The Department also proposes a technical corrections to §59.2 to replace "grantee" with "recipient" in the regulatory text to align with the way the term is used in Federal and HHS regulations.

B. Section 59.5 What requirements must be met by a family planning project?

The Department proposes revising §59.5(a)(1) to define what constitutes a broad range of acceptable and effective family planning methods and services. The proposed revision revises

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[38] CDC. Health Equity. Accessed on March 12, 2021 from https://www.cdc.gov/chronicdisease/healthequity/index.htm.
[39] White House. Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Accessed on March 8, 2021 from https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.
[40] Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Accessed on March 8, 2021 from https://www.ncbi.nlm.nih.gov/books/NBK222274/.
[41] SAMHSA. SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach. Accessed on March 8, 2021 from https://ncsacw.samhsa.gov/userfiles/files/SAMHSA_Trauma.pdf.

the 2000 regulations by removing the existing ambiguity and defining what constitutes a broad range of acceptable and effective family planning methods and services. The revised definition of the broad range of methods and services is aligned with the definition used in practice/policy guidance. Moreover, the same definition is included in CDC and OPA's *Recommendations for Providing Quality Family Planning Services.*[42] This revision will result in increased equitable access to a broad range of family planning methods and services to all Title X clients and more clarity in defining those services.

The Department proposes revising §59.5(a)(1) to require service sites that do not offer a broad range of family planning methods and services on-site to provide clients with a referral for where they can access the broad range and ensure, when feasible, that the referral provided does not unduly limit client access to services, such as excessive distance or travel time to the referral location or referral to services that are cost-prohibitive for the client. While an organization that offers only a single method of family planning may participate as part of a Title X project as long as the entire project offers a broad range of family planning services, offering only a single method of family planning could unduly limit Title X clients, especially low-income clients, by reducing access to a client's method of choice. The Department proposes revising the 2000 regulations to require sites that do not offer the broad range of methods on-site to be able to provide clients with a referral to a provider who does offer the client's method of choice. In addition, the referral provided must be client-centered and not unduly limit access to the client's method of choice. This revision will help to improve access to client-centered services.

The Department proposes to revise §59.5(a)(3) so that family planning services are required to be client-centered, culturally and linguistically appropriate, inclusive, trauma-informed, and

[42] CDC (2014). Providing Quality Family Planning Services, Recommendations of CDC and the U.S. Office of Population Affairs. MMWR, 63(4).

ensure equitable and quality service delivery consistent with nationally recognized standards of care. This revision to the 2000 regulations is aimed at increasing access and ensuring equity in all services provided, which is especially important for the Title X program that prioritizes services for low-income clients. Including within the regulation a specific focus on services that are client-centered, culturally and linguistically appropriate, inclusive, trauma-informed, and ensure equitable and quality service delivery will result in improved services provided to clients. These new terms are defined in the proposed regulation under §59.2, and the added definitions were derived from existing definitions in use by the Federal Government or major medical associations.

The Department proposes revising §59.5(a)(8) to include widely accepted practices on grant billing practices that were included in previous Title X Family Planning Guidelines. These revisions incorporate language that was included in the 2014 Title X Program Requirements. The 2014 Title X Program Requirements were developed to assist grantees in understanding and implementing the family planning services grants. The 2014 Title X Program Requirements described the various requirements applicable to the Title X program, as set out in the Title X statute and implementing regulations, and in other applicable Federal statutes, regulations, and policies. These billing practices, which are widely accepted in the Title X community, indicate that: (1) family income should be assessed before determining whether copayments or additional fees are charged; and (2) insured clients whose family income is at or below 250% FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied. These revisions address areas of confusion for grantees prior to the 2014 Title X Program Requirements that were clarified in that document.

The Department proposes adding §59.5(a)(9) to ensure grantee income verification policies align with the mission of Title X services being prioritized for low-income clients. This addition aims

to address an area of common confusion among Title X grantees, which has resulted, in some instances, in a burden being placed on low-income clients. First, a requirement is added (using text from the previous 2014 Title X Program Requirements) to indicate that grantees should take reasonable measures to verify client income. In addition, a new requirement is added to use client self-reported income if the income cannot be verified after reasonable attempts. Without this additional statement, several Title X grantees have established policies to charge full price for services following unsuccessful attempts to verify income, even when the self-reported income is below 250% of the Federal poverty level (FPL) and would have otherwise qualified for no or reduced cost services. This proposed revision will greatly improve accessibility and affordability of services for low-income clients consistently across all Title X grantees.

The Department proposes adding §59.5(a)(12) to retain some, but not all, language from the 2019 Final Rule on notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking. The notification and reporting requirements are important for Title X providers as mandatory reporters under state laws and protect Title X clients. In addition, this regulation formalizes requirements contained in an annual appropriations rider related to Title X that Congress has included since FY 1999, requiring that, ‘‘[n]otwithstanding any other provision of law, no provider of services under Title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.’’

The Department proposes adding §59.5(a)(13) to describe requirements related to subrecipient monitoring and reporting. This addition requires Title X grantees to report on the subrecipients and referral agencies involved in their Title X projects, and to provide their plan for oversight and monitoring of their subrecipients in grantee reports. The regulation no longer requires grantees to report detailed information about each subrecipient and referral agency such as

location and specific expertise, which will reduce the increased reporting burden required by the 2019 Final Rule.

The Department proposes revising §59.5(b)(1) to acknowledge that consultation for medical services related to family planning can be provided by healthcare providers beyond the physician. The proposed revision acknowledges that consultation for healthcare services related to family planning may be by a physician, but may also be by other healthcare providers, including physician assistants and nurse practitioners.

The Department proposes revising §59.5(b)(3)(iii) to reflect the desire to engage diverse individuals to make services accessible. This revision adds language to clarify the intent at engaging diverse individuals to ensure access to equitable, affordable, client-centered, quality family planning services.

The Department proposes revising §59.5(b)(8) to add language to the existing 2000 regulation text to include primary healthcare providers in the list of referrals and to state that referrals are to be to providers in close proximity when feasible to the Title X site in order to promote access to services and provide a seamless continuum of care.

The Department also proposes including several technical corrections to §59.5. The technical correction proposed in §§59.5(a)(4) and 59.6(b)(2) replaces the word “handicapped condition” with “disability” in both sections in order to avoid negative connotations and correct outdated terminology. The technical correction proposed to §59.5(a)(5) replaces the word “women” with “client”, and the technical correction proposed to §59.5(a)(6) and (7) replaces the word “persons” with “clients” to use inclusive language. The technical correction proposed to §59.5(a)(11) replaces the term “sub-grantees” with “subrecipients”. The technical correction

proposed to §59.5(b)(3) clarifies that focus of this section is on community education, participation, and engagement, and should not be confused with the Information and Education Advisory Committee requirement under §59.6.

