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 Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Office of Population Affairs (OPA) in the Office of the Assistant Secretary for Health issues this final rule to revise the regulations that govern the Title X family planning program (authorized by Title X of the Public Health Service Act) by readopting the 2000 regulations, with several revisions to ensure access to equitable, affordable, client-centered, quality family planning services for clients, especially low-income clients. The effect of this 2021 final rule is to revoke the requirements of the 2019 regulations, including removing restrictions on nondirective options counseling and referrals for abortion services and eliminating requirements for strict physical and financial separation between abortion-related activities and Title X project activities, thereby reversing the negative public health consequences of the 2019 regulations. OPA also makes several revisions to the 2000 regulations to increase access to equitable, affordable, client-centered, quality family planning services.

DATES: This rule is effective November 8, 2021.

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SUPPLEMENTARY INFORMATION: As described in the 2021 Notice of Proposed Rulemaking (NPRM) (86 FR 19812, April 15, 2021), the Department proposed to revoke the 2019 Title X regulations (84 FR 7714, March 4, 2019) and readopt the 2000 regulations (65 FR 41270, July 3, 2000) with 14 revisions and 10 technical corrections. Revisions were proposed to 59.2, 59.5(a)(1), 59.5(a)(3), 59.5(a)(8), 59.5(a)(9), 59.5(a)(12), 59.5(a)(13), 59.5(b)(1), 59.5(b)(3), 59.5(b)(8), 59.6, 59.7, 59.10, and 59.11. Technical corrections were proposed to 59.2, 59.5(a)(4), 59.5(a)(5), 59.5(a)(6), 59.5(a)(7), 59.5(a)(11), 59.5(b)(3), 59.6(b)(2), 59.8, and 59.12. HHS received comments on all of the revisions proposed in the NPRM, except the revision to 59.11. In addition, the Department received comments on three of the 10 technical corrections, including the technical corrections to 59.5(a)(4), 59.5(a)(5), and 59.12.

Based on the comments received in response to the NPRM, the Department adopts eight of the revisions initially proposed in the NPRM and nine of the technical corrections initially proposed in the NPRM as final without additional changes. This includes the revisions to 59.5(a)(3), 59.5(a)(8), 59.5(a)(9), 59.5(b)(3), 59.5(b)(8), 59.6, 59.7, and 59.11. This also includes the technical corrections to 59.2, 59.5(a)(4), 59.5(a)(5), 59.5(a)(6), 59.5(a)(7), 59.5(a)(11), 59.5(b)(3), 59.6(b)(2), and 59.8. Further, based on the comments received in response to the NPRM and a subsequent, new interpretation by the Department since the NPRM was issued, the final rule includes nine additional revisions and six additional technical corrections to what was proposed in the NPRM. The nine revisions include (a) additional modifications to four of the provisions initially revised in the NPRM (59.2, 59.5(a)(1), 59.5(b)(1), and 59.10); (b) additional modifications to one of the provisions with a technical correction in the NPRM (59.5(a)(4)); (c) removal of three of the revised provisions in the NPRM (59.5(a)(12), 59.5(a)(13), and 59.12); and (d) revisions to one provision not originally proposed for revision in the NPRM (59.5(b)(6)). The six additional technical corrections include minor clarifications to 59.2, 59.5(a)(1), 59.5(a)(4), and 59.6 and two technical corrections to 59.5(b)(7) and 59.7 to reflect inclusive language.

Detailed descriptions of all revisions, modifications, and technical corrections are included later in this final rule. In addition to revoking the 2019 rule, this final rule includes the following revisions to the 2000 rule: Adding several new definitions; requiring sites that do not offer a broad range of contraceptive methods on-site to provide a prescription to the client for their method of choice or referrals, as requested; requiring that family planning services be client-centered, culturally and linguistically appropriate, inclusive, trauma-informed, and capable of ensuring equitable and quality service delivery; clarifying requirements around billing practices and income verification; enabling a broader range of clinical service providers to direct family planning services and to provide consultation for medical services related to family planning; clarifying the intent of community education; clarifying the purpose and responsibilities of the Information and Education Advisory Committee; including referral for primary healthcare providers; expanding the grant review criteria to address equity; including language to safeguard client confidentiality; and removing the list of other applicable regulations from the regulatory text.

The Secretary of the Department of Health and Human Services (the Secretary) issues the below regulations establishing requirements for recipients of family planning services grants under section 1001 of the Public Health Service (PHS) Act, 42 U.S.C. 300. The rules below adopt, with the modifications described above, the regulations proposed for public comment on April 15, 2021 at 86 FR 19812. They accordingly revoke the 2019 final rule, *Compliance with Statutory Program Integrity Requirements,* promulgated on March 4, 2019 (84 FR 7714).

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I. Background

As discussed in the NPRM (86 FR 19812, April 15, 2021), in 2019, the Secretary issued a final rule for the Title X program titled *Compliance with Statutory Program Integrity Requirements,* which substantially revised the longstanding polices and interpretations defining what abortion-related activities were permissible under the program, given Title X's statutory prohibition on abortion services. That statutory prohibition, section 1008 (42 U.S.C. 300a–6), provides that ''[n]one of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.'' The 2000 regulations, which were in effect prior to the 2019 regulations and which reflected compliance standards that had been in effect for nearly the entirety of the Title X program, had been widely accepted by grantees, had enabled the Title X program to operate successfully, and had not resulted in any litigation.

The rules issued on March 4, 2019 (84 FR 7714): (1) Required strict physical and financial separation between abortion-related activities and Title X project activities, (2) required significant reporting by Title X grantees in grant applications and required reports about all subrecipients, referral agencies, or other partners who receive Title X funds, (3) removed the requirement for pregnancy options counseling upon request and permitted nondirective counseling only by an advanced practice provider, (4) prohibited Title X-funded entities from referring for abortion, while requiring referral for prenatal care, regardless of a client's request, and (5) required providers to maintain detailed records on adolescent clients, including age of their sexual partners and specific actions taken to encourage family participation.

In the 2019 rule, the Department stated that it ''believes the provisions of this final rule provide much needed clarity regarding the Title X program's role as a family planning program that is statutorily forbidden from paying for abortion and funding programs/projects where abortion is a method of family planning. The Department believes that the 2000 regulations fostered an environment of ambiguity surrounding appropriate Title X activities.'' 84 FR at 7721 (March 24, 2019). This belief about the ambiguity, however, lacked any specific evidence. OPA closely monitors Title X grantee compliance through regular grant reports, compliance monitoring visits, and legally required audits, and it has done so since the beginning of the program. Close oversight of Title X grantees for decades uncovered no misallocation of Title X funds by grantees. OPA oversight did identify occasional instances where grantees were in need of updating their written policies to clearly reflect the Title X statutory language, but OPA never found any instance where grantees were co-mingling funds with activities not allowed under the statute or regulations.

In response to concerns that the 2019 rule imposed undue and improper restrictions on grantees, the Department recently conducted a fresh review of the factual assertions that accompanied that rule. In particular, the Department carefully reviewed over 30 Government Accountability Office (GAO), Office of the Inspector General (OIG), and Congressional Research Service (CRS) reports involving the Title X program from 1975 to 2021. Directly contradicting the factual assertions accompanying the 2019 rule, that recent review found only minor compliance issues with grantees—and those only in two GAO reports from the 1980s. Those two reports 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 (July 3, 2000). While those forty-year-old 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.'' Since those reports, there has been no evidence of compliance issues regarding section 1008 by Title X grantees that would justify the greatly increased compliance costs for grantees and oversight costs for the federal government the 2019 rule required. Experience under the 2019 rule has only underscored these concerns. Based on that experience—which was not and could not have been available to the Department at the time the 2019 rule was promulgated—we have determined that the 2019 rule has led to a diversion of funds from the core purpose of Title X: To provide a broad range of family planning services. Those funds are now being spent on 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, and in some instances they are inconsistent with nationally recognized standards of care.

The significant negative public health consequences of the March 4, 2019 rule have become clear over the past two years, and the rule was extremely controversial from the beginning. The rule was immediately challenged in several district courts by 22 states and the District of Columbia, the American Medical Association, Title X grantee organizations, and individual grantees, with support from major medical organizations, including the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the American Academy of Family Physicians, the Society for Adolescent Health and Medicine, and the Society for Maternal-Fetal Medicine. The 2019 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* v. *Sullivan,* 500 U.S. 173 (1991) in upholding the rule. A majority of the *en banc* panel found, consistent with *Rust,* that the Department ''could'' interpret section 1008 as it did in the 2019 rule, and that 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 that the 2019 rule violated an annual appropriations rider requiring nondirective counseling, the non-directive mandate.[1]

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.

While courts and judges were split on the ultimate legality of the 2019 rule, evidence of the negative public health consequences of the rule quickly became clear, and significant. After the implementation of the 2019 rule, 19 Title X grantees out of 90 total grantees withdrew from the program. The 19 grantees that withdrew from the Title X program included 11 State Departments of Health and independent Family Planning Associations and eight Planned Parenthood organizations.[2]

These organizations made clear to the Department in formal correspondence that they relinquished their grants out of concern that the 2019 rule interfered with the patient-provider relationship and compromised their ability to provide quality healthcare to all clients. One organization commented that ''the Final Rule makes it impossible for us to provide healthcare and information to patients consistent with medical ethics and evidence-based standards of care.'' Another organization stated that the 2019 rule ''would fundamentally compromise the relationship our patients have with us as trusted providers of this most personal and private healthcare.'' Another organization said that ''the new regulations interfere with a healthcare provider's ability to provide healthcare in accordance with accepted standards of care for reproductive health.'' Still another said, ''these new rules require our providers to deprive their patients of the information and services they need to make and carry out fully informed decisions about their reproductive health. Our providers' ethical and professional responsibilities do not allow this.'' Although it might have been possible, at the time the 2019 rule was promulgated, to predict that providers would withdraw, any such prediction would have been uncertain. That so many providers did in fact withdraw from the program is a change in circumstances that, in the Department's view, demands reconsideration of the 2019 rule.

In addition to the grantees that withdrew from Title X completely, many other grantees that continued to receive Title X funding had subrecipients and service sites within their existing networks withdraw from the program. Overall, 19 grantees, including 231 subrecipients and 945 service sites, withdrew from the Title X program shortly after the rule took effect. Additionally, 18 grantees that continued in the program reported losses to their service network (*i.e.,* exiting subrecipients) because of the 2019 final rule. As a result, the Title X program provided services to 844,083 fewer clients in 2019 compared to 2018.[3] Comparing Family Planning Annual Report (FPAR) data for 2018 and 2019, OPA estimates that 94% (or 789,960) of the total decrease (844,083) in clients can be attributed to the 2019 rule. A total of 41 states and two territories saw a decrease in clients served in 2019 compared to 2018. Of those, seven saw a decline of more than 40 percent in clients served (AK, HI, MD, UT, VT, WI, and WV), seven saw a decline of 31–40 percent (CA, CT, ME, MN, NH, NM, and NY), seven saw a decline of 21–30 percent (AZ, IL, MA, MT, NJ, OR, and WA), seven saw a decline of 11–20 percent (IA, IN, MI, OH, PA, VA, and the Marshall Islands), nine saw a decline of 5–10 percent (AL, AR, KY, NE, NC, ND, SC, TN, and WY), and six saw a decline of five percent or less (DE, CO, LA, OK, SD, and the U.S. Virgin Islands). Only nine states, six territories and the District of Columbia saw their number of clients served stay the same (FL, KS, MO, RI, and TX) between 2018 and 2019 (±1%) or increase (GA, ID, MS, NV, six territories, and DC), with the majority experiencing a small annual increase of between 70 to 3,000 clients. Minor fluctuations notwithstanding, 789,960 fewer clients were served, which had a disproportionate impact on minority clients, adolescent clients, lower-income individuals, and those without insurance—all outcomes directly attributable to the 2019 rule. Most concerningly, there are six states that formerly had Title X services that currently have no Title X services available (HI, ME, OR, UT, VT, and WA) and seven states with Title X services available on a very limited basis (AK, CT, IL, MA, MN, NH, and NY). The Department believes that these stark facts, which became clear only after the promulgation of the 2019 rule, justify reconsideration of that rule.

To ensure continuity of services and maintain a safe environment for clients and staff during the pandemic, Title X providers followed guidance issued by the Centers for Disease Control and Prevention (CDC), OPA, and others to manage supply and staffing shortages, and they implemented creative strategies tailored to their circumstances and clientele (virtual telehealth, for example). Despite these efforts, in 2020 vs. 2019, Title X had 193 fewer subrecipients (867 vs. 1,060) and 794 fewer service sites (3,031 vs. 3,825). The decrease in the size of the Title X service network appears to have substantially reduced the availability of and, consequently, access to Title X services. In 2020, Title X served 1.6 million fewer family planning users than in 2019 (1.5 million vs. 3.1 million), and Title X service sites delivered care to 302 fewer users per site (507 vs. 809). Furthermore, in 2020, Title X conducted almost 2.0 million fewer family planning encounters than in 2019 (2.7 million vs. 4.7 million). While the 2020 data undoubtedly reflect the public health emergency related to the COVID–19 pandemic, the pattern of the losses in the program initiated by the 2019 rule was exacerbated in 2020 for an already disrupted and weakened network.

Of additional concern, the 2019 rule has had a disproportionate impact on low-income clients, who are precisely the population that the Title X program was established to serve. The 2019 rule has significantly decreased the number of low-income, uninsured, and racial and ethnic minorities accessing Title X services. Following implementation of the 2019 rule, 573,650 fewer clients under 100 percent of the federal poverty level (FPL); 139,801 fewer clients between 101 percent FPL to 150 percent FPL; 65,735 fewer clients between 151 percent FPL and 200 percent FPL; and 30,194 fewer clients between 201 percent FPL to 250 percent FPL received Title X services. This contradicts the purpose and intent of the Title X program, which is to prioritize and

[1] Both circuit courts also differed on the permissibility of the rule under section 1554 of the Affordable Care Act.

[2] Withdrawn grantees included (1) Family Planning Association of Maine, Inc., (2) Hawaii Department of Health, (3) Health Imperatives, Inc. (MA), (4) Illinois Department of Health, (5) Maryland Department of Health, (6) Massachusetts Department of Public Health, (7) Oregon Health Authority, (8) Planned Parenthood Association of Utah, (9) Planned Parenthood Minnesota, North Dakota, South Dakota, (10 & 11) Planned Parenthood of Great Northwest & the Hawaiian Islands (two separate grants), (12) Planned Parenthood of Greater Ohio, (13) Planned Parenthood of Illinois, (14) Planned Parenthood of Northern New England, (15) Planned Parenthood of Southern New England, (16) Public Health Solutions (NY), (17) New York Department of Health, (18) Vermont Agency of Human Services, and (19) Washington State Department of Health.

[3] (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.*

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 Black or 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.[4] Additionally, 151,375 fewer adolescent clients received essential family planning services in 2019. The Department believes these new facts warrant a reconsideration of the 2019 rule.

The mandate of the Title X program is to support access to critical family planning and preventive health services; unfortunately, the result of the 2019 rule ran counter to that effort. The 2019 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 sexually transmitted infections (STIs). More specifically, in 2019 compared 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). 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. 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.[5]

In the 2019 rule, the Department stated that the rule was ''expected to increase the number of entities interested in participating in Title X as grantees or subrecipient service providers and, thereby, to increase patient access to family planning services focused on optimal health outcomes for every Title X client.'' 84 FR at 7782 (March 24, 2019). However, this expectation proved unwarranted. Despite several attempts, OPA has been unable to recruit new grantees and new providers into the Title X program to fill the current gaps in services resulting from implementation of the 2019 rule. First, OPA issued competitive supplemental funding of $33.7 million to 50 existing Title X grantees in fiscal year 2019 to expand their Title X services. Unfortunately, even with the additional funding, the majority of states were not able to increase the number of service sites in their Title X networks. From 2018 to 2020, 38 states and territories saw a decrease in the number of service sites in their networks, 12 saw no change in their number of service sites, and only nine saw an increase in the number of service sites. Analyzing users between 2018–2020 for those nine states that gained service sites, six still lost users (WV, AZ, DE, NE, CO, and TX) while three gained users (GA, NV, and Palau). Next, OPA issued a competitive funding announcement in fiscal year 2020 to recruit new grantees to provide Title X services in unserved or underserved states and communities. The number of applications received was so low (eight 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 OPA was only able to fund grantees to provide services in three states with no or limited Title X services at the time.

The lack of organizations applying for Title X grant funding following implementation of the 2019 rule and the lack of new service sites willing to join existing Title X grantees as providers strongly suggest that the Department was wrong to believe that the 2019 rule would increase the number of grantees and providers. Rather, the 2019 rule appears to have had the opposite effect and resulted in a significant loss of grantees, subrecipients, and service sites, and close to one million fewer clients served from 2018 to 2019. The Department believes that this record warrants a change in course.

The decline in clients served and services provided is devastating. The Title X program is the only federal grant program dedicated to providing comprehensive family planning and related preventive health services. Title X clinics provide services to clients, with priority given to persons from low-income families. Title X services are voluntary, confidential, and provided regardless of one's ability to pay. For many clients, Title X clinics are their only ongoing source of healthcare and health education. In fact, six in 10 women who go to a publicly funded family planning clinic consider it their usual source of medical care.[6]

While some family planning providers that withdrew from the Title X program were able to continue providing reproductive health services at some level in the absence of Title X funding, the services provided were not the same as those provided under Title X. Grantees that relinquished their Title X funding at the time made clear that they were not able to provide the same breadth of services as they had been able to under Title X and were not able to provide services using the same schedule of discounts as required in the Title X program. According to several comments received, the loss of Title X funding meant that organizations had to adjust their fee schedules and push more costs for services to the clients. As a result, organizations saw more clients forgoing recommended tests, lab work, STI testing, clinical breast exams, and pap tests. Further, due to costs, organizations saw some family planning clients outside of the Title X network choose less effective methods of birth control.

