No. 19-35386

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

STATE OF OREGON et al.,
Plaintiffs-Appellees,

v.

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

AMERICAN MEDICAL ASSOCIATION et al.,
Plaintiffs-Appellees,

v.

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

On Appeal from the United States District Court for the District of Oregon, Nos. 19-cv-317, 19-cv-318 (McShane, J.)

ANSWERING BRIEF OF PLAINTIFFS-APPELLEES AMERICAN MEDICAL ASSOCIATION, OREGON MEDICAL ASSOCIATION, PLANNED PARENTHOOD FEDERATION OF AMERICA, INC., PLANNED PARENTHOOD OF SOUTHWESTERN OREGON, PLANNED PARENTHOOD COLUMBIA WILLAMETTE, THOMAS N. EWING, M.D., AND MICHELE P. MEGREGIAN, C.N.M. FOR AFFIRMANCE OF THE PRELIMINARY INJUNCTION

PAUL R.Q. WOLFSON
KIMBERLY A. PARKER
ALBINAS J. PRIZGINTAS
JOSHUA M. KOPPEL
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
(202) 663-6000

ALAN E. SCHOENFELD
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800
alan.schoenfeld@wilmerhale.com

Counsel for Planned Parenthood Federation of America, Inc., Planned Parenthood of Southwestern Oregon, Planned Parenthood Columbia Willamette, Thomas N. Ewing, M.D., and Michele P. Megregian, C.N.M.

ADDITIONAL COUNSEL ON INSIDE COVER

June 28, 2019

JEREMY D. SACKS
PER A. RAMFJORD
KENNON SCOTT
STOEL RIVES LLP
760 SW Ninth Avenue, Suite 3000
Portland, OR 97205
Tel.: (503) 224-3380
Fax: (503) 220-2480
jeremy.sacks@stoel.com
per.ramfjord@stoel.com
kennon.scott@stoel.com

Counsel for All Plaintiffs

HELENE T. KRASNOFF
CARRIE Y. FLAXMAN
PLANNED PARENTHOOD
FEDERATION OF AMERICA, INC.
1110 Vermont Avenue, NW, Suite 300
Washington, D.C. 20005
Tel.: (202) 973-4800
Fax: (202) 296-3480
helene.krasnoff@ppfa.org
carrie.flaxman@ppfa.org

Counsel for Planned Parenthood Federation of America, Inc., Planned Parenthood of Southwestern Oregon, Planned Parenthood Columbia Willamette, Thomas N. Ewing, M.D., and Michele P. Megregian, C.N.M.

BRIAN D. VANDENBERG
LEONARD A. NELSON
ERIN G. SUTTON
AMERICAN MEDICAL ASSOCIATION
Office of General Counsel
300 N. Wabash Avenue
Chicago, IL 60611
Tel.: (312) 464-5532
Fax: (312) 224-6924
brian.vandenberg@ama-assn.org
leonard.nelson@ama-assn.org
erin.sutton@ama-assn.org

Counsel for American Medical Association and Oregon Medical Association

MARK BONANNO
OREGON MEDICAL ASSOCIATION
General Counsel
11740 SW 68th Parkway, Suite 100
Portland, OR 97223
Tel.: (503) 619-8117
Fax: (503) 619-0609
mark@theoma.org

Counsel for American Medical Association and Oregon Medical Association

CORPORATE DISCLOSURE STATEMENT

Under Federal Rule of Appellate Procedure 26.1, the corporate Plaintiffs—the American Medical Association; the Oregon Medical Association; Planned Parenthood Federation of America, Inc.; Planned Parenthood Southwestern Oregon; and Planned Parenthood Columbia Willamette—disclose that they have no parent corporation, nor is there a publicly held corporation that owns 10% or more of their stock.

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INTRODUCTION

This case involves a challenge to an HHS regulation that would warp and decimate a public health program that provides millions of Americans critical and often life-saving care every year. Congress enacted Title X in 1970 to ensure that all individuals, especially those with low incomes, have access to reproductive health care. The program has been an extraordinary success. Title X has helped reduce unintended pregnancy and abortion rates to "historic lows" and has provided millions of screenings for cancer, sexually transmitted infections, and HIV. ER8.

HHS's Final Rule threatens to undo that progress. *See generally* 84 Fed. Reg. 7,714 (Mar. 4, 2019). The Rule would require, among other things, that Title X providers withhold information about abortion from pregnant patients, even if a patient asks for that information and even if an abortion is in her best medical interest—and would also require those providers to force on their patients information about non-abortion options they do not want or need. Because those requirements violate fundamental medical ethics, the Rule would compel many providers to leave Title X. In particular, Planned Parenthood—which alone serves approximately 40% of *all* Title X patients—would be forced to withdraw from the program. And the Rule would impose onerous separation provisions requiring providers to establish separate facilities and to employ duplicative personnel and

medical records if they engage in virtually any abortion-related activity. Those separation requirements are both cost-prohibitive and harmful to patient health but have no demonstrated benefit to the integrity of the program.

Immediately after HHS issued the Rule, 21 States and the District of Columbia filed suit. So did the American Medical Association, Planned Parenthood, and the National Family Planning & Reproductive Health Association, among others. Those critical Title X stakeholders unanimously highlighted that the Rule would have devastating consequences for themselves, patients, and public health.

On an extensive record and after thorough briefing and argument, the district court correctly ruled that Plaintiffs are likely to prevail on their challenges to the Rule. The Rule is contrary to law. In the Nondirective Mandate, enacted by Congress every year since 1996 in annual appropriations acts, Congress has required that all pregnancy counseling provided by Title X projects be "nondirective." But the Rule requires Title X projects to steer patients away from abortion and toward carrying a pregnancy to term. And in §1554 of the Affordable Care Act, Congress has forbidden HHS from promulgating "any regulation" that would create unreasonable barriers to care, impede timely access to care, interfere with patient-provider communications, or violate medical ethics. But the Rule would do all of those forbidden things. The Rule is also arbitrary and capricious.

In particular, HHS disregarded the devastating public health consequences of the Rule, which will force providers out of the program, and the Rule's conflict with established principles of medical ethics.

The district court also properly found that an injunction should issue because the Rule would irreparably harm patients, providers, and public health. Above all, as the district court found, the Rule "will result in less contraceptive services, … less early breast cancer detection, less screening for cervical cancer, less HIV screening, … less testing for sexually transmitted disease," "more unintended pregnancies," and "more women suffering adverse reproductive health symptoms." ER6, ER32. HHS, in contrast, would suffer "no harm" from preserving the longstanding status quo pending final judgment. ER7.

HHS relies principally on *Rust v. Sullivan*, 500 U.S. 173 (1991), claiming that the Rule cannot be unlawful because it is similar to a 1988 rule upheld in *Rust*. The district court correctly rejected that argument. This case is controlled not by *Rust*—which held only that the 1988 rule did not contravene federal law as it stood at the time—but by the Nondirective Mandate and §1554 of the ACA, which Congress enacted after *Rust*. Those provisions change the governing law, but "live in harmony" with §1008 and raise no issue of implied repeal. ER17-18.

Finally, HHS's challenge to the scope of the district court's injunction fails as well. HHS invokes a severability clause, but never explains why or how the

Rule could be severable, and it is not. Moreover, given the vast extent of Plaintiffs' involvement in the Title X program, the district court correctly concluded that a narrower injunction could not provide Plaintiffs complete relief.

STATEMENT OF JURISDICTION

Plaintiffs agree with HHS's statement of jurisdiction.

ISSUES PRESENTED

1. Whether the Rule likely violates the Nondirective Mandate, which requires that "all pregnancy counseling" under Title X be "nondirective."

2. Whether the Rule likely violates §1554 of the ACA.

3. Whether the Rule is likely arbitrary and capricious where HHS failed to consider important factors, including that the Rule would result in a mass exodus of providers from the Title X program and cause grave consequences for public health.

4. Whether the district court properly found that the Rule would cause irreparable harm for Title X patients, providers, and public health and that HHS would suffer no harm from preserving the status quo pending final judgment.

5. Whether the district court properly exercised its discretion in enjoining the Rule in its entirety.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes, regulations, and other material are contained in the Addendum.

STATEMENT OF THE CASE

A. Title X

1. Enactment and extraordinary success

Congress enacted Title X "to assist in making comprehensive voluntary family planning services readily available to all persons desiring such services." Pub. L. No. 91-572, §2(1), 84 Stat. 1504, 1504 (1970). Through grants to health care providers, Title X supports vital reproductive health care services, including contraception, testing and treatment for sexually transmitted infections (STIs), breast and cervical cancer screening, and pregnancy testing and counseling, including referrals. *E.g.*, ER179-180.

"[T]he Title X program has been a great success in meeting its stated goals" (ER8) and has resulted in tremendous public-health benefits. "By regularly providing millions of patients with contraceptive services, the Title X program has significantly reduced the rates of unintended pregnancy and abortion," which are now at "historic lows." ER8. And through millions of STI tests and cancer screens, Title X has contributed to the prevention, early detection, and treatment of STIs and cervical and breast cancer. *See id.*

Plaintiffs are leading health care organizations and individual health care professionals and have participated in the Title X program for decades. *See, e.g.*, SER11; ER38. The AMA is the largest professional association of physicians, residents, and medical students in the United States. ER37. AMA members counsel pregnant women on their options, including abortion, as part of Title X projects. ER34; *see also, e.g.*, ER38; ER50.

Planned Parenthood affiliates operate more than 600 health centers across the nation. SER6; *see* ER34. They are safety-net providers serving those with the fewest resources, and they operate on tight budgets focused on patient care and education services. SER6; *see* ER31. More than half of Planned Parenthood's health centers are in rural or underserved areas. SER7; *see* ER31. Planned Parenthood alone serves approximately 40% of *all* patients who receive care under Title X. *See* ER33; SER3. Through Title X in 2017, Planned Parenthood health centers provided an estimated 2,720,000 STI tests, 196,000 breast exams, and 183,000 Pap tests. SER12.

2. Statutory and regulatory history concerning pregnancy counseling and separation requirements

Section 1008 of Title X provides that no program funds "shall be used in programs where abortion is a method of family planning." 42 U.S.C. §300a-6. HHS's regulations have thus long prohibited Title X projects from providing abortions, and have required Title X grantees who provide abortions outside the

Title X project to keep such activities "separate and distinct from Title X project activities." 65 Fed. Reg. 41,281, 41,282 (July 3, 2000). Since the program's inception, however, Title X care has been delivered by reproductive health care providers who—*outside* the Title X program, with *non*-Title X funds—also provide abortion services. Providers have also long been authorized to use common facilities, staff, and health records systems for Title X projects and any "[n]on-Title X abortion activities." *Id.*

Moreover, HHS has made clear for virtually the entire history of the program that §1008 does not prevent Title X providers from communicating with their patients about abortion. *See* ER9; 65 Fed. Reg. 41,270, 41,271-41,272 (July 3, 2000). Consistent with fundamental medical ethics, Title X regulations have long required that providers offer pregnant women the opportunity to receive nondirective counseling on *all* their medical options, including abortion. *See, e.g.*, 65 Fed. Reg. at 41,270; *see also* ER49-50; ER39-40; SER70; AMA Comment Ltr. 1 (July 31, 2018).

There was one brief exception to this longstanding regulatory framework. In 1988, HHS issued a rule that prohibited Title X projects from counseling their patients about abortion or referring them to abortion providers. *See* 53 Fed. Reg. 2,823, 2,945 (Feb. 2, 1988). HHS also required Title X grantees to "physically" separate their Title X services from abortion-related services, including through

"separat[e] … facilities," "separate personnel," and "separate accounting records." *Id.* at 2,940, 2,945; *see also* 65 Fed. Reg. at 41,275.

The Supreme Court upheld the 1988 rule against certain statutory and constitutional challenges in *Rust v. Sullivan*, 500 U.S. 173 (1991). But HHS reversed itself just six months later: "[R]esponding to widespread concerns that [the 1988 rule] would interfere with the doctor-patient relationship," President George H.W. Bush issued a directive to HHS "cutting back significantly on [the rule's] scope and proscriptions." *National Family Planning & Reproductive Health Ass'n v. Sullivan*, 979 F.2d 227, 230, 235 (D.C. Cir. 1992). As President Bush declared: "'[P]atients and doctors can talk about absolutely anything they want, and they should be able to do that.'" *Id.* at 230. The 1998 rule was never fully implemented. When President Clinton took office, he directed HHS to suspend the 1988 rule and promulgate new regulations. 58 Fed. Reg. 7,462 (Feb. 5, 1993).

Meanwhile, Congress acted to ensure that patients would receive vital information as they always had. In 1996 and every year since then, Congress has mandated in Title X appropriations acts that "all pregnancy counseling" under Title X "shall be nondirective." *E.g.*, Pub. L. No. 115-245, 132 Stat. 2981, 3070-3071 (2018) ("Nondirective Mandate"). As HHS acknowledges in the Rule, this Mandate requires the "meaningful presentation of options" without "'suggesting or

advising one option over another.'" 84 Fed. Reg. at 7,716. Nondirective counseling "present[s] the options in a factual, objective, and unbiased manner" and thus ensures that patients "take an active role in processing their experiences and identifying the direction of their interaction." *Id.* at 7,716, 7,747.

In 2000, consistent with the Nondirective Mandate, HHS issued a new rule repudiating the 1988 rule and requiring that patients be offered, and receive as requested, "nondirective counseling" on *all* pregnancy options, including abortion. 65 Fed. Reg. at 41,270; ER11-12. As HHS explained at the time, "[t]he policies reflected in, and interpretations reinstituted in conjunction with, the [2000 rule] … have been used by the program for virtually its entire history." 65 Fed. Reg. at 41,271; *see* ER9. HHS further explained that the 2000 rule's requirements accord with "medical ethics and good medical care," and also implement Congress's "repeated[]" mandate "that pregnancy counseling in the Title X program be 'nondirective.'" 65 Fed. Reg. at 41,273. Conversely, the 1988 rule had "endanger[ed] women's lives and health by preventing them from receiving complete and accurate medical information and interfere[d] with the doctor-patient relationship by prohibiting information that medical professionals are otherwise ethically and legally required to provide to their patients." *Id.* at 41,270.

In the 2000 rule, HHS also repudiated the 1988 rule's physical separation requirement. Consistent with long-settled agency practice, the 2000 rule required

Title X grantees to ensure that Title X funds were not used for any "[n]on-Title X abortion activities" and to keep such activities "separate and distinct from Title X project activities." 65 Fed. Reg. at 41,282. But the rule expressly authorized "shared facilities," "common staff," and "single file system[s]." *Id.* As HHS explained, the physical separation contemplated by the 1988 rule was inconsistent "with the efficient and cost-effective delivery of family planning services." *Id.* at 41,276.

In 2010, as part of the Affordable Care Act, Congress acted again to protect the provider-patient relationship from government interference. Setting forth a forceful restriction on *any* HHS regulation that harms patient care in any one of six enumerated ways, Congress required:

> Notwithstanding any other provision of this Act, the Secretary of Health and Human services shall not promulgate any regulation that—
>
> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

Pub. L. No. 111-148, §1554, 124 Stat. 119, 259 (2010) (codified at 42 U.S.C. §18114).