C. Section 59.6 What procedures apply to ensure the suitability of informational and educational material?

The Department proposes deleting prior §59.5(a)(11) related to the Advisory Committee and consolidating with §59.6; and revising §59.6 to clarify intent and remove areas of confusion for grantees regarding the Advisory Committee and other miscellaneous other provisions. The 2000 regulations included information about the Information & Education Advisory Committee in two sections (§§59.5(a)(11) and 59.6, which was confusing to Title X grantees. The result is that this revision consolidates all of the Advisory Committee information in one place, under section §59.6.

In addition, the Department is proposing several minor revisions to clarify that the regulation applies to both print and electronic materials, that the upper limit on council members should be determined by the grantee, that the factors to be considered for broad representation on the Advisory Committee match the definition of inclusivity earlier in the regulation, and that materials will be reviewed for medical accuracy, cultural and linguistic appropriateness, and inclusivity and to ensure they are trauma-informed.

D. Section 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

The Department proposes enabling the Department to consider the ability of the applicant to advance health equity when awarding grant funds. Advancing health equity is critical to the mission of the Title X program. Adding this additional criterion to the 2000 regulations brings

the total number of criteria from seven to eight.

E. Section 59.8 How is a grant awarded?

The Department proposes a technical correction to revise §59.8 to change "project period" to "anticipated period" since HHS is in the process of adopting revised definition and project period will no longer be used.

F. Section 59.10 Confidentiality.

The Department proposes revising §59.10 to include a widely accepted practice related to client confidentiality. This proposed revision will add a widely accepted practice in the Title X community that had been previously included in the 2014 Title X Program Requirements, indicating that reasonable efforts must be made to collect charges without jeopardizing client confidentiality. The Department believes that the Title X program will be strengthened by including this clarification within the revised 2000 regulations.

In addition, the Department proposes adding a requirement that grantees must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client. Since state and local laws may vary across jurisdictions (e.g., some are likely to result in notification to the policyholder that the client has received services, others provide for an "opt out" process whereby the client can elect that such a notification will not be made), this addition will ensure that the client understands the implications for using their insurance and the options available for them to maintain confidentiality.

G. Section 59.11 Additional conditions

The Department proposes revising §59.11 to add "during" the period of the award to allow for imposition of additional conditions, during the period of award in addition to "prior to and at the time of any award", under circumstances where recipient performance or organizational risk change, e.g. if a recipient is failing to perform we may impose new conditions mid-award to require corrective action per 45 CFR 75.207.

H. Section 59.12 What other HHS regulations apply to grants under this subpart?

The Department proposed a technical correction to §59.12 to update the regulations that apply to 42 CFR part 59, subpart A. The proposal includes a reference to 45 CFR part 87 ("Equal Treatment for Faith-based Organizations") on the list of regulations that apply to the Title X family planning services program.

V. Regulatory Impact Analyses

A. Introduction

HHS has examined the impacts of the proposed rule under Executive Order 12866 on Regulatory Planning and Review, Executive Order 13563 on Improving Regulation and Regulatory Review, Executive Order 13132 on Federalism, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct HHS to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). HHS believes that this proposed rule is not an economically significant regulatory action as defined by Executive Order 12866 because it would not result in annual effects in excess of $100 million.

The Regulatory Flexibility Act requires HHS to analyze regulatory options that would minimize any significant impact of a rule on small entities. The proposed rule, if finalized, would lessen administrative burdens for grantees of all sizes. Therefore, the Secretary certifies this proposed rule, if finalized, would not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 605.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires HHS to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments or has federalism implications. The proposed rule will not have a significant impact on state funds as, by law, project grants must be funded with at least 90 percent Federal funds. 42 U.S.C. 300a-4(a). The Department has determined that this proposed rule does not impose such costs or have any federalism implications. The Department expects that while some states may not support the policies contained in this proposed rule, many states and local health departments will support the policies contained in this proposed rule, and that it will increase participation by states (many of who dropped out under the 2019 rule).

B. Summary of Costs, Benefits and Transfers

This proposed rule would revise the 2019 Final Rule by readopting the 2000 regulations, with several modifications, and returning the program to the compliance regime as it existed prior to the 2019 rule's implementation. The proposed approach would allow the Title X program grantees, subrecipients, and service sites to have a greater impact on public health than under the current regulatory approach.

We predict that this proposed rule would increase the number of grantees receiving Title X funds. In turn, the additional service sites supported by funding would result in additional clients served under the program. These clients receive access to contraception, public health screening including clinical breast exams and Papanicolau (Pap) testing, and testing for sexually transmitted infections. These services result in a reduction in unintended pregnancy, earlier detection of breast and cervical cancer, and earlier detection of sexually transmitted infections including chlamydia, gonorrhea, syphilis, and human immunodeficiency virus (HIV). This screening and testing can result in significant cost savings from earlier treatment and other interventions. This proposed rule would also increase the diversity of grantees receiving funds, including geographic diversity to states that do not currently have a Title X grantee.

The proposed rule would also focus grantees on providing services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery. This focus is especially important for the Title X program that prioritizes services for low-income clients.

This regulatory impact analysis reports the activity occurring at Title X funded sites to provide policymakers with this information. However, the direct impact within the program does not account for services that continue to be provided at sites not receiving Title X funding, filling the gap left by

providers that withdrew from the program following the restrictions placed on funding included in the 2019 Final Rule.

C. Preliminary Economic Analysis of Impacts

a. Background

The Title X National Family Planning Program, administered by the U.S. Department of Health and Human Services (HHS), Office of Population Affairs (OPA), is the only Federal program dedicated solely to supporting the delivery of family planning and related preventive healthcare. The program is designed to provide "a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)" with priority given to persons from low-income families. In addition to offering these methods and services on a voluntary and confidential basis, Title X-funded service sites provide contraceptive education and counseling; breast and cervical cancer screening; sexually transmitted infections (STIs) and HIV testing, referral, and prevention education; and pregnancy diagnosis and counseling. The program is implemented through competitively awarded grants to state and local public health departments and family planning, community health, and other private nonprofit agencies. In fiscal year 2021, the Title X program received approximately $286.5 million in discretionary Federal Title X funding.