The 2019 rule abandoned major portions of *Providing Quality Family Planning Services: Recommendations from Centers for Disease Control and Prevention and the U.S. Office of Population Affairs* (QFP),[7] such as nondirective options counseling and referrals, and the client-centered approach recommended by QFP, over the objection of every major medical organization and without any countervailing public health rationale. QFP recommendations support providers in delivering quality family planning services and define family planning services within a broad context of preventive services, to improve health outcomes for individuals and their (future) children. QFP recommendations are based on a rigorous, systematic, and transparent review of the evidence and were developed with input from a broad range of clinical experts, OPA, and the CDC. These recommendations not only improve the quality of care provided to family planning clients, but they foster a supportive and communicative relationship between provider and patient. As evident from grantee relinquishment letters and comments

[4] (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.*

[5] (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.*

[6] Frost, J., Gold., Hasstedt, K., & Sonfield, A. (2014). Moving Forward: Family Planning in the Era of Health Reform. New York: Guttmacher Institute.

[7] CDC. (2014). 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.*

received in response to the 2021 NPRM, abandoning major portions of this approach has damaged the patient-provider relationship. Moreover, the 2019 rule required prenatal referral even if the patient objected, an approach which also does not comport with well-accepted public health and clinical care principles.

On January 28, 2021, President Biden issued a ''Memorandum on Protecting Women's Health at Home and Abroad.'' [8] The Memorandum stated that ''[w]omen should have access to the healthcare they need. For too many women today, both at home and abroad, that is not possible. Undue restrictions on the use of Federal funds have made it harder for women to obtain necessary healthcare. The Federal Government must take action to ensure that women at home and around the world are able to access complete medical information, including with respect to their reproductive health.'' The Memorandum then instructed the Department to ''review the Title X Rule and any other regulations governing the Title X program that impose undue restrictions on the use of Federal funds or women's access to complete medical information and shall consider, as soon as practicable, whether to suspend, revise, or rescind, or publish for notice and comment proposed rules suspending, revising, or rescinding, those regulations, consistent with applicable law, including the Administrative Procedure Act.''

HHS reviewed the 2019 regulations pursuant to the President's memorandum. Following this review, on April 15, 2021, the Department issued a Notice of Proposed Rulemaking (NPRM) for public comment (86 FR 19812, April 15, 2021), proposing rules to revise the 2019 regulation by essentially readopting the 2000 regulations. 65 FR 41270 (July 3, 2000). The 2000 regulations were consistent with applicable statutory commands, were widely accepted by grantees, enabled the Title X program to operate successfully, and led to no litigation over their permissibility.

Based on the evidence that has emerged since the adoption of the 2019 rule, as well as a fresh consideration of the evidence that existed at the time, the negative public health consequences of the 2019 rule are clear. The rule dramatically reduced access to family planning and preventive health services that are essential for hundreds of thousands of clients, especially for the low-income clients Title X was specifically created to serve. The 2019 rule decreased the number of providers willing to participate in the Title X program, further reducing access to family planning services within states across the country and in rural and urban communities alike. The 2019 rule shifted the Title X program away from its history of providing client-centered quality family planning services and instead set limits on the patient-provider relationship and the information that could be provided to the patient by the provider. The 2019 rule resulted in increased costs for grantee reporting that are unnecessary for ensuring grantee compliance. 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 and other disproportionately impacted communities, such as those in rural regions, minority clients, and adolescent clients, are relegated to inferior access. The populations served by Title X may already face health inequities driven by financial and access barriers to quality care that would be exacerbated by continuing to allow limited or delayed healthcare choices and biased or insufficient healthcare information. Given that so many individuals depend on the Title X program as their primary source of healthcare, the Department recognizes that this is a situation that must be rectified with urgency in the interest of public health and equity.

Most importantly, in readopting the 2000 rule, this final rule removes the strict physical separation requirements that were imposed on top of existing obligations for separation between abortion services and Title X project related activities. It also allows Title X providers to provide truly nondirective counseling and refer their patients for all services desired by the client, including abortion services. The 2000 regulations successfully governed the Title X program for decades and were widely accepted by grantees.

The 2019 rule imposed an interrelated set of requirements that are difficult to disentangle provision by provision. For example, 59.5(a)(5) prohibited funded projects from providing, promoting, referring, or supporting abortion as a method of family planning. Section 59.13 concurrently required assurance that a project did not ''include abortion as a method of family planning'' backed by documentary evidence of Subsections 59.14–59.16. The interrelatedness of these requirements was underscored by 59.7(b) requiring applicants to ''clearly address how the proposal will satisfy the requirements of the regulation,'' before even proceeding to competitive consideration. Most of the 2019 provisions did not function independently of each other.

The Department did initially propose keeping portions of two provisions from the 2019 rule regarding compliance reporting (59.5(a)(12)) on state sexual abuse notification laws and subrecipient monitoring (59.5(a)(13)). As further explained below, these provisions created administrative costs for grantees and the government with no measurable benefits. These provisions, like the entire 2019 rule, depended on assumptions about how the program should work and grantee compliance even with no evidence of grantee non-compliance.

Given these considerations, the Department has determined that the most appropriate course is to revoke the 2019 rule in its totality. Every court to rule on the 2019 rule also believed that all of its provisions were of a piece and either struck down or upheld the rule in its entirety. See, *e.g., Mayor of Baltimore* v. *Azar,* 973 F3d 258, 292 (4th Cir. 2020) (''Despite the severability clause, the Final Rule is not severable because it is clear HHS 'intended the [Final Rule] to stand or fall as a whole,' and the agency desired 'a single, coherent policy, the predominant purpose of which' is to reinstitute the 1988 Rule.'').

As compared to the 2019 rule, new provisions added to the re-adoption of the 2000 rule operate independently of each other—and the 2000 rule—to enhance the program. Particularly as the program operated for decades under the 2000 rule, the 2021 additions are severable from the 2000 rule. For example, while adding to the statutory goals of reaching low-income and underserved individuals, if the added grant evaluation criteria of equity, 59.7(a)(3), was excised, the program could still accomplish its mission successfully using the 2000 criteria alone. And, were a court to strike down the new income verification measures in 59.5(a)(9), the program would be able to accomplish its mission using the 2000 criteria alone.

In addition to readopting the requirements as they existed prior to the 2019 rule, the 2021 rule also includes several revisions that will strengthen the Title X program and ensure access to equitable, affordable, client-centered, quality family planning services for all clients, especially for low-income clients, while retaining the longstanding prohibition on directly promoting or performing abortion that follows from

[8] Available at *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/28/memorandum-on-protecting-womens-health-at-home-and-abroad/.*

Section 1008's text and subsequent appropriations enactments.

Advancing equity for all, including people from low-income families, people of color, and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality, is a priority for the Department, for OPA, and for the Title X program. By focusing on advancing equity in the Title X program, we can create opportunities to support communities that have been historically underserved, which benefits everyone. The 2021 rule was written to ensure that the predominantly low-income clients who rely on Title X services as their usual source of medical care have access to the same quality healthcare, including full medical information and referrals, that higher-income clients and clients with private insurance are able to access. Key strategies for advancing equity include removing barriers to accessing services, improving the quality of services, and providing services that are client-centered. Several revisions in the rule focus on improving access to services. These revisions include clearly defining what constitutes a broad range of acceptable and effective family planning methods and services, requiring service sites not offering a broad range of methods on-site to provide a prescription to the client for their method of choice or referrals, as requested, clarifying required billing practices and income verification for low-income clients, enabling a broader range of clinical services providers to direct Title X services and to provide consultation for medical services, and strengthening client confidentiality.

Several revisions in the 2021 rule focus on improving quality of Title X services. These revisions include clearly defining quality healthcare as safe, effective, client-centered, timely, efficient, and equitable; incorporating QFP's definition of family planning into the regulation; and requiring all family planning services to be delivered consistent with nationally recognized standards of care. Finally, several revisions in the 2021 rule focus on ensuring client-centered care. These revisions include clearly defining client-centered care as being respectful of, and responsive to, individual client preferences, needs, and values and where client values guide all clinical decisions, and requiring all family planning services to be client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed.

II. Public Comment and Departmental Response

The Department provided a 30-day public comment period for the proposed rule. That period closed on May 17, 2021. A total of 180,266 public comments were submitted to *www.Regulations.gov* or directly to the Department.

With this 2021 final rule, the Department revokes the requirements of the 2019 regulations (84 FR 7714, March 24, 2019) and readopts the 2000 regulations (65 FR 41270, July 3, 2000) with several revisions. In the section below, the Department discusses the public comments, its responses, and the text of the final rules. The Department first presents a summary of public comments received related to revoking the 2019 regulation and readopting the 2000 regulation. The Department then provides a summary of comments received regarding the revisions and technical corrections proposed in the NPRM to specific provisions of the 2000 regulations. The NPRM proposed 14 revisions, including to 59.2, 59.5(a)(1), 59.5(a)(3), 59.5(a)(8), 59.5(a)(9), 59.5(a)(12), 59.5(a)(13), 59.5(b)(1), 59.5(b)(3), 59.5(b)(8), 59.6, 59.7, 59.10, and 59.11. The NPRM also proposed 10 technical corrections, including to 59.2, 59.5(a)(4), 59.5(a)(5), 59.5(a)(6), 59.5(a)(7), 59.5(a)(11), 59.5(b)(3), 59.6(b)(2), 59.8, and 59.12. The Department received comments on all the revisions proposed in the NPRM and three of the 10 technical corrections. The Department did not receive comments on the revision to 59.11, nor to the technical corrections to 59.2, 59.5(a)(6), 59.5(a)(7), 59.5(a)(11), 59.5(b)(2), 59.5(b)(3), or 59.8. A summary of comments and the Department's response are only provided for those revisions and technical corrections that received comments. In addition, the Department received public comments requesting a revision to 59.5(b)(6) that was not proposed in the NPRM, but that is related to the revision that was proposed in the NPRM to 59.5(b)(1). A summary of these comments and the Department's response are also included below.

After considering the comments, the Department adopts the regulations proposed for public comment on April 15, 2021 at 86 FR 19812 with nine additional revisions and six additional technical corrections to what was proposed in the NPRM.

General Comments Related To Revoking 2019 Regulations and Readopting the 2000 Regulations

A. Compliance With Section 1008 (42 U.S.C. 300a–6)

Comments: Thousands of comments expressed concern that the program's returning to the 2000 regulations violated both the Title X statute and the Court's holding in *Rust* v. *Sullivan,* 500 U.S. 173 (1991). Many comments stated referral for abortion ''squarely'' violated the ''plain'' ''clear'' text of section 1008. Many of these same comments also asserted the statute requires separation from abortion activities because they are programs ''where'' abortion is a method of family planning. Both comments believing the 2000 rule to be unlawful, and those affirming it to be lawful, cited *Rust* as well as legislative history in making their arguments.

Those opposing the proposed rule also stressed that private organizations have no right to federal funding, much less to federal funding to perform abortions. These comments stated that ''[m]oney is fungible,'' and reverting to the 2000 rule will create so-called ''slush funds'' and infrastructure for organizations to perform abortions in violation of section 1008. They also suggested that the 2000 rule lacked any mechanism to ensure compliance with the statute, and that the NPRM, in fact, violates the statute because the proposed definition of ''family planning'' includes related ''pregnancy counseling'' which requires referral for abortion when requested (59.5(a)(5)). Many comments asserted that revoking the 2019 rule would allow grantees to engage in lobbying and other activities encouraging abortion that violate section 1008.

Response: As stated in the NPRM, the Supreme Court held in *Rust:* ''[W]e agree with every court to have addressed the issue that the language is ambiguous. The language of § 1008—that 'none of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning'—does not speak directly to the issues of counseling, referral, advocacy, or program integrity.'' *Rust* at 184. No court adjudicating the 2019 rule found that the separation, referral, or other requirements were required by *Rust.* Such a finding would be contrary to the primary holding in *Rust.* Counseling for abortion, including referral when requested, has never been held to constitute a violation of section 1008.

Interpreting section 1008 to prohibit referrals and require strict separation would also be inconsistent with nearly

40 years of agency practice under the program across numerous administrations. Such an interpretation would also appear contrary to decades of close Congressional oversight, including annual Title X appropriations riders, and a specific annual line item appropriation through which Congress can be—and has been—quite clear as to how the agency should operate.

In readopting the 2000 rule, the program is also reinstating interpretations and policies under section 1008 of the statute that were in place for much of the program's history and published in the **Federal Register** in 2000. 65 FR 41281 (July 3, 2000). Those program policies discuss, for example, the requirements for separation: ''Separation of Title X from abortion activities does not require separate grantees or even a separate health facility, but separate bookkeeping entries alone will not satisfy the spirit of the law. Mere technical allocation of funds, attributing federal dollars to non-abortion activities, is not a legally supportable avoidance of section 1008.'' 65 FR at 41282 (July 3, 2000). Also, ''[w]hile a Title X project may provide a referral for abortion, which may include providing a patient with the name, address, telephone number, and other relevant factual information (such as whether the provider accepts Medicaid, charges, etc.) about an abortion provider, the project may not take further affirmative action (such as negotiating a fee reduction, making an appointment, providing transportation) to secure abortion services for the patient.'' 65 FR at 41281 (July 3, 2000). Finally, while a Title X project may not advocate for abortion as a method of family planning, it ''may be a dues paying participant in a national abortion advocacy organization, so long as there are other legitimate program-related reasons for the affiliation (such as access to certain information or data useful to the Title X project).'' *Id.* Interested entities are encouraged to consult this notice.

The Department agrees that it is not under a duty to subsidize abortion. It does not do so, and it is prohibited from doing so. As discussed in the NPRM, legislative history and longstanding appropriations riders prohibit Title X funds from being expended on abortion. See, *e.g.,* Consolidated Appropriations Act, 2021, Public Law 116–260, Div. H, sec. 207, 134 Stat. 1182, 1590. More generally, Section 507 of the Consolidated Appropriations Act, 2021 prohibits federal funds from being used for abortion except for cases of rape, incest, or maternal health. *Id.* at sec. 507. As discussed in the NPRM and above, the Department employs a variety of mechanisms to enforce such restrictions, such as regular grant reports, compliance monitoring visits, third-party audits, compliance guidance, and grantee education. None of these oversight tools have uncovered any more than minimal problems with grantee compliance under section 1008.

The Department also agrees that no particular private organizations have a right to Title X funding. The program is returning to the program requirements in operation for the majority of its history because those requirements best serve individual clients and the public health. In the wake of the 2019 rule, both private organizations and states withdrew from the program, leaving multiple states without any Title X providers and the agency struggling to meet its mandate to provide family planning services for low-income populations in areas of high need. Though in some places organizations and jurisdictions were able to temporarily provide resources to replace the loss of Title X funds, providers were not always able to provide the same scope of services or seamless care coordination that Title X projects can provide. Public comments from those organizations made clear that they were not able to provide the same breadth of services, nor were they able to provide services with the same schedule of discounts for low-income clients.

The Department disagrees that Title X grant funds allow for the ''creation of slush funds'' or that those funds are ''fungible.'' As stated above, the Department has multiple methods by which it confirms that grant funds are spent for grant purposes, and it has concluded that grantees comply, not just with section 1008, but with Congressional directives and other requirements of the program. Again, the 2019 rule could point to no significant compliance issues related to the diversion of Title X grant funds, and a fresh review of decades of evidence has uncovered no such issues. A ban on organizations receiving Title X funds for lawful activities outside of the Title X project would go beyond the 2019 rule and raise serious constitutional issues. And even if such a restriction might conceivably be lawful, the Department clearly has the discretion to open eligibility to the most qualified Title X providers.[9]

[9] Zolna, M.R., & Frost, J.J. (2017, August 2). *Publicly funded family planning clinics in 2015: Patterns and trends in service delivery practices and protocols.* Guttmacher Institute. Retrieved from *https://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.*

B. Data on Negative Public Health Consequences of 2019 Rule

Comments: A few comments took issue with data presented in the NPRM. They stated that the Department used flawed data and failed to account for the effects of COVID–19, instead attributing the loss of grantees and subrecipients and the decline in services to the 2019 rule. One comment stated that the Department does not have data to assess the effect of the 2019 rule. Another comment argued that the decline in clients served is the result of a long time decline since the 2000 rule. One of those same comments reflected the belief that the decline in services is instead related to changes in insurance, changes in poverty, and use of the most effective contraceptive methods, and that declines have been continuous since 2000.

Some of the comments also took issue with the Department's position that the withdrawal of grantees from the program in response to the 2019 rule resulted in a decline in services, as they stated those services were continued with state and private funds and not discontinued, and the Department's claims of fewer services provided is ''a red herring.'' The same comment pointed out the proposed rule noted that seven states saw an increase in clients after the 2019 rule. Another comment cited Planned Parenthood data showing that Planned Parenthood provided more services in 2020 compared to 2019 and that other providers stepped in to fill the gaps in services left when Planned Parenthood exited the Title X program. It cited Ohio as an example and said that additional clients would be served post-COVID–19. A final opposing comment claimed that the number of new providers applying for Title X funds increased after the publication of the 2019 rule.

In contrast, numerous comments supported the 2021 NPRM and shared data on the negative impact that the 2019 rule has had in their states and communities, reinforcing the Department's statements in the NPRM. Many of the comments spoke to the drastic reduction in clients they were able to serve after the 2019 regulation. One comment stated, ''throughout the history of Title X, since its inception in 1970, there has never been as sharp a decline in the number of patients served by the program as occurred between 2018 and 2019.'' More than losing numbers of clients, numerous comments spoke to the types of clients they have not been able to serve and the nature of services that are being lost because clients cannot afford those services.

Several comments noted that the 2019 regulation is disproportionately impacting rural regions, minority clients, adolescent clients, lower-income individuals, and those without insurance, particularly in states that have not expanded Medicaid.

Contrary to the comments that expressed Planned Parenthood affiliates were able to provide more services after leaving the Title X program, Planned Parenthood affiliates themselves, in addition to other commenters, indicated that without Title X funding, they have had to adjust their sliding fee scales, pushing more costs onto the clients. Comments stated that this has resulted in clients forgoing recommended tests, lab work, STI testing, clinical breast exams, and Pap tests in large numbers. Further, these comments provided evidence that some clients are choosing less effective methods of birth control due to costs. Other comments stated that the changes in fees have pushed their clients into seeking care elsewhere, interrupting their continuity of care. One comment reported that the loss of Title X funding resulted in loss of eligibility for the 340B Drug Pricing Program, requiring the agency to dispose of contraceptive methods purchased under the 340B Program and repurchasing them at higher market prices.