B. 2019 Rule

Notwithstanding the success of Title X under regulations largely unchanged for decades, in June 2018, HHS proposed to implement drastic regulatory changes. *See* 83 Fed. Reg. 25,502 (June 1, 2018). The proposed rule was opposed by virtually every leading health care organization in the United States.

The AMA explained that the proposal would dangerously interfere with the patient-physician relationship and conflict with physicians' ethical obligations "by directing clinicians to withhold information critical to patient decision-making." AMA Comment Ltr. 1-2 (July 31, 2018). Planned Parenthood warned that the proposal would force a mass exodus of providers from the Title X program—including all Planned Parenthood affiliates and numerous States—leaving many patients without access to care. PPFA Comment Ltr. 15-16 (July 31, 2018).

HHS issued the Rule on March 4, 2019, with a 60-day effective date. As with the proposal, the Rule consists of two central, integrated provisions—the Gag and Separation Requirements.

1. Gag Requirement

The Rule restricts information Title X providers may give their pregnant patients—regardless of what their patients want ("Gag Requirement").

First, the Gag Requirement *bans* providers from referring their pregnant patients to abortion providers—even when that is the patient's expressed wish; but

it *mandates* referrals for prenatal care—even when the patient has no such interest. 84 Fed. Reg. at 7,788-7,789 (§§59.5(a)(5), 59.14(a), 59.14(b)(1)); ER21-23. Thus, Title X providers are prohibited from telling a pregnant patient how and where she can obtain an abortion, but must provide that information for prenatal care.

Title X projects may furnish patients who want an abortion a "list" of certain health care providers. 84 Fed. Reg. at 7,789 (§59.14(b)(1)(ii)). But the list is distorted by design—it must be skewed to ensure that the patient *not* learn which providers offer abortions. The list may include only "comprehensive primary health care providers (including providers of prenatal care)," *id.* (§59.14(b)-(c))—*not* reproductive health care specialists. And although some, but not the majority, of those providers *may also* provide abortion as part of their comprehensive health care services, "[n]either the list nor project staff may identify which providers on the list perform abortion." *Id.* Thus, the list must conceal from the patient which providers—if any (SER174-175)—would be willing to provide abortion services (*see* ER22-23).

Second, although the Rule purports to permit "nondirective counseling on abortion," 84 Fed. Reg. at 7,730, that is not the case. Even when a patient specifically seeks information about abortion *only*, practitioners must disregard the patient's decision. If a practitioner provides any information about abortion in response to the patient's request, she must *also* counsel the patient about other

options she *does not want* and must tell patients about the "risks and side effects to … [the] unborn child." *Id.* at 7,747.

2. Separation Requirement

The Rule imposes onerous physical separation requirements, such as separate facilities, personnel, workstations, and medical records, for any Title X grantee that engages in "prohibited activities," 84 Fed. Reg. at 7,789—virtually anything concerning abortion ("Separation Requirement"). The "prohibited activities" are defined by cross-reference to other sections of the Rule, including the Gag Requirement. *Id.* Thus, Title X projects must physically separate not only from anyone who *provides* abortions *outside* Title X, but also anyone who makes *referrals* for abortions or does anything HHS might think "encourage[s], promote[s], or advocate[s]" for abortion. *Id.* at 7,788, 7,789. HHS imposed these requirements despite citing no evidence of any misuse of Title X funds in the past. ER6.

C. Procedural History

Immediately after HHS issued the Rule, Plaintiffs filed suit and then promptly moved for a preliminary injunction. Plaintiffs argued that the Rule was contrary to federal law—the Nondirective Mandate and §1554 of the ACA—and was arbitrary and capricious, and that the harms and equities favored an injunction.

On April 29, the district court preliminarily enjoined the Rule, finding each factor in Plaintiffs' favor. ER35.

The district court held that Plaintiffs are "likely to succeed on the merits of their claims that the Final Rule is contrary to law." ER7. The court rejected HHS's principal argument that the Rule must be upheld under *Rust*. *Rust*, the court explained, held that §1008 of Title X was "ambiguous" (ER17) and that the 1988 rule was a "'permissible'" construction of that statute (ER16). But the Nondirective Mandate and §1554 of the ACA changed the law while "liv[ing] in harmony" with §1008 of Title X, thus raising no issue of implied repeal. ER17-18.

The court then held that the Gag Requirement "is the very definition of directive counseling." ER21. Under the Rule, "the medical professional no longer provides neutral, factual information 'consistent with the client's express need,'" but rather steers the patient away from abortion. ER21-22. The court also held that both the Gag and Separation Requirements likely violate §1554 of the ACA. ER26-27, 29 n.8.

The court further held that Plaintiffs demonstrated "a likelihood of success on the merits of their claim[] that the Rule is … arbitrary and capricious." ER32. HHS failed adequately to consider that "the Rule appears to force medical providers to either drop out of the program or violate their codes of professional

ethics" (ER27), and "failed to adequately account for the impact the Rule will have on women, particularly women in rural areas" (ER31).

The court then found that Plaintiffs, patients, and public health would be irreparably harmed absent an injunction. ER32-33. As the court made clear, the Rule will force a large number of Title X providers to leave the program. ER33. "Planned Parenthood's absence" alone, the court found, "would create a vacuum for family planning services" that other safety-net clinics would be unable to fill. ER31. Serious health consequences would result. ER31-32. The Rule would "increase not only unintended (and riskier) pregnancies, but abortions as well," and "result in less testing" for breast and cervical cancer, "increased STIs, and more women suffering adverse reproductive health symptoms." ER32 (citation omitted).

The court further found that the balance of equities "tips sharply" in favor of an injunction. ER33. "[T]he risk of irreparable damage to the health of women and communities is grave," the court found, while preserving the status quo under the current regulations "poses no harm to Defendants." ER7.

Finally, the court found it necessary to enjoin any enforcement of the Rule. ER34. The court recognized that this Court had "recently outlined concerns regarding overbroad injunctions." *Id.* Applying that precedent, the court concluded that the scope of its injunction was "'necessary to redress the injury

shown by the plaintiff[s]'" because "the harm to Plaintiffs would occur in every state." *Id.*

HHS appealed and, on May 10, also moved this Court to stay the injunction pending appeal. Dkt. 15. More than a month later, on June 20, a motions panel (Leavy, Callahan, and Bea, JJ.) issued an order staying the preliminary injunction. Dkt. 58. Plaintiffs immediately moved for an administrative stay (Dkt. 59) and sought reconsideration en banc (Dkt. 61). Both motions are still pending.[1]

D. Other Proceedings

Two other district courts in this Circuit have preliminarily enjoined the Rule (those injunctions were also stayed by the motions panel). *See Washington v. Azar*, 376 F. Supp. 3d 1119, 1132 (E.D. Wash. 2019); *California v. Azar*, __ F. Supp. 3d __, 2019 WL 1877392, at *44 (N.D. Cal. 2019); *see also Mayor & City Council of Baltimore v. Azar*, 2019 WL 2298808, at *14 (D. Md. May 30, 2019) (enjoining Rule in Maryland). Each court rejected HHS's argument that *Rust* resolves this case, and each one concluded that the Rule is likely contrary to law—the Nondirective Mandate and §1554. *See, e.g.*, *California*, 2019 WL 1877392, at

[1] If the stay order has not been vacated before a merits panel hears this appeal and the merits panel deems itself bound by the stay order, *compare Innovation Law Lab v. McAleenan*, 924 F.3d 503, 518 (9th Cir. 2019) (Fletcher, J., concurring in result), *with Lair v. Bullock*, 798 F.3d 736, 747 (9th Cir. 2015), Plaintiffs respectfully submit that the merits panel should consider this brief as setting forth additional reasons why initial hearing en banc is appropriate. Plaintiffs have requested initial hearing en banc by separate filing this same day.

*15-16, 18-19, 23-26. Moreover, on the harms and equities, each court underscored the strength of the plaintiffs' evidence and the absence of HHS's. The *California* court found, for example, that HHS was "unable to articulate any real harm" from maintaining the status quo. *Id.* at *1; *accord Washington*, 376 F. Supp. 3d at 1131-1132.

SUMMARY OF THE ARGUMENT

I. The district court correctly held that Plaintiffs are likely to succeed on the merits. The Rule is contrary to federal law. By steering pregnant women toward carrying their pregnancies to term and away from abortion, the Rule violates the Nondirective Mandate. Furthermore, through both the Gag and Separation Requirements, the Rule contravenes every prohibition in §1554 of the ACA—a forceful restriction on HHS's authority to issue "any regulation" that interferes with patient care in any one of six enumerated ways. HHS's central argument is that *Rust* forecloses those conclusions. But the district court correctly found that the Nondirective Mandate and the ACA change the applicable law since *Rust*, while living in harmony with §1008.

The Rule is also arbitrary and capricious. HHS failed to consider critically important evidence militating against the Rule, including that it violates established standards of medical ethics and would force out of the program providers serving approximately 40% of all Title X patients, impose enormous costs on already-

strained Title X project budgets, and—above all—harm patients and public health. HHS offered nothing more than speculation that the number of Title X providers may, somehow, increase in response to the Rule. And it provided unsupported estimates of minimal costs of compliance that are grossly understated. The district court correctly found that HHS's speculation is no answer to the clear record evidence that the Rule will decimate the Title X program.

II. The district court correctly found that Plaintiffs, their affiliates and members, and the patients they serve will be irreparably harmed. Plaintiffs presented overwhelming evidence that the Rule will result in a mass—forced—exodus of providers from the program. Grave and irreparable consequences will result. Most importantly, patient care will suffer.

HHS, by contrast, will not suffer any harm if the Rule is preliminarily enjoined, and the district court properly found that the balance of the equities and the public interest tip sharply in Plaintiffs' favor. HHS identifies no discernible public health benefits from its Rule and cites no evidence of misuse of Title X funds over the past 50 years.

III. The scope of the district court's injunction is proper. HHS makes a meager attempt to argue that the Rule is severable, but fails to explain how the court could have crafted a narrower remedy given the centrality and interrelatedness of the unlawful Gag and Separation Requirements. And given the

significant extent of Plaintiffs' involvement in the Title X program, complete relief can only be achieved through a nationwide injunction.

STANDARD OF REVIEW

A plaintiff seeking a preliminary injunction must establish that (1) it is "likely to succeed on the merits," (2) it is "likely to suffer irreparable harm in the absence of preliminary relief," (3) "the balance of equities tips in its favor," and (4) "an injunction is in the public interest." *Recycle for Change v. City of Oakland*, 856 F.3d 666, 669 (9th Cir. 2017) (alterations omitted). "'[A] stronger showing of one element may offset a weaker showing of another.'" *Id.* A preliminary injunction is thus warranted when the plaintiff raises "'serious questions'" on the merits and "'the balance of hardships tips sharply in [the plaintiff's] favor.'" *Puente Ariz. v. Arpaio*, 821 F.3d 1098, 1103 n.4 (9th Cir. 2016).

This Court reviews "the district court's issuance of a preliminary injunction for an abuse of discretion." *adidas Am., Inc. v. Skechers USA, Inc.*, 890 F.3d 747, 753 (9th Cir. 2018). "'[L]egal issues underlying the injunction are reviewed de novo,'" and "the district court's factual findings are reviewed for clear error." *Id.* "The scope of a preliminary injunction is … reviewed for abuse of discretion." *United States v. Schiff*, 379 F.3d 621, 625 (9th Cir. 2004).

ARGUMENT

I. THE DISTRICT COURT CORRECTLY CONCLUDED THAT PLAINTIFFS ARE LIKELY TO PREVAIL ON THE MERITS

A. The Rule Is Likely Contrary To Federal Law

The district court correctly concluded that the Rule is likely contrary to both the Nondirective Mandate and §1554 of the ACA. First, the Rule requires Title X projects to provide directive counseling that steers patients toward continuing a pregnancy to term and away from abortion—regardless of what the patient wants or what is in her best interest. Second, the Rule contravenes §1554 in every respect: The Rule creates unreasonable barriers and impedes timely access to care by making it more difficult for Title X patients to obtain information and health care services, interferes with patient-provider communications regarding pregnancy options, and violates standards of medical ethics by prohibiting health care professionals from providing complete information about a patient's pregnancy options.

Contrary to what HHS claims, *Rust* does not save the Rule. The statutory scheme has changed since the Supreme Court decided that case nearly 30 years ago. Both the Nondirective Mandate and §1554 limit HHS's discretion to restrict pregnancy counseling and interfere with patient care, and under those governing federal laws, the Rule must fall.

1. The Gag Requirement likely violates the Nondirective Mandate

The Nondirective Mandate requires that "all pregnancy counseling" by a Title X project be "nondirective." The Mandate thus requires that counseling about a patient's options be responsive to the patient's wishes and not driven by ideological considerations.

The Gag Requirement violates that Mandate by skewing the counseling by a Title X project in favor of continuing a pregnancy to term and away from abortion. It does so in three ways: (1) it *bans* referrals for abortion but *mandates* referrals for prenatal care—regardless of what a patient wants; (2) it requires the project, when making referrals for a patient that wants an abortion, to hide information about abortion providers; and (3) it requires the project to speak to a patient about options she *does not want*, even when she seeks information only about abortion. As the district court concluded, those terms direct pregnant patients away from abortion and toward continuing a pregnancy to term—"the very definition of directive counseling." ER21.

a. The referral provisions require directive counseling

i. If a patient tells the provider that she wants information about abortion, "the provider is mandated to refuse to provide the referral the client wants, and instead provide a referral the client neither needs nor requested"—information about prenatal care. ER21. By design, this scheme steers patients

toward carrying a pregnancy to term and thereby violates the Nondirective Mandate: The provider is required to withhold information the patient wants about abortion and to give her other information she does *not* want but the government wants her to have.

Moreover, the restrictions on the list Title X projects may offer patients also result in directive counseling. ER22-23. When a pregnant patient seeks an abortion, the project may *not* identify any provider as one willing to offer abortion and may *not* refer the patient to a reproductive health care specialist. Rather, the provider may only provide a list of "comprehensive primary health care providers …, some, but not the majority, of which [may] also provide abortion as part of their comprehensive health care services." 84 Fed. Reg. at 7,789 (§59.14(c)). But "[n]either the list nor project staff may identify which providers on the list perform abortion." *Id.* Thus, a patient choosing a provider at random is likely *not* to reach—and may *never* reach—an abortion provider.[2] This list is designed to cause delay and confusion, as the patient works her way through it trying to find, perhaps in vain, the provider she needs. The effect is to "'harm and confuse all patients'

[2] A patient may *never* reach the provider she needs because a Title X project is permitted to limit its list "to those that do not provide abortion." 84 Fed. Reg. at 7,789 (§59.14(c)(2)). It may not even be possible to include an abortion provider on the list because abortions are often offered by specialized reproductive health providers—not "comprehensive primary health care providers." *See* SER174-175.

during a medically and emotionally sensitive period and 'ultimately threaten their health and well-being.'" *California*, 2019 WL 1877392, at *8.

HHS offers several arguments why these provisions do not violate the Nondirective Mandate. All lack merit.