On March 4, 2019, HHS published a final rule to "prohibit family planning projects from using Title X funds to encourage, promote, provide, refer for, or advocate for abortion as a method of family planning; require assurances of compliance; eliminate the requirement that Title X projects provide abortion counseling and referral; require physical and financial separation of Title X activities from those which are prohibited under section 1008; provide clarification on the appropriate use of funds in regard to the building of infrastructure, and require additional reporting burden from grantees."

b. Market Failure or Social Purpose Requiring Federal Regulatory Action

The regulatory impact analysis associated with the 2019 Final Rule predicted that the additional restrictions on grantees would result in "an expanded number of entities interested in participating in Title X." Further, the analysis suggested the 2019 Final Rule would result in "enhanced patient service and care." Contrary to these predictions, during the initial period of the 2019 Final Rule's implementation, the policy appears to have had the opposite effect. As we describe in greater detail in the Baseline Section, the restrictions included in the 2019 Final Rule are associated with a substantial reduction in the number of Title X grantees, subrecipients, and service sites, resulting in a corresponding reduction in total clients served. This is particularly troubling, since the Title X program serves a low-income population that is particularly vulnerable to losing access to these services. This proposed rule is needed to improve the functioning of Government and the effectiveness of the Title X program.

c. Purpose of the Proposed Rule

This proposed rule would revise the regulations that govern the Title X family planning services program by revoking the 2019 Final Rule and readopting the 2000 regulations with several modifications. The proposed approach would allow the Title X program grantees, subrecipients, and service sites to have a greater impact on public health than under the current regulatory approach.

d. Baseline Conditions and Impacts Attributable to the Proposed Rule

We adopt a baseline that assumes the requirements of the 2019 Final Rule remain in place over the period of our analysis. To characterize the real-world impact of the Title X program under this regulatory approach, we develop an annual forecast of grantees, subrecipients, service sites, and total clients served. The key inputs to our forecast are historical data on Title X service grantees. For fiscal years 2016-2019, this information is summarized in the 2019 Title X Family Planning Annual Report.

We supplement this information with unpublished preliminary estimates of the impact for fiscal year 2020. Table D1 summarizes these data.

Table D1 - Title X Service Grantees

Year	2016	2017	2018	2019	2020
Grantees	91	89	99	100	73
Subrecipients	1,117	1,091	1,128	1,060	803
Service Sites	3,898	3,858	3,954	3,825	2,682
Clients Served	4,007,552	4,004,246	3,939,749	3,095,666	1,536,744

Source: Title X Family Planning Annual Report, 2019: Exhibit A-2a, and unpublished preliminary estimates for FY2020.

The data for fiscal years 2016-2019 included all grantees, subrecipients, and service sites operating at any time during the year. The adoption of the 2019 Title X Final Rule occurred mid-year in 2019. Following this regulation, 19 grantees, 231 subrecipients, and 945 service sites withdrew from the Title X program. The reduced number of grantees, subrecipients, services sites, and clients served observed in 2019 and 2020 cannot be explained by a reduction in discretionary funding for the program, which has remained constant at $286.5 million throughout this time period. Since the 2019 figure includes clients served by these service sites for about half of the year, adopting 3.1 million clients served as an annual forecast would likely overstate activity in the program under the current regulations. Indeed, preliminary figures for FY2020 indicate that only about 1.5 million clients were served. However, this figure likely represents an underestimate for a typical year of the program under the current regulations since services were likely disrupted by the ongoing public health emergency.

As our primary estimate, we adopt 2,512,066 clients served as the baseline annual impact of Title X under the policies of the 2019 Final Rule. This 2.5 million corresponds to the number of clients served in 2019 among remaining grantees as of March 2021. For comparison, this primary estimate represents a 37% reduction in clients served compared to the average of clients served from 2016 to 2018. In the Uncertainty and Sensitivity Analysis Section, we adopt the 1.5 million client figure as a lower-bound estimate, and 3.1 million clients as an upper-bound estimate of the annual program impact under the baseline.

Table D2 summarizes our baseline forecast for the same categories of historical data presented in Table D1. We adopt the current count for grantees, subrecipients, and services sites. We assume these figures will be constant over time horizon of this analysis.

Table D2 - Baseline Forecast of Title X Services

Baseline Forecast	Annual
Grantees	73
Subrecipients	803
Service Sites	2,682
Clients Served	2,512,066

In addition to the reduction in grantees, subrecipients, service sites, and total client served, we note that six states currently have no Title X services, including HI, ME, OR, UT, VT, and WA. There are six additional states that have limited Title X services, including AK, CT, MA, MN, NH, and NY.[43]

[43] As noted earlier, seven states (CO, DE, KY, ND, NM, NV, TX) experienced a meaningful increase in the number of Title X clinics after the 2019 regulatory change.

In line with the reduction in clients served under the 2019 Final Rule, data also reveal a significant drop in services provided For example, when comparing 2019 figures to 2018, 225,688 fewer clients received oral contraceptives; 49,803 fewer clients received hormonal implants; and 86,008 fewer clients received intrauterine devices (IUDs). For oral contraceptives and IUDs, this was a 27% reduction; and for hormonal implants, a 21% reduction. These percentages are similar in magnitude to the 21% reduction in clients served in 2019 compared to 2018. Additionally, 90,386 and 188,920 fewer Pap tests and clinical breast exams, respectively, were performed in 2019 compared to 2018. Confidential HIV tests decreased by 276,109. Testing for sexually transmitted infections (STIs) decreased by 256,523 for chlamydia, by 625,802 for gonorrhea, and by 77,524 for syphilis.

For our forecast of services provided under our baseline scenario, we adopt the most recent percentage of clients receiving each service in the 2019 Title X Family Planning Annual Report. For example, in 2019, about 23% of female clients received a clinical breast exam. We assume the same share of clients will be served by Title X for screening and sexually transmitted infection testing. Table D3 reports our best estimate of the annual services provided under the baseline scenario. We describe these services in greater detail later in this Section.

Table D3 – Baseline Title X Cancer Screening and Sexually Transmitted Infection Testing

Year	Annual
Clinical Breast Exams	509,550
Pap Tests	443,087
Chlamydia Test	1,266,508
Gonorrhea Test	1,420,198
Syphilis Test	536,619
Confidential HIV Test	777,536

Source: Calculations based on Title X Family Planning Annual Report, 2019: Exhibits 26 and 29.

We predict that the main effect of the proposed rule would be to return to Title X program impact levels observed prior to the 2019 Final Rule. Our estimates of the long-run equilibrium of grantees, subrecipients, service sites, and total client served are informed by the data from fiscal years 2016-2018, the last three years of data that are unaffected by the drops experienced following the 2019 Final Rule. Specifically, we adopt the average across these three years as our long-run estimates. These averages are 93 grantees, 1,112 subrecipients, 3,903 service sites, and about 4.0 million clients served.

To complete our forecast of the policy scenario, we assume that it will take two years for program participation and clients served to achieve the long-run equilibrium estimates. This two-year phase-in is consistent with a scenario in which most service sites that withdrew from the Title X program have remained open, with some operating at a lower capacity, than they did prior to the 2019 Final Rule. It is also consistent with an expectation that many of the grantees and service sites that withdrew from the program would be able to rejoin if this proposed rule were finalized. In year one, following the effective date of the proposed rule, the number of clients served would increase to about 3.2 million. In year two, this number would increase again to about 4.0 million and remain there for the duration of our analysis. These figures are presented in Table D4. We acknowledge uncertainty in this estimate, and include a discussion in the Uncertainty and Sensitivity Section, below.