The Attorneys General of 22 states and the District of Columbia commented that the emergency, one-time,[10] and private funding made available to replace the loss of Title X funding has strained state budgets and could not be sustained, creating uncertainty for the future of their family planning providers. Additionally, several comments noted that the fundraising activities necessitated after leaving the Title X program have come at a cost and have resulted in providers having to scale back or eliminate educational and outreach programs in many states. Other comments noted that it was extremely burdensome to try to identify and recruit additional providers to fill the gaps left after the 2019 rule. Many commenters expressed strong interest in rejoining the Title X network once the current rule is replaced. Finally, several states reported that while their efforts were refocused on recruiting and onboarding new providers into their Title X network under the 2019 rule, they faced much resistance and/or a lack of interest, and their provider networks did not increase under this rule, continuing to adversely impact the communities they serve.

Response: The Department believes that the negative public health consequences of the 2019 rule are clear. The rule dramatically reduced access to essential family planning and related preventive health services for hundreds of thousands of clients, especially for the low-income clients Title X was specifically created to serve. The 2019 rule decreased the number of providers willing to participate in the Title X program, further reducing access to essential family planning services within states and communities across the country.

The Department disagrees that the data cannot distinguish between enactment of the 2019 rule and the pandemic. The 2019 rule officially took effect mid-year in 2019, but COVID–19 was not announced as a national emergency until early 2020. The Department has data to assess the impact of the 2019 rule through FPAR and grantee progress reports, including data on the decrease in the number of clients served in 2019 when the rule was in place and prior to COVID–19. As stated in the Background section, 19 grantees, 231 subrecipients, and 945 service sites immediately withdrew from the Title X program. As a result, the Title X program provided services to 844,083 fewer clients in 2019 compared to 2018, prior to the implementation of the 2019 rule, approximately a 22 percent decrease. A total of 41 states and two territories saw a decrease in clients served in 2019 compared to 2018; five states saw their number of clients served stay the same; and four states, five territories, and the District of Columbia saw an increase in clients served from 2018 to 2019, with the majority experiencing a small annual increase of between 70 to 3,000 clients. Minor fluctuations notwithstanding, 844,083 fewer clients were served, disproportionately impacting lower-income individuals, minority clients, adolescent clients, and those without insurance. There are currently six states with no Title X services available and seven states with Title X services available on a very limited basis. Ultimately, the hundreds of thousands of clients who lost access to Title X services as a result of the 2019 rule lost access to critical family planning and preventive health services. As noted in the background, this included declines in contraceptive services, Pap tests, clinical breast exams, and HIV and STI testing.

The Department agrees that a few states were able to increase their service sites following the 2019 rule, but these are the exception. From 2018 to 2020, 34 states and territories saw a decrease in the number of service sites in their network, 18 saw no real change in their number of services sites, and only seven saw an increase in the number of service sites. OPA attempted to recruit new grantees to provide Title X services through a competitive funding opportunity, but OPA only received eight applications and was only able to provide services in three of the states with no or limited Title X services at the time. Some comments opposing the 2021 NPRM specifically cited Ohio as an example of a state that would be able to increase clients served post-COVID–19. Despite the state health department receiving additional funds to provide Title X services following the departure of another grantee, FPAR data from Ohio, however, do not provide any clear support for this claim and reinforce that capacity among entities is not necessarily equivalent. According to the FPAR data from Ohio, the state experienced a 10 percent decline in service sites between 2018 and 2020, an 18 percent decline in clients from 2018 to 2019, and a 57 percent decline in clients from 2019 to 2020. While many states and territories experienced a decline in clients from 2019 to 2020 due to COVID–19, Ohio's percentage decline in clients from 2019 to 2020 ranked 18th in order of states from largest decline to smallest decline. Seventeen states experienced a larger decline in clients from 2019 to 2020, and 41 states and territories experienced a smaller decline in clients. The data show that even if the same amount of funding is provided to a different set of grantees in a given area, it does not necessarily follow that the same number of clients will be served or same number of services will be provided, depending on the differences in grantee service capacity. Existing Title X grantees also experienced great difficulty recruiting new sites and new providers into their existing Title X networks under the 2019 regulations, as evidenced by the lack of states experiencing an increase in their number of service sites. Overall, it is clear that the 2019 rule directly resulted in a significant loss of grantees, subrecipients, and service sites, and close to one million fewer clients served from 2018 to 2019.

While some states and organizations were able to provide family planning and related preventive health services in the absence of Title X funding, the comments made clear that they were not providing the full scope of services provided under the Title X program, they were not provided following the

[10] States that provided emergency funding include CA, MA, MD, NY, OR, WA, and VT.

same standards as in Title X, and the same schedule of discounts and subsidies were not applied as required in the Title X program. Finally, many of the states that provided emergency or one-time funds, or those organizations that were able to raise funds privately, indicated through their comments that they could only do so on a very short-term basis, that it was not sustainable for the long term, and that it came at a price—requiring elimination of other critical services.

Given the data presented in the preamble and the data presented above, the Department disagrees with the claim that Title X services would improve after COVID–19 (absent a change in the 2019 rule). The loss in clients served, the states with no service providers, and the states with limited service providers occurred in 2019 after enactment of the 2019 rule and prior to COVID–19, making it unlikely that the number of clients served or services provided would increase to pre-2019 levels or above without a change to the 2019 rule. Comparing FPAR data for 2018 (''typical year'') and 2019 (post 2019 rule but pre-COVID), OPA estimates that 94% (789,960) of the total decrease (844,083) in family planning clients between 2019 and 2020 can be attributed to the 2019 rule. Further comparing FPAR data for 2018 (''typical year'') and 2020 (post-COVID), OPA estimates that 63% (or 1.5 million) of the total decrease (2.4 million) in family planning users between 2018 and 2020 can be attributed to the final rule. The grantees and subrecipients that left the program have indicated that they will not return to the program under the 2019 rule. Coupled with the lack of additional applicants to the Department's funding opportunity, the Department maintains the decline in access, clients, and services from 2018 levels will continue until a new rule is in place.

C. Grantee and Subrecipient Compliance

Comments: Several comments expressed concern that the 2021 NPRM did not include language from 59.1 in the 2019 rule, stating, ''the requirements imposed by these regulations apply equally to grantees and subrecipients.'' Several comments also expressed concern that the 2021 NPRM did not include language from 59.13 specifically requiring grantees to provide assurance that their project does not provide abortion and does not include abortion as a method of family planning. One comment stated that ''[t]he removal of an explicit compliance requirement, without at minimum an explanation that subrecipients are assumed to have to comply with all Title X regulations, suggests that such compliance is no longer required.''

Another comment claimed that the departure of providers from the Title X network after the introduction of the 2019 rule confirmed that Title X funding had been used by those providers for impermissible purposes. Additionally, the comment claimed that the withdrawal demonstrates an unwillingness to comply with program requirements, and that ''healthcare providers were accepting Title X funding for years without complying with the statutory requirements of the program.''

Response: The Department disagrees with the comments and does not believe that it is necessary to include language within the Title X regulations stating that the regulations apply equally to grantees and subrecipients because this is already a requirement in the HHS grants regulations that apply to Title X grantees. All Title X grantees are subject to 45 CFR part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards. In fact, Title X Notices of Funding Opportunity (NOFOs) state that successful applicants that accept an award agree that the award and all activities under the award are subject to all provisions of 45 CFR part 75. Specifically, 45 CFR 75.352 sets out the requirements for pass-through entities and clearly specifies that ''all pass-through entities must (a) ensure that every subaward is clearly identified to the subrecipient as a subaward and includes the following information at the time of the subaward and if any of these data elements change, include the changes in subsequent subaward modification. . . . Required information includes . . . (2) All requirements imposed by the pass-through entity on the subrecipient so that the Federal award is used in accordance with Federal statutes, regulations and the terms and conditions of the Federal award.'' Given that Title X grantees are required to follow 45 CFR part 75, and since 45 CFR part 75 makes clear that all requirements of the grant, including federal statutes, regulations, and terms and conditions of the federal award, apply to all subrecipients, the Department believes it is clear that the Title X regulations will continue to apply equally to all grantees and subrecipients without needing to include separate language in the Title X regulations.

Similarly, the Department does not deem it necessary to include language within the regulation itself requiring grantees to provide assurance that their project does not provide abortion and does not include abortion as a method of family planning. The Department has explicitly stated in all NOFOs that all grantees must comply with the Title X statute, regulations, and legislative mandates, and applicants certify in the application materials that they ''[w]ill comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies governing this program.'' Additionally, compliance with program statutes and appropriations act requirements is included as a standard term of the grant award. Therefore, during the application process, and by accepting funds, grantees have assured their compliance to the statute, regulations, and legislative mandates.

The Department also disagrees with the contention that withdrawal of organizations following the 2019 rule proves that these organizations were non-compliant with the statutory requirements. The primary reasons cited by most grantees for withdrawing from the Title X program after promulgation of the 2019 rule was out of concern that the 2019 rule interfered with the patient-provider relationship and compromised their ability to provide quality healthcare to all clients. For certain grantees, the regulation was also in direct conflict with laws established by their state.

Furthermore, there is no evidence to suggest that the grantees that withdrew from the Title X program had had any difficulties complying with the Title X statute, regulations, or legislative mandates. OPA practices, and practiced long before the 2019 rule, robust monitoring processes to ensure grantee compliance with the statute and regulations, including through regular grant reports, compliance monitoring visits, and legally required audits. As stated in the Background section, close oversight of Title X grantees for almost two decades under the 2000 rule uncovered no misallocation of Title X funds by grantees. OPA oversight did identify occasional instances over the years where grantees needed to update their written policies to clearly reflect the Title X statutory language, but OPA never found any instance where grantees were co-mingling funds with activities not allowed under the statute. The Department believes that grantee compliance with the Title X statute and regulations has not been an issue throughout the history of the Title X program, and the compliance monitoring methods that have historically been applied by OPA prior to the 2019 rule have ensured that

grantees have an understanding of the statute and how to comply with it. The Department rejects as without merit the comments that these grantees were accepting Title X funding for years without complying with statutory requirements. Neither the 2019 rule itself nor any comments to the 2021 NPRM cited evidence of widespread noncompliance.

D. Application of Conscience and Religious Freedom Statutes to Title X

Comments: The Department received thousands of comments on the preamble language concerning the application of the conscience statutes to Title X. As further discussed in the NPRM, Congress has passed several laws protecting the conscience rights of providers, particularly in the area of abortion. For instance, under 42 U.S.C. 300a–7, the Church amendments, grantees may not require individual employees who have objections to abortion to provide such abortion counseling, or those who have objections to sterilization procedures to perform, assist in the performance of, or provide counseling regarding sterilizations. Since 2005, Congress has also annually enacted an appropriations rider, the Weldon amendment, 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, Public Law 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.

Many commenters expressed a belief that the statutory conscience protections prohibited the agency from promulgating any counseling or referral requirements. Conversely, some asserted that the conscience statutes have no bearing on what requirements Title X could impose on grantees by regulation. Many comments asserted that these statutes had to be incorporated into the Title X regulatory text for them to be operative or the rule to be lawful. Some stated that the statutes themselves violated the separation between church and state. Several other comments cited a concern that applications from providers objecting to abortion counseling or referral would not be favorably evaluated. Many also suggested that the Department should simply allow for abortion counseling and referral rather than requiring it, since the conscience statutes protect objecting providers from those requirements in any case.

Beyond the Church and Weldon Amendments, a few comments also stated that requiring abortion counseling or referral automatically violated the Religious Freedom Restoration Act (RFRA), 42 U.S.C. 2000bb through 42 U.S.C. 2000bb–4. At least one comment suggested that the counseling and referral requirements coerced speech in violation of the First Amendment for those providers who object.

Response: The conscience statutes have been the subject of multiple rulemakings and numerous lawsuits in the last 13 years. Most recently, the Department finalized a rule in 2019 providing definitions and an enforcement mechanism for several statutes protecting medical providers who have conscience-based objections to certain activities. *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority,* 84 FR 23170 (May 21, 2019). That rule was vacated by three different courts. *New York* v. *HHS,* 414 F. Supp. 3d 475, 536 (S.D.N.Y. 2019) (appeal in abeyance); *Washington* v. *Azar,* 426 F. Supp. 3d 704, 722 (W.D. Wash. 2019) (same); *City & Cty. of San Francisco* v. *Azar,* 411 F. Supp. 3d 1001 (N.D. Cal. 2019) (same). While the statutes may at times interact with the requirements of Title X, interpreting these laws is beyond the scope of this rule and the HHS Office for Civil Rights (OCR) has been delegated authority to receive complaints under these provisions.

Moreover, as the DC Circuit pointed out when the Weldon Amendment was enacted and the 2000 Title X rule was in effect, ''a valid statute always prevails over a conflicting regulation,'' *Nat'l Family Planning & Reprod. Health Ass'n* v. *Gonzales,* 468 F.3d 826 (D.C. Cir. 2006). This is true whether an overriding statute is incorporated into regulatory text or not. The applicability of other rules and laws are best evaluated by consulting those rules and laws and then seeking guidance from the agencies responsible for implementing them. Particularly in areas where the administrative rules may be modified or statutory directions may change from appropriation to appropriation, it is unwise for OPA to formalize interpretations beyond its own statutory authority.

Irrespective of the points made above, as recounted in the NPRM, objecting individuals and grantees will not be required to counsel or refer for abortions in the Title X program in accordance with applicable federal law. OPA has long worked with grantees and providers to ensure appropriate compliance with conscience laws as well as continuity of care. As stated above, OCR has been delegated authority to receive any complaints related to the conscience protections and will continue to enforce them. As discussed in the NPRM, recognition of provider conscience rights has been the position of the Department since before the 2000 rule. See 65 FR at 41274 (2000 rule, stating that under ''42 U.S.C. 300a–(d), ''grantees may not require individual employees who have such objections to provide such counseling.''). However, as also discussed in the 2000 final rule, the Secretary was unaware then—and is still unaware—''of any current grantees that object to the requirement for nondirective options counseling.'' *Id.*

Just as non-objecting providers should not dictate the provision of information and referrals by those who do object, the existence of statutory conscience protections for providers does not preclude other willing providers from providing referrals or counseling for abortion within the program. With this final rule, the Department is emphasizing the importance of ensuring access to equitable, affordable, client-centered, quality family planning services. Client-centered care is defined as being respectful of, and responsive to, individual client preferences, needs, and values, and ensures that the client's values guide all clinical decisions. With an emphasis on providing services that are client-centered, the default should be the fullest provision of information to clients. Providers may avail themselves of existing conscience protections and file complaints with OCR, which will be evaluated on a case-by-case basis as is done with other complaints.

As noted in previous iterations of both sets of rules, the conscience provisions and Title X rules have existed side by side for decades with very little conflict, or even interaction. From 1993 to 2017, Title X received no reports of grantees or individuals objecting to the regulatory requirement to counsel or refer for abortions when requested. See *Nat'l Family Planning & Reprod. Health Ass'n,* 468 F.3d at 830 (''[T]here are structural reasons to doubt that the issue will ever come up. In 2000 HHS Secretary Shalala declined to create a specific exception from the pending [Title X] regulation's mandatory referral requirement for organizations resisting provision of abortion counseling or referrals; she explained that she was ''unaware of *any* current grantees that object to the requirement for nondirective options counseling, so this suggestion appears to be based on more of a hypothetical than an actual concern.''). As with any issue facing Title X grantees and applicants, the program will work to provide guidance to grantees and coordinate any

conflicts with the OCR. A case-by-case approach to investigations will best enable the Department to deal with any perceived conflicts within fact-specific situations.

The Department declines to definitively interpret RFRA or the First Amendment in this context for largely the same reasons. Not only do the conscience protections more specifically allow providers to object to referral and counseling for abortion requirements, but the Title X rules in force for decades prior to the 2019 rule also existed side by side with RFRA and the First Amendment with no conflict. However, in light of the comments received, and to eliminate any confusion, the Department has noted in this final regulation that ''[p]roviders may separately be covered by federal statutes protecting conscience and/or civil rights.''

E. Options Counseling

Comments: The Department received thousands of comments expressing support for ''the reinstatement of the requirement to offer nondirective options counseling to pregnant patients.'' Many comments expressed support for reversing the 2019 rule's restrictions on what referrals can be provided to clients and allowing providers to offer patients complete information about their healthcare options and refer patients to providers who offer services to meet those needs. One comment stated that ''reinstating the 2000 regulations would remove this undue governmental interference into medical care and will help ensure patients receive medically accurate, comprehensive information from their physicians.''

The Department also received comments in opposition to removing restrictions on referring for abortion services and requiring nondirective counseling. Several comments opposed removing restrictions on what referrals can be provided to clients in general, and a few opposed removing restrictions which state that only advanced practice providers can provide nondirective counseling. Many comments opposing the rule expressed a belief that the information and counseling requirements in this provision violate section 1008 of the Title X statute. Others believed that requiring ''that grantees refer (sic) individuals to abortion providers conflicts with the free speech and religious freedom of grantees.'' Still others expressed concern that the requirement could limit the type of providers in the program due to conscience concerns.

Response: The Department appreciates the comments in support of this provision. The Department believes that offering pregnant clients the opportunity to receive neutral, factual information and nondirective counseling on all pregnancy options—and providing referral upon request for option(s) the client wishes to receive—are critical for the delivery of quality, client-centered care. The Department agrees that restoring this provision will remove unnecessary limitations governing the patient-provider relationship and will enable healthcare providers to offer complete and medically accurate information and counseling to their clients.