HHS argues (Br. 24) that the "*failure*" to refer a patient for abortion "does not *direct* the patient to do anything." But the directive aspect is not the failure to refer for abortion alone; it is the *prohibition* against doing so combined with a *mandate* to refer for continuing to term—made even worse by the *suppression* of information about which providers offer abortions. As HHS itself recognized in the Rule, "[n]ondirective counseling is designed to assist the patient in making a free and informed decision" and "involves presenting the options in a factual, objective, and unbiased manner …, rather than … a subjective or coercive manner." 84 Fed. Reg. at 7,747; *see supra* pp.8-9. Presenting information about how and where clients can obtain certain services, while suppressing that information about other services, does not help the patient make a "free and informed decision" and is not "objective" or "unbiased." Rather, this skewed provision of information is designed to direct a patient toward one particular

option—carrying a pregnancy to term. The point to the patient is clear: She *should* obtain prenatal care but should *not* get an abortion.[3]

HHS acknowledges in the Rule that the selective provision of information—precisely what the referral provisions require—*is* directive. At the same time that HHS bans providers from giving patients information about how to obtain an abortion and requires the provider to refer patients for prenatal care, the Rule does not permit patients to be counseled only on abortion even if that is what those patients want. To justify the latter prohibition, HHS states that if abortion were "the only option presented[,] … the counseling would violate … the Congressional directive that all pregnancy counseling be nondirective." 84 Fed. Reg. at 7,747. But HHS cannot have it both ways. The selective presentation of information—withholding information that the patient *seeks*—violates the Nondirective Mandate.

HHS also argues (Br. 24) that restricting the presence of abortion providers on the list "further[s] … the nondirective provision by ensuring that the list is not used to 'steer clients to abortion.'" But HHS ignores that an abortion referral under the longstanding rules is provided *only at the patient's request*; HHS never

[3] HHS argues (Br. 24) that the Rule requires referrals for prenatal care because such care is "necessary" for all pregnant women. But it does not explain why that is true for a woman who has decided to terminate her pregnancy, and it is not. *See, e.g.*, ER55. Nor does HHS explain why a Title X provider should give a patient seeking an *abortion* a referral instead to an *adoption* agency. *See* ER22 & n.4.

explains how there can be steering when a patient herself has "identif[ied] the direction of the interaction," 84 Fed. Reg. at 7,716. Moreover, by HHS's logic, if the mere presence or identification of abortion providers on a list steers a patient toward an abortion (again, the option the patient wants), then surely the requirement that providers refer for prenatal care (even where the patient does *not* want that) steers patients toward carrying a pregnancy to term.

ii. HHS seeks to avoid the Nondirective Mandate (Br. 25) by claiming it "does not apply to referrals." As the district court correctly concluded, HHS's narrow view of the term "counseling" is wrong. ER18-19; *accord California*, 2019 WL 1877392, at *16-17; *Baltimore*, 2019 WL 2298808, at *10.

HHS itself has expressed its understanding in the Rule that nondirective pregnancy counseling includes referrals. HHS states, for example, that "*nondirective pregnancy counseling can include* counseling on adoption, and *corresponding referrals* to adoption agencies." 84 Fed. Reg. at 7,730 (emphasis added). As another example, HHS states that "Title X providers may provide adoption *counseling, information, and referral … as part of nondirective postconception counseling*." *Id.* at 7,733-7,734 (emphasis added). HHS thus views referrals as "part of … counseling" when the referral is for adoption—just

not for abortion. That inconsistency fatally undermines the government's own argument.[4]

Congress has similarly expressed the understanding that referrals are part of counseling. In creating the Infant Adoption Awareness Training Program, Congress instructed HHS to make grants to train health-center staff "in providing adoption information *and referrals* to pregnant women on an equal basis with all other courses of action *included in nondirective counseling* to pregnant women." 42 U.S.C. §254c-6(a)(1) (emphasis added). The term "counseling" in the Nondirective Mandate should be given the same meaning. *See Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 290 (2010) ("'[A] legislative body generally uses a particular word with a consistent meaning in a given context.'" (alteration in original)). HHS offers (Br. 27) a new interpretation of §254c-6 in its brief, but that litigation position is inconsistent with HHS's own Rule. *See* 84 Fed. Reg. at 7,733 ("Congress has expressed its intent that postconception adoption information and *referrals be included as part of any*

[4] HHS claims (Br. 26) that, in 2000, HHS did not view the Nondirective Mandate as covering referrals. In fact, HHS discussed the Nondirective Mandate in the context of "the requirement for nondirective counseling and referral," using the terms separately but recognizing that Congress's requirement that "counseling" be nondirective applies to both. 65 Fed. Reg. at 41,273. HHS also asserts (Br. 26) that, in 2000, HHS stated that the 1988 regulations were a permissible interpretation of statute. In fact, HHS stated that those regulations were permissible *in 1988*, *see* 65 Fed. Reg. at 41,277, not that they were permissible *in 2000—i.e.*, after enactment of the Nondirective Mandate.

nondirective counseling in Title X projects when it passed [§254c-6(a)(1)]" (emphasis added)). Moreover, Congress elsewhere has used the term "counseling" to include referrals, such as in directing funding to states that provide HIV/AIDS testing and, "for those individuals with a positive test result, post-test counseling (*including referrals for care*)." 42 U.S.C. §300ff-33 (emphasis added).[5]

A definition of counseling that includes referrals also comports with how medical professionals understand the term. *See Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 372 (1986) ("[T]echnical terms of art should be interpreted by reference to the trade or industry to which they apply[.]"). HHS's own evidence-based recommendations for "Pregnancy Testing and Counseling" state: "[pregnancy] test results should be presented to the client, followed by a discussion of options and appropriate referrals." CDC & OPA, *Providing Quality Family Planning Services* 13-14 (2014); *see also, e.g.*, ER53 ("Referrals are an integral part of counseling and the fundamental medical principle of continuity of care.").

[5] HHS errs in relying (Br. 25) on a failed 1992 bill. "'[I]t is the enacted text … that prevails.'" *Cohen v. United States*, 650 F.3d 717, 730 (D.C. Cir. 2011). For the reasons just discussed, that text confirms that referrals are part of counseling. Moreover, that Congress and HHS have at times referred to counseling and referral separately (*see* HHS Br. 25-26) does not warrant a different conclusion. "[T]he phrase 'counseling and referral' occasionally used by HHS is more sensibly read as simply describing sequential aspects of the same process." *California*, 2019 WL 1877392, at *17.

Finally, HHS's erroneous construction cannot be reconciled with Congress's evident purpose in the Nondirective Mandate—to permit a pregnant woman to make her own decision about her health care without steering from her provider. It is implausible "that Congress would so adamantly require that all pregnancy counseling be nondirective, only to later allow the provider to refer a woman seeking an abortion to an adoption agency." ER22 n.4. Congress did not intend for Title X providers to check off a nondirective-counseling box and then tell the patient whom she should see to receive the *government's* preferred treatment.

b. Even aside from the referral provisions, the Rule requires directive counseling

The Rule is directive "[r]egardless of the referral process." ER19; *accord California*, 2019 WL 18773952, at *18. When a patient seeks information about abortion only, the provider, if providing that abortion-related information, must *also* give information "regarding some other option the client has no use for, even when it is not requested by the client or even medically relevant." ER21; *see* 84 Fed. Reg. at 7,747 ("[A]bortion must not be the only option presented[.]"). The Rule thus enlists providers in trying to override the patient's intent to obtain an abortion.

HHS attempts (Br. 28) to label this requirement "the neutral presentation of other options." But counseling about options *against the patient's wishes* is inherently directive. *See, e.g.*, ER41-42. Indeed, as HHS previously

acknowledged: "If projects were to counsel on an option even where a client indicated that she did not want to consider that option, there would be a real question as to whether the counseling was truly nondirective or whether the client was being steered to choose a particular option." 65 Fed. Reg. at 41,273.

HHS also contends (Br. 29) for the first time on appeal that the term "nondirective" does not mean "equal," but that misses the point. The Nondirective Mandate's operating principle is *patient*-directed treatment—*i.e.*, where the patient "identif[ies] the direction of the interaction," 84 Fed. Reg. at 7,716. As explained, the Rule requires Title X providers to steer patients who have stated they want an abortion away from that option and toward continuing a pregnancy to term.

2. The Rule likely violates §1554 of the ACA

The district court also correctly concluded that Plaintiffs are likely to prevail on their claim that the Rule violates §1554 of the ACA. *See* ER23-27, 29 n.8.

a. The Gag Requirement violates §1554

The Gag Requirement violates each of the statute's six enumerated provisions. It dictates what a provider must and must not say to a patient about her pregnancy options. The Rule thus "interferes with communications regarding a full range of treatment options between the patient and the provider" and "restricts the ability of health care providers to provide full disclosure of all relevant

information to patients making health care decisions." 42 U.S.C. §18114(3), (4); *see* ER29 n.8.

The Gag Requirement also contravenes "the ethical standards of health care professionals," 42 U.S.C. §18114(5), by prohibiting Title X projects from providing pregnant patients with information about all their options. *See* ER27-29 & n.8. The AMA's Code of Medical Ethics states that medical professionals must "[p]resent relevant information accurately and sensitively, in keeping with the patient's preferences," and that "withholding information without the patient's knowledge or consent is ethically unacceptable." AMA, *Code of Medical Ethics* §§2.1.1(b), 2.1.3 (2016); *see* AMA Comment 3; PPFA Comment 11; ER39-40; ER49. Rules of ethics that govern other health care professionals are to the same effect. *See, e.g.*, American Academy of Nursing Comment Ltr. 4 (July 26, 2018); *see also California*, 2019 WL 1877392, at *24.

Furthermore, by prohibiting Title X projects from providing information about how and where a pregnant patient can obtain abortion services, the Gag Requirement will delay and disrupt Title X patients' care, "creat[ing] … unreasonable barriers to [patients'] ability … to obtain appropriate medical care" and "imped[ing] timely access to health care services." *Id.* §18114(1), (2); *see* ER29 n.8; ER53; SER72, 119, 120-123, 176-178, 191. HHS simply assumed away this problem in the Rule, declaring that "[i]nformation about abortion and abortion

providers is widely available and easily accessible, including on the internet." 84 Fed. Reg. at 7,746. That is an "astonishing response" for an agency charged with implementing a program designed to reach patients with limited means. *California*, 2019 WL 1877392, at *23 n.13. As commenters explained, many such patients have "low 'health literacy,' meaning the knowledge and ability to navigate the health care system," and "[s]ome patients also lack regular access to communications tools (*e.g.*, internet, phone) that are needed to access and research information on their own." Ryan Health Comment Ltr. 3 (July 31, 2018).

The Gag Requirement will also create unreasonable barriers and impede timely access to care by forcing providers out of the Title X program. As the district court found, the record makes clear that many providers will be forced to withdraw from Title X rather than violate their ethical and professional responsibilities. ER31; SER2. Without Title X funds, many providers will have to close clinics or reduce services. *See, e.g.*, SER21, 25, 28. As the district court found, other safety-net clinics cannot fill the gap in services that would result. ER31.

b. The Separation Requirement violates §1554

The Separation Requirement contravenes §1554 because it creates unreasonable barriers, and impedes timely access, to care. *See* ER26-27.

The onerous requirements imposed by the Separation Requirement will force Title X providers who engage in abortion-related activities with *non*-Title X funds—including providing referrals for abortion—to leave the Title X program. *See* PPFA Comment 33; Guttmacher Institute Comment Ltr. 9 (July 31, 2018); ER44-45; SER19-21; SER43-45; SER58-60; SER180-184. The Rule requires those grantees to alter their facilities to create separate "treatment, consultation, examination and waiting rooms" and "office entrances and exits," 84 Fed. Reg. at 7,789 (§59.15(b))—at an estimated cost exceeding $536,000 per facility, PPFA Comment 32. Grantees that cannot renovate existing facilities would be forced out of the program unless they can obtain new facilities, at an estimated cost exceeding $1 million each—a price that is out of reach for many grantees operating on shoe-string budgets. *Id.* at 32-33.

Title X grantees that engage in abortion-related activities outside the program will also be required to incur exorbitant costs to establish and maintain separate health records systems, telephone systems, information technology systems, educational services, and websites, and to hire separate personnel. *See* PPFA Comment 32-33; *see also* AMA Comment 4; NY State Department of Health Comment Ltr. 8-19 (July 30, 2018). For many grantees, those expenses will far exceed the amount of Title X funding they receive. *See, e.g.*, SER43-45, 58-59. Those requirements are not only cost-prohibitive; they are—in particular,

the requirement of separate medical records—"harmful to patient care" and will "endanger patient safety." SER20.

It will be patients—above all—who suffer. Those patients will have to look elsewhere for care, but as the record shows, many will not find a place to obtain it. *See, e.g.*, Guttmacher Comment 9-10; SER185-188. Many of Planned Parenthood's health centers, for example, are located in areas where patients have limited access to other reproductive health care providers. *See* ER31; PPFA Comment 33. Other Title X projects, which are already overburdened, cannot absorb the Title X caseload of those grantees that would leave the program. ER31; SER189-190; Guttmacher Comment 9-10.

c. HHS's §1554 arguments are unavailing

HHS stretches to avoid a straightforward application of §1554's plain text. First, HHS contends that Plaintiffs waived their challenge under §1554. That is incorrect. Plaintiffs and numerous other commenters put HHS on notice that the proposed rule violated each substantive prohibition contained in §1554. *See* ER25; *California*, 2019 WL 1877392, at *20-21. Planned Parenthood explained in its comments, for example, that the proposed rule would "contravene the ethical and professional commitments of health care providers," "harm patients seeking abortions by introducing extraordinary difficulties into the already arduous process of obtaining one," and cause patients "to delay or forgo basic preventive services."

PPFA Comment 10, 20, 33. Commenters addressed in detail objections under each substantive prong of §1554.[6]

HHS understood those comments in §1554's terms, recognizing, for example, that "commenters assert that proposed changes could reduce access to services" and "violate[] ethical standards." 84 Fed. Reg. at 7,722, 7,758; *see Native Ecosystems Council v. Dombeck*, 304 F.3d 886, 899 (9th Cir. 2002) (where the agency "understood plaintiffs to raise the issue" and "addressed this concern in

[6] In the order of §1554's prohibitions, see for example the following comments: **1. Unreasonable Barriers to Care.** *See, e.g.*, Attorneys General for California et al. Comment Ltr. 4, 6 (July 30, 2018) (proposed rule "seeks to create barriers to access to women's healthcare"; "[t]hese government-imposed barriers to the physician-patient relationship interfere with the provision of medical care and will impede public health"). **2. Impediments to Timely Access to Care.** *See, e.g.*, Center for Reproductive Rights (CRR) Comment Ltr. 12 (July 31, 2018) ("The proposed rule would result in medically unnecessary and inappropriate delays in care[.]"). **3. Interference with Patient-Provider Communications.** *See, e.g.*, AMA Comment 1 (proposed rule "dangerously interfere[s] with the patient-physician relationship"); American College of Nurse-Midwives Comment Ltr. 2 (July 31, 2018) ("proposed rule limits how Title X providers can discuss and/or counsel on the full-range of sexual and reproductive health care options"). **4. Restrictions on Full Disclosure of Relevant Information.** *See, e.g.*, CRR Comment 41 (proposed rule "undermines the right to information by censoring health care providers from informing patients of all their options related to abortion"). **5. Violation of Ethical Standards.** *See, e.g.*, AMA Comment 1 (proposed rule "conflict[s] with physicians' ethical obligations"). **6. Limitation of Availability of Health Care Treatment for the Full Duration of a Patient's Needs.** *See, e.g.*, American Public Health Association Comment Ltr. 3 (July 30, 2018) ("Limiting support for comprehensive reproductive health services takes us back to failed policies that harm women's health.").

its decision," there is no waiver). Contrary to the government's assertion (Br. 34), HHS had opportunity to "'apply its expertise'" and create a record for review.