Table D4 - Policy Scenario Forecast of Title X Service Grantees

Year	2022	2023	2024	2025	2026
Grantees	80	86	93	93	93
Subrecipients	906	1,009	1,112	1,112	1,112
Service Sites	3,089	3,496	3,903	3,903	3,903
Clients Served	3,247,958	3,983,849	3,983,849	3,983,849	3,983,849

To characterize the effect of the proposed rule, we compare the policy scenario forecast to the baseline forecast described in the previous section. Table D5 reports the difference between these two scenarios, which represents the net effect of the proposed rule. For example, in year 1 after this rule is effective, the number of clients served would be about 736,000 higher than under the baseline scenario. Approximately 88% of clients served in 2016-2018 are female, and we use this percentage to estimate the increase in clients served by sex under the policy scenario.

Table D5 - Effect of the Proposed Rule on Title X Services

Year	2022	2023	2024	2025	2026
Increase in Grantees	7	13	20	20	20
Increase in Subrecipients	103	206	309	309	309
Increase in Service Sites	407	814	1,221	1,221	1,221
Increase in Clients Served	735,892	1,471,783	1,471,783	1,471,783	1,471,783
Female	648,996	1,297,992	1,297,992	1,297,992	1,297,992
Male	86,896	173,791	173,791	173,791	173,791

Clients served under the Title X program experience outcomes that include reducing unintended pregnancy through greater access to contraception. The averted unintended pregnancies translate to a reduction in unplanned births, a reduction in abortions, and reduction in miscarriages. Also, Title X clients receive cancer screenings and testing for sexually transmitted infections. These screenings and testing can identify treatable conditions, improving the quality of life and extending the lives of beneficiaries. In the case of sexually transmitted infections, additional testing can reduce the likelihood of further infections and future infertility. This proposed rule would expand service to

socioeconomically disadvantaged populations, most of whom are female, low income, and young. We discuss this in greater detail in the Section on Distributional Effects.

To further explore the likely effect of the Title X program on unintended pregnancy, we rely on existing methodology for estimating number of unintended pregnancies prevented each year among U.S. women who depend on publicly funded family planning services.[44] Among this subgroup of women who use any method of contraception, 46 in 1,000 women are expected to experience an unintended pregnancy. This figure can be compared to 296 unintended pregnancies per 1,000 women who are unable to access public family planning services. We apply this estimate of a reduction of 250 unintended pregnancies per 1,000 contraception clients to the number of additional female clients served under the Title X program who adopt any method of contraception.

For year 1, we multiply 735,892 clients by 88% to yield 648,996 clients who are women. Among female clients, approximately 14% indicate they are not using a method of contraception, according to figures in the 2019 Title X Family Planning Annual Report. We reduce the potential number of clients that would potentially reduce the likelihood of an unintended pregnancy by 14% to yield 558,205 clients expected to benefit from a contraceptive method. Approximately 47% of unintended pregnancies result in unplanned births, 34% in abortion, and 19% in a miscarriage.[45]

Table D6 - Effect of the Proposed Rule on Title X-Associated Contraception

Year	2022	2023	2024	2025	2026
Clients Served	735,892	1,471,783	1,471,783	1,471,783	1,471,783

[44] Jennifer J. Frost and Lawrence B. Finer (2017). Memo entitled "Unintended pregnancies prevented by publicly funded family planning services: Summary of results and estimation formula." https://www.guttmacher.org/sites/default/files/pdfs/pubs/Guttmacher-Memo-on-Estimation-of-Unintended-Pregnancies-Prevented-June-2017.pdf. Accessed on March 14, 2021.

[45] Jennifer J. Frost, Lori F. Frohwirth, Nakeisha Blades, Mia R. Zolna, Ayana Douglas-Hall, and Jonathan Bearak (2017). "Publicly Funded Contraceptive Services at U.S. Clinics, 2015. https://www.guttmacher.org/sites/default/files/report_pdf/publicly_funded_contraceptive_services_2015_3.pdf. Accessed on March 14, 2021.

Women Served	648,996	1,297,992	1,297,992	1,297,992	1,297,992
Women Served Using Contraception	558,205	1,116,411	1,116,411	1,116,411	1,116,411

Unintended and unplanned pregnancies increase the risk for poor maternal and infant outcomes. Women who give birth following an unintended or unplanned pregnancy are less likely to have benefitted from preconception care, to have optimal spacing between births, and to have been aware of their pregnancy early on, which in turn makes it less likely that they would have received prenatal care early in pregnancy.[46,47]

Title X funding recipients also perform preventive health services such as cervical and breast cancer screening, and testing for sexually transmitted infections, including chlamydia, gonorrhea, syphilis, and HIV. Table D6 presents the effect of the proposed rule on Title X-associated cervical and breast cancer screenings. These figures are calculated by multiplying the number of additional women served by the program in each year by about 23% for clinical breast exams, of which 5% result in a referral for further evaluation; and 20% for Pap testing, of which 13% with a result of atypical squamous cells (ASC) that require further evaluation and possibly treatment, and 1% of which have a high-grade squamous intraepithelial lesion (HSIL)[48] or higher, indicating the presence of a more severe condition.

Clinical breast exams can identify women requiring further evaluation of an abnormal finding. Pap test (or pap smear test) results can indicate viral infections that, when untreated, can turn into cervical cancer. The Pap test results can also detect cervical cancer cells. At a population level, these screenings save lives by helping women identify cancer earlier, and preventing other conditions from developing into cancer.

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[46] Jessica D. Gipson, Michael A. Koenig, and Michelle J. Hindin. "The Effects of Unintended Pregnancy on Infant, Child, and Parental Health: A Review of the Literature." Studies in family planning 39.1 (2008): 18–38. Web.
[47] Power to Decide. Maternal and Infant Health and the Benefits of Birth Control in America. Accessed on March 8, 2020 from https://powertodecide.org/sites/default/files/resources/supporting-materials/getting-the-facts-straight-chapter-3-maternal-infant-health.pdf.
[48] HSIL is the abnormal growth of certain cells on the surface of the cervix.

Table D7 - Effect of the Proposed Rule on Title X-Associated Cervical and Breast Cancer Screening Activities

Year	2022	2023	2024	2025	2026
Clinical Breast Exams	149,269	298,538	298,538	298,538	298,538
Referred	7,463	14,927	14,927	14,927	14,927
Pap Tests	129,799	259,598	259,598	259,598	259,598
Tests with ASC or higher	17,304	34,609	34,609	34,609	34,609
Tests with HSIL or higher	195	391	391	391	391

Table D7 presents the effect of the proposed rule on Title X-associated testing for sexually transmitted infections among female clients. These are calculated by adopting estimates that 49% of women are tested for chlamydia; 55% for gonorrhea; 19% for syphilis; and 28% for HIV. Table D6 presents the same information for men. The share of male clients tested for these infections are the following: 61% for chlamydia, 68% for gonorrhea, 39% for syphilis, and 53% for HIV.