The Department's response to comments opposing this provision is included earlier in Section II. *A. Compliance with Section 1008 (42 U.S.C. 300a–6) and D. Application of Conscience Statutes to Title X.* The NPRM language for this provision would restore the regulatory text from the 2000 regulation, which successfully governed the Title X program for decades without opposition from major medical organizations and was widely accepted by grantees.

F. Subrecipient Nondiscrimination

Comments: The Department received many comments on state policies restricting subrecipient participation for reasons unrelated to the provider's ability to provide care. The majority of these comments favored a regulatory prohibition on such restrictions because they often exclude the best family planning providers for no discernible purpose. Many comments stated that ''State policies putting restrictions on how state funds are allocated, called 'tiering,' make it difficult or impossible for privately operated reproductive health-focused providers to receive funding. Tiering and other prohibitions against abortion providers often exclude the specialist providers that are the most qualified and best equipped to help Title X patients achieve their family planning goals.'' Such restrictions, which are in place in approximately 15 states, can make access for certain sub-populations and geographic areas more difficult. Many comments stressed that ''expelling well-qualified, trusted family planning providers from publicly funded health programs like Title X has adverse effects on patients' access to critical family planning and sexual healthcare.''

The Department also received many comments, including from multiple state Attorneys General, condemning any regulation in this area. Many of these objections stated that such a regulation would undermine federalism and ''intrude on the States' self-governance for no good reason,'' and, most prominently, violate the Congressional Review Act, 5 U.S.C. 801–808. Under that law, an agency may not promulgate a rule that is ''substantially the same'' as one that has been disapproved by Congress. In 2016, the Department enacted a rule barring projects from rejecting sub-grantees for non-programmatic reasons. 81 FR 91852 (Dec. 19, 2016). Congress subsequently revoked the rule. P.L. 115–23 (4/13/2017). Multiple comments asserted that any regulation in this area would be unlawful unless Congress specifically authorized it.

Response: All proposed additions to the 2000 rule received an overwhelmingly positive response, except the proposal to include a subrecipient non-discrimination provision. After carefully considering several factors, the agency is declining to include a subrecipient non-discrimination provision in this rulemaking. Foremost among the Department's considerations is the sense of urgency in the interest of public health to complete this rulemaking. This schedule allows for a final rule to be effective before the award of the next round of competitive funding for the Title X program. This, in turn, will enable applicants that previously withdrew from participation in the program as a result of the previous regulation to apply for funding.

The Department still believes state restrictions on subrecipients unrelated to care hamper the ability of the program to achieve its goals. However, the overriding task of this rulemaking is to undo the negative public health effects of the previous rule. That result is most effectively reached by not including a subrecipient non-discrimination provision in this rulemaking. Organizations in states with restrictive laws may still apply directly to receive Title X grants (*see* PHS Act sec. 1001(b); 59.3).

G. Other Comments

Comments: While many comments were specific to certain sections of the proposed rule, a sizeable number were more general in nature, or commented on portions of the preamble. Many of these general comments were summarized in detail in the sections above, and the remainder of the general comments are summarized here.

Of those that support the proposed rule, a large number of comments expressed general support for removing the harmful effects of the 2019 rule on Title X services. A similarly large

number felt that the 2019 rule negatively impacted the number of clients served and that the proposed rule will increase the number of clients served. Many comments supported being able to expand access to Title X services across the nation and within states and territories. They felt that the proposed rule will result in more Title X grantees and service sites and will increase the diversity of grantees. Many other comments expressed support that the proposed rule will increase health equity and decrease health disparities by increasing the number of marginalized and vulnerable groups served by Title X.

Many comments expressed a belief that the proposed rule will result in improved health outcomes and that the 2019 rule had a negative impact on public health. Others supported the emphasis in the proposed rule on quality family planning and felt that the proposed rule will result in improved quality of care. Many comments expressed a belief that the proposed rule better aligns with the mission of Title X and that it will result in cost savings.

Of those that oppose the proposed rule, many expressed general opposition to the elimination of the 2019 rule, and a large number expressed a belief that the proposed rule does not align with the mission of Title X. Several comments expressed a belief that the proposed rule will result in negative health outcomes. A small number of comments raised concern that the proposed rule will result in a decrease in quality of care and would cost more to implement compared to the 2019 rule.

The Department also received several comments that were not relevant to the 2021 rule. These included several comments expressing opposition to the use of hormone therapy for adolescents, a few comments requesting that the Department include specific services within Title X that are already included in Title X (*e.g.,* STI testing, cervical cancer prevention and treatment), and several personal testimonials either for or against family planning in general, but not specific to the 2021 rule.

Response: The Department agrees with the comments in support of the proposed rule and disagrees with the comments opposed to the proposed rule. The Department believes that the negative public health consequences of the 2019 rule are clear. As stated in the Background section, the 2019 rule dramatically reduced access to essential family planning and preventive health services for hundreds of thousands of clients, especially for the low-income clients Title X was specifically created to serve. The 2019 rule decreased the number of providers willing to participate in the Title X program, further reducing access to essential family planning services within states and communities across the country. The 2019 rule shifted Title X away from its history of providing client-centered, quality family planning services and instead set limits on the patient-provider relationship and the information that could be provided to the patient by the provider. The 2019 rule resulted in increased costs for grantee reporting that are unnecessary for ensuring grantee compliance. The Department believes that 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.

The Department will continue to enforce and monitor grantee compliance with all Title X statutory requirements and legislative mandates. The Department disagrees with comments that it is necessary to include language repeating the legislative mandates within the regulation itself. As noted above with respect to Section II. *C. Grantee and Subrecipient Compliance,* OPA explicitly states in NOFOs that all grantees must comply with the Title X statute, regulations, and legislative mandates, and applicants certify in the application materials that they will comply with federal law; compliance with program statutes and appropriations act requirements is also included as a standard term of the Title X grant award. Therefore, during the application process as well as by accepting funds, grantees have assured their compliance to the statute, regulations, and legislative mandates. Furthermore, OPA includes the legislative mandates in its grantee orientation and trainings and regularly monitors grantee compliance with the legislative mandates through grantee reporting and compliance monitoring visits.

The Department believes that the adoption of the 2021 proposed rule (86 FR 19812, April 15, 2021), with minor modifications discussed in this rule, will result in increased access to equitable, affordable, client-centered, quality family planning services. This will result in improved outcomes for all clients served by Title X. Additionally, the 2021 rule will ensure that the predominantly low-income clients who rely on Title X services as their usual source of medical care have access to the same quality healthcare, including full medical information and referrals, that higher-income clients and clients with private insurance are able to access.

Comments Regarding Proposed Revisions and Technical Corrections to the 2000 Regulation

§ 59.2. Definitions

In the NPRM, the Department proposed revising section 59.2 of the 2000 regulations by adding several new and modified definitions. The NPRM included a new definition of family planning services consistent with the definition included in QFP. The NPRM also included a new definition of service site consistent with the previous Title X Family Planning Guidelines that implemented the 2000 regulations, the 2014 *Program Requirements for Title X Funded Family Planning Projects* (''2014 Title X Program Requirements''). Finally, the NPRM included new definitions for adolescent-friendly health services, client-centered care, culturally and linguistically appropriate services, health equity, inclusivity, quality healthcare, and trauma-informed services. All new definitions included in the NPRM were taken from federal government agencies or major medical associations. The NPRM also retained definitions from the 2000 regulation for the following terms: Act, family, low-income, non-profit, Secretary, and state.

Comments: The Department received numerous comments in support of the new or revised definitions in the NPRM. Many comments expressed strong general support for the newly-proposed definitions, including definitions for client-centered care, cultural and linguistic appropriateness, family planning services, health equity, inclusivity, and trauma-informed. Numerous comments stated that ''the proposed rule's definitions help to illustrate key aspects of quality care'' and that ''defining how services should be provided is an important step toward a more equitable Title X program.'' Numerous comments expressed specific support for the emphasis on health equity in the proposed rule. Comments expressed that the ''added definition for health equity underscores the goal of ensuring that all Title X patients have the opportunity to attain their full health potential.'' Many comments also expressed support for the definition of family planning services, and specifically the inclusion of ''FDA-approved'' contraceptive products and reinstatement of the term ''medically approved'' to the definition. Several comments were supportive of not

including women whose employers do not cover contraception for religious reasons in the definition of low-income. One comment expressed support for the NPRM's ''returned focus on Title X's priority population—low-income clients—and removal of the 2019 rule's re-definition of 'low income' to use the program to pay for contraceptive services for any people whose employers refuse to include coverage for such services in their employer sponsored insurance due to religious or moral objections.'' Several comments also expressed support for using more inclusive terminology throughout the NPRM and expressed that '''client' is more reflective of the diverse population of patients served by the Title X program.''

Several comments, while supportive of the definitions included in the NPRM, did request specific revisions to many of the new or revised definitions. Several comments requested that the Department explicitly include systemic racism within the definition of health equity. Another comment requested that the Department revise the definition of health equity by expanding ''the umbrella term 'socially determined circumstances' to 'other circumstances that are socially, economically, demographically, or geographically determined.' '' One comment requested that the Department revise the definition of adolescent-friendly services to include ''developmentally appropriate services that support the healthy cognitive, physical, sexual, and psychosocial development of adolescents as they transition from childhood to adulthood and account for their unique needs, including with respect to confidentiality, legal status, and autonomy.'' Other comments asked the Department to revise the definition of inclusivity to include non-religious people and the intersex community. One comment requested that the definition of trauma-informed care be revised to prevent future discrimination of transgender people by ''clarifying that a trauma-informed program should not result in discrimination against any population.''

The Department also received several comments opposing the new or revised definitions. A few comments opposed the definition of client-centered care and felt that it raised conscience concerns. Other comments opposed the definition of family planning services and specifically opposed removing abstinence and preconception health from the definition. One comment opposed the definition and said that ''medically approved'' did not include natural family planning. Another comment questioned why the definition of family planning services did not emphasize ''supporting unexpected pregnancies with assistance required by families and mothers—including emotional, educational, financial, and healthcare supports.'' Other comments expressed general opposition to the definition of family planning services and felt that the definition included abortion and abortion-related services.

One comment stated that the definition of health equity was vague and undermined the priority for serving low-income clients. Another comment stated that the focus on health equity was ''targeting minority communities to restrict pregnancy,'' and another stated that the focus on equity was unnecessary because of protections already included in the Constitution. One comment opposed the definition of cultural and linguistically appropriate services and expressed that ''the phrase 'culturally and linguistically appropriate services' may bless health practices, based on cultural norms, that lead to negative health outcomes.'' One comment opposed the definition of ''trauma-informed'' and said it was vague and that it was not clear what was required to be trauma-informed.

One comment opposed the definition of inclusivity and felt that it would drive faith-based providers out of the program. Another comment took issue with the definition of ''inclusivity'' and stated that ''segregation or prioritization of Title X services by protected classes such as race violates the Constitution and several civil rights laws.'' A few comments opposed the use of the word ''client'' instead of ''woman'' throughout the NPRM and felt that the change in language was a disservice to women. Two comments opposed removing women who cannot receive contraception from their employer because they have a religious or moral objection from the definition of low-income. A few comments opposed the definition of quality healthcare. One comment opposed including client-centered and equitable within the definition of quality. Still another comment stressed that improving the quality of healthcare is a ''dynamic process'' and that ''this dynamism requires a nimbleness often unattainable by national requirements.'' The commenter requested that the definition of quality be amended to allow ''maximum flexibility at the state and local level to establish standards of care.''

Response: The Department appreciates the supportive comments regarding the new and revised definitions in the NPRM and believes that clear definitions for terms used throughout the regulations are important for consistent implementation. The Department acknowledges comments requested revisions to many of the definitions; however, the Department believes that it is important to use widely accepted and commonly used definitions from other federal agencies and national medical organizations as the foundation for the regulation. For this reason, the Department will not revise the proposed definitions as requested by several comments.

The Department disagrees that the definition of client-centered care raises conscience concerns. The purpose of the rule and the definitions is to refocus the program as a client-centered one, where well-being of the patient, not the provider, is the primary goal. As stated earlier, providers may avail themselves of existing conscience protections and file complaints with OCR, which will be evaluated on a case-by-case basis as is done with other complaints.

The Department also disagrees with comments objecting to the definition of family planning services. The definition of family planning services within the NPRM is consistent with the definition of family planning services in QFP. Contrary to some of the comments opposed to the definition of family planning services, the definition does include preconception health, natural family planning, and abstinence (as a component of natural family planning). Family planning services include a broad range of services related to achieving pregnancy, preventing pregnancy, and assisting clients in achieving their desired number and spacing of children. Also, given that the focus of Title X is on helping clients achieve pregnancy, prevent pregnancy, and achieve their desired number and spacing of children, the Department responds to comments requesting that Title X provide support to clients once they become pregnant by noting that this is beyond the scope of the Title X program. Further, as is clear from section 1008 of the Title X statute, none of the funds appropriated for Title X are used in programs where abortion is a method of family planning. No court has found the decades-long practice of referral upon request to violate that prohibition.

The Department disagrees with comments expressing concern with the definitions of health equity, cultural and linguistic appropriateness, inclusive, low-income, quality, and trauma-informed. The definitions proposed in the NPRM are widely used definitions from other federal agencies and major

medical organizations. The Department also disagrees that the definition of inclusive will drive faith-based organizations out of Title X or that it will segregate services; rather, the goal is to ensure that all people can actively participate in and benefit from family planning services. Finally, the Department disagrees with comments opposing the use of the word ''client'' and believes that it is important that the words used in Title X fully reflect the diversity of Title X clients.

In conclusion, the Department adopts the definitions from the NPRM for this provision as final with one revision and one technical correction. Given the revisions described later to 59.5(b)(1) and 59.5(b)(6) to include reference to ''clinical services providers'' in the regulatory text, the Department is adding a definition for ''clinical services provider'' to the final rule in 59.2. The definition of clinical services provider comes from OPA's FPAR and has been widely used as a definition for Title X grantees to guide their FPAR data collection and reporting. As taken from FPAR, a clinical services provider is defined as ''physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care.''

One technical correction in the final rule is to the definition of family planning services. The definition in the NPRM stated, ''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.'' Since the FDA does not approve contraceptive ''services,'' but rather approves, clears, and authorizes (for purposes of this rulemaking, ''FDA-approved'') ''contraceptive products,'' the definition in the final 2021 rule is revised. The final definition will now read, ''Family planning services include a broad range of medically approved services, which includes FDA-approved contraceptive products 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.''

In addition to this revised definition for family planning services, the definitions from the NPRM for Act, adolescent-friendly health services, client-centered care, culturally and linguistically appropriate services, family, health equity, low-income, inclusive, non-profit, quality healthcare, Secretary, service site, state, and trauma-informed are all adopted as final.

§ 59.5(a)(1). Broad Range of Acceptable and Effective Medically Approved Family Planning Methods and Services

In the NPRM, the Department proposed revising section 59.5(a)(1) of the 2000 regulation to require sites that do not offer the broad range of methods on-site to provide clients with a referral to a provider who does offer the client's method of choice. In addition, the NPRM specified that the referral must ''not unduly limit the client's access to their method of choice.'' The complete NPRM language for this provision stated, ''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.'' The proposed revisions recognized that 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 the broad range of methods and services, offering only a single method of family planning could impact client access.

Comments: The Department received many comments in support of section 59.5(a)(1), especially in support of the requirement that Title X projects provide a broad range of acceptable and effective medically approved family planning methods. Many comments expressed support for reinstating the term ''medically approved'' to the provision. Several comments requested that the Department add more specificity to the regulations to further define what is meant by ''a broad range of methods.'' One comment requested that the Department ''expect Title X agencies to offer 'many' or 'almost all of the most commonly used' methods, and use referrals as an option of last resort.'' Another comment requested the Department to ''require each site to have at least one type of each provider-administered method in stock, and to have a process in place to offer other methods of contraception by prescription if not stocked in the clinic.''

The Department also received many comments expressing concern about allowing an organization to participate as part of a Title X project if it only offers a single method of family planning, as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. Several comments expressed concern that ''allowing Title X sites to offer a single method of contraception conflicts with Quality Family Planning standards and HHS' stated goals regarding quality, client-centered care, and health equity.'' Several other comments requested that ''if HHS continues to allow specific sites to offer a single method of contraception, HHS must clarify that the method be medically approved and effective.''

The Department received further comments regarding the language in the NPRM requiring sites that do not offer the broad range of methods and services to ''provide a referral, and the referral must not unduly limit the client's access to their method of choice.'' Many comments expressed support for requiring that sites refer clients if the site does not offer the client's method of choice. Some comments expressed concern that it was unclear what was meant by ''not unduly limit the client's access'' and how the requirement would be enforced across diverse communities. Some comments expressed concern that rural communities with more limited access to refer clients to other organizations nearby would be penalized if the referral was considered to unduly limit the client's access. Some comments asserted that requiring referrals for a client's method of choice would result in faith-based and natural family planning providers leaving the Title X network. Several other comments expressed concern that the referral requirement was ''vague and

does not go far enough.'' One comment asked the Department to ''clearly outline the reasons and/or circumstances under which a Title X site may be excused from offering a broad range of medically approved methods and parameters, including a maximum 'reasonable' distance a Title X patient would have to travel to get their method of choice.'' Another comment asked the Department to closely monitor the accessibility of referrals made by Title X sites. Other comments asked the Department to provide a specific number of minutes or miles from the Title X project to the referral location and to require that referrals be only to another Title X site to ensure the same discounted services would be available.

Response: The Department appreciates the supportive comments for this provision in the 2021 rule. Since acceptable and effective medically approved family planning methods can change over time, the Department does not believe that additional specificity regarding what is meant by a broad range of methods and services is necessary within the regulatory text. Instead, the Department will provide additional guidance and technical assistance to assist grantees in complying with the regulation and ensuring access to a broad range of acceptable and effective methods and services across their service sites.

The Department acknowledges the comments expressing concern with allowing an organization to participate in a Title X project if it only offers a single method of family planning as long as the overall project offers the broad range of methods and services. For much of the Title X program's history, including in the 2000 regulations, the regulation has included this provision. The Department believes that retaining this provision in the 2021 rule is important to ensure flexibility in addressing community needs and recognizes that not all Title X service sites may be able to provide access to all methods and services. The Department will monitor and provide technical assistance to ensure that each grantee provides access to the broad range of acceptable and effective medically approved family planning methods and services to their clients.