There is no requirement that commenters cite the specific statutory provision a proposed rule offends. *See, e.g.*, *Lands Council v. McNair*, 629 F.3d 1070, 1076 (9th Cir. 2010). Nor is this case where commenters raised "merely the same general legal issue," *Koretoff v. Vilsack*, 707 F.3d 394, 398 (D.C. Cir. 2013) (per curiam)—*e.g.*, that the Rule is contrary to law. Rather, commenters raised the substantive arguments Plaintiffs raise here—that the Rule violates medical ethics, creates unreasonable barriers to care, impedes timely access to care, and interferes with patient-provider communications. *See supra* n.6.

HHS also argues (Br. 34-35) that the Rule does not "create unreasonable barriers" or "impede timely access" to care because it leaves patients "'in no different position than … if the Government had not enacted Title X.'" That argument proceeds from the wrong premise—a counterfactual world where Title X does not exist. Congress *has* enacted Title X. Section 1554 takes the real world as a given and asks whether HHS's *regulation* has any statutorily forbidden consequences. That is clear from §1554's text, which prohibits HHS from issuing "any regulation" running afoul of its terms. The Rule violates §1554 because the record evidence shows that patients' access to care would be unreasonably delayed and disrupted compared to the situation in which the Rule had not been

promulgated—that is, if the 2000 regulations continued to govern. Similarly, the Rule violates medical ethics whereas the 2000 regulations do not.

Moreover, HHS's argument would render §1554 inapplicable to the vast array of federally funded programs that are vital to public health, such as Medicare, Medicaid, and the Public Health Service Act. Nothing in the text of §1554 suggests that Congress intended that provision to be so anemic. To the contrary, Congress specified that HHS shall not promulgate "any" regulation with the prohibited effects. Congress's choice of the word "any" without qualification demonstrates its broad sweep. *See Ali v. Federal Bureau of Prisons*, 552 U.S. 214, 219 (2008) ("'the word "any" has an expansive meaning'").[7]

3. *Rust* does not control this case

HHS relies heavily on *Rust* (*e.g.*, Br. 15-21) and maintains that it forecloses any contrary-to-law claim. That is wrong. *See* ER17-18.

In *Rust*, the Supreme Court concluded that "[t]he language of § 1008" was "ambiguous," and "does not speak directly to the issues of counseling, referral, advocacy, or program integrity." 500 U.S. at 184. Given that ambiguity, the Court deferred to the agency's "permissible" construction, *id.* at 184, 187-188, but it did

[7] HHS's reliance on *Rust* (Br. 35)—which rejected an argument that the 1988 rule unconstitutionally burdened a woman's right to abortion—is unavailing. On a constitutional challenge, the appropriate comparator is the situation where Congress had not enacted Title X at all, because the constitutional question is whether the government, generally, has interfered with the right. But that is not true of the statutory inquiry under §1554.

not hold that §1008 *required* the restrictions on counseling and referral that HHS had adopted in the 1988 rule.

Since *Rust*, the Nondirective Mandate and the ACA have imposed new constraints on how HHS may administer the Title X program. *See* ER17-18. Separately and together, they prevent HHS from using Title X providers, contrary to their ethical tenets and their patients' preferences, to steer patients away from (or toward) abortion or to otherwise harm patient care in enumerated ways.

HHS recognized in the Rule that the Nondirective Mandate changed the law after *Rust*. *See* 84 Fed. Reg. at 7,720. Indeed, that is why, according to HHS, it purported to allow what it calls "nondirective counseling on abortion," after initially suggesting it would ban such counseling, *see* 83 Fed. Reg. at 25,530. As HHS explained, the counseling provisions of the Rule "are more permissive than the 1988 regulations" because they "implement[] [the] appropriations rider" requiring pregnancy counseling to be nondirective. 84 Fed. Reg. at 7,725.[8]

HHS nonetheless argues (Br. 30-32) that the presumption against implied repeals forecloses the district court's interpretation of the Nondirective Mandate

[8] *See id.* at 7,730 ("Taking … the annual appropriations provision[] and section 1008 together, the Department has concluded that Title X projects may … provide nondirective counseling on abortion generally[.]"); *id.* at 7,760 ("The Department believes these [appropriations] enactments make it appropriate for the Department to allow nondirective pregnancy counseling …, even if the counseling includes nondirective counseling on abortion.").

and §1554. That argument fails. It cannot be reconciled with HHS's own acknowledgement that the Nondirective Mandate *does* affect the scope of its authority under Title X in general and §1008 in particular. The Nondirective Mandate (and §1554) *did* alter the law in significant respects, and HHS is bound by those changes.

In any event, no "implied repeal" is implicated here. Under the presumption against implied repeals, a court should not read two statutory provisions to be in irreconcilable conflict, such that the later statute impliedly repeals the earlier, "unless the later statute expressly contradicts the original act or unless such a construction is absolutely necessary in order that the words of the later statute shall have any meaning at all." *National Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 662 (2007) (quotation marks and alterations omitted). As the district court explained, however, "Section 1008, the appropriations language, and the ACA restrictions … live in harmony." ER18. Section 1008 of Title X continues to prohibit the use of Title X *funds* for abortion, while the Nondirective Mandate and §1554 of the ACA restrict the government's ability to interfere with the provider-patient relationship or create barriers to timely access to care. *See* ER18; *cf. National Ass'n of Home Builders*, 551 U.S. at 664-666 (construing the Endangered Species Act to not create an irreconcilable conflict with the Clean Water Act).

It is not an "implied repeal" to discern the scope of HHS's authority under §1008 in conjunction with subsequent enactments such as the Nondirective Mandate and the ACA, which narrowed that authority. The Supreme Court, per Justice Scalia, has rejected HHS's argument (Br. 31-32) that subsequent enactments narrowing the range of permissible constructions of an earlier statute amount to implied repeals:

> Repeal by implication of an express statutory text is one thing; it can be strongly presumed that Congress will specifically address language on the statute books that it wishes to change. But repeal by implication of a legal disposition implied by a statutory text is something else. The courts frequently find Congress to have done this—whenever, in fact, they interpret a statutory text in the light of surrounding texts that happen to have been subsequently enacted. This classic judicial task of reconciling many laws enacted over time, and getting them to "make sense" in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute.

United States v. Fausto, 484 U.S. 439, 453 (1988) (internal citations omitted). In other words, the conclusion that a later statute constraints the potential *implications* of an earlier statute does not raise an issue of implied repeal; rather, it represents the "classic judicial task of reconciling … laws enacted over time." *Id.* Indeed, the Supreme Court has made clear that "[a]t the time a statute is enacted, it may have a range of plausible meanings. Over time, however, subsequent acts can shape or focus those meanings." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143 (2000). And "'a specific policy embodied in a later federal statute

should control … construction of the earlier statute, even though it has not been expressly amended.'" *Id.* (alterations omitted). That is exactly the situation here.

The district court properly concluded that the Nondirective Mandate and §1554 narrowed the scope of HHS's authority under §1008 and had to be consulted in determining whether the agency's approach upheld as "permissible" in *Rust* can survive those later enactments. The district court's construction of the Nondirective Mandate and §1554 does not repeal §1008; rather, it properly harmonizes all those provisions.

HHS also argues (Br. 30, 35) that the district court's construction of the Nondirective Mandate and §1554 is "implausible" because Congress is presumed not to "'hide elephants in mouseholes.'" But an appropriations rider indicating how money is to be spent in the very paragraph appropriating that money is no mousehole. Nor was the ACA, which was intended to overhaul the American health care system. And it is hardly surprising that Congress did not expressly address *Rust* when enacting the Nondirective Mandate and §1554; the 1988 rule had already been suspended when the Nondirective Mandate was first enacted in 1996, and long repudiated by 2010 when the ACA was enacted.

Finally, HHS argues (Br. 35-36) that §1554 does not apply to regulations enacted pursuant to HHS's authority under Title X because, in the case of a conflict, "the specific governs the general." This argument fails for the same

reasons explained above—§1008 and §1554 do not conflict. The district court did not read §1554 to displace §1008; rather it read §1008 "in the light of" the subsequently enacted statute to "'make sense' [of them] in combination," as it was required to do. *Fausto*, 484 U.S. at 453. In any event, §1554 is more specific in prohibiting HHS from issuing regulations that create barriers to care, interfere with patient-provider communications, or violate medical ethics.[9]

B. The District Court Correctly Found That The Rule Is Likely Arbitrary And Capricious

The district court found that Plaintiffs "demonstrated a likelihood of success on the merits of their claims that the Final Rule is … arbitrary and capricious," because HHS "failed to seriously consider persuasive evidence that the Final Rule would force providers to violate their ethical obligations" or the effect on women and public health. ER30-32. That conclusion is correct.[10]

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[9] HHS does not argue—as it did in the district court—that §1554 governs only regulations promulgated under the ACA. The argument is thus waived, in addition to being contrary to statute.

[10] HHS seizes on an earlier passage in the court's decision and asserts (Br. 36-37) that "it is insufficient" for Plaintiffs to raise "serious questions as to the merits." That assertion ignores the court's conclusion and the analysis preceding it. Moreover, any such argument is waived because HHS did not object when Plaintiffs cited that standard below, and is meritless because Ninth Circuit precedent endorses that standard (*see supra* p.19).

1. The Gag Requirement is arbitrary and capricious

a. HHS failed to account adequately for the fact that the Gag Requirement is contrary to medical ethics. As explained (*supra* pp.11), virtually all leading health care organizations, including the AMA and Planned Parenthood, commented that the Gag Requirement forces health care professionals to violate their ethical responsibilities and thus that numerous providers will be forced to leave the Title X program if it goes into effect. ER27-29; *see, e.g.*, AMA Comment 3; PPFA Comment 15-16; NFPRHA Comment Ltr. 4 (July 31, 2019). For example, as the AMA made clear, the Gag Requirement would compel physicians to violate their ethical obligations not to "withhold[] information without the patient's knowledge or consent," and to "[h]onor a patient's request not to receive certain medical information," AMA, *Code of Medical Ethics* §2.1.3; *see* ER28-29; ER39-40.

In the face of "persuasive evidence" from the leading experts on medical ethics—including the AMA, the group that "literally wrote the book on medical ethics" (ER28-29)—HHS was required to provide a reasoned explanation for reaching a different conclusion. But, as the district court found, HHS "never addressed and does not appear to have even considered," the objections from the AMA and many others. ER29-30. HHS stated that it "disagree[d]," and "believe[d] that the final rule adequately accommodates medical professionals and

their ethical obligations while maintaining the integrity of the Title X program." 84 Fed. Reg. at 7,724. An unexplained statement that HHS "disagree[s]," *id.*, with comments and relevant experts does not constitute reasoned decisionmaking, *see Beno v. Shalala*, 30 F.3d 1057, 1074-1075 (9th Cir. 1994).

HHS argues (Br. 37) that the district court did not consider HHS's more "extensive explanation" at page 7,748 of the Rule. That discussion is hardly extensive. HHS said there that it "does not believe the Court in *Rust* upheld a rule that required the violation of medical ethics." 84 Fed. Reg. at 7,748. But *Rust* did not address whether the 1988 rule violated medical ethics.[11] HHS also relies on its view that federal and state conscience laws *permit* certain health care professionals not to assist in or refer for abortion. *Id.* But a law that might permit providers to *choose* not to comply with ethical requirements is different in kind from a rule *prohibiting* providers from complying with those requirements.

HHS also argues (Br. 38-39) that the Rule does not violate medical ethics because Title X is a "limited" program in that it only subsidizes certain health care services. But HHS points to nothing suggesting that medical ethics permit a physician or other provider in these circumstances to withhold information a

[11] HHS points (Br. 38) to the dissenting opinion in *Rust*, which mentioned "the ethical responsibilities" of medical professionals in the context of its First Amendment analysis, 500 U.S. at 213-214 (Blackmun, J., dissenting). The Court disagreed with the dissent's method of analysis, but did not speak to the issue of medical ethics.

patient seeks—or to force information onto a patient who does not want it—simply because the provider is acting in the context of a government program with a limited scope. Again, the record evidence is to the contrary. *See, e.g.*, ER40.

b. HHS also acted arbitrarily and capriciously by disregarding the evidence that Planned Parenthood—which serves 40% of Title X patients—and many other Title X providers would be forced to leave the program if the Gag Requirement were to take effect. *See* ER31-32. Moreover, Planned Parenthood made clear that, as a result, its affiliates would be forced to close clinics, reduce services, and lay off staff—further disrupting and delaying care for patients. PPFA Comment 15-17; SER24-29. HHS said nothing about the mass exodus that the Rule would cause and instead simply asserted, without evidence, that the Rule "will contribute to more clients being served, gaps in service being closed, and improved client care." 84 Fed. Reg. at 7,723.

As the district court found, "HHS fails to show its work. There is no transparency and no way to find out what, if anything, HHS based its assumptions on." ER32. The administrative record established that other safety-net family-planning providers would be unable to absorb all the patients of those that leave the program, leaving many patients without access to vital, life-saving services. *See, e.g.*, Guttmacher Comment 20; PPFA Comment 16. When asked in the *California* case for evidence upon which HHS based the claim that new providers

would be able to fill the gap in services, counsel for HHS simply responded that it was "just intuitive." *California*, 2019 WL 1877392, at *12. "Intuition is no rebuttal to Plaintiffs' evidence of threatened irreparable harm" to Title X patients. *Id.*

Agency predictions "'must be based on some logic and evidence, not sheer speculation.'" *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014). The D.C. Circuit's recent decision in *National Lifeline Association v. FCC*, 921 F.3d 1102 (D.C. Cir. 2019), is instructive. That case involved the FCC's "fundamental change" to a program that provided voice and broadband services to certain low-income consumers. *Id.* at 1106. The court of appeals held that the FCC's action was arbitrary and capricious because it "evince[d] no consideration of the exodus of … providers from" the program. *Id.* at 1105. The court recognized that it must "'give appropriate deference to predictive judgments' by an agency where supported by '[s]ubstantial evidence,'" but found that principle inapplicable because the agency "summarily" concluded that its action would support the expansion of providers but "referred to no evidence that … providers will make up the gap in services." *Id.* at 1113.

HHS similarly failed to address the exodus of providers from the Title X program as a result of the Rule. And HHS cited no evidence when it claimed that the Rule may result in more patients being served. That HHS pointed to no

evidence is unsurprising. The evidence contradicts HHS's unsupported claims. *See, e.g.*, SER189-190.

HHS invokes (Br. 41) the statement in the Rule that the agency "expects that honoring statutory protections of conscience in Title X may increase the number of providers in the program." 84 Fed. Reg. at 7,780. But HHS already honors those laws, and allows those Title X providers that object to abortion not to refer for it. HHS points in its brief (at 41) to a recent lawsuit filed by "a new network of providers," Obria Group, Inc., supposedly in support of the proposition that faith-based providers were limiting the scope of their practice under the 2000 regulations but would now "participate in the Title X program" under the Rule. That reliance on the Obria lawsuit is misleading: In response to that lawsuit, HHS touts its "longstanding policy," in existence for more than 10 years, of not enforcing the 2000 rule's "abortion referral" provisions against "Title X providers with religious objections to such referrals." SER205-206. By HHS's own admission—and contrary to what the government asserts in its brief—nothing prevents a provider with "'deep religious objections'" from participating under the 2000 rules (*id.*). HHS therefore could not reasonably conclude that the Rule was necessary to expand such participation.