Table D8 – Additional Women Tested for Sexually Transmitted Infections Under Title X

Year	2022	2023	2024	2025	2026
Chlamydia	318,008	636,016	636,016	636,016	636,016
Gonorrhea	356,948	713,895	713,895	713,895	713,895
Syphilis	123,309	246,618	246,618	246,618	246,618
Confidential HIV	181,719	363,438	363,438	363,438	363,438

Table D9 – Additional Men Tested for Sexually Transmitted Infections Under Title X

Year	2022	2023	2024	2025	2026

Chlamydia	53,006	106,013	106,013	106,013	106,013
Gonorrhea	59,089	118,178	118,178	118,178	118,178
Syphilis	33,889	67,779	67,779	67,779	67,779
Confidential HIV	46,055	92,109	92,109	92,109	92,109

Table D8 reports the total clients tested for sexually transmitted infections. These tests can identify treatable conditions that can cause discomfort, permanent damage to reproductive systems including infertility, and in certain cases, death. The 2019 Title X Family Planning Annual Report indicates confidential HIV testing identifies a positive case for approximately 0.38% of all HIV tests performed. If the proposed rule is finalized, Title X would be associated with identifying an additional 873 positive cases of HIV. In subsequent years, this number would increase to 1,745. Testing for these sexually transmitted infections can also reduce the likelihood that an individual will spread an infection. In addition to testing, Title X-funded service sites also provide HIV/AIDS prevention education. Pre-exposure prophylaxis (PrEP) has emerged as an effective HIV prevention strategy for individuals who are most at risk, and the inclusion of PrEP in the HIV prevention services provided at Title X sites is becoming an increasingly important method for protecting individuals of all ages from acquiring HIV.

Table D10 - Additional Clients Tested for Sexually Transmitted Infections Under Title X

Year	2022	2023	2024	2025	2026
Chlamydia	371,014	742,029	742,029	742,029	742,029
Gonorrhea	416,037	832,074	832,074	832,074	832,074
Syphilis	157,199	314,397	314,397	314,397	314,397
Confidential HIV	227,774	455,547	455,547	455,547	455,547
Positive Test Results	873	1,745	1,745	1,745	1,745

Services of the type provided under Title X likely result in reduced costs to taxpayers as a result of a reduction in unintended pregnancies, pre-term and low-birthweight births, sexually transmitted infections, infertility, and cervical cancer. This report[49] estimates that each dollar spent on these services results in a net Government saving of $7.09. We do not replicate the calculations, but note that they are derived from cost savings associated with averting unintended pregnancy and complications such as pre-term and low birth-weight births. These cost savings are also derived from detecting and treating sexually transmitted infections that would have resulted in more serious outcomes, including infertility, cancer, and death.

In addition to the effects described above, this proposed rule would also enhance the equity and dignity associated with access to family planning services provided by Title X. A recent research brief summarized interviews with 30 women sharing their experiences with contraceptive access, providing suggestive evidence that birth control has an important positive impact on women's lives. Interviewees noted that birth control allowed women to "to pursue academic and professional goals, achieve financial stability, and maintain their mental and physical health."[50] These recent interviews are consistent with the historical experience of the importance of birth control. For example, one econometric study identifies a causal relationship between the introduction and diffusion of the birth control pill and the increase in women enrolling in professional degree programs and increasing the age at first marriage.[51] Title X services help connect women with the free contraception provided by the Affordable Care Act, which allows them to experience these and other positive outcomes associated with access to contraception.

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[49] Jennifer J. Frost, Adam Sonfield, Mia R. Zolna, and Lawrence B. Finer (2014). "Return on Investment: a fuller assessment of the benefits and costs of the US publicly funded family planning program" Milbank Quarterly 2014 Dec;92(4):696-749.

[50] Rebecca Peters, Sarah Benetar, Brigette Courtot, and Sophia Yin (2019). "Birth Control is Transformative." Urban Institute. https://www.urban.org/sites/default/files/publication/99912/birth_control_is_transformative_1.pdf. Accessed April 6, 2021.

[51] Goldin, Claudia and Lawrence F. Katz (2002). "The power of the pill: Oral contraceptives and women's career and marriage decisions." *Journal of Political Economy* 110(4): 730-770.

Researchers have identified other economic, social, and health impacts of increased access to family planning, contraception, and treatment. For example, Bailey et al. (2019) finds "that children born after the introduction of Federal family planning programs were 7 percent less likely to live in poverty and 12 percent less likely to live in households receiving public assistance." They perform an additional bounding analysis, which suggests that about two thirds of the estimated gains are due to increases in the incomes of parents.[52] A recent summary discusses other impacts of access to family planning services in the United States and in other countries, which extends beyond women and girls, to their children and wider communities.[53]

The calculations above represent observable metrics of the effect of the Title X program, which is important for evaluating the direct effect of the program. For this reason, the scope of our analysis initially focuses on clients served and services provided by Title X facilities. To properly account for the net effect of the proposed rule when comparing the baseline scenario to the policy scenario, we would need to assess the extent to which clients and services continue to be provided through other channels than Title X funded sites without the proposed rule. As a general matter, the impacts of this proposed rule may include:

- transfers between grantees and would-be grantees within the Title X program;
- other transfers (for example, if Title X newly funds medical services that would, in the absence of the proposed rule, be provided by charitable organizations or other private payers); and
- societal benefits and costs to the extent that the volume or characteristics (such as location, which determines travel costs) of medical services would differ with and without the proposed rule.

As noted earlier in this preamble, all Planned Parenthood affiliates—which, in 2015, served 41 percent of all contraceptive clients at Title X-funded service sites—withdrew from Title X due to the 2019 Final

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[52] Bailey, Martha J., Olga Malkova, Zoë M. McLaren (2019). "Does Access to Family Planning Increase Children's Opportunities? Evidence from the War on Poverty and the Early Years of Title X." *Journal of Human Resources* 54:4 pp. 825-856. doi:10.3368/jhr.54.4.1216-8401R1.

[53] Emily Sohn (2020). "Strengthening society with contraception." *Nature* 588, S162-S164.