The Department disagrees that the referral requirement will result in faith-based and natural family planning providers leaving the Title X network. This is in part based on our longstanding experience with the program which for decades has included faith-based and natural family planning providers. The requirement for referral is intended to support continuity of care for Title X clients. There are any number of opportunities by which this requirement could be fulfilled including directly by the clinic site or by the grantee in instances when a provider objects or lacks capacity to fulfill this requirement. An array of providers, including those that only offer a single method on-site, have successfully participated in the Title X program for decades. The Department will monitor and provide technical assistance to ensure that supporting client access to requested methods and services does not violate federal conscience laws. As part of the statutory mandate, Title X projects must provide natural family planning services, and the program will work with projects to ensure they provide all statutorily required services. Again, the Department is emphasizing in this final rule the importance of ensuring access to client-centered care. Client-centered care is defined as being respectful of, and responsive to, individual client preferences, needs, and values, and ensuring that client values guide all clinical decisions. With an emphasis on providing services that are client-centered, the default should be the fullest provision of information and services to clients.

The Department understands, based on the comments received, that it is challenging to include within the regulation a requirement that sites must provide a referral that does ''not unduly limit the client's access.'' The Department fully recognizes that the referrals available to each Title X site will differ depending on what other referral resources are available within or near the community. Some communities may have access to a wide range of providers to refer clients to within the same community, while other sites may need to refer clients to organizations located farther away. Given the challenges in having one standard definition for what is considered undue burden across all Title X sites, the Department has decided to revise section 59.5(a)(1) to remove the requirement that ''the referral must not unduly limit the client's access to their method of choice.''

In addition to the revision to remove this requirement, the final rule will also include one technical correction for this provision. The Department recognizes that if a Title X site does not have the client's method of choice available on-site, the provider may be able to provide the client with a prescription for their method of choice, rather than having to provide a referral to another provider. To better account for this, the final provision will now require sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services to provide a prescription to the client for their method of choice or referrals, as requested. As a point-of-entry to care, Title X sites often have robust referral networks with other safety-net agencies that are attuned to the needs of the client populations that they serve. While a prescription or referral does not guarantee a client the same schedule of discounts as at a Title X site, experience suggests that the family planning safety net recognizes and takes steps to limit accessibility burdens, including financial constraints, for the clients they serve. In addition, the Department will provide additional guidance and technical assistance to grantees to help them promote accessibility and limit patient burden.

With the revisions noted above, the revised language for the 2021 rule for 59.5(a)(1) is, ''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 prescription to the client for their method of choice or referrals, as requested.'' This revised language is adopted as final.

§ 59.5(a)(3). Services are Client-Centered, Culturally and Linguistically Appropriate, Inclusive, and Trauma-Informed; Protect the Dignity of the Individual; and Ensure Equitable and Quality Service Delivery Consistent With Nationally Recognized Standards of Care

In the NPRM, the Department proposed revising section 59.5(a)(3) of the 2000 regulations. In addition to providing services that protect the dignity of the individual as required in the 2000 regulations, the NPRM stated, ''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.'' These revisions were aimed at increasing access and ensuring equity in all services provided, which the Department believes is especially important for the Title X program with a statutory priority on serving low-income clients. In addition, the Department believes that the revisions will result in improved services for clients.

Comments: The Department received numerous comments in support of this revised provision. Many comments expressed full support for the provision and urged the Department to adopt it as quickly as possible. Others expressed specific support for the requirement that services be client-centered: ''We support that the proposed rule names the importance of using client-centered models of care.'' Still others expressed specific support for the inclusion of QFP within the 2021 rule and the requirement that Title X services be consistent with nationally recognized standards of care. One comment said, ''[T]he Proposed Rule will again base the standards of care for the Title X program on the QFP guidelines and require that Title X clients receive high-quality, client-centered care that includes comprehensive, medically accurate counseling and information, and referrals for any other services sought.''

The Department received a few comments opposed to this provision. One comment felt that requiring services to be client-centered, inclusive, and trauma-informed would create additional ''burden on applicants and providers to ensure equity within their programs.'' Another comment argued with the definition of client-centered care and believed that it violated conscience protections. Still another expressed concern that the requirement for equity in conjunction with the requirement for inclusivity would violate civil rights laws and the Constitution ''by giving certain classes of people preferential treatment.''

Response: The Department appreciates the comments in support of this provision and agrees that providing services in a manner required by this provision will advance equity, increase access, improve outcomes for Title X clients, and reinforce the longstanding requirement that ''[s]ervices must be provided in a manner which protects the dignity of the individual.'' The Department disagrees that the requirements of this provision will result in additional burden for applicants or providers, rather the requirements of this provision simply ensure that all Title X services are of the highest quality and align with nationally recognized standards of care. The Department also disagrees that the requirements of this provision violate conscience protections and provides a specific response to comments concerning conscience earlier in Section II. *D. Application of Conscience Statutes in Title X.* Finally, the requirements of this provision do not give preferential treatment to any clients, but rather aim to ensure that all people can actively participate in and benefit from family planning services. In conclusion, the Department adopts the language from the NPRM for *§ 59.5(a)(3)* as final without revisions.

§ 59.5(a)(4). Services Do Not Discriminate Against any Client Based on Religion, Race, Color, National Origin, Disability, Age, Sex, Sexual Orientation, Gender Identity, Sex Characteristics, Number of Pregnancies, or Marital Status

The NPRM proposed the same regulatory text for this provision as has been included in the 2000 regulations, which read ''Provide services without regard of religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status.''

Comments: The Department received several comments regarding this provision and specifically expressing concerns with the phrase ''without regard of.'' Several comments expressed concern with the specific phrase and stated that ''if Title X providers are intended, as stated in the proposed rule, to work towards advancing health equity, it is imperative that care is delivered in a way that intentionally centers and considers the identity and needs of the patient.'' Several comments requested that the Department revise the provision to instead say ''provide services in a manner that does not discriminate against any patient based on religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status'' which they felt better supports health equity.

Response: The Department agrees with the comments and believes that revising the language as requested more clearly meets the intent of this provision, which is to prevent discrimination in the provision of services.

In addition, the Department is updating ''sex'' in 59.5(a)(4) to include sexual orientation, gender identity, and sex characteristics consistent with the section 1557 of the Affordable Care Act, case law, Executive Order 13988 (86 FR 7023, Jan. 25, 2021), and Departmental policy (*https://www.hhs.gov/about/news/2021/05/10/hhs-announces-prohibition-sex-discrimination-includes-discrimination-basis-sexual-orientation-gender-identity.html*). In *Bostock* v. *Clayton County,* 140 S. Ct. 1731 (2020), the U.S. Supreme Court held that Title VII of the Civil Rights Act of 1964 prohibition on employment discrimination based on sex encompasses discrimination based on sexual orientation and gender identity. Courts have now begun consistently interpreting similar language—'because of sex'— in other statutes to encompass these protections. See *Grimm* v. *Gloucester Cty. Sch. Bd.*, 972 F.3d 586, 616–617 (4th Cir 2020) (relying on Bostock to interpret Title IX as prohibiting policy prohibiting transgender student from using bathroom consistent with his gender identity). Moreover, as the Department of Justice has recently emphasized ''Discrimination against intersex individuals is similarly motivated by perceived differences between an individual's specific sex characteristics and their sex category (either as identified at birth or some subsequent time) . . . it is impossible to discuss intersex status without also referring to sex.'' Title IX (justice.gov). As a result of the case law and Administration policy, the Department adds ''sexual orientation'', ''gender identity'', and ''sex characteristics'' to 59.5(a)(4).[11] The revised language for the 2021 rule for 59.5(a)(4) is ''Provide services in a manner that does not discriminate against any client based on religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status.'' This revised language is adopted as final.

§ 59.5(a)(8). Charges for Services With a Schedule of Discounts

In the NPRM, the Department proposed revising section 59.5(a)(8) of the 2000 regulations by including widely accepted billing practices from the 2014 Title X Program Requirements. The NPRM text reads, ''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.

[11] This language reflects requirements on Title X projects principally engaged in healthcare activities under 42 CFR part 59. If grants for the production of informational materials were again to be made under PHSA § 1005, this definition might not apply.

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 percent FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.''

Comments: The Department received several comments on this provision specifically seeking closer alignment of HRSA's (Health Resources & Service Administration) Health Center Program (authorized by Section 330 of the PHS Act) and OPA's Title X Program to minimize administrative burden for dually funded grantees. Specifically, one comment suggested modifying the proposed language in § 59.5(a)(8)(ii) to include additional language about sliding fee discounts from the Health Center Program Compliance Manual that states that sliding fee discounts are ''subject to potential legal and contractual restrictions.'' Another comment lauded § 59.5(a)(8)(ii) for ensuring that clients with family income at or below 250 percent FPL do not pay more than what they would otherwise pay under the schedule of discounts; however, the comment expressed that this ''requirement violates insurance contracts and contradicts the guidance of other funders (*e.g.,* HRSA).'' Yet another comment expressed the need for additional guidance specific to Title X grantees and subrecipients operating under the Health Center Program, to assist with alignment of billing practices.

Response: The Department fully supports minimizing administrative burden for grantees funded under both the Title X program and HRSA's Section 330 Health Center Program, recognizing that providers that dually participate in the two programs have been one of the fastest growing segments of the Title X provider network. Similar to the Health Center Program's statutory requirement that health centers must operate in a manner such that no patient shall be denied service due to an individual's inability to pay, the Department also believes, and the Title X statute requires, that an individual's ''economic status shall not be a deterrent to participation'' in Title X program services. See PHS Act sec. 1006(c). The Department does not believe that adding to this rule the commenter's suggested language with respect to the Health Center Program Compliance Manual is warranted as it is taken out of context and does not state the statutory requirement. The Department believes that adding language requested in the comments could hinder Title X clients who qualify for sliding fee discounts from receiving the discounts, which is contrary to Title X's mandate of prioritizing services to low-income clients. Further, OPA clarifies how Title X grantees may remain in compliance with Title X Program requirements when integrating services with HRSA's Health Center Program grantees and look-alikes in OPA Program Policy Notice: 2016–11: Integrating with Primary Care Providers.''

Rather than revising the regulation and risk Title X clients not receiving all discounts for which they qualify, OPA will continue to work closely with HRSA to ease administrative burden for grantees funded under both programs. The Department will provide additional guidance and technical assistance to dually funded grantees aimed at reducing administrative burden. In conclusion, the Department adopts the language from the NPRM for *§ 59.5(a)(8)* as final without revisions.

§ 59.5(a)(9). Reasonable Measures To Verify Client Income

In the NPRM, the Department proposed adding a new section 59.5(a)(9) to include one requirement from the 2014 Title X Program Requirements that grantees take reasonable measures to verify client income, and a new requirement that grantees use client self-reported income if the income cannot be verified after reasonable attempts. The Department believes that these proposed revisions will greatly improve accessibility and affordability of services for low-income clients consistently across all Title X grantees.

The NPRM text reads, ''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.''

Comments: The Department received several comments supporting the use of self-reported income. Comments received from members of the House of Representatives stated, ''[W]e support the Department's stance that patients be allowed to self-report their income, removing an unnecessary potential barrier to care.'' Other comments expressed support that ''cost should not be a barrier'' to receiving services. Still other reaffirmed support that allowing use of self-reported income ''will greatly improve accessibility and affordability for low-income and uninsured patients seeking care from Title X program grantees.'' One comment felt that the provision did not go far enough and asked that the language ''explicitly state that a client's self-reported income is sufficient, and that providers do not need to verify client income.''

The Department also received several comments on this provision specifically seeking closer alignment between Title X and HRSA's Health Center Program (authorized by Section 330 of the PHS Act) to minimize administrative burden for dually funded grantees. Several comments felt that allowing a client's self-reported income in cases where a client's income cannot be verified despite reasonable attempts is inconsistent with the Health Center Program guidance. Comments reported that ''health centers have broad discretion to determine the appropriate means to assess patient income and family size. While allowing self-declaration is typical in the health center program, some health centers have opted to adopt a policy establishing that self-declaration, without supporting documentation, is not an acceptable means to verify income for every patient.''

Response: The Department appreciates the supportive comments and agrees that the requirements in this provision will greatly improve accessibility and affordability of services for low-income clients consistently across all Title X grantees. The elimination of barriers to Title X services for low-income clients is important to the Title X program. The Department disagrees that the requirements in 59.5(a)(9) are not compatible with HRSA's guidance. HRSA requires health centers to operate in a manner such that no patient shall be denied service due to an individual's inability to pay; further, HRSA Health Center Program grantees are required to establish systems for sliding fee scale eligibility that comply with statutory requirements under section 330 of the PHS Act and regulatory requirements under 42 CFR 51c.303(f) and 56.303(f), which do not preclude self-declaration of income and family size. The Department believes that the HRSA Health Center Program requirements are fully consistent with the language in § 59.5(a)(9). A strict standard of income verification at a particular health center is a choice that does not warrant weakening a standard in Title X that the

Department has created to support and reinforce the program's statutory obligation to prioritize services to persons from low-income families. In conclusion, the Department adopts the language from the NPRM for *§ 59.5(a)(9)* as final without revisions.

§ 59.5(a)(12). State Reporting Laws

In the NPRM, the Department proposed adding 59.5(a)(12) to retain some, but not all, language from the 2019 rule on notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, or human trafficking. The NPRM language stated, ''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.''

Comments: Many comments supported the elimination of section 59.17 from the 2019 rule. Comments supported eliminating ''the 2019 rule's attempt to give HHS substantial oversight over compliance with complex state reporting requirements.'' Many comments noted that ''professionals providing services in Title X-funded sites are aware of their reporting obligations, already receive training on them, and make reports in compliance with these requirements.'' Other comments stressed that determining compliance with state reporting laws lies with state authorities and noted that state reporting laws ''are complex and vary widely from state to state.''

One comment written in opposition to the NPRM expressed that the NPRM excluded ''the mandatory reporting of sex trafficking and violence by intimate partners.'' Another comment requested that the 2019 Title X requirement for mandatory reporting be kept fully intact. Another comment expressed concern that the proposed rule did not include the minor age record-keeping requirements and made an assertion that ''[t]his lack of record keeping serves to enable sex traffickers and abusers to continue undetected in their abuse.'' The comment proposed reinstatement of these requirements and further proposed rescinding the funding of any grant recipient who fails to screen for and report sexual abuse or sex trafficking.

Response: The Department agrees with comments that all Title X recipients must follow state reporting laws and must comply with mandatory reporting requirements regarding child abuse, child molestation, sexual abuse, rape, or incest. The Department disagrees with the assertion that ''. . . lack of record keeping serves to enable sex traffickers and abusers to continue undetected in their abuse.'' States have already established specific guidelines on the details that must be included in mandatory reports. As such, the Department believes that it is not necessary to impose this additional reporting burden through Title X regulations.

Since 1999, Congress has required, through the annual appropriations bill 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.'' All requirements in the appropriations riders are legislative mandates for the Title X program and all Title X grantees must comply with them. The Department will continue to enforce and monitor grantee compliance with all Title X statutory requirements and legislative mandates, including the mandate that ''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.''

As noted above with respect to Section II. C. *Grantee and Subrecipient Compliance,* OPA explicitly states in NOFOs that all Title X grantees must comply with the Title X statute, regulations, and legislative mandates. In addition, Title X applicants certify in the application materials that they will comply with federal law, and compliance with federal law, and compliance with program statutes and appropriations act requirements is also included as a standard term of the Title X grant award. Therefore, during the application process as well as by accepting funds, grantees have assured their compliance to the statute, regulations, and legislative mandates. Furthermore, OPA includes the legislative mandates in its grantee orientation and trainings and regularly monitors grantee compliance with the legislative mandates through grantee reporting and compliance monitoring visits. OPA has consistently documented compliance with this mandated requirement and will continue to do so. A 2005 OIG report (OEI–02–03–00530) found that OPA has informed and periodically reminded Title X grantees of their responsibilities regarding state child-abuse and sexual-abuse reporting requirements.

Given the comments received and that Title X compliance with state mandatory reporting is already required through a legislative mandate for the Title X program, the Department does not deem it necessary to include this provision within the final regulation itself. Furthermore, this provision was a part of the 2019 rule that is being rescinded as a whole because it was a set of interrelated requirements that did not promote the public health or solve any Title X compliance concerns. In conclusion, the Department removes language from the NPRM for *§ 59.5(a)(12)* from the 2021 final rule.

§ 59.5(a)(13). Subrecipient Monitoring

In the NPRM, the Department proposed adding 59.5(a)(13) to retain some, but not all, of the language from the 2019 rule related to subrecipient monitoring and reporting. This addition required 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 NPRM language stated, ''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.''

Comments: The Department received several comments expressing concerns with the requirements of this provision and the high reporting burden associated with it. One comment requested that section § 59.5(a)(13) be

removed completely because of the additional reporting requirements it creates. Another comment requested that the Department only require grantees to submit the additional information required by this provision for subrecipients during regular reports but not during the initial application. The comment expressed a concern that for large Title X networks, ''providing a description of all referral agencies and individuals, and outlining collaborations with each subrecipient, will still pose a significant burden for Title X grantees, particularly at the time of application when applicants are often afforded 60 days or less to apply.'' Many other comments requested that the Department revise the language in this provision to focus only on subrecipients and not referral agencies ''due to high burden'' of reporting given the size of grantee networks and the high number of possible referrals made by individual sites. One comment stressed that ''under the 2000 regulations, past grantees were required to monitor each organization and ensure that their clinic sites had appropriate referrals, that they were available to all clinic personnel, and that clients' medical charts reflected appropriate referrals given and follow-up performed. However, grantees were not required to gather every referral source and report this information to HHS. This requirement will likely create an administrative burden that could be accomplished through HHS monitoring of grantees.''