Moreover, contrary to HHS's assertion (Br. 42), the district court did not hold that HHS must "identify in advance" those providers who will purportedly

step in. It held only that HHS must have some basis to conclude that sufficient numbers of providers could step in to cover the gap in services caused by the Rule. ER32; *see, e.g.*, *National Lifeline*, 921 F.3d at 1113.[12]

The Gag Requirement is also arbitrary and capricious because HHS failed to account for the serious adverse health outcomes its Rule would cause. HHS stated that it was "not aware, either from its own sources or from commenters, of actual data that could demonstrate a causal connection between the … rulemaking and an increase in unintended pregnancies, births, or costs associated with either." 84 Fed. Reg. at 7,775. But the administrative record is full of that "actual data," *id.* For example, one expert commenter (and declarant here) explained in detail the harms to public health that have occurred when Planned Parenthood has lost public funding in the past—including HIV outbreaks and spikes in unintended pregnancies. *See* Brindis Comment Ltr. 6-7, 12 (July 31, 2018); SER125-126.

[12] HHS cites (Br. 41) a footnote in the Rule to support its conclusion, which references an online poll of "faith-based medical" providers from 2009. The poll described in that footnote (84 Fed. Reg. at 7,781 n.139) found only that those providers would "limit the scope of their practice of medicine" if HHS did not enforce conscience protections. *See* Freedom2Care & Christian Medical Association, *Two National Polls Reveal Broad Support for Conscience Rights in Healthcare* 4 (Apr. 8, 2009). So at most, results from a decade ago show that faith-based providers consider it important that HHS do exactly what it has said it already does with respect to those who object to providing abortion referrals. The cited survey offers no basis for HHS's unsupported conclusion that new providers "may," 84 Fed. Reg. at 7,780, fill the gap left behind by providers who are forced to leave the program.

Commenters also explained that if Title X providers are barred from referring for abortion, patients who want or need to terminate their pregnancy will face delays in care and increased risk of complications from a delayed abortion, *see* PPFA Comment 14, 20-21, as well as increased risk that pregnancy will cause or exacerbate other conditions, *see* EAH Comment Ltr. 4 (July 30, 2018). HHS cannot simply brush aside evidence of patient harm. *See, e.g.*, *National Lifeline*, 921 F.3d at 1113.

2. The Separation Requirement is arbitrary and capricious

First, the Separation Requirement imposes enormous costs on providers with no demonstrated benefit. The Rule provides no evidence of misuse of Title X funds over the past half century, nor any evidence that the current and longstanding audit process, with which Title X providers have long complied, is not an adequate safeguard. *See* ER6. HHS resorts instead to speculation about the "risk[s]" of "appearance[s]," "perception[s]," and "potential" misuse of funds. 84 Fed. Reg. at 7,764. That language speaks volumes. Such "sheer speculation," *Sorenson*, 755 F.3d at 708, cannot justify imposing extremely onerous costs on Title X grantees.

Second, the administrative record establishes that many Title X providers will not be able to meet those costs and will therefore be forced to leave the program. HHS claimed, again without evidence, that the Separation Requirement will cost $30,000 per site. 84 Fed. Reg. at 7,782. But Planned Parenthood

explained—citing actual cost estimates and past experience—that the Separation Requirement is likely to cost approximately $625,000 per affected site, or 20 times HHS's estimate. PPFA Comment 32. HHS ignored this. HHS further failed to account for any costs beyond the first year—which are likely to reach into the millions of dollars. *See id.* at 32-33; SER59. And HHS estimated that only 20% of Title X service sites would be affected by the Separation Requirement, using the percentage of Title X sites co-located with programs that offer abortion. 84 Fed. Reg. at 7,781. But the Rule would require separation for any grantee that even *refers patients to* abortion providers.

Third, the Rule ignores the "serious reliance interests," *FCC v. Fox Tel. Stations, Inc.*, 556 U.S. 502, 515 (2009), engendered by the rules that have been in place for decades. Title X grantees have structured their programs around the longstanding regulations—for example, investing significant resources to build facilities that can accommodate both Title X projects and other programs to efficiently provide health care services to low-income people. And low-income patients have long relied on free or low-cost reproductive health care from these providers. Again, this case is analogous to *National Lifeline*, where the D.C. Circuit held that the agency failed to take into consideration two sets of reliance interests: those of the "providers that had crafted business models and invested

significant resources into providing" the services, and those of the "two-thirds of subscribers relying on [such] providers for their … service." 921 F.3d at 1114.

Fourth, HHS failed to consider the harms to public health caused by the Separation Requirement. As explained above, compliance with the Separation Requirement will be prohibitive for many grantees and harmful to patient care. *See supra* pp.32-33, 48-49. But HHS brushed this evidence aside, ignoring that many grantees will be forced to leave the Title X program and close clinics, thereby reducing access to reproductive care and adversely affecting patient health. *See id.*; PPFA Comment 33; NFPRHA Comment 37.

HHS again invokes (Br. 38-40) *Rust* to argue that Plaintiffs' arbitrary-and-capricious arguments are foreclosed. But in 1988, HHS issued the rule "in the wake of" and "in direct response to" reports from the General Accounting Office and Office of the Inspector General. 500 U.S. at 187. Thirty years have passed, and *this* Rule is supported by nothing similar—even with decades of experience after the 1988 rule was suspended and withdrawn. Moreover, under settled law, the Rule may be only upheld, if at all, on the basis of HHS's reasoning during the *2018-2019* rulemaking process. *See Michigan v. EPA*, 135 S. Ct. 2699, 2710 (2015). HHS may not rely on any purported factual bases supporting a rule promulgated decades ago without some evidence that the same facts exist today. *See Sierra Club v. EPA*, 671 F.3d 955, 966, 698 (9th Cir. 2012).

II. THE DISTRICT COURT CORRECTLY FOUND THAT THE EQUITIES WEIGH IN FAVOR OF AN INJUNCTION

A. Plaintiffs Will Suffer Irreparable Harm Absent An Injunction

The district court correctly found that Plaintiffs, patients, and public health would be irreparably harmed absent preliminary relief. ER32-33; *accord California*, 2019 WL 1877392, at *1, *8-13; *Baltimore*, 2019 WL 2298808, at *12-13; *Washington*, 376 F. Supp. 3d at 1131-1132. If the Rule takes effect, every Planned Parenthood affiliate that currently participates in Title X will be compelled to leave the program. SER2, 16-18. As Planned Parenthood explained, "[t]he gag on medical speech … is fundamentally at odds with Planned Parenthood's mission and the ethical and professional obligations of Planned Parenthood's health care professionals," and the Separation Requirement would be prohibitively expensive and harmful for patient care. SER2-3. Above all, patient care would suffer.

The Rule will harm every Planned Parenthood affiliate that currently participates in Title X. All affiliates will be forced to leave the program, which will seriously impair their mission of providing reproductive health care to low-income individuals. Many affiliates will be forced to reduce hours and services, lay off staff, or close health centers altogether. SER45-46, 60-61. For example, if Planned Parenthood of Greater Ohio loses Title X funding, it would have a budget shortfall of more than $3 million, and would likely have to lay off at least 10 staff members and close two of its 19 health centers. SER25.

Such harms cannot be remedied even if the Rule is enjoined at the end of litigation. Providers that have withdrawn from the Title X program may not be able to rejoin until the next grant cycle, years away. Lost Title X funds cannot be recouped from the federal government. *See California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018), *cert. denied*, __ S. Ct. __, 2019 WL 1207008 (June 17, 2019). Laid off staff and clinicians cannot be easily re-hired, and health centers that are closed cannot be easily re-opened. *See* SER25. Plaintiffs will also be irreparably harmed by the loss of patients and goodwill that will result if Planned Parenthood has to turn away patients because of closures, service reductions, or a lack of funds to subsidize care for those who cannot afford it. SER17; *see adidas Am.*, 890 F.3d at 756-757; *Humana, Inc. v. Jacobson*, 804 F.2d 1390, 1394 (5th Cir. 1986). And Plaintiffs' ability to carry out their core mission will be impaired. SER2; *see, e.g.*, *Valle del Sol Inc. v. Whiting*, 732 F.3d 1006, 1029 (9th Cir. 2013).[13]

Even more troubling is the irreparable harm that Plaintiffs' patients would suffer. Planned Parenthood affiliates serve many regions where other providers could not absorb the influx of patients left behind if their local Planned Parenthood

[13] Contrary to HHS's assertion (Br. 43), none of these harms are "[o]rdinary compliance costs." They are injuries occasioned by Plaintiffs' inability to comply with the Rule, and thus their inability to participate in Title X. Nor are Plaintiffs' injuries "predicated on their view of the merits" (HHS Br. 44); rather they are based on Plaintiffs' professional obligation to uphold medical ethical standards and to provide comprehensive, nonjudgmental care to their patients.

health center were to close. *Supra* pp.31-33, 44-46; *see also* Guttmacher Comment 10 & Tables 1-3; SER23, 170-171. Those impacts will disrupt care not just for patients who rely on Title X for subsidized care, but for all patients served by affected facilities. *See, e.g.*, SER13. For many patients, losing access to Planned Parenthood would mean losing access to critical and often life-saving services. *See* Brindis Comment 12; SER6, 160-161. Grave health consequences would result. ER33; *see also* SER6, 120-124, 172. Moreover, cuts in care will hit especially hard in rural communities and communities of color that already face systemic obstacles to health care. *See* ER31; SER127-128, 137-138.

2. HHS faults (Br. 42-43) the district court for not crediting HHS's prediction that new Title X providers would fill any gaps. As explained, however, that prediction was not credible because it was not based on any evidence, *see supra* pp.44-46. Moreover, even if new providers applied for Title X grants, that would not ameliorate the harm to Planned Parenthood from having to withdraw from the program.

HHS also attempts (Br. 42-43) to dismiss the harms as "chain[s] of speculation." That is wrong. Planned Parenthood submitted evidence that, because of the Rule's unethical and harmful requirements, *every* Planned Parenthood affiliate in the program will be forced to withdraw it if the Rule takes effect. SER2, 16-20. As the district court found, the consequent harms are borne

out by extensive record evidence and experience. *See* ER6, 32-33; SER125-126, 188-191. Moreover, as the district court also found, HHS "failed to introduce any evidence on the issue." ER32-33. Thus, the "only evidence before [the court was] that if the Final Rule goes into effect, many Title X providers," including Planned Parenthood, will "exit the program" rather than violate "established standards of medical ethics" and make the costly changes needed to comply with the Separation Requirement. ER33.

B. The Public Interest And Balance Of The Equities Tip Sharply In Plaintiffs' Favor

The district court correctly found that the balance of equities and public interest "tip[] sharply in favor of the Plaintiffs." ER33; *accord California*, 2019 WL 1877392, at *13-14; *Baltimore*, 2019 WL 2298808, at *12-13; *Washington*, 376 F. Supp. 3d at 1132. As the district court found, the evidence "leads to the inescapable conclusion that the Final Rule will result in negative health outcomes for low income women and communities[,] … less contraceptive services, more unintended pregnancies, less early breast cancer detection, less screening for cervical cancer, less HIV screening, and less testing for sexually transmitted disease." ER6; *see* ER34. This Court has recognized that "individuals' interests in sufficient access to health care" is paramount, and that the public interest and balance of equities weigh in favor of an injunction where such access would otherwise be interrupted. *E.g.*, *Dominguez v. Schwarzenegger*, 596 F.3d 1087,

1098 (9th Cir. 2010), *vacated and remanded on other grounds by Douglas v. Independent Living Ctr. of S. Cal., Inc.*, 565 U.S. 606 (2012).

Meanwhile, neither the public nor HHS would suffer any harm from the status quo. "The current regulations have been in place for nearly 50 years and have an excellent track record" (ER34), and HHS "cannot point to one instance where Title X funds have been misapplied" under those rules (ER6).

HHS argues that it "sustains irreparable harm whenever it 'is enjoined … from effectuating statutes enacted by representatives of [the] people.'" HHS Br. 44-45 (quoting *Maryland v. King*, 567 U.S. 1301 (2012) (Roberts, C.J., Circuit Justice)). But the district court did not enjoin enforcement of a statute enacted by the legislature; it enjoined enforcement of a rule the court found likely to be contrary to federal law. Here, "the public … has an interest in ensuring that 'statutes enacted by [their] representatives' are not imperiled by executive fiat." *East Bay Sanctuary Covenant v. Trump*, 909 F.3d 1219, 1255 (9th Cir. 2018) (alteration in original).

HHS also argues (Br. 45) that grantees will be harmed by uncertainty about the application process or compliance deadlines. That argument is waived because it was not raised below. Moreover, a preliminary injunction *reduces* uncertainty by maintaining the decades-long status quo. Finally, just months ago—after HHS issued the Rule but before its effective date—HHS awarded Title X grants to

providers under the very set of longstanding regulations it now seeks to displace by this Rule. *See* HHS.Add.34 (Dkt. 15). The preliminary injunction avoids the turmoil caused by drastically changing the rules mid-grant.

III. THE SCOPE OF THE INJUNCTION IS PROPER

A. The district court correctly enjoined the Rule in full. In one cursory paragraph (Br. 50-51), HHS insists that the Rule is severable, but it never elaborates. It does not attempt to explain how or why the two central provisions of the Rule that the district court found likely unlawful could be severed without affecting the balance of the Rule.

Even when a rule contains a severability clause, a court must ensure that "the balance of the rule can function independently" before severing its unlawful aspects. *MD/DC/DE Broadcasters Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001). That is not the case here. The Gag and Separation Requirements are the central provisions of the Rule. Moreover, they are expressly integrated. The Rule requires Title X projects to physically separate their Title X activities from so-called "prohibited activities," 84 Fed. Reg. at 7,789, which are defined by cross-reference to, among other things, the Gag Requirement, *id.* In other words, "any activity prohibited by the Gag [Requirement] must have no connection, physically or financially," to Title X projects. ER24. So, for example, if the Gag Requirement is unlawful (as indeed it is), then the so-called "prohibited activities"

in the Separation Requirement must, at least in part, no longer be prohibited. The Separation Requirement would no longer make any sense, and at a minimum would have to be rewritten.

The Court should reject HHS's unexplained severability request. *See Texas v. EPA*, 829 F.3d 405, 435 (5th Cir. 2016) (staying regulation "in its entirety" because agency "offer[ed] nothing beyond … cursory comment").

B. "In crafting an injunction," the district court recognized, "'[t]he scope of remedy must be no broader and no narrower than necessary to redress the injury shown by the plaintiff[s].'" ER34. Under that standard, the district court properly enjoined any enforcement of the Rule because "the harm to Plaintiffs would occur in every state." *Id.*

Plaintiffs have shown that they and their members or affiliates that participate in Title X will be injured by the Rule. All participating AMA members will be faced with the Hobson's choice of continuing to provide Title X care or abiding by their professional ethics, and all participating Planned Parenthood affiliates will be compelled to withdraw from the program rather than comply with a Rule that violates those ethics. *See supra* pp.11, 30-31, 42, 44. Furthermore, Planned Parenthood affiliates operate as Title X direct grantees, subgrantors, and subgrantees (SER12), and AMA members work within both grantee and subgrantee agencies.