Rule. However, a comparison of Planned Parenthood's two most recent annual financial reports indicates no subsequent decrease in the number of patients served and an increase, from 9.8 million to 10.4 million, in the number of services provided per annum (pre-pandemic).[54] Although such year-to-year comparisons are simplistic and a focus on just one organization (even a prominent one, with extensive activities) has obvious limitations, this evidence may suggest that the Title X program impacts quantified elsewhere in this regulatory impact analysis may largely be associated with transfers. Although there are notable challenges with quantifying the benefit, cost and transfer impacts of the proposed rule, we request comment that might facilitate refinement of the analysis prior to regulatory finalization.

e. Further Discussion of Distributional Effects

The Title X program is designed to provide services with priority given to persons from low-income families. According to the most recent data, 64% of clients have income under 101% of the Federal poverty level; 14% between 101% and 150%; 7% between 151% to 200%; 3% between 201% and 250%; 7% over 250%; and 5% have an unknown or unreported income level. Among program clients, 33% are Hispanic or Latino of all races; 3% are Asian and Not Hispanic or Latino; 22% are Black or African American and Not Hispanic or Latino; 32% are White and Not Hispanic or Latino; and 5% are Other or Unknown and Not Hispanic or Latino; and 4% are Unknown or not Reported. Furthermore, the Title X statutory directive requires Title X projects to provide services for adolescents without required parental consent. This makes Title X a critical source of sexual and reproductive healthcare for young people. In 2019, 2% program clients were younger than 15, and 8% were younger than 18. Additional information about the number and distribution of all family planning clients by age and year are

[54] Please see https://www.plannedparenthood.org/uploads/filer_public/2e/da/2eda3f50-82aa-4ddb-acce-c2854c4ea80b/2018-2019_annual_report.pdf and https://www.plannedparenthood.org/uploads/filer_public/67/30/67305ea1-8da2-4cee-9191-19228c1d6f70/210219-annual-report-2019-2020-web-final.pdf. The latter report indicates that Planned Parenthood conducted a major fundraising campaign with the 2019 Title X regulatory changes as its key motivating message. If funds are more efficiently gathered and distributed via a program such as Title X than through such private campaigns, the efficiency would represent a cost savings attributable to the proposed rule.

available in Exhibit A-3a of the 2019 Title X Annual Report. The benefits of revoking the 2019 Final Rule would likely accrue roughly in proportion with these income and race and ethnicity figures. The costs of revoking the 2019 Final Rule would likely accrue proportional to the income and other demographics of the general public.

This proposed rule would also likely have important geographic effects. As described in greater detail in the Baseline Section, 6 States currently have no Title X services, and 6 additional states have limited Title X services. This proposed rule would likely result in restoration of services to individuals in these States.

f. Uncertainty and Sensitivity Analysis

All of the major drivers of the quantified effects of this analysis are dependent on our forecast of the baseline number of clients served. We acknowledge the uncertainty in this baseline and have performed a sensitivity analysis to quantify its importance. For our primary baseline, we chose 2.5 million annual clients of Title X services, which corresponds to the number of clients in fiscal year 2019 among remaining grantees. As a sensitivity analysis, we investigate the effect of the proposed rule compared to a baseline with 1.5 million clients, corresponding to preliminary estimates for fiscal year 2020. For comparison, we also looked at the effects using an upper bound of 3.1 million clients served, which is the reported figure for 2019, but which includes 19 grantees, 231 subrecipients, and 945 service sites that withdraw from the Title X program following the 2019 Final Rule.

Table F1 presents the number of clients served under different assumptions of the baseline. We also recalculate the number of clients served for the proposed rule scenario for each of the baseline assumptions. Since the number of clients served in the first year is the midpoint between the baseline and long-run equilibrium figure, the number of clients served in fiscal year 2022 under the proposed rule

would be lower for the lower-bound scenario than the primary baseline. Similarly, the number of clients served under the proposed rule would be higher in the upper-bound scenario.

Table F1 - Title X Clients Served Under Different Baseline Assumptions

Year	Baseline	Baseline, LB	Baseline, UB	Proposed Rule	Proposed Rule, LB	Proposed Rule, UB
2022	2,512,066	1,536,744	3,095,666	3,247,958	2,760,297	3,539,758
2023	2,512,066	1,536,744	3,095,666	3,983,849	3,983,849	3,983,849
2024	2,512,066	1,536,744	3,095,666	3,983,849	3,983,849	3,983,849
2025	2,512,066	1,536,744	3,095,666	3,983,849	3,983,849	3,983,849
2026	2,512,066	1,536,744	3,095,666	3,983,849	3,983,849	3,983,849

Table F2 calculates the effect of the proposed rule under different baseline assumptions. These estimates are reported by year, as well as in present value and annualized for the 5-year time horizon of our analysis, applying a 3% and a 7% discount rate. Under the lower-bound baseline scenario, the proposed rule would have about a 66% greater impact on the number of clients served in annualized terms under the primary baseline scenario. Under the upper-bound baseline scenario, the proposed rule would have about a 64% lesser impact.

Table F2 - Effect of the Proposed Rule Under Different Baseline Assumptions

Year	Proposed Rule	Proposed Rule, LB	Proposed Rule, UB
2022	735,892	1,223,553	444,092
2023	1,471,783	2,447,105	888,183
2024	1,471,783	2,447,105	888,183

2025	1,471,783	2,447,105	888,183
2026	1,471,783	2,447,105	888,183
PDV, 3%	6,025,877	10,019,109	3,636,461
PDV, 7%	5,346,852	8,890,107	3,226,687
Annualized, 3%	1,315,778	2,187,718	794,038
Annualized, 7%	1,304,047	2,168,214	786,959

As discussed earlier, we acknowledge uncertainty in how quickly the Title X program will be able to restore service to levels experienced prior to the drops associated with the 2019 Final Rule. Our primary analysis adopts a two-year phase for grantees, subrecipients, service sites, and clients served to reach our long-run equilibrium estimates. If a large number of service sites have shut down permanently, the assumption of a two-year phase in would likely result in an overestimate of the proposed rule's effect over the time horizon of the analysis. Similarly, if a small number of service sites have shut down, the analysis would tend to underestimate the effect of the proposed rule. Therefore, as a second sensitivity analysis, we present estimates that adopt alternative assumptions about the length of time it will take to reach the long-run equilibrium estimates. Table F3 presents our primary estimates, based on a two-year phase in, estimates without a phase in, and estimates with a 3-year phase in assumption.

Table F3 - Title X Clients With Different Phase-in Assumptions

Year	Baseline	Proposed Rule, 2-year Phase In	Proposed Rule, No Phase In	Proposed Rule, 3-year Phase In
2022	2,512,066	3,247,958	3,983,849	3,002,660
2023	2,512,066	3,983,849	3,983,849	3,493,255
2024	2,512,066	3,983,849	3,983,849	3,983,849
2025	2,512,066	3,983,849	3,983,849	3,983,849
2026	2,512,066	3,983,849	3,983,849	3,983,849

Table H4 calculates the effect of the proposed rule with different phase-in assumptions. These estimates are reported by year, as well as in present value and annualized for the 5-year time horizon of our analysis, applying a 3% and a 7% discount rate. Compared to our primary estimates, the assumption of

no phase in yields annualized effects of the proposed rule that are about 12% higher. Assuming a 3-year phase in yields annualized effects that are about 12% lower than the primary estimates.