Response: It is clear from the comments received that the proposed requirements in § 59.5(a)(13) are unnecessarily burdensome for grantees and will result in Title X staff having to spend valuable time on administrative reporting that could otherwise be spent providing services to clients. The Department agrees that monitoring how grantees are involving and monitoring their subrecipients in their project and the composition of grantee referral networks can be achieved through the Department's existing grantee compliance monitoring system. Departmental grants regulations at 45 CFR 75.352 already document the requirements for pass-through entities and specify the reporting required of grantees for all pass-through entities. Furthermore, this provision was a part of the 2019 rule that is being rescinded as a whole because it was a set of interrelated requirements that did not promote the public health or solve any Title X compliance concerns.

Given the challenges noted with this provision and the additional reporting burden it would place on grantees, the Department has decided to remove *§ 59.5(a)(13)* from the 2021 final rule.

§ 59.5(b)(1) Provide Medical Services Related to Family Planning

In the NPRM, the Department proposed revising section 59.5(b)(1) of the 2000 regulations to acknowledge that consultation for medical services related to family planning can be provided by healthcare providers beyond the physician. Specifically, the NPRM stated, ''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.'' The proposed revision acknowledged that consultation for healthcare services related to family planning may be by a physician, but may also be by other healthcare providers, specifically acknowledging participation by physician assistants and nurse practitioners.

Comments: The Department received numerous comments supporting this revised provision, specifically in support of the recognition that a broad range of healthcare providers, in addition to physicians, have an important role to play in providing medical services related to family planning. Comments expressed agreement that ''other clinicians often play an important role in providing family planning counseling and other services.'' In addition, numerous comments asked the Department to clarify that this provision includes a broader range of healthcare providers beyond just physician assistants and nurse practitioners, as noted in the preamble of the NPRM. One comment asked that the Department use the definition of Clinical Services Provider from FPAR. Many other comments stated that ''it is important to note that 'consultation by a [healthcare] provider' is not and should not be limited only to the examples cited by HHS, as these CSPs represent only one facet of healthcare providers in Title X settings.''

In addition to the numerous comments related to the array of healthcare professionals that are responsible for clinical service provision in Title X, the Department also received numerous comments asking for the language of this provision to be revised to clearly reflect telehealth as an acceptable service delivery modality. Several comments expressed the importance of telehealth, especially throughout the COVID–19 pandemic, in allowing many Title X clients to continue to safely access essential services. Many comments expressed concern with the Department's use of the word ''telemedicine'' in the NPRM instead of ''telehealth'' and felt that telehealth refers ''to a broader scope of remote healthcare services than telemedicine and includes non-clinical services like counseling and education.'' Several comments specifically asked the Department to revise § 59.5(b)(1) to be clear within the regulation that family planning services can be provided ''in person or via telehealth.'' Other comments asked the Department to specify within the regulation that telehealth services can include ''audio-only modalities'' and expressed that ''all forms of telehealth modalities, including audio-only must be covered to remove any barriers of access for patients.'' One comment asked the Department to provide guidance to Title X grantees on how to use telehealth services to ensure access, equity, and quality.

Response: The Department appreciates the comments in support of this provision, especially those that recognize the role of a broader range of healthcare providers in delivering family planning services. It was never the Department's intention to imply that the only healthcare providers who could provide consultation under this provision were physician assistants and nurse practitioners. Physician assistants and nurse practitioners were included in the NPRM preamble to provide examples, but not to be exclusionary. The Department agrees with comments recommending use of the definition of Clinical Services Providers from FPAR to determine who is eligible as a healthcare provider under this provision and, as noted in the discussion related to Section 59.2 *Definitions,* is adding this definition to the final rule. The FPAR definition for Clinical Services Providers includes ''physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care.''

The Department agrees with the comments reiterating the importance of telehealth and the role of telehealth services in expanding access to services and advancing equity. The Department had always intended for the final rule to apply to family planning services

provided in-person or via telehealth and had specifically stated in the NPRM that the Department was ''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.'' Telehealth has played a critical role for Title X in responding to the COVID–19 pandemic. By utilizing telehealth modalities, Title X grantees were able to continue to provide essential family planning services throughout the pandemic. With the onset of COVID–19, the vast majority of Title X grantees transitioned to some form of telehealth service delivery in order to continue providing services while limiting contact between individuals and protecting client safety. Telehealth was commonly used by Title X grantees for non-urgent visits that did not require a physical exam. Of importance, more than half of the grantees that were able to deliver telehealth during COVID–19 reported to OPA in their progress reports that they intended to continue offering telehealth services even after the pandemic ends, due to the advantages for both clients and staff.

Given the comments received, the Department believes that it is important to include language specifically in the regulatory text to clarify that telehealth services also constitute appropriate service delivery. The Department also agrees with the request to use the term ''telehealth'' rather than ''telemedicine'' to be clear that telehealth services include non-clinical services like counseling and education. While cognizant that synchronous telehealth services may be delivered through different modes of technology and that audio-only modalities may mitigate access barriers, particularly for those with limited internet and/or cellular data, the Department does not agree that the regulatory text needs to be so specific to reference the use of ''audio-only modalities,'' especially given how rapidly technology can change. Instead, the Department will provide additional training and technical assistance to grantees on the use of various telehealth modalities to improve access, quality, and equity.

With the revisions noted above, the revised language of 59.5(b)(1) for the 2021 rule is, ''Provide for medical services related to family planning (including consultation by a clinical services provider, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.'' This revised language for *§ 59.5(b)(1)* is adopted as final.

§ 59.5(b)(3) Community Education, Participation, and Engagement

In the NPRM, the Department proposed revising section 59.5(b)(3) of the 2000 regulations to reflect the desire to engage diverse individuals to make services accessible. Specifically, the NPRM stated, ''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.'' The revision added language to clarify the intent to engage diverse individuals to ensure access to equitable, affordable, client-centered, quality family planning services.

Comments: The Department received one comment expressing support for 59.5(b)(3), especially emphasizing the importance of the participation and engagement of diverse individuals in making family planning services accessible, equitable, and client-centered. The Department received one comment asking that the language of 59.5(b)(3) be revised to ''be clear that the needs of adolescents and young adults'' are included in community education, participation, and engagement.

Response: The Department appreciates the comments in response to this provision. Community education, participation, and engagement are important for Title X projects because they help ensure that the community is aware of the Title X program and the services available. In addition, community participation and engagement are critical to helping Title X providers better understand and center the needs and experiences of the community and the clients served. Together, community education, participation, and engagement are foundational for ensuring access, equity, and quality through the provision of Title X services.

In response to the one comment requesting a revision to the provision, the Department believes that the proposed regulatory text is broad and already includes the needs of adolescents and young adults as currently written. The Department does not believe that additional revisions are needed to the regulatory text in order to respond to the comment received. In conclusion, the Department adopts the language from the NPRM for *§ 59.5(b)(3)* as final without revisions.

59.5(b)(6) Services Under Direction of Clinical Services Provider

The NPRM proposed the same regulatory text for this provision as has been included in the 2000 regulations, which read, ''Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.''

Comments: The Department received numerous comments requesting revisions to the regulatory text for this provision. Comments requested that the regulation expand beyond physician-only directed services. Several comments requested that the text be revised to be consistent with the revisions to § 59.5(b)(1), which recognized the importance of a broader range of healthcare providers, in addition to physicians, in providing family planning services. Several comments requested revisions to expand direction of family planning services to very specific types of healthcare providers. One comment asked that the language clarify that nurse practitioners have the authority to direct family planning programs. Another comment asked that the language be revised from physician to ''licensed healthcare provider.'' Still another asked that this section be revised to specifically authorize physician assistants to direct family planning services.

Several other comments were specific to advanced practice registered nurses (APRNs) and asked that the language specify that APRNs ''be able to serve as the medical director (in states with full practice authority).'' One commenter pointed out that ''while state licensure rules vary, many states have granted full practice authority to APRNs, enabling independent practice.'' Another comment requested that the Department consider whether registered nurses could direct family planning services ''especially in areas of provider shortage.'' A final comment asked for the text to be amended to allow services provided ''under the direction of an advanced practice clinician, if the services offered are within their scope of practice and if allowable under state law.''

Response: Given the comments received, the Department agrees that having consistency between 59.5(b)(1) and 59.5(b)(6) is important to more clearly reflect the role of a broader range of healthcare providers in providing

Title X services. The Department also agrees with comments that other healthcare providers, including physician assistants and APRNs in many states, have authority to direct family planning programs and should be included within the regulation.

As stated earlier, the Department received comments in response to 59.5(b)(1) asking for more clarity on the term ''healthcare providers'' included in the NPRM, with many comments recommending use of the term ''clinical services provider'' as defined by OPA in FPAR. As a result, the Department has revised the final language for 59.5(b)(1) to use the term ''clinical services provider'' instead of ''healthcare provider'' and has revised 59.2 to include the FPAR definition of ''clinical services provider'' in the regulatory text. The FPAR definition for clinical services provider includes ''physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care.''

To ensure consistency between 59.5(b)(1) and 59.5(b)(6) as requested in the public comments, the Department has revised the language for the 2021 rule for *59.5(b)(6)* to, ''Provide that family planning medical services will be performed under the direction of a clinical services provider, with services offered within their scope of practice and allowable under state law, and with special training or experience in family planning.'' This revised language for *§ 59.5(b)(6)* is adopted as final.

59.5(b)(8) Coordination and Use of Referrals and Linkages

In the NPRM, the Department proposed revising section 59.5(b)(8) of the 2000 regulations to add language to include primary healthcare providers in the list of referrals and to state that referrals are to be to providers in close proximity to the Title X site when feasible. The NPRM stated, ''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.''

Comments: The Department received several comments expressing support for revising the provision to include primary healthcare providers in the list of referrals and to require that referrals be to nearby providers, when feasible. One comment expressed support and said that ''referring Title X patients to local primary care physicians would facilitate access to continuous, comprehensive healthcare.'' Several other comments expressed support and stressed the existing collaborative relationships between many HRSA-funded health centers and Title X sites. Comments expressed that ''referral relationships allow the health center and the Title X site to become more familiar with one another's operations and service lines, often serving as a useful precursor to a more integral relationship in the future.''

Response: The Department appreciates the many supportive comments in response to this revised provision. The Department agrees that it is important for Title X clinics to provide referrals and linkages to a wide range of healthcare services to help facilitate access for Title X clients to needed healthcare services beyond family planning. Given that the Department received no comments expressing concern with or opposition to the proposed modification, the Department adopts the language from the NPRM for *§ 59.5(b)(8)* as final without revisions.

§ 59.6 Suitability of Informational and Educational Material

In the NPRM, the Department proposed revising the 2000 regulations by combining requirements specific to the Information and Education Advisory Committee (''Advisory Committee'') that were in sections 59.5(a)(11) and 59.6 and consolidating all of the Advisory Committee information in one place, under section 59.6. The NPRM proposed several revisions to 59.6 to clarify that the regulation applies to both print and electronic materials (in both the title of the section and regulatory text), 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.

Specifically, the NPRM states:

''(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 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 as 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.''

Comments: The Department received one comment in support of the proposed revisions that expressed that ''this will ensure that information and materials provided to clients are appropriate and suitable for the specific communities to be served.'' Another

comment shared specific support for the requirement that grantees provide ''culturally and linguistically appropriate'' materials. One comment opposed to this provision expressed that the language in 59.6 ''remains overly narrow and prescriptive'' and recommended that the language be revised to require ''a Community Advisory Board charged with a broad array of responsibilities to ensure the appropriateness of Title X services for intended communities.'' Another comment opposed ''underrepresented communities'' in composition of the advisory council and claimed that ''to the extent it results in segregation or prioritization of Title X services or committee membership by protected classes such as race, it violates the Constitution and several civil rights laws.'' This same comment also opposed having the advisory committee review materials to certify that they are trauma-informed and inclusive.

Response: The Department appreciates the supportive comment in response to this provision. The role of the Advisory Committee is critically important to ensure that the information and educational materials provided to Title X clients are factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma-informed. Engaging the community and population served in the Advisory Committee itself is a key strategy to inform the grantee about the needs and experiences of the community and population served, and to make sure that the information and education materials are appropriate for the community and population served.

The Department disagrees with the comment that the language in 59.6 is too narrow and prescriptive. The Department believes that the requirements set forth in 59.6 are critical for ensuring that informational and educational materials provided to Title X clients are factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma-informed. In addition, the Title X statute prescribes requirements related to the informational and educational materials developed or made available under the project, including that they ''will be suitable for the purposes of [Title X] and for the population or community to which they are to be made available, taking into account educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials'' (PHS Act sec. 1006(d)(1)), and also prescribes requirements related to the Advisory Committee, including that the ''committee shall include individuals broadly representative of the population or community to which the materials are to be made available'' (PHS Act sec. 1006(d)(2)).

The Department also disagrees with the comment that the regulation is segregating or prioritizing services or committee members. The text of the provision calls for the Committee membership to include ''individuals broadly representative of the population or community for which the materials are intended. . . . Including but not limited to individuals who belong to underserved communities.'' Since all communities served are different, the aim of this provision is to ensure the committee is representative of the community and population served, as required by the statute. The Department disagrees with the opposition to having the Advisory Committee review materials to ensure they are inclusive and trauma-informed. Providing information and educational materials that are inclusive and trauma-informed are a critical component of providing quality, client-centered care.

The Department does not believe that revisions are needed to the regulatory text included in the NPRM. As a result, the Department adopts the language from the NPRM for *§ 59.6* as final with a technical correction to include ''sex characteristics''.

§ 59.7 Grant Review Criteria

In the NPRM, the Department proposed revising section 59.7 of the 2000 regulations to add one additional review criterion that the Department may consider in deciding which family planning projects to fund and in what amount, which is ''the ability of the applicant to advance health equity.'' Adding this new criterion to the 2000 regulations brings the total number of grant review criteria specified in the regulation from seven to eight. Advancing health equity is critical to the mission of the Title X program. The addition of this grant review criterion will help ensure that grant funds are awarded to those applicants who are best able to help the Department in achieving the goal of advancing health equity through the Title X program.

Comments: The Department received several comments in response to this revised provision asking for additional details in future funding opportunities about what the new criterion means and how it will be measured. One comment provided specific examples of how the Department could operationalize the new grant review criterion. Another comment asked the Department to ''develop additional guidance and tools that Title X sites and other healthcare organizations can readily implement'' to meaningfully advance health equity. Still another comment expressed concern that the NPRM did not include an explanation ''for how a Title X project can, in fact, ensure equity in general and specifically in a way that does not lead to actual discrimination based on a protected basis.''

Response: The Department appreciates the comments and recommendations received. The grant review criteria from the 2000 regulation include several criteria aimed at assessing the need, capacity, and ability of the applicant organization, including the relative need of the applicant, the capacity of the applicant to make rapid and effective use of the federal assistance, the adequacy of the applicant's facilities and staff, the relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project, and the degree to which the project plan adequately provides for the requirements set forth in these regulations. In addition, the grant review criteria from the 2000 regulation include two criteria aimed at assessing need in the communities served, including the number of clients, and, in particular, the number of low-income clients to be served; and the extent to which family planning services are needed locally.

The Department believes that adding the new grant review criterion to assess the ability of the applicant to advance health equity is important to enable OPA to more fully assess the extent to which the applicant's project will promote health equity through the Title X services provided. Under 59.2, health equity is defined as ''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.''

Adding a focus on advancing health equity will not lead to discrimination or preferential treatment as expressed by some comments opposed to the NPRM. Rather, including a focus on advancing health equity aims to ensure that all people can actively participate in and benefit from family planning services. By advancing equity across the federal government, we can create opportunities for the improvement of communities that have been historically underserved, which benefits everyone. The federal government's goal in advancing equity is to provide everyone

with the opportunity to reach their full potential.

To measure the ability of an applicant to advance health equity, OPA could assess how the location of planned Title X service sites compares to the need for family planning services within the communities served. OPA also could assess how the applicant plans to provide services in a manner that is culturally and linguistically appropriate. OPA could assess how the project plans to monitor outcomes by clients' income, race, ethnicity, geographic location, etc., as well as how the project plans to address differences in outcomes through the Title X services provided. OPA could also ask applicants to describe the uptake of services by client demographics to identify existing disparities and to describe how they would work to reduce existing disparities in service provision. In addition, some agencies within the Department have incorporated disparity impact statements as a part of the post-grant award process. Disparity impact statements are just one example of a tool that OPA may consider in order to measure demographic, cultural, and linguistic data that identify the population(s) in which health disparities exist and the quality improvement plan designed to address the noted disparities. These are just examples of how this new grant review criterion could be operationalized within future NOFOs.

The Department will provide details on how all grant review criteria will be measured in future NOFOs, including the new grant review criterion on advancing health equity. The Department also plans to develop training and technical assistance products to assist family planning providers in advancing health equity.

In conclusion, the Department adopts the language from the NPRM for *§ 59.7* as final with one technical correction to replace ''his estimate'' with ''an estimate'' to reflect inclusive language.

§ 59.10. Confidentiality

In the NPRM, the Department proposed revising the provision of the 2000 regulations related to confidentiality, which was section 59.11 in the 2000 regulations, but is now section 59.10, to add a widely accepted practice in the Title X community, indicating that reasonable efforts must be made to collect charges without jeopardizing client confidentiality. In addition, the Department proposed 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 was added to ensure that the client understands the implications for using their insurance and the options available for them to maintain confidentiality.

Specifically, the NPRM stated, ''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.''

Comments: The Department received numerous comments in support of this provision and the proposed revisions. Many comments expressed support for restoring ''the confidentiality protections that have been a hallmark of the Title X program.'' Several comments expressed support for allowing ''providers to return to the high standard of confidentiality that all patients, including adolescents, deserve when accessing healthcare services, especially ones as potentially sensitive as family planning and sexual health.'' Several comments also specifically supported the new language on potential disclosure to policyholders.

The Department also received numerous comments requesting further revisions to the regulatory text for 59.10. Numerous comments urged the Department to add language to the regulatory text to clarify that ''Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services.''