HHS has "fail[ed] to explain how the district court could have crafted a narrower injunction that would provide complete relief to the plaintiffs, including the entity plaintiffs," *Regents of the Univ. of Cal. v. U.S. Dep't of Homeland Sec.*, 908 F.3d 476, 512 (9th Cir. 2018). A narrower injunction would cause myriad problems—which HHS ignores—resulting in patchwork application of inconsistent and unworkable requirements to grantees, subgrantees, practitioners, and patients. If, for example, the Rule were enforced against a grantee who had a Planned Parenthood affiliate as a subgrantee, that grantee might be required to implement policies binding subgrantees or decide to withdraw from the program, both of which would thereby impair Planned Parenthood's rights and harm their patients.

Accordingly, any injunction must cover the Plaintiffs; their members or affiliates; and their (and their members' and affiliates') employers, subgrantors, and subgrantees. Moreover, as noted, AMA members and Planned Parenthood affiliates provide Title X services throughout the country. Given the extent of Plaintiffs' involvement in the Title X program, the district court acted well within its discretion in concluding that its injunction would be the only feasible way to provide complete relief to Plaintiffs.

HHS asserts (Br. 48-49) that, "with respect to the organizational plaintiffs," the injunction should be narrowed to only those "specific members those organizations relied upon for standing." This argument is waived because it was

not raised in the district court. *See Armstrong v. Brown*, 768 F.3d 975, 981 (9th Cir. 2014). It is also meritless.

This Court has recognized that an injunction should provide complete relief to "the members" of an associational plaintiff. *Easyriders Freedom F.I.G.H.T. v. Hannigan*, 92 F.3d 1486, 1496 (9th Cir. 1996). Furthermore, a core purpose of associational standing is to permit people to join together "to create an effective vehicle for vindicating interests that they share with others" and to facilitate the efficient adjudication of common rights. *International Union, United Auto., Aerospace & Agric. Implement Workers of Am. v. Brock*, 477 U.S. 274, 288, 290 (1986). Thus, an association need not demonstrate injury to each individual member to establish standing; one member suffices. *See, e.g.*, *Oregon Advocacy Ctr. v. Mink*, 322 F.3d 1101, 1112 (9th Cir. 2003). That efficiency would be lost if associations were required to show harm to each member in order for any relief to apply to that member. HHS cites no authority supporting its novel argument. Indeed, HHS cites (Br. 47) *Planned Parenthood Federation of America v. Bowen* as an example of a *properly* limited injunction, but that case refutes the government's argument. The *Bowen* order recognized that relief for a plaintiff serving in a representative capacity must extend to its members—and covered both the named plaintiffs *and* their affiliates in its injunction. Add.80-81. In any event,

the record demonstrates that the associational members would all suffer similar injury here. *E.g.*, SER18.

CONCLUSION

The district court's preliminary injunction should be affirmed.

Respectfully submitted.

/s/ Alan E. Schoenfeld

ALAN E. SCHOENFELD
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
Tel.: (212) 230-8800
Fax: (212) 230-8888

alan.schoenfeld@wilmerhale.com
Counsel for Planned Parenthood Federation of America, Inc., Planned Parenthood of Southwestern Oregon, Planned Parenthood Columbia Willamette, Thomas N. Ewing, M.D., and Michele P. Megregian, C.N.M.

PAUL R.Q. WOLFSON
KIMBERLY A. PARKER
ALBINAS J. PRIZGINTAS
JOSHUA M. KOPPEL
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
Tel.: (202) 663-6000
Fax: (202) 663-6363
paul.wolfson@wilmerhale.com
kimberly.parker@wilmerhale.com
albinas.prizgintas@wilmerhale.com
joshua.koppel@wilmerhale.com
Counsel for Planned Parenthood Federation of America, Inc., Planned Parenthood of Southwestern Oregon, Planned Parenthood Columbia Willamette, Thomas N. Ewing, M.D., and Michele P. Megregian, C.N.M.

JEREMY D. SACKS
PER A. RAMFJORD
KENNON SCOTT
STOEL RIVES LLP
760 SW Ninth Avenue, Suite 3000
Portland, OR 97205
Tel.: (503) 224-3380
Fax: (503) 220-2480
jeremy.sacks@stoel.com
per.ramfjord@stoel.com
kennon.scott@stoel.com
Counsel for All Plaintiffs

BRIAN D. VANDENBERG
LEONARD A. NELSON
ERIN G. SUTTON
AMERICAN MEDICAL ASSOCIATION
Office of General Counsel
300 N. Wabash Avenue
Chicago, IL 60611
Tel.: (312) 464-5532
Fax: (312) 224-6924
brian.vandenberg@ama-assn.org
leonard.nelson@ama-assn.org
erin.sutton@ama-assn.org
Counsel for American Medical Association and Oregon Medical Association

MARK BONANNO
OREGON MEDICAL ASSOCIATION
General Counsel
11740 SW 68th Parkway, Suite 100
Portland, OR 97223
Tel.: (503) 619-8117
Fax: (503) 619-0609
mark@theoma.org
Counsel for American Medical Association and Oregon Medical Association

HELENE T. KRASNOFF
CARRIE Y. FLAXMAN
PLANNED PARENTHOOD
FEDERATION OF AMERICA, INC.
1110 Vermont Avenue, NW, Suite 300
Washington, D.C. 20005
Tel.: (202) 973-4800
Fax: (202) 296-3480
helene.krasnoff@ppfa.org
carrie.flaxman@ppfa.org
Counsel for Planned Parenthood Federation of America, Inc., Planned Parenthood of Southwestern Oregon, Planned Parenthood Columbia Willamette, Thomas N. Ewing, M.D., and Michele P. Megregian, C.N.M.

June 28, 2019

STATEMENT OF RELATED CASES

Other than those cases identified in Appellants' brief, there are no known related cases pending in this Court.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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42 U.S.C. §300a-6.
Prohibition against funding programs using abortion as family planning method

None of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning.

Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. 115-245, div. B, tit. II, 132 Stat 2981, 3070-3071

Family Planning

For carrying out the program under title X of the PHS Act to provide for voluntary family planning projects, $286,479,000: Provided, That amounts provided to said projects under such title shall not be expended for abortions, that all pregnancy counseling shall be nondirective, and that such amounts shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.

42 U.S.C. §18114. Access to therapies

Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that—

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 59

[HHS–OS–2018–0008]

RIN 0937–ZA00

Compliance With Statutory Program Integrity Requirements

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, HHS. Department of Health and Human Services.

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) to ensure compliance with, and enhance implementation of, the statutory requirement that none of the funds appropriated for Title X may be used in programs where abortion is a method of family planning and related statutory requirements. Accordingly, OPA amends the Title X regulations to clarify grantee responsibilities under Title X, to remove the requirement for nondirective abortion counseling and referral, to prohibit referral for abortion, and to clarify compliance obligations with state and local laws. In addition, Title X regulations are amended to clarify access to family planning services where an employer exercises a religious or moral objection. Finally, Title X regulations are amended to require physical and financial separation to ensure clarity regarding the purpose of Title X and compliance with statutory program integrity provisions, and to encourage family participation in family planning decisions, as required by Federal law.

DATES: *Effective date:* This rule is effective on May 3, 2019.

Compliance date: Compliance with the physical separation requirements contained in § 59.15, is required March 4, 2020.

Compliance with the financial separation requirements contained in § 59.15 is required by July 2, 2019. Until that date, the Department will expect grantees to comply with either § 59.15 or the ''Separation'' section of the guidance at 65 FR 41281, 41282.

Compliance with §§ 59.7 and 59.5(a)(13) is required by July 2, 2019.

Compliance for reporting, assurance, and provision of service in §§ 59.5(a)(12) and (13) as it applies to all required reports, 59.5(a)(14), (b)(1) and (8), 59.13, 59.14, 59.17, and 59.18 is required by July 2, 2019.

Compliance for all other requirements of this final rule is required by the effective date, that is, by May 3, 2019.

FOR FURTHER INFORMATION CONTACT: The Office of the Assistant Secretary for Health (OASH) at (202) 690–7694, *ASH@hhs.gov,* or by mail at 200 Independence Avenue SW, Washington, DC 20201

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I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this rule is to finalize, with changes in response to public comments, revisions to the Title X family planning regulations proposed on June 1, 2018.[1] This rule, promulgated pursuant to the Department's authority,[2] will ensure compliance with, and enhance implementation of, the statutory requirement that none of the funds appropriated for Title X may be used in programs where abortion is a method of family planning, as well as related statutory requirements. In addition, the rule ensures that grantee responsibilities, referral requirements, and documentation obligations are clear under the Title X program. The rule also clarifies that provision of family planning services under Title X may be available under the good reason exception at the discretion of the project director for women denied coverage for contraceptives if the sponsor of their health plan exercises a religious or moral exemption recognized by the Department.[3] The rule protects vulnerable populations by ensuring Title X providers comply with State reporting requirements. And, consistent with Federal law, the rule encourages family participation in family planning decisions of minors except where the minor is or may be the victim of child abuse or incest. To ensure the best applicants are chosen, the rule expands review and selection criteria to include provisions that will help evaluate applicants' adherence to statutory requirements and goals. In addition, the rule formally repeals the 2016 amendments to the Title X eligibility requirements, which were nullified by a joint resolution of disapproval, under the Congressional Review Act, signed by the President. This rule will protect the integrity of the Title X program, pursuant to congressional purpose, to offer a broad range of family planning methods and services and improve the quality of programs that specifically provide support in this area.

2. Summary of the Major Provisions

a. Clear Financial and Physical Separation

This rule finalizes requirements that ensure clear physical and financial separation between a Title X program and any activities that fall outside the program's scope. This physical and financial separation will ensure compliance with the statutory requirement that Title X funding not support programs where abortion is a method of family planning—and is consistent with the plain text of Section 1008, legislative history, and case law. In particular, the rule protects against the intentional or unintentional co-mingling of Title X resources with non-Title X resources or programs by amending the Department's regulation finalized on July 3, 2000, (the ''2000 regulations''), which required no physical separation and only limited financial separation.[4] This rule will require Title X providers to maintain physical and financial separation from locations which provide abortion as a method of family planning.

Together, these changes address several concerns of the Department. They address concerns over the fungibility of Title X resources and the potential use of Title X resources to support programs where, among other things, abortion is a method of family planning. They address the potential for ambiguity between approved Title X activities and non-Title X activities and services, which creates significant risk for public confusion over the scope of Title X services, including whether Title X funds are allocated for, or spent on, non-Title X services, including abortion-related purposes. And they address the concern that Title X resources could facilitate the development of, and ongoing use of, infrastructure for non-Title X activities. The Department seeks to protect Title X (and Title X funds) as the only discrete, domestic, Federal grant program focused solely on the provision of cost-effective family planning methods and services. The final rule thus requires physical and financial separation to protect the statutory integrity of the Title X program, to eliminate the risk of co-mingling or misuse of Title X funds, and to prevent the dilution of Title X resources.

b. Ensure Transparency for Legal and Ethical Use of Taxpayer Dollars Among Subrecipients

This rule facilitates the legal and ethical use of taxpayer dollars by implementing reporting requirements with respect to the use of Title X funds. The 2000 regulations do not require grantees to submit significant information to the government about their subrecipients, referral agencies, or other partners to whom Title X funds may flow. This lack of reporting can be a significant barrier to the Department's ability to ensure Title X funds are directed only to Title X activities. Accordingly, the final rule requires that Title X grant applicants include, as part of their applications, a list of all planned subrecipients, detailed descriptions of the extent of services and collaboration with subrecipients, and a clear explanation of how the applicant, if successful, would conduct an oversight program with respect to its subrecipients.[5] The final rule defines a subrecipient as any entity that provides family planning services with Title X funds under a written agreement with a grantee or another subrecipient. Consistent with grant reporting requirements, grantees must regularly report and demonstrate their own compliance, as well as ensure the compliance of their subrecipients with all statutory and regulatory requirements. The Department will also require grantees to establish a plan to ensure that they and their subrecipients comply with all applicable State reporting requirements of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking, adequately train staff regarding such requirement and include protocols that ensure such minors are provided counseling on how to resist attempts to coerce them into engaging in sexual activities; and will commit to preliminary screening of such minors. The final rule establishes that the continuation of funding for grantees and subrecipients is contingent on their demonstration to the satisfaction of the Secretary that the statutory and regulatory requirements of Title X have been met. To ensure proper accounting of Title X funds, the Secretary may

[1] *See* Compliance with Statutory Program Integrity Requirements, 83 FR 25502 (proposed June 1, 2018) (to be codified at 42 CFR part 59).

[2] For a detailed discussion regarding statutory authority, *see infra* Section II. Statutory Authority, Overview, Analysis, and Response to Public Comments.

[3] *See* Religious exemptions in connection with coverage of certain preventive services, 45 CFR 147.132 (2019); *see also* Moral exemptions in connection with coverage of certain preventive health services, 45 CFR 147.133 (2019).

[4] *See* Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, 42 CFR part 59, which omit any mention of physical or financial separation; *see also* Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, 65 FR 41270, 41275–41276 (July 3, 2000) where the Department discusses its decision in the 2000 regulation to require financial separation, while choosing to not require physical separation.

[5] To further ensure program transparency (and ensure a seamless continuum of care), applicants and grantees are also required to provide certain information about agencies or individuals providing referral services and their collaborations with such referral agencies and individuals.

review grantee and subrecipient records to ensure regulatory compliance.

To increase program integrity, the Department will also increase various monitoring and reporting requirements. Under the final rule, grantees will be required to receive approval for any change in the use of grant funds, and to fully account for and justify charges against the Title X grant. The final rule will also increase monitoring requirements to better ensure appropriate billing practices. And because the 2000 regulations offer scant guidance on the Anti-lobbying Act and appropriations law provisions applicable to Title X, this final rule will require Title X grantees to provide assurances satisfactory to the Secretary that they both understand and agree to the prohibition against lobbying and political activity in the Title X project.