Table F4 - Effect of the Proposed Rule With Different Phase-in Assumptions

Year	Proposed Rule, 2-year Phase In	Proposed Rule, No Phase In	Proposed Rule, 3-year Phase In
2022	735,892	1,471,783	490,594
2023	1,471,783	1,471,783	981,189
2024	1,471,783	1,471,783	1,471,783
2025	1,471,783	1,471,783	1,471,783
2026	1,471,783	1,471,783	1,471,783
PDV, 3%	6,025,877	6,740,335	5,325,293
PDV, 7%	5,346,852	6,034,601	4,689,098
Annualized, 3%	1,315,778	1,471,783	1,162,802
Annualized, 7%	1,304,047	1,471,783	1,143,627

g. Analysis of Regulatory Alternatives to the Proposed Rule

We analyzed two alternatives to the approach under the proposed rule. We considered one option to maintain many elements of the 2019 Final Rule and to impose additional restrictions on grantees. This approach would exacerbate the trends of reduced Title X grantees, subrecipients, service sites, and clients served that we have observed under the 2019 Final Rule. Second, we considered revising the 2019 Final Rule by readopting many elements of the 2000 regulations, but adopting additional flexibilities for grantees and reducing programmatic oversight. However, our experience suggests the compliance regime as it existed prior to the 2019 Final Rule was effective.

VI. Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Paperwork Reduction Act

This proposed rule contains information collection requirements (ICRs) that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 1. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA. The collections of information required by the proposed rule relate to § 59.5 (What requirements must be met by a family planning project?) and § 59.7 (What criteria would the Department of Health and Human Services use to decide which family planning services projects to fund and in what amounts?).

Proposed § 59.4 would require Title X grant applicants to describe how the proposed project would satisfy the regulatory requirements for the Title X program in their applications. All other reporting burden associated with grant applications is already approved via existing Grants.gov common forms.

Proposed § 59.5 would require Title X providers to report, in grant applications and in all required reports, information regarding subrecipients and referral agencies and individuals, including a

description of the extent of collaboration and a clear explanation of how the grantee would ensure adequate oversight and accountability.

Proposed § 59.5 would also require Title X grantees to provide appropriate documentation or other assurance satisfactory to the Secretary that it has in place and has implemented a plan to comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking. It would also require Title X grantees to maintain records to demonstrate compliance with the requirements of § 59.5, and make continuation of funding for Title X services contingent upon demonstrating to the Secretary that the criteria have been met.

Burden of Response: The Department is committed to leveraging existing grant, contract, annual reporting, and other Departmental forms where possible, rather than creating additional, separate forms for recipients to sign. We anticipate two separate burdens of response: (1) assurance of compliance; and (2) documentation of compliance. The burden for the assurance of compliance is the cost of grantee and/ or subrecipient staff time to (a) review the assurance language as well as the underlying language related to stated requirements; (b) to review grantee and/ or subrecipient policies and procedures or to take other actions to assess grantee and/or subrecipient compliance with the requirements to which the grantee and/or subrecipient is required to assure compliance.

The labor cost would include a lawyer spending an average of 1 hour reviewing all assurances and a medical and health service manager spending an average of one hour reviewing and signing the assurances at each grantee and subrecipient. We estimate the number of grantees and subrecipients at 1060, based on 2019 number of Title X grantees and subrecipients, as represented in Title X FPAR data. The mean hourly wage (not including benefits and overhead) for these occupations is $69.86 per hour for the lawyer and $55.37 per hour for the medical and health service manager. The labor cost is

$132,750 in the first year (($69.86 × 1 + $55.37 × 1) × 1060 grantees and subrecipients). We estimate that the cost, in subsequent years, would be $95,700 which would represent an annual allotment of 30 minutes for the lawyer and one hour for the medical and health service manager (($69.86 × 0.5 + $55.37 × 1) × 1060 grantees and subrecipients).

The Department estimates that all recipients and subrecipients will review their organizational policies and procedures or take other actions to self-assess compliance with applicable Title X requirements each year, spending an average of 4 hours doing so. The labor cost is a function of a lawyer spending an average of 2 hours and a medical and health service manager spending an average of 2 hours. The labor cost for self-assessing compliance, such as reviewing policies and procedures, is a total of $265,500 each year (($69.86 × 2 + $55.37 × 2) × 1060 grantees and subrecipients).

The burden for the documentation of compliance is the cost of grantee and/ or subrecipient staff time to (a) complete reports regarding information related to subrecipients, referral agencies and individuals involved in the grantee's Title X project.

The labor cost would include a medical and health services manager spending an average of two hours each year to complete reports regarding information related to subrecipients, and referral agencies and individuals involved in the grantee's Title X project at each grantee and subrecipient. The labor cost will be $117,400 each year ($55.37 × 2 hours × 1060 grantees and subrecipients).

TABLE 1—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS OR BURDEN OF RESPONSE IN YEAR ONE/SUBSEQUENT YEARS FOLLOWING PUBLICATION OF THE FINAL RULE

Regulation burden	OMB control No.	Respondents responses	Hourly rate ($)	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)
Assurance of Compliance ……	……0938-New……	1060/1060	62.62/62.62	6/5.44	6360/5766	398,250/361,200
Documentation of Compliance …….		1060/1060	55.37/55.37	2/2	2120/2120	117,400/117,400

Total cost …….	…0938-New…… …….. ……....	…… ……	…… ……..….	…… ……	…… ……..…..	516,650/478,600

Note: The Department asks for public comment on the proposed information collection including what additional benefits may be cited as a result of this proposed rule. Comments regarding the collection of information proposed in this proposed rule must refer to the proposed rule by name and docket number, and must be submitted to both OMB and the Docket Management Facility where indicated under ADDRESSES by the date specified under DATES. When it issues a final rule, the Department plans to publish in the Federal Register the control numbers assigned by the Office of Management and Budget (OMB). Publication of the control numbers notifies the public that OMB has approved the final rule's information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 42 CFR Part 59

Birth control, Contraception, Family planning, Grant programs, Health facilities, Title X.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

PART 59—GRANTS FOR FAMILY PLANNING

For the reasons set out in the preamble, subpart A of part 59 of title 42, Code of Federal Regulations, is hereby proposed to be revised to read as follows:

Subpart A—Project Grants for Family Planning Services

Sec.

Subpart A—Project Grants for Family Planning Services

Authority: 42 U.S.C. 300a-4.

§ 59.1 To what programs do the regulations in this subpart apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public

Health Service Act (42 U.S.C. 3200) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

§ 59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Adolescent-friendly health services are services that are accessible, acceptable, equitable, appropriate and effective for adolescents.