Comments underscored that this language has been longstanding guidance from OPA for the Title X program and is included in *OPA Program Policy Notice 2014–01: Confidential Services to Adolescents.* One comment stated, ''We encourage you to take all possible steps when finalizing the rule to ensure that adolescents are treated with the same client-centered approach as all other patients at Title X-funded health centers.'' In addition, many comments generally opposed the removal of language from the regulation that encouraged family participation in the decision of a minor patient to seek family planning services and requested that the language be added back into the final regulation.

Several other comments expressed concern with a new rule from the HHS Office of the National Coordinator for Health Information Technology (ONC) about Electronic Health Records and information blocking. Several comments requested that the Department confirm in the final rule that withholding of sensitive information in compliance with 59.10 would ''fall within the ONC rule's privacy exception and would not constitute information blocking.''

Response: The Department appreciates the comments in support of the revised provision in the NPRM. The Department agrees with comments to add specific language to the final rule regarding adolescent confidentiality to reflect Title X legal requirements. Since 1981, the Title X statute has required that, ''to the extent practical, [grantees] shall encourage family participation'' in Title X projects. 42 U.S.C. 300(a). However, such involvement is not mandatory and grantees are required to protect clients' confidentiality. Specifically with respect to adolescents, courts have for decades recognized minors' rights to receive confidential services under the Title X program. See, *e.g., Planned Parenthood Federation of America, Inc.* v. *Heckler, 712 F.2d 650* (D.C. Cir., 1983) (Title X expressly protects minors' rights to seek services confidentially). *See also OPA Program Policy Notice* 2014–01: Confidential Services to Adolescents.

The Department does not agree that specific language needs to be added to the final rule to clarify the applicability of the ONC rule to Title X. Instead, as described below related to section 59.12, OPA suggests that grantees seek guidance from ONC with respect to the applicability of the information-blocking provision, as ONC administers this rule and, thus, would be in the best position to interpret it. With this revision, the final language in the 2021 rule for 59.10 is, ''(a) 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.

(b) To the extent practical, Title X projects shall encourage family participation.[12] However, Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services.

This revised language for *§ 59.10* is adopted as final.

§ 59.12 Other Applicable Regulations

In the NPRM, the Department included the same regulatory text as had been included in section 59.10 of the 2000 regulations, which is a list of additional HHS regulations that apply to the Title X family planning services program. The NPRM proposed a technical correction to update the list of applicable regulations by adding 45 CFR part 87.

Comments: Many comments that generally support the rule disagree with the proposed technical correction to section 59.12, which includes a reference to 45 CFR part 87 (''Equal Treatment for Faith-based Organizations'') in the list of regulations that apply to the Title X program. Such comments argued that this rule does not apply to Title X because the previous administration explicitly declined to apply this rule to Title X in the faith-based organizations rule issued on December 17, 2020 (s*ee* 85 FR 82037, 82117). Additionally, these comments argued that 45 CFR part 87 does not apply to the Title X program because it is a health services program, and 45 CFR part 87 only applies to social services programs; thus, the reference to this regulation should be removed from section 59.12 of the final rule. Other comments argued that, if the Department is planning to make technical corrections to update the list of regulations that apply to the Title X program, it should take the opportunity to clarify the applicability of 45 CFR part 92 (''Nondiscrimination on the Basis of Race, Color, National Origin, Sex, Age, or Disability in Health Programs or Activities Receiving Federal Financial Assistance and Programs or Activities Administered by the Department of Health and Human Services Under Title I of the Patient Protection and Affordable Care Act or by Entities Established Under Such Title'') as well as the statute under which it was authorized, section 1557 of the Affordable Care Act. These comments stipulated that if the Department makes changes to this regulation in the future, section 59.12 should be updated at that time to include 45 CFR part 92 on this list of applicable regulations.

Comments opposing the rule agreed with the inclusion of 45 CFR part 87 in section 59.12, but questioned why the Department did not include an explanation for deleting references to the now-superseded 45 CFR part 92 (''Uniform administrative requirements for grants and cooperative agreements to state and local governments''). These comments also argued that the Department should include a reference to 45 CFR 88 (''Protecting Statutory Conscience Rights in Health Care; Delegations of Authority'') on the list of applicable regulations, as it will apply to the Title X program once related litigation is resolved.

Response: The Department appreciates the comments addressing the proposed technical corrections to 45 CFR 59.12, but has decided to eliminate that section from the final rule in its entirety. Since the regulations that apply to the Title X program will apply of their own accord, whether or not they are cross-referenced in 42 CFR part 59, subpart A, the Department has concluded that the list of applicable regulations in 59.12 serves no useful purpose and, in contrast, may be misleading. The Department is concerned that since regulations are amended frequently, any current listing of applicable regulations could soon become outdated. Additionally, while all of the longstanding Departmental regulations, such as those prohibiting discrimination, still apply, the Department is concerned that the 59.12 list may provide a false impression that only the regulations included in this section apply to the Title X program. The Department believes that Title X grantees can more accurately assess which regulations apply to the Title X program by reviewing the regulations at issue and, in some instances, seeking guidance from the agencies which administer them. For example, several comments, in the context of addressing the confidentiality provisions, questioned the applicability of the information-blocking provisions in the ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' rule (85 FR 25642, May 1, 2020). As that rule is administered by the HHS Office of the National Coordinator for Health Information Technology (ONC), ONC would be in the best position to interpret that rule.

Most importantly, OPA provides information to Title X grantees regarding which regulations apply to their Title X programs and is committed to providing ongoing guidance and assistance as questions arise. OPA includes information about applicable regulations in grant documents, such as NOFOs and Notices of Award, and in technical assistance webinars. Given that grantees can receive accurate and up-to-date information from OPA about which regulations apply to their Title X programs, the Department has decided to delete section 59.12 from the final rule.

III. Regulatory Impact Analysis

A. Introduction

The Department has examined the impact of the final 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 the Department 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). The Department believes that this final rule is not an economically significant regulatory action as defined by Executive Order 12866 because it will not result in annual effects in excess of $100 million.

The Regulatory Flexibility Act requires the Department to analyze regulatory options that would minimize any significant impact of a rule on small entities. The final rule will lessen

[12] 42 U.S.C. 300(a) states: ''To the extent practical, entities which receive grants or contracts under this subsection shall encourage family participation in projects assisted under this subsection.''

administrative burdens for grantees of all sizes. Therefore, the Secretary certifies that the final rule will 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 the Department 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 final rule will 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 final 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 final 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 final rule, many states and local health departments will support the policies contained in this final rule, and that it will increase participation by states (many of which withdrew as a result of the 2019 rule).

B. Summary of Costs, Benefits and Transfers

This final rule will revise the regulations that govern the Title X family planning services program by revoking the 2019 rule and readopting the 2000 regulations with several modifications. This approach will 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 final rule will increase the number of grantees receiving Title X funds. In turn, the additional service sites supported by funding will result in additional clients served under the program. These clients receive access to contraception, and public health screening including clinical breast exams, Papanicolau (Pap) testing, and testing for STIs. These services result in improved family planning and birth spacing, earlier detection of breast and cervical cancer, and earlier detection of sexually transmitted infections including chlamydia, gonorrhea, syphilis, and human immunodeficiency virus (HIV), all of which correlate to net savings for the government. This screening and testing can result in significant cost savings from earlier treatment and other interventions. This final rule will also increase the diversity of grantees receiving funds, including geographic diversity to states that do not currently have a Title X grantee.

The final rule will 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 rule.

C. Comments on the Preliminary Economic Analysis and Our Responses

On April 15, 2021, the Department issued a proposed rule to revise regulations relating to the Title X program. The Department prepared a preliminary regulatory impact analysis (PRIA) for the proposed rule. Many comments were outside the scope of this rule. The paragraphs below describe and respond to the comments received on the PRIA.

Summary of comments addressing the PRIA that were generally opposed to the rulemaking:

Several of the comments suggested that the Department used flawed data in its forecasts or failed to account for COVID–19 in the PRIA. Several of the comments suggested that the Department does not have data to assess the effect of the 2019 rule, arguing that COVID–19 is a complicating factor. Several comments noted that clients served under the Title X program declined between 2009 and 2018, suggesting long-term trends can account for some of the reduction in clients served under the 2019 rule. Other comments noted that long-term demographics trends are responsible for the decline in services, such as rise in median household income, rise in individuals with private insurance, and more diverse options available in the healthcare market.

Several of the comments suggested that grantees withdrawing from the program may not have resulted in a decline in services, and that some services were continued with state and private funds. Several comments pointed out that some states saw an increase in clients after the 2019 rule. One comment argued that, when one of two Ohio grantees left the program, the remaining grantee prevented a gap in coverage.

Responses to comments addressing the PRIA that were generally opposed to the rulemaking:

The primary estimate of the baseline Title X service grantees, subrecipients, service sites, and clients served are derived from calendar year 2019 figures, which predate COVID–19. The PRIA's estimate of the likely effect of the proposed rule is to gradually return to the level of grantees, subrecipients, service sites, and clients that the program supported in calendar years 2016 to 2018, which also predates COVID–19. COVID–19 may complicate attempts to precisely estimate the magnitude of the effect of the 2019 rule on the Title X program, but pre-pandemic data from calendar year 2019 preceding COVID–19 reveals a significant drop-off in grantees, subrecipients, service sites, and clients supported by the program, which are contrary to the predictions in the 2019 rule.[13] The Department acknowledges the uncertainty in the forecast of the baseline scenario of no regulatory action by including a sensitivity analysis in the PRIA. The upper-bound forecast of 3,095,666 clients served annually by the Title X program under the baseline scenario of the 2019 rule is well below the approximately 4 million clients served during calendar years 2016 to 2018.

The Department disagrees with the suggestion that long-term trends drove the reduction in clients served under the 2019 rule. Between calendar years

[13] If adjustment to the requirements of the 2019 rule took time for grantees and prospective new grantees (and possibly continues to do so), then immediate post-issuance difficulties in obligating Title X funds could ease over the years, which would in turn lead to a trend back toward pre-2019 Title X service levels even in the analytic baseline. However, the effects of the COVID–19 pandemic would obscure, in the available data, whether such trends are present or absent.

2009 and 2014, the number of clients reported served by the Title X program declined from 5.2 million to 4.1 million, with an average annual decline in clients served by about 211 thousand per year. Between calendar years 2014 and 2018, the number of clients served fell more gradually, with an average annual decline in clients served of about 48 thousand per year. In calendar year 2019, the number of clients served fell by about 844 thousand. The Department believes it is appropriate to attribute the bulk of the reduction in clients served during calendar year 2019 to the 2019 rule.

The Department agrees with the comments that state and private funding likely averted some of the public health consequences that would have otherwise occurred in the immediate time period following implementation of the 2019 rule. The Department acknowledged this limitation in the PRIA and noted that one effect of the proposed rule would be ''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).'' The Department noted that several states contributed emergency or one-time funds. It is not clear whether state or private funding will be available for the full-time horizon of the analysis, which begins in calendar year 2022.

While the PRIA reported that ''seven states (CO, DE, KY, ND, NM, NV, TX) experienced an increase in the number of Title X *clinics* after the 2019 regulatory change,'' this observation is different than the claim about increases in *clients.* Colorado, Delaware, Kentucky, North Dakota, New Mexico, and Texas all saw declines in the number of female users served in 2019 and 2020 compared to 2018 (male users saw declines as well). Nevada increased the number of female users from 9,236 in 2018 to 11,156 in 2019, and again to 11,190 in 2020. The specific claim about Ohio cannot be supported with the available data. Ohio Title X grant recipients reported 83,497 female clients served in 2018, dropping to 68,669 in 2019, and dropping further still to 27,322 in 2020. Similarly, given the implementation of the 2019 rule occurred midway through the calendar year, the 2019 data likely mask the full negative impact of the 2019 rule that year.

Summary of comments addressing the PRIA that were generally supportive of the rulemaking:

Several comments agreed with the observation in the PRIA that the 2019 rule resulted in a reduction in grantees and clients served under the Title X program. Several comments gave examples of states or other entities that saw a decrease in clients served. Several comments discussed the disproportionate impact the 2019 rule had on low-income individuals, individuals in rural communities, people of color, and other populations. Several comments discussed the impact of the 2019 rule on the quality of family planning services outside the Title X program, as well as the financial impact on clients receiving services outside the Title X program. Several comments argued that other sources of funding besides the Title X program, including state funding, would not be reliable sources of funding in the future.

Responses to comments addressing the PRIA that were generally supportive of the rulemaking:

The Department appreciates the specific examples provided in comments and agrees with the assessment that the 2019 rule resulted in a reduction in grantees and clients served at the national level, and that these effects were more pronounced in certain regions, communities, and demographic groups. The PRIA concluded, and this regulatory impact analysis affirms, that this rulemaking will likely result in an increase in clients served within the Title X program compared to a baseline of no further regulatory action. The Department also maintains the finding in the Further Discussion of Distributional Effects Section in the PRIA in this analysis that the effects of this final rule will accrue approximately in proportion with income and race and ethnicity figures typically served by the Title X program.

The Department agrees that services provided outside the Title X program were not always identical to Title X-funded services. While some providers were able to provide reproductive health services in the absence of Title X funding, comments disclose that they were not providing the same services provided in Title X program. Specifically, commenters suggested that services provided outside of the Title X program did not follow the same standards as in Title X, and that the schedule of discounts and subsidies were not applied as required in the Title X program.

The Department agrees with the comments that other sources of funding besides the Title X program may not be reliable sources of funding over calendar years 2022 through 2026, the time horizon of the PRIA and this final regulatory impact analysis. The Department has expanded the discussion of this point in the analysis.

Comments Received in Response to Executive Order 13132 Federalism Review

Comment: Several comments were critical of the Regulatory Impact Analysis, stating that it ignores the federalism implications of the proposed rule. These comments argued that the proposed rule compels states to adopt policies that conflict with their own laws, particularly with regard to subrecipient restrictions that several states have put in place, and other state-described ''integrity requirements.'' Additionally, several comments raised concerns that the Department did not extend the comment period to specifically study the federalism impacts. Other comments expressed a belief that the proposed rule would have no federalism effects as it is a discretionary grant program in which states can choose to participate or not.

Response: While the Department agrees that states have an interest in enforcement of their statutes, it believes that this final rule respects federalism, as it does not interfere with state laws. As noted previously, the Department has decided not to include a subrecipient nondiscrimination provision in the final rule at this time and, thus, concerns raised by these comments about harm to state program integrity requirements or a need to extend the deadline to assess the impact of this harm are now moot.

Additionally, while states are eligible to apply for Title X grants, the Title X statute was not enacted as a federal-state cooperative statute, as is made clear by the eligibility of nonprofit, private entities to apply for grants directly. And, since the Department is free to attach reasonable conditions to the awarding of funds to carry out best its statutory goals and these conditions only apply to the receipt of federal Title X funds, states that object to the rule requirements or believe that there is a conflict with state law priorities are free to opt out of the federal grant program. Thus, the final rule does not interfere with state laws or have federalism implications, as state laws are only implicated if those states with contrary state laws wish to apply for Title X funds.

D. Summary of Changes

The Department has revised the economic analysis of impacts to account for additional information, newer data, and in response to comments. Many of the estimates and Tables have been updated to account for minor revisions to the calendar year 2020 data. For example, Table D1 now identifies 75

Grantees, 867 Subrecipients, 3,031 Service Sites, and 1,536,743 Clients Served, compared to 73 Grantees, 803 Subrecipients, 2,682 Service Sites, and 1,536,744 Clients Served reported in the PRIA. These revised estimates carry through to other estimates and Tables.

As described in greater detail in the Preamble, the final rule adopts eight of the fourteen revisions initially proposed in the NPRM and nine of the ten technical corrections initially proposed in the NPRM as final without additional changes. Based on the comments received in response to the NPRM and a subsequent, new interpretation by the Department since the NPRM was issued, the final rule includes nine additional revisions and six additional technical corrections compared to what was proposed in the NPRM. This analysis has been updated to be consistent with these changes, but these changes do not substantially alter the estimates of the quantified economic impacts.

E. Final Economic Analysis of Impacts

a. Background

The Title X 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; 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 funding.[14]

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 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 rule would result in ''enhanced patient service and care.'' Contrary to these predictions, during the initial period of the 2019 rule's implementation, the policy appears to have had the opposite effect. As described in greater detail in the Baseline section, the restrictions included in the 2019 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. The Department is compelled to act quickly to ameliorate these negative consequences by promulgating this final rule since the Title X program serves a low-income population that is particularly vulnerable to losing access to these services. This final rule is needed to improve the functioning of government and the effectiveness of the Title X program.

c. Purpose of the Rule

This final rule will revise the regulations that govern the Title X family planning services program by revoking the 2019 rule and readopting the 2000 regulations with several modifications. This approach will 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 Rule

The Department adopts a baseline that assumes the requirements of the 2019 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, the Department developed an annual forecast of grantees, subrecipients, service sites, and total clients served. The key inputs to the forecast are historical data on Title X service grantees. For calendar years 2016 to 2020, this information is summarized in the 2020 Title X Family Planning Annual Report.

TABLE D1—TITLE X SERVICE GRANTEES

Year	2016	2017	2018	2019	2020
Grantees	91	89	99	100	75
Subrecipients	1,117	1,091	1,128	1,060	867
Service Sites	3,898	3,858	3,954	3,825	3,031
Clients Served	4,007,552	4,004,246	3,939,749	3,095,666	1,536,743

Source: Title X Family Planning Annual Report, 2020: Exhibit A–2a.

The data for calendar years 2016–2019 included all grantees, subrecipients, and service sites operating at any time during the year. The implementation of the 2019 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 more than 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 2020 approximate that only 1.5 million clients were served. However, this figure likely represents an underestimate for a typical year of the

[14] Does not include supplemental funding.

program under the current regulations since services were likely disrupted by the ongoing public health emergency.

As the primary estimate, the Department adopts 2,512,066 clients served as the baseline annual impact of Title X under the policies of the 2019 rule. This 2.5 million-figure corresponds to the number of clients served in 2019 among remaining grantees as of March 2021. For comparison, this primary estimate represents a 37 percent reduction in clients served compared to the average of clients served from 2016 to 2018. In the Uncertainty and Sensitivity Analysis Section, the Department adopts 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 the baseline forecast for the same categories of historical data presented in Table D1. The Department adopts the current count for grantees, subrecipients, and services sites and assumes constant funding and that these figures will be constant over the time horizon of this analysis.