The Department believes that these changes will ensure that OPA has the information necessary to determine whether Title X projects, grantees, and subrecipients are compliant with the statutory and regulatory provisions applicable to the program.

c. Nondirective Pregnancy Counseling Permitted, Not Required

This rule finalizes several regulatory provisions designed to ensure that the requirements of the Title X regulations are consistent with certain laws that protect the conscience rights of individuals and entities who decline to perform, participate in, or refer for, abortions. The 2000 regulations require Title X projects to provide abortion referral [6] and nondirective counseling on abortion, if requested. The Department believes this requirement is inconsistent with federal conscience laws and, as discussed below with respect to the referral provision, also violates Section 1008. With respect to conscience, the regulatory requirement to counsel on abortion, if requested, conflict with HHS enforced statutes protecting conscience in health care, including the Church Amendment,[7] Coats-Snowe Amendment [8] and the Weldon Amendment [9] for individual and institutional entities who object. The Department acknowledged this conflict in the 2008 conscience regulations, stating that its ''current regulatory requirement that grantees must provide counseling and referrals for abortion upon request . . . is inconsistent with the health care provider conscience protection statutory provisions and this regulation.'' Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 FR 78072, 78087 (Dec. 19, 2008). The proposed rule in this rulemaking similarly recognized the ongoing conflict between the 2000 regulation and conscience protections. In the 2008 provider conscience regulation, the Department stated that OPA was ''aware of this conflict with the statutory requirements [of the Church, Coats-Snowe, and Weldon Amendments] and, as such, would not enforce this Title X regulatory requirement on objecting grantees or applicants,'' *id.,* but was unable to directly address the Title X requirements, given the rulemaking context. The Department believes that it is appropriate and necessary to revise the Title X regulatory text to eliminate the provisions which are inconsistent with the health care conscience statutory provisions.[10]

Under the final rule, the Title X regulations no longer require pregnancy counseling, but permits the use of Title X funds in programs that provide pregnancy counseling, so long as it is nondirective. Nondirective pregnancy counseling is the meaningful presentation of options where the physician or advanced practice provider (APP) [11] is ''not suggesting or advising one option over another.'' 138 Cong. Rec. H2822, H2826, 1992 WL 86830. Section 1008 and its legislative history offers additional clarity specifically as to abortion, where the physician or APP cannot engage in ''promoting, encouraging, or advocating abortion.'' *Id.* at H2829. Nondirective counseling does not mean that the counselor is uninvolved in the process or that counseling and education offer no guidance, but instead that clients take an active role in processing their experiences and identifying the direction of the interaction. In nondirective counseling, the Title X physicians and APPs promote the client's self-awareness and empower the client to be informed about a range of options, consistent with the client's expressed need and with the statutory and regulatory requirements governing the Title X program. In addition, the Title X provider may provide a list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), some (but not the majority) of which may provide abortion in addition to comprehensive primary care.

Accordingly, this final rule eliminates the abortion counseling requirements in the 2000 regulations, consistent with the Department's interpretation of federal conscience laws and Section 1008. This rule continues to allow nondirective pregnancy counseling, as discussed in more detail below.

[6] Referral for abortion is discussed in the next section.

[7] The Church Amendments, among other things, prohibit certain HHS grantees from discriminating in the employment of, or the extension of staff privileges to, any health care professional because they refused, because of their religious beliefs or moral convictions, to perform or assist in the performance of any lawful sterilization or abortion procedures. The Church Amendments also prohibit individuals from being required to perform or assist in the performance of any health service program or research activity funded in whole or in part under a program administered by the Secretary contrary to their religious beliefs or moral convictions. *See* 42 U.S.C. 300a–7.

[8] The Coats-Snowe Amendment bars the federal government and any State or local government that receives federal financial assistance from discriminating against a health care entity, as that term is defined in the Amendment, who refuses, among other things, to provide referrals for induced abortions. *See* 42 U.S.C. 238n(a).

[9] The Weldon Amendment was added to the annual 2005 health spending bill and has been included in subsequent appropriations bills. *See* Consolidated Appropriations Act, 2018, Public Law 115–141, Div. H, sec. 507(d), 132 Stat. 348, 764; Consolidated Appropriations Act, 2017, Public Law 115–31, Div. 507(d), 131 Stat. 135, 562. The Weldon Amendment bars the use of appropriated funds on a federal agency or programs, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not, among other things, refer for abortions.

[10] In the preamble to the 2000 regulations, the Department addressed a comment that the requirement to provide options counseling ''should not apply to employees of a grantee who object to providing such counseling on moral or religious grounds,'' and rejected it, contending that it is not necessary because, under the Church Amendments, ''grantees may not require individual employees who have such objections to provide such counseling,'' but ''in such cases the grantees must make other arrangements to ensure that the service is available to Title X clients who desire it.'' 65 FR 41270, 41274 (July 3, 2000). But the evidence collected in the Department's 2018 conscience proposed rule, 83 FR 25502, 25506 (June 1, 2018), suggests that neither grantees nor their employees may know of the requirements of the Church Amendment. More importantly, the Department's 2000 analysis failed to consider that the Coats-Snowe Amendment (and the subsequently passed Weldon Amendment) protects institutional health care providers from discrimination by federal programs, including Title X, on the basis of their refusal to counsel or refer for abortion and, thus, that ''under section 245 of the Public Health Service Act and the Weldon Amendment, the Department cannot . . . enforce 42 CFR 59.5(a)(5) against an otherwise eligible grantee or applicant who objects to the requirement to counsel on or refer for, abortion.'' 73 FR at 78088.

[11] Under this final rule, nondirective counseling may be provided by physicians and advanced practice providers. As discussed in detail below, the final rule defines ''advanced practice providers'' as including physician assistants and advanced practice registered nurses.

d. Referral for Abortion as a Method of Family Planning Prohibited, No Longer Required

This rule finalizes the revocation of the requirement that Title X projects refer for abortion, and finalizes the prohibition against using Title X funds to refer for abortion as a method of family planning, or to perform, promote, or support abortion as a method of family planning. Although the 2000 regulations require Title X programs to refer for abortion when requested by a client,[12] the Department no longer believes that the requirement is appropriate or permissible. Like the counseling requirement, the Department believes the referral requirement is in conflict with federal conscience protections, such as the Church, Coats-Snowe, and Weldon Amendments, for individual and institutional entities which object, and is finalizing the proposal to remove that requirement from the regulations. Furthermore, the Department believes that, in most instances when a referral is provided for abortion, that referral necessarily treats abortion as a method of family planning. The Department believes both the referral for abortion as a method of family planning, and such abortion procedure itself, are so linked that such a referral makes the Title X project or clinic a program one where abortion is a method of family planning, contrary to the prohibition against the use of Title X funds in such programs. The Department, thus, views such abortion referrals in the Title X project as a violation of Section 1008, which prohibits the use of Title X funds in programs where abortion is a method of family planning. *See* 42 U.S.C. 300a–6. Even if the referral requirement was not in tension with these statutes, the Department believes that such a requirement may deter qualified providers from applying for Title X grants or participating in Title X projects, and may introduce ambiguity about the use of Title X funds to support abortion as a method of family planning. Accordingly, this final rule removes the requirement that Title X funded entities refer for abortion, and prohibits Title X projects from referring for abortion as a method of family planning, or from performing, promoting, referring for, or supporting abortion as a method of family planning.

e. Sexual Abuse Reporting Requirements Training and Protocols

This rule finalizes the requirement that Title X programs and providers comply with State and local sexual abuse reporting requirements, as well as the requirement for training and clinic protocols on such requirements and related issues, to ensure that Title X providers meet the applicable statutory and regulation reporting requirements of the Title X program and treat the survivors of sexual abuse and assault with dignity and compassion, without hindering State and local efforts to prevent sexual abuse.[13] Section 59.11 of the 2000 regulations, on the confidentiality of Title X records, provides that personal information may not be disclosed absent consent by the individual, except to provide treatment, or as required by law, ''with appropriate safeguards for confidentiality.'' *See* 42 CFR 59.11. To ensure that Title X grantees and subrecipients comply with applicable reporting requirements, the Department clarifies in this final rule that concerns about confidentiality of information may not be used as a rationale for noncompliance with such reporting laws.

As established in § 59.17 of this final rule, Title X providers are required to comply with all State and local laws regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, or human trafficking. The 2000 regulations permit the use of confidential information obtained by project staff to comply with State and local reporting requirements,[14] but do not expressly address the appropriations law requirement to report certain crimes, nor impose a federal obligation on Title X grantees and subrecipients to comply with State reporting or notification requirements. The final rule clarifies that Title X grantees and subrecipients must comply with State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and/or human trafficking. To ensure compliance with that obligation and to ensure the appropriate care for such patients, their safety, and their personal empowerment, the final rule requires Title X grantees and subrecipients to have in place a plan to implement the specific reporting requirements that apply to them in their State (or jurisdiction), as well as to provide for annual training for all personnel with respect to these requirements, how such reports are to be made, and appropriate interventions, strategies, and referrals.

As part of prevention, protection, and risk assessment efforts, grantees and subrecipients are required to include in such plans, protocols to identify individuals who are victims of sexual abuse or targets for underage sexual victimization and to ensure that every minor who presents for treatment is provided counseling on how to resist attempts to coerce minors into engaging in sexual activities.[15] Title X projects are also required, under this final rule, to conduct a preliminary screening of any minor who presents with an STD, pregnancy, or suspicion of abuse, in order to rule out victimization of the minor. Section 59.17 requires grantees and subrecipients to maintain records that would identify, among other things, the age of any minor clients served, the age of their sexual partner(s) where required by State law, and what reports or notifications were made to appropriate State agencies. The Department will use this documentation to ensure appropriate compliance with State notification laws.

f. Family Participation in Family Planning Decisionmaking

This rule finalizes requirements that Title X providers encourage appropriate family participation in family planning decisions, as required by Federal law.[16] The Title X statute itself requires the encouragement of such family

[12] *See* 42 CFR 59.5; 65 FR 41270, 41278 (July 3, 2000).

[13] *See* Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Public Law 115–245, Div. B, sec. 208, 132 Stat. 2981, 3070 (''HHS Appropriations Act 2019'') (emphasizing the Congressional expectation that ''Notwithstanding 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.'').

[14] *See* 42 CFR 59.11.

[15] The annual appropriations laws also impose on Title X recipients the obligation to provide ''counseling to minors on how to resist attempt to coerce minors into engaging in sexual activities.'' *See* HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. 2981, 3070; Consolidated Appropriations Act, 2018, Public Law 115–141, Div. H, sec. 207, 132 Stat. 348, 736; Consolidated Appropriations Act, 2017, Public Law 115–31, Div. H, sec. 207, 131 Stat. 135, 538; Consolidated Appropriations Act, 2016, Public Law 114–113, Div. H, sec. 207, 129 Stat 2242, 2620. Such requirement is also consistent with Title X's direction to provide special services for adolescents.

[16] Title X requires that, ''[t]o the extent practical, entities which receive grants or contracts under this subsection shall encourage familiy [sic] participation in projects under this subsection.'' 42 U.S.C. 300(a). Congress also includes a rider in HHS's annual appropriations act that provides that ''[n]one of the funds appropriated in this Act may be made available to any entity under title X of the PHS Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services.'' HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. 2981, 3070; Consolidated Appropriations Act 2018, Public Law 115–141, Div. H, sec. 207, 132 Stat. 348, 736.

participation to the extent practical,[17] and the Department will continue to enforce compliance with this provision. An appropriations rider specifically emphasizes that grantees encourage family participation ''in the decision of minors to seek family planning services.'' [18] Accordingly, to ensure compliance with these requirements and the policy underlying them, the Department will also require specific recordkeeping with respect to such encouragement for minors. To ensure compliance with the requirement that Title X projects encourage family participation in the decision of minors to seek family planning services, § 59.5(a)(14) requires Title X projects to document in each minor's medical records the specific actions taken to encourage such family participation or the specific reason why such family participation was not encouraged. Consistent with the revision to the unemancipated minor example in the definition of ''low income family'' that the Department finalizes in this rule, documentation of such encouragement is not required if the Title X provider documents in the medical record that (1) the minor is suspected to be the victim of child abuse or incest and (2) it has, if permitted or required by applicable State or local law, reported the situation to the relevant authorities. These requirements are sensitive to confidentiality issues as well as reporting requirements for abuse.

g. Expanded Review and Selection Criteria

This rule updates and expands the review and scoring criteria applicable to grant applications, to ensure the criteria serve as a meaningful instrument to assess the quality of the applicant and the application. The 2000 Title X regulations set forth application review criteria that give the Department significant flexibility in determining awards but lack rigor, making it possible for less qualified applicants to garner high scores and affording the Department little help in selecting strong Title X grantees. The amended and revised § 59.7 ensures that successful applicants both meet the statutory requirements of the Title X program and are adequately responsive to the statutory goals and purposes of the Title X program. Under this rule, any grant application that does not clearly address how the proposal will satisfy the requirements of the rule would not proceed to the competitive review process, but would be deemed ineligible for funding.

The Department will explicitly summarize each requirement of the Title X regulations (or include the entire regulation) within the Funding Announcement and will require applicants to describe how they affirmatively comply, or would affirmatively comply with each provision. Once an applicant successfully demonstrates such affirmative compliance with the Title X regulations (a yes/no issue), the Department will consider each applicant competitively according to the criteria set forth in the regulation. The first criterion ensures that the project offers a broad range of acceptable and effective family planning methods and services and does not use abortion as a method of family planning. The second criterion looks at the relative need of the applicant and whether the applicant will make rapid and effective use of the funds. The third criterion takes into account the number of patients being served, while also considering the availability of family planning services in the proposed area. The fourth criterion considers the extent to which the services are needed in that local area and if the applicant proposes innovative ways to provide services to unserved or underserved patients. These provisions better achieve the statutory requirements and goals of Title X and increase competition and rigor among applicants, encouraging broader and more diverse applicants and better ensuring the selection of quality applicants.

h. Formal Revocation of Compliance with Title X Requirements by Project Recipients in Selecting Subrecipients

This rule formally revokes the 2016 amendments to the Title X eligibility requirements. In 2016, the Department finalized a rule that amended Title X eligibility requirements, prohibiting any grantee/recipient making service subawards as part of its Title X project, from excluding an entity from receiving a subaward for reasons other than its ability to provide Title X services. Compliance With Title X Requirements by Project Recipients in Selecting Subrecipients, 81 FR 91852, 91859–91860 (Dec. 19, 2016) (adding paragraph (b) to 45 CFR 59.3) (the ''2016 regulation''). The Department's stated reason for issuing the rule was to respond to new approaches to competing or distributing Title X funds that were being employed by several States. *Id.* at 91858–91859. The 2016 regulation took effect on January 18, 2017, but was nullified under the Congressional Review Act on April 13, 2017, when the President signed House Joint Resolution 43. *See* Public Law 115–23, 131 Stat. 89. Consistent with the joint resolution of disapproval, this rule repeals the 2016 regulation and, thus, permits States and other Title X grantees freely to select Title X subrecipients so long as they comply with the statutory, regulatory, and policy provisions in the funding announcement.

3. Summary of Costs, Savings and Benefits of the Major Provisions

Provision	Savings and benefits	Costs
Clear Financial and Physical Separation	The purpose of this provision is to ensure that the regulatory language is consistent with Section 1008 of the Public Health Service Act. The Department estimates no specific economic savings from finalizing this part of the rule. However, the Department expects the quality of Title X services to improve as Title X funds are focused and prioritized according to the statutory parameters.	The Department estimates that there will be transition costs where certain other programs that shared facilities with Title X programs must now establish separate physical facilities. After receiving public comments, the Department estimates physical compliance costs to be $36.08 million.

[17] The Department notes that, although section 1001 of the PHS Act states that ''[t]o the extent *practicable,* entities which receive grants or contracts under this subsection shall encourage family participation in projects assisted under this subsection,'' PHS Act § 1001(a), in the U.S. Code, 42 U.S.C. 300(a), the word ''practical'' is used in the provision. The Department believes that the two words are intended to have the same meaning and uses the two words interchangeably when discussing the statutory requirement.

[18] *See* HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. 2981, 3070.