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

Culturally and linguistically appropriate services are respectful of and responsive to the health beliefs, practices and needs of diverse patients.

Family means a social unit composed of one person, or two or more persons living together, as a household.

Family planning services include a broad range of medically approved contraceptive services, which includes Food and Drug Administration (FDA)-approved contraceptive services and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services.

Health equity is when every person has the opportunity to attain their full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances.

Inclusivity ensures that all people are fully included and can actively participate in and benefit from family planning, including, but not limited to, individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.

Low-income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). "Low-income family" also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

Nonprofit, as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

Quality healthcare is safe, effective, client-centered, timely, efficient, and equitable.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Service site is a clinic or other location where Title X services (under the Act) are provided to clients. Title X recipients and/or their subrecipients may have service sites.

State includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlaying Islands (Midway, Wage, et al.), the Marshall Islands, the Federated State of Micronesia and the Republic of Palau.

Trauma-informed means a program, organization, or system that is trauma-informed realizes the widespread impact of trauma and understands potential paths for recovery; recognizes the signs and symptoms of trauma in clients, families, staff, and others involved with the system; and responds by fully integrating knowledge about trauma into policies, procedures, and practices, and seeks to actively resist re-traumatization.

§ 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

§ 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain—

(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) A budget and justification of the amount of grant funds requested;

(3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) Such other pertinent information as the Secretary may require.

§ 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services, preconception health services, and adolescent-friendly health services). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services, must be able to provide a referral to the client's method of choice and the referral must not unduly limit the client's access to their method of choice.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a

voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the applicant.[1]

[1] 42 U.S.C. 300a-8 (Section 205 of Pub. L. 94-63) states: "Any (1) officer or employee of the United States, (2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than $1,000 or imprisoned for not more than one year, or both."

(3) Provide services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery consistent with nationally recognized standards of care.

(4) Provide services without regard of religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status.

(5) Not provide abortion as a method of family planning. A project must:

(i) Offer pregnant clients the opportunity to be provided information and counseling regarding each of the following options:

(A) Prenatal care and delivery;

(B) Infant care, foster care, or adoption; and

(C) Pregnancy termination.

(ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling.

(6) Provide that priority in the provision of services will be given to clients from low-income families.

(7) Provide that no charge will be made for services provided to any clients from a low-income family except to the extent that payment will be made by a third party (including a Government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to clients other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

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

(9) Take reasonable measures to verify client income, without burdening clients from low-income

families. Recipients that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients' self-report. If a client's income cannot be verified after reasonable attempts to do so, charges are to be based on the client's self-reported income.

(10) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX, or XXI agency is required.

(11)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subrecipients which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subrecipients in the ongoing policy decision making of the project.

(12) Title X projects shall comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking (collectively, "State notification laws"). Title X projects must provide appropriate documentation or other assurance satisfactory to the Secretary that it:

(i) Has in place and implements a plan to comply with State notification laws.

(ii) Provides timely and adequate annual training of all individuals (whether or not they are employees) serving clients for, or on behalf of, the project regarding State notification laws; policies and procedures of the Title X project and/or for providers with respect to notification and reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence and human trafficking; appropriate interventions, strategies, and referrals to improve the safety and current situation of the patient; and compliance with State notification laws.

(13) Ensure transparency in the delivery of services by reporting the following information in grant applications and all required reports:

(i) Subrecipients and agencies or individuals providing referral services and the services to be provided;
(ii) Description of the extent of the collaboration with subrecipients, referral agencies, and any individuals providing referral services, in order to demonstrate a seamless continuum of care for clients; and

(iii) Explanation of how the recipient will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including consultation by a healthcare provider, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the

effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical service agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for opportunities for community education, participation, and engagement to:

(i) Achieve community understanding of the objectives of the program;

(ii) Inform the community of the availability of services; and

(iii) Promote continued participation in the project by diverse persons to whom family planning services may be beneficial to ensure access to equitable, affordable, client-centered, quality family planning services.

(4) Provide for orientation and in-service training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.

(8) Provide for coordination and use of referrals and linkages with primary healthcare providers, other providers of healthcare services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other Federal programs, who are in close physical proximity to the Title X site, when feasible, in order to promote access to services and provide a seamless continuum of care.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the recipient. The recipient must be prepared to substantiate that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

§ 59.6 What procedures apply to assure the suitability of informational and educational material (print and electronic)?

(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials (print and electronic) developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of Title X of the Act. The project shall not disseminate any such

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materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) *Size*. The Committee shall consist of no fewer than five members and up to as many members the recipient determines, except that this provision may be waived by the Secretary for good cause shown.

(2) *Composition*. The Committee shall include individuals broadly representative of the population or community for which the materials are intended (in terms of demographic factors such as race, ethnicity, color, national origin, disability, sex, sexual orientation, gender identity, age, marital status, income, geography, and including but not limited to individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality).

(3) *Function*. In reviewing materials, the Advisory Committee shall:

(i) Consider the educational, cultural, and diverse backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(ii) Review the content of the material to assure that the information is factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma informed;

(iii) Determine whether the material is suitable for the population or community to which is to be made available; and

(iv) Establish a written record of its determinations.

§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of clients, and, in particular, the number of low-income clients to be served;

(2) The extent to which family planning services are needed locally;

(3) The ability of the applicant to advance health equity;

(4) The relative need of the applicant;

(5) The capacity of the applicant to make rapid and effective use of the Federal assistance;

(6) The adequacy of the applicant's facilities and staff;

(7) The relative availability of non-Federal resources within the community to be served and the degree to which those resources are committed to the project; and

(8) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

§ 59.8 How is a grant awarded?

(a) The notice of grant award specifies how long Department of Health and Human Services (HHS) intends to support the project without requiring the project to recompete for funds. This anticipated period will usually be for three to five years.

(b) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A recipient must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the recipient's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR part 75.

§59.10 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipient must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client.

§59.11 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to, at the time of, or during any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

§59.12 What other HHS regulations apply to grants under this subpart?

Attention is drawn to the following the HHS regulations which apply to grants under this subpart. These include:

Table 1 to §59.12

37 CFR part 401	Rights to inventions made by nonprofit organizations and small business firms under Government grants, contracts, and cooperative agreements
42 CFR part 50, subpart D	Public Health Service grant appeals procedure
45 CFR part 16	Procedures of the Departmental Grant Appeals Board
45 CFR part 75	Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards
45 CFR part 80	Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of Title VI of the Civil Rights Act of 1964
45 CFR part 84	Nondiscrimination on the basis of handicap in programs and activities receiving or benefitting from Federal financial assistance
45 CFR part 87	Equal treatment for faith-based organizations
45 CFR part 91	Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

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