TABLE D2—BASELINE FORECAST OF TITLE X SERVICES

Baseline forecast	Annual
Grantees	75
Subrecipients	867
Service Sites	3,031
Clients Served	2,512,066

In addition to the reduction in grantees, subrecipients, service sites, and total client served, the Department notes 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.[15]

In line with the reduction in clients served under the 2019 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 percent reduction, and for hormonal implants, a 21 percent reduction. These percentages are similar in magnitude to the 21 percent 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 STIs decreased by 256,523 for chlamydia, 625,802 for gonorrhea, and 77,524 for syphilis. Appendix A of the FPAR contains national annual trends for many of the services discussed above. The reductions in services reported in 2019 compared to 2018 represent the largest year-over-year reductions in services for each reported measure since at least 2014. Similar to the earlier discussion relating to long-term trends relating to clients, we attribute the bulk of the reductions to these services to the 2019 final rule.

For the forecast of services provided under the baseline scenario, the Department adopts the percentage of clients receiving each service in the 2019 Title X Family Planning Annual Report. For example, in 2019, about 23 percent of female clients received a clinical breast exam. The Department assumes the same share of clients will be served by Title X for screening and STI testing. Table D3 reports the best estimate of the annual services provided under the baseline scenario. These services are described 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.

The Department predicts that the main effect of the final rule would be to return to Title X program impact levels observed prior to the 2019 rule. The estimates of the long-run equilibrium of grantees, subrecipients, service sites, and total clients served are informed by the data from 2016 to 2018, the last three years of data that are unaffected by the declines experienced following the 2019 rule. Specifically, the Department adopts the average across these three years as the long-run estimates. These averages are 93 grantees, 1,112 subrecipients, 3,903 service sites, and approximately 4.0 million clients served.

To complete the forecast of the policy scenario, the Department assumes 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 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 the NPRM issued on April 15, 2021, were finalized. In year one, following the effective date of the proposed rule, the number of clients served would increase to approximately 3.2 million. In year two, this number would increase again to approximately 4.0 million and remain constant for the duration of the analysis. These figures are presented in Table D4. The Department acknowledges uncertainty in this estimate and includes 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	84	93	93	93	93
Subrecipients	990	1,112	1,112	1,112	1,112
Service Sites	3,467	3,903	3,903	3,903	3,903
Clients Served	3,247,958	3,983,849	3,983,849	3,983,849	3,983,849

[15] 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.

To characterize the effect of the final rule, the Departments compares 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 one after this rule is effective, the number of clients served would increase by approximately 736,000 as compared to the baseline scenario. Approximately 88 percent of clients served in 2016 to 2018 are female, and the Department uses 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	9	18	18	18	18
Increase in Subrecipients	123	245	245	245	245
Increase in Service Sites	436	872	872	872	872
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 STIs. These screenings and testing can identify treatable conditions, improving the quality of life and extending the lives of beneficiaries. In the case of STIs, additional testing and corresponding earlier treatment can reduce the likelihood of worse health outcomes and future infertility resulting from those infections. This final rule will expand service to socioeconomically disadvantaged populations, most of whom are female, low-income, and young. The Department discusses 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.[16] 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 publicly funded family planning services. The Department applies 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 one, the analysis reflects multiplying 735,892 clients by 88 percent to yield 648,996 female clients. Among female clients, approximately 14 percent indicate they are not using a method of contraception, according to figures in the 2019 Title X Family Planning Annual Report. The analysis reduces the potential number of clients that would potentially reduce the likelihood of an unintended pregnancy by 14 percent to yield 558,205 clients expected to benefit from a contraceptive method. Approximately 47 percent of unintended pregnancies result in births, 34 percent in abortion, and 19 percent in a miscarriage.[17]

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
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 pregnancies increase the risk for poor maternal and infant outcomes. Women who give 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 care early in pregnancy.[18] [19]

Title X funding recipients also perform preventive health services such as cervical and breast cancer screening, and testing for STIs, including chlamydia, gonorrhea, syphilis, and HIV. Table D7 presents the effect of the final 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 approximately 23 percent for clinical breast exams, of which five percent result in a referral for further evaluation; and 20 percent for Pap testing, of which 13 percent with a result of atypical squamous cells (ASC) that require further evaluation and possibly

[16] 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.

[17] 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.

[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.*

treatment, and one percent of which have a high-grade squamous intraepithelial lesion (HSIL) [20] or higher, indicating the presence of a more severe condition.

Clinical breast exams can identify patients requiring further evaluation of an abnormal finding. Pap tests (or pap smear tests) can detect precancers and cervical cancer cells and can also be tested for viral infections that can turn into cervical cancer. At a population level, these screenings save lives by helping patients identify cancer earlier and by preventing other conditions from developing into cancer.

TABLE D7—EFFECT OF THE FINAL 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 D8 presents the effect of the proposed rule on Title X-associated testing for STIs among female clients. These are calculated by adopting estimates that 49 percent of women are tested for chlamydia, 55 percent for gonorrhea, 19 percent for syphilis, and 28 percent for HIV. Table D9 presents the same information for men. The share of male clients tested for these infections are the following: 61 percent for chlamydia, 68 percent for gonorrhea, 39 percent for syphilis, and 53 percent 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 D10 reports the additional total clients tested for STIs under Title X. 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 percent of all HIV tests performed. Under the final rule, testing under Title X is estimated to identify an additional 873 positive cases of HIV in the first year. In subsequent years, this estimate increases to 1,745. Testing for these STIs 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

Additional services of the type provided under Title X will likely result in reduced costs to taxpayers in line with a reduction in unintended pregnancies, pre-term and low birth weight births, STIs, infertility, and

[20] HSIL is the abnormal growth of certain cells on the surface of the cervix.

cervical cancer. One report estimates that each dollar spent on these services results in a net government saving of $7.09.[21] 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 STIs that would have resulted in more serious outcomes, including infertility, cancer, and death.

In addition to the effects described above, the final rule will 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.'' [22] 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.[23] As of a result of the Affordable Care Act's contraceptive coverage requirement, Title X can play a critical role, helping provide insured clients with access to contraception without cost-sharing alongside its longstanding role supporting contraceptive access without cost-sharing for Medicaid beneficiaries and those whose incomes are equal to or less than 100 percent of the federal poverty level (FPL), which allows these clients to experience these and other positive outcomes associated with access to contraception.

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 seven 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.[24] 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.[25]

The tables above present 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 the analysis initially focuses on clients served and services provided by Title X-funded sites. To properly account for the net effect of the final rule when comparing the baseline scenario to the policy scenario, the Department 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 final rule may include:

- Transfers between grantees and prospective 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 final 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, citing the 2019 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).[26] 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.

The Department received a number of public comments drawing connections between the short-term effects of the 2019 rule and long-term potential for a reduction in total family planning clients served, not limited to the Title X program. For example, two states (NY, WA) reported receiving emergency reserve funds through state funding in order to sustain the level of care that they provided under Title X; however, both noted that this funding is not reliable and sustainable from year to year. One grantee in Maine reported keeping all clinics open and operating with the use of the association's reserve funds and through private fundraising, which was an unsustainable and impractical task to continue. Another provider also reported fundraising to maintain care while also noting the administrative burden; however, many health centers were forced to close or reduce hours due to the lack of Title X funding. The same organization also reported the need to scale back or eliminate education and outreach programs in many states. These public comments suggest that the long-term effect of the 2019 rule would have been to reduce clients served and family planning services provided beyond the Title X program.

In addition to the effects on the quantity of services, several comments discussed the effects on the quality of services provided. One organization and the Attorneys General of 22 states and the District of Columbia noted that losing Title X providers had a negative effect on patients that sought care. They argued that it was more difficult for patients to obtain culturally competent care and that the requirements of the 2019 rule placed a burden on providers and their method of pregnancy counseling, as they were ''inconsistent with the standards of care and required incomplete and confusing lists and referrals for pregnant clients.'' Finally, several states reported that while their efforts were refocused to recruiting and

[21] 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.

[22] 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.

[23] 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.

[24] 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.

[25] Emily Sohn (2020). ''Strengthening society with contraception.'' *Nature* 588, S162–S164.

[26] 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.*

onboarding new providers into their Title X network under the 2019 rule, they faced resistance or a lack of interest, and their provider networks did not increase under the 2019 rule, continuing to adversely impact the communities they serve.

These public comments suggest that the effects identified in this regulatory impact analysis for the time horizon covering calendar year 2022 through 2026 are unlikely to be limited to a reversal of what was observed immediately after issuance of the 2019 final rule. The Department acknowledges persistent challenges with clearly disaggregating the effects that represent transfers from effects that represent benefits and costs as a result of this final rule; however, it is important to reiterate that total Title X funding remained unchanged upon issuance of the 2019 final rule and will be unchanged as a result of this final rule, so while some entities receive less funding (and they and their clients experience regulation-induced ancillary harm, which can manifest itself in the quantity or quality of associated services), other entities receive more funding. The Department maintains the analytical approach of estimating the number of additional clients served and services provided under the Title X program under this final rule, while acknowledging challenges in quantitatively assessing whether this final rule will result in additional clients served and family planning services provided, not limited to the Title X program, as compared to the baseline of no further regulatory action. Despite such uncertainty, analysis based on evidence available at this time generally supports a conclusion that the projections accompanying the 2019 rule have not been borne out.

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 2019 figures, 64 percent of clients have income under 101% of the federal poverty level; 14 percent between 101 percent FPL and 150 percent FPL; seven percent between 151 percent FPL to 200 percent FPL; three percent between 201 percent FPL and 250 percent FPL; seven percent over 250 percent FPL; and five percent have an unknown or unreported income level. Among program clients, 33 percent self-identified as Hispanic or Latino of all races; three percent as Asian and Not Hispanic or Latino; 22 percent as Black or African American and Not Hispanic or Latino; 32 percent as White and Not Hispanic or Latino; five percent as Other or Unknown and Not Hispanic or Latino; and four percent are Unknown or Not Reported. Furthermore, Title X requires Title X projects to provide services for adolescents without required parental consent, thereby making Title X a critical source of sexual and reproductive healthcare for young people. In 2019, two percent of program clients were younger than 15, and eight percent were younger than 18. Additional information about the number and distribution of all family planning clients by age and year are available in Exhibit A–3a of the 2019 Family Planning Annual Report. The benefits of revoking the 2019 rule would likely accrue proportionally with these income and race and ethnicity figures. The costs of revoking the 2019 rule would likely accrue proportionally to the income and other demographics of the general public.

This final rule will also likely have important geographic effects. As described in greater detail in the Baseline section, six states currently have no Title X services, and six additional states have limited Title X services. This final rule is expected to 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 the forecast of the baseline number of clients served. The Department acknowledges the uncertainty in this baseline and has performed a sensitivity analysis to quantify its importance. For the primary baseline, the analysis uses 2.5 million annual clients of Title X services, which corresponds to the number of clients in calendar year 2019 among remaining grantees. For its sensitivity analysis, the Department investigates the effect of the proposed rule compared to a baseline with 1.5 million clients, corresponding to the estimates for 2020. For comparison, the analysis reviewed 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 withdrew from the Title X program following the 2019 rule.

Table F1 presents the number of clients served under different assumptions of the baseline. The analysis also recalculates the number of clients served for the final 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 2022 under the final rule is lower for the lower-bound scenario than the primary baseline. Similarly, the number of clients served under the final rule is 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	1,536,743	3,095,666	3,247,958	2,760,296	3,539,758
2023	2,512,066	1,536,743	3,095,666	3,983,849	3,983,849	3,983,849
2024	2,512,066	1,536,743	3,095,666	3,983,849	3,983,849	3,983,849
2025	2,512,066	1,536,743	3,095,666	3,983,849	3,983,849	3,983,849
2026	2,512,066	1,536,743	3,095,666	3,983,849	3,983,849	3,983,849

Table F2 calculates the effect of the final rule under different baseline assumptions. These estimates are reported by year, as well as in present value and annualized for the five-year time horizon of the analysis, applying a three percent and a seven percent discount rate. Under the lower-bound baseline scenario, the final rule will have about a 66 percent greater impact on the number of clients served in annualized terms under the primary baseline scenario. Under the upper-bound baseline scenario, the final rule will have approximately a 64 percent lesser impact.

TABLE F2—EFFECT OF THE PROPOSED RULE ON TITLE X CLIENTS 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	2,447,106	888,183
2024	1,471,783	2,447,106	888,183
2025	1,471,783	2,447,106	888,183
2026	1,471,783	2,447,106	888,183
PDV, 3%	6,025,877	10,019,113	3,636,461
PDV, 7%	5,346,852	8,890,110	3,226,687
Annualized, 3%	1,315,778	2,187,719	794,038
Annualized, 7%	1,304,047	2,168,215	786,959

As discussed earlier, the Department acknowledges uncertainty in how quickly the Title X program will be able to restore service to levels experienced prior to the declines associated with the 2019 rule. The primary analysis adopts a two-year phase for grantees, subrecipients, service sites, and clients served to reach the 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 final 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 final rule. Therefore, as a second sensitivity analysis, the Department presents estimates that adopt alternative assumptions about the length of time it will take to reach the long-run equilibrium estimates. Table F3 presents the primary estimates of clients served, based on a two-year phase-in, estimates without a phase-in, and estimates with a three-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 F4 calculates the effect of the final rule with different phase-in assumptions. These estimates are reported by year, as well as in present value and annualized for the five-year time horizon of the analysis, applying a three percent and a seven percent discount rate. Compared to the primary estimates, the assumption of no phase-in yields annualized effects of the final rule that are approximately 12 percent higher. Assuming a three-year phase-in yields annualized effects that are about 12 percent lower than the primary estimates.

TABLE F4—EFFECT OF THE PROPOSED RULE ON TITLE X CLIENTS 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

The Department analyzed two alternatives to the approach under the final rule. The Department considered one option to maintain many elements of the 2019 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 rule. Second, the Department considered revising the 2019 rule by readopting many elements of the 2000 regulations, but adopting additional flexibilities for grantees and reducing programmatic oversight. However, experience suggests the compliance regime as it existed prior to the 2019 rule was effective.

IV. Environmental Impact

The Department has 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.

V. Paperwork Reduction Act

This final 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. No public comments were provided on the proposed information collections for § 59.4, 59.5, and 59.7 proposed in the NPRM. OMB filed comment on this NPRM and assigned OMB Control Number 0970–0211. As previously stated in the preamble, the final rule is revoking the 2019 final rule in its entirety. As a result, the final rule does not include information data collection required under § 59.5(a)(12) to provide documentation or assurance to HHS of a plan to comply with state notifications laws, and it does not include the requirement under § 59.5(a)(13) to report information to HHS on subrecipients. However, additional information collection was identified related to § 59.4, 59.5, and 59.7. The final rule is revising the information collections to reflect the additional estimated burden for the Title X grant requirements under § 59.4, 59.5, and 59.7. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 1.

§ 59.4 requires Title X grant applicants to describe how the proposed project would satisfy the regulatory requirements for the Title X program in their applications, including the specific project requirements under § 59.5 and the grant review criteria specified under § 59.7. We estimate that the time necessary for each Title X applicant to include this information in their grant applications would be 70 hours. All other reporting burden associated with grant applications is already approved via existing *Grants.gov* common forms.

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. The burden for describing the Title X grant requirements is the cost for each applicant to include this information in their grant applications. The labor cost would consist of a medical and health service manager spending an average of 70 hours writing and incorporating the Title X program information in their grant applications. The Department estimates the number of applicants at 136, based on the number of eligible applicants who applied to the Title X national grant competition before the 2019 final rule was in effect. The mean hourly wage (not including benefits and overhead) is $55.37 per hour for the medical and health service manager.[27] The labor cost per application is $3,875.90. ($55.37 × 70 hours), and the total labor cost is $527,122.40 ($3,875.90 × 136 applications).

TABLE 1—ESTIMATED BURDEN FOR DESCRIBING THE TITLE X GRANT REQUIREMENTS IN THE GRANT APPLICATION FOLLOWING PUBLICATION OF THE FINAL RULE

Regulation burden	OMB control No.	Applicant responses	Hourly rate ($)	Burden per response (hours)	Total annual burden (hours)	Labor cost of application ($)
Title X Grant Requirements	0970–0211	136	55.37	70	9,520	527,122.40
Total cost						527,122.40

List of Subjects in 42 CFR Part 59

Family planning, Grant programs-health, Health professions, Abortion, Birth control, Title X.

Xavier Becerra,

Secretary, Department of Health and Human Services.

42 CFR Part 59

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 revised to read as follows:

Subpart A—Project Grants for Family Planning Services

Sec.

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

Subpart A—Project Grants for Family Planning Services

§ 59.1 To what programs do these regulations 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. 300) 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.

Clinical services provider includes physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related

[27] 2019 labor costs for medical and health service managers, *https://www.bls.gov/oes/2019/may/oes119111.htm.*

preventive health, and basic infertility care.

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 services, which includes Food and Drug Administration (FDA)-approved contraceptive products 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 all persons have 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.

Inclusive is when 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 (HHS) 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 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, Wake, 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 prescription to the client for their method of choice or referrals to another provider, as requested.

(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]

(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 in a manner that does not discriminate against any client based on religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status.

(5) Not provide abortion as a method of family planning.[2] A project must:

(i) Offer pregnant clients the opportunity to be provided information

[1] 42 U.S.C. 300a–8 provides that any officer or employee of the United States, 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 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.

[2] Providers may separately be covered by federal statutes protecting conscience and/or civil rights.

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 percent of the 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.

(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 clinical services provider, examination, prescription and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, 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 clinical services provider, with services offered within their scope of practice and allowable under state law, and 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 their 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 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, sex characteristics, 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;

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

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

(v) 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 an 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 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.

(a) 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.

(b) To the extent practical, Title X projects shall encourage family participation.[3] However, Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services.

§ 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.

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[3] 42 U.S.C. 300(a).