Provision	Savings and benefits	Costs
Ensure Transparency for Legal and Ethical Use of Taxpayer Dollars among Subrecipients.	The purpose of this provision is to ensure that Title X funds are allocated and accounted for both by Title X grantees and by the Department. The Department estimates no specific cost savings from finalizing this part of the Rule. However, the Department expects that enhanced accounting and monitoring will result in more effective use of Title X resources.	The Department estimates, in part based on public comments, that the cost of implementing additional reporting and training requirements will be $8.53 million. Medical and health services managers will spend an average of four hours each year to complete reports regarding information related to subrecipients, and referral agencies and individuals involved in the grantee's Title X project at each grantee and subrecipient. The labor cost will be $254,000 each year ($52.58 per hour × 4 hours × 1,208 grantees and subrecipients).
Nondirective Pregnancy Counseling Permitted, Not Required.	The purpose of this provision is to remove the requirement that providers provide pregnancy counseling, particularly, abortion counseling. Eliminating the requirement to counsel for abortion, and allowing non-directive pregnancy counseling in general, will relieve burdens by giving projects flexibility, and relieve burdens on conscience that some entities and individuals experienced from complying with the previous requirement, or provide more flexibility for applicants that otherwise might not have applied due to the burdens on conscience of the previous requirement. This rule will also reduce the regulatory burden associated with monitoring and Title X providers for compliance with the abortion counseling requirement.	The Department estimates no costs from finalizing this part of the rule.
Abortion Referral Prohibited, No Longer Required.	The purpose of this provision is to remove the requirement for, and institute a prohibition against abortion referral in the Title X program. Eliminating the requirement to refer for abortion will relieve burdens on conscience that some entities and individuals experienced from complying with the previous requirement, and provide more flexibility for applicants that otherwise might not have applied due to the burdens on conscience of the previous requirement. This rule will also reduce the regulatory burden associated with monitoring and regulating Title X providers for compliance with the abortion referral requirement.	The Department estimates no costs associated with removing the requirement for abortion referral. The addition of a prohibition against abortion referral will involve no additional monitoring costs, as current mechanisms in place are expected to be sufficient.
Sexual Abuse Reporting Requirements Training and Protocols.	The purpose of this provision is to ensure providers are complying with State and local sexual abuse reporting requirements. The Department estimates no specific economic savings from finalizing this part of the rule. However, the Department expects Title X providers will be more informed about State and local reporting requirements, and therefore, will protect vulnerable populations.	The Department estimates that individuals involved with delivering family planning services would require an average of 4 hours of training in the first year following publication of this rule. In subsequent years, the Department assumes that this new information would be incorporated into existing training requirements, resulting in no incremental burden. As a result, using wage information provided in Table 2, this would imply costs of $2.71 million in the first year following publication of a final rule in this rulemaking.
Family Participation in Family Planning Decisionmaking.	The purpose of this provision is to ensure compliance with the requirement by Congress to encourage family participation in family planning decisionmaking, and to include this requirement in regulation. The Department estimates no specific economic savings from finalizing this part of the rule. However, the Department expects Title X providers will encourage parent and child communication as is expected under Federal law.	The Department estimates that complying with the requirement to encourage family participation will result in 75% (600,000) of adolescent patients' medical records requiring appropriate documentation. As a result, using wage information provided, this would imply costs of $2.0 million in the each year following publication of a final rule in this rulemaking.

Provision	Savings and benefits	Costs
Expanded Review and Selection Criteria	The purpose of this provision is to increase the quality and expand the specificity of grant application review criteria. The Department estimates no specific economic savings from finalizing this part of the rule. However, these criteria will better achieve the statutory requirements and goals of Title X by increasing competition and rigor among applicants, encouraging broader and more diverse applicants and better ensuring the selection of quality applicants.	
Formal Revocation of Compliance with Title X Requirements by Project Recipients in Selecting Subrecipients Rule.	The purpose of this provision is to finalize the revocation of the 2016 regulation. The Department estimates no specific economic savings from finalizing this part of the rule as it is a formal repeal of a change that was nullified by under the Congressional Review Act.	The Department estimates no costs from finalizing this part of the rule as it is a formal repeal of a change that was nullified by joint resolution of disapproval under the Congressional Review Act that was signed by the President.

B. Background

Title X of the Public Health Service Act, 42 U.S.C. 300 through 300a–6, was enacted in 1970 by Public Law 91–572, 84 Stat. 1504. As amended, it authorizes the Secretary of Health and Human Services, among other things, ''to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents).'' 42 U.S.C. 300(a).

Presently, the Title X program funds approximately 90 public health departments and community health, family planning, and other private nonprofit agencies through grants, supporting delivery of family planning services at almost 4,000 service sites.[19] As a program designed to provide voluntary family planning services, the Title X program should help men, women, and adolescents make healthy and fully informed decisions about starting a family and determining the number and spacing of children.

Section 1008 of the Act contains the following prohibition, which has not been altered since it was enacted in 1970: ''None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.'' 42 U.S.C. 300a–6. The Conference Report described the purpose of this provision as follows:

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

H.R. Rep. No 91–1667, at 8–9 (1970) (Conf. Rep.). Later Congresses have, through annual appropriations provisions, reiterated aspects of this requirement, for example, by adding that ''amounts provided to said [voluntary family planning] projects under such title shall not be expended for abortions.'' *See, e.g.,* HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat. at 3070.

Since it originally created the Title X program in 1970, Congress has, from time to time, imposed additional requirements on it, including the following:

- Requirement that ''all pregnancy counseling shall be nondirective.'' [20]
- Obligation to ensure that Title X funds ''shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.'' [21]
- Requirement that Title X (1) projects provide distinct services for adolescents; [22] (2) service providers encourage family participation in family planning services including, but not limited to, those for minors; [23] (3) grantees certify to the Secretary that they ''provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.'' [24]
- Condition 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.'' [25]

Title X authorizes the Secretary to promulgate regulations governing the program. 42 U.S.C. 300a–4. In the preamble to the proposed rule, the Department explained that, since 1971, it has repeatedly exercised rulemaking authority with respect to the Title X program. The Department began issuing regulations implementing Title X, including section 1008, in 1971. *See* 36 FR 18465 (Dec. 15, 1971). Although those regulations, and revised regulations issued in 1980, 45 FR 37436 (Jun. 3, 1980), as well as guidelines promulgated in 1981, prohibited Title X projects from providing abortion as a method of family planning, they did not

[19] Fowler et al., *Family Planning Annual Report: 2017 National Summary* (Aug. 2018), *https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2017-national-summary.pdf.*

[20] *See* Omnibus Consolidated Rescissions and Appropriations Act of 1996, Public Law 104–134, sec. 104, 110 Stat. 1321 (1996) (''Omnibus Appropriations Act 1996''); HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat. at 3070–71.

[21] HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat. at 3071.

[22] *See* 42 U.S.C. 300(a) (requirement to provide ''a broad range of acceptable and effective family planning methods and services (including . . . services for adolescents)'').

[23] *See* Omnibus Budget Reconciliation Act of 1981, Public Law 97–35, sec. 931(b)(1), 95 Stat. 357, 570 (1981) (amending Section 1001(a) of the Public Health Service Act to require that ''[t]o the extent practical, entities which receive grants or contracts . . . shall encourage family participation in projects assisted under this subsection.''); 42 234 U.S.C. 300(a); Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1998, Public Law 105–78, sec. 212, 111 Stat. 1467, 1495 (''HHS Appropriations Act 1998''); HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090.

[24] Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1998, Public Law 105–78, sec. 212, 111 Stat. 1467, 1495; HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090.

[25] HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 208, 132 Stat. at 3090.

provide further guidance on the application of that prohibition.

On February 2, 1988, the Secretary of Health and Human Services promulgated Title X regulations (the ''1988 regulations'') to give specific program guidance regarding the statutory prohibition on the use of Title X funds in programs where abortion is a method of family planning. *See* Statutory Prohibition on Use of Appropriated Funds in Programs Where Abortion is a Method of Family Planning; Standard of Compliance for Family Planning Services Projects, 53 FR 2922 (Feb. 2, 1988). The 1988 regulations had several key features to support compliance with the statutory prohibition. To more effectively implement section 1008, the regulations prohibited Title X projects from counseling or referring project clients for abortion as a method of family planning; required grantees to separate their Title X project—physically and financially—from prohibited abortion-related activities; and established compliance standards for family planning projects under Title X to specifically prohibit certain actions that promote, encourage, or advocate abortion as a method of family planning, such as the use of project funds for lobbying for abortion, developing and disseminating materials advocating abortion, or taking legal action to make abortion available as a method of family planning. *See* 53 FR 2945.

The 1988 regulations were upheld on both statutory and constitutional grounds by the United States Supreme Court in *Rust* v. *Sullivan,* 500 U.S. 173 (1991). In *Rust,* the Supreme Court rejected claims that the regulations violated the Administrative Procedure Act (APA), the First Amendment, the Fifth Amendment, or the Title X statute. Regarding the APA, the Court applied *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984), reasoning that ''substantial deference'' was owed ''to the interpretation of the authorizing statute by the agency authorized with administering it.'' 500 U.S. at 184. Accordingly, it reaffirmed that ''[a]n agency is not required to 'establish rules of conduct to last forever,' but rather 'must be given ample latitude to 'adapt [its] rules and policies to the demands of changing circumstances.'' 500 U.S. at 186–187. The Court declined to view the regulations skeptically because they represented a change in policy; instead, the Court noted that it ''has rejected the argument that an agency's interpretation 'is not entitled to deference because it represents a sharp break with prior interpretation' of the statute in question.'' *Id.* The Court concluded that the regulations' ''program integrity'' requirements—the portions of the regulations mandating separate facilities, personnel, and records—were ''based on a permissible construction of the statute and are not inconsistent with congressional intent.'' *Id.* at 188. Accordingly, the Court ''defer[red] to the Secretary's reasoned determination that the program integrity requirements are necessary to implement the prohibition.'' *Id.* at 190.

The Court further upheld the prohibition on abortion counseling and referral, as well as the requirement of physical and financial program separation, as consistent with the First Amendment. *Id.* at 192–198. The Court held the ''Government has no constitutional duty to subsidize an activity merely because the activity is constitutionally protected and [Congress] may validly choose to fund childbirth over abortion and 'implement that judgment by the allocation of public funds' for medical services relating to childbirth but not to those relating to abortion.'' *Id.* at 201 (internal quotations omitted). The Court concluded that the regulations were ''a permissible construction of Title X.'' *Id.* at 203.

The 1988 regulations were operative until February 5, 1993, when President Clinton suspended them pursuant to a Presidential Memorandum, The Title X ''Gag Rule'', 58 FR 7455 (Feb. 5, 1993), and the Department issued a proposed rule, Standards of Compliance for Abortion-Related Services in Family Planning Service Projects, 58 FR 7464 (Feb 5, 1993), that it finalized seven years later as the 2000 regulations. *See* 65 FR 41270 (July 3, 2000). The 2000 regulations essentially returned to the 1981 regulations (with one revision), which eliminated the provisions of the 1988 regulations that (1) prohibited Title X projects from counseling or referring project clients for abortion as a method of family planning; (2) required grantees to separate their Title X project physically and financially from any abortion activities; and (3) implemented compliance standards for family planning projects under Title X that specifically prohibit certain actions designed broadly to promote or encourage abortion as a method of family planning, such as the use of project funds to lobby for abortion, to develop and disseminate materials advocating abortion, or to take legal action to make abortion available as a method of family planning. While a contemporaneous notice stated that more than separate bookkeeping entries and allocation of funds was necessary to separate Title X project activities from non-Title X abortion activities, that notice nevertheless discussed and approved shared facilities, staff, and records, as long as costs were pro-rated and properly allocated. *See* Provision of Abortion-Related Services in Family Planning Service Projects, 65 FR 41281, 41282 (July 3, 2000). The 2000 regulations also required that Title X providers offer nondirective counseling on, and referral for, abortion at the request of a Title X client, despite the statutory prohibition on funding programs where abortion is a method of family planning and the adoption of the Coats-Snowe Amendment in 1996 and Weldon Amendment in 2005, which prohibited the federal government and State and local governments that receive federal financial assistance from discriminating against health care entities that refuse, among other things, to refer for abortion.

On December 19, 2016, the Department finalized a rule that amended Title X eligibility requirements, requiring that no grantee making subawards for the provision of services as part of its Title X project prohibit an entity from receiving a subaward for reasons other than its ability to provide Title X services. 81 FR 91852, 91860 (Dec. 19, 2016). The Department's stated reason for issuing the rule was to respond to new approaches to competing or distributing Title X funds that were being employed by several States. The 2016 regulation took effect on January 18, 2017, but was nullified under the Congressional Review Act, when the President signed the Joint Resolution of Disapproval, on April 13, 2017. *See* Title X Requirements by Project Recipients in Selecting Subrecipients, Public Law 115–23, 131 Stat. 89 (April 13, 2017).

On June 1, 2018, the Department published a proposed rule in the **Federal Register**, through which it solicited public comments on proposed changes to the 2000 Title X regulations and the formal revocation of the 2016 regulation in accordance with the Joint Resolution of Disapproval. *See* 83 FR 25502, 25504–25505 (June 1, 2018). The Department 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. This uncertainty was reflected in many of the public comments that argued Title X

should support statutorily prohibited activities, such as abortion. This rule rectifies the ambiguity created by the 2000 regulations. Specifically, this rule:

- Clearly delineates a bright line between Title X and non-Title X activities;
- provides grantees direction on how to ensure that no Title X funds are expended where abortion is a method of family planning;
- increases the ability of applicants to receive funding for innovative projects that propose to serve underserved and unserved populations; and
- offers additional protection to patients who may be victims of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking.

II. Statutory Authority, Overview, Analysis, and Response to Public Comments

The Department provided a 60-day public comment period for the proposed rule that closed on July 31, 2018. The Department received over 500,000 public comments,[26] which are posted at *www.regulations.gov.* After considering the comments, the Department finalizes the proposed rule with the changes discussed below. In this preamble, the Department discusses the public comments, its responses, and the text of the final rules.

The Department proposed to revise the authorities cited for the regulations at 42 CFR part 59, subpart A, from ''42 U.S.C. 300a–4'', to ''42 U.S.C. 300 through 300a–6''. Some commenters support the Department's authority to modify Title X regulations. Other commenters contend that the Department does not have authority to make various changes. The Department has legal authority under section 1006 of the Public Health Service Act, 42 U.S.C. 300a–4, to promulgate and amend regulations to implement the Title X family planning program, and sections 1001 through 1008 of the Public Health Service Act (42 U.S.C. 300 through 300a–6) include substantive provisions which the Department implements through such regulations. The Department has repeatedly exercised its authority to issue regulations to guide Title X grantees in carrying out the program. Section 1006 of the Act states that ''[g]rants and contracts made under this title shall be made in accordance with such regulations as the Secretary may promulgate,'' and section 1001 also specifies that the Secretary shall by regulation specify certain rights to apply for grants or contracts. The grant of regulatory rulemaking authority in section 1006 is sufficient authority to support all of the requirements adopted through this final rule. However with respect to various details of these final rules, the Department also relies on section 1008 and other directives throughout the Title X statute, as well as appropriations provisos and riders governing the Title X program. The final rule is designed to refocus the Title X program on its statutory mission—the provision of voluntary, preventive family planning services specifically designed to enable individuals to determine the number and spacing of their children—while clarifying that women must be referred for appropriate, medically necessary care identified during preconception screening and for prenatal care services, since such care is important for both the health of the women and for healthy pregnancy and birth. The Department believes this final rule provides appropriate guidance for compliance with such requirements.

Therefore, the Department finalizes, without change, its proposed revision to the authorities cited for 42 CFR part 59, subpart A.

Comments supporting or challenging the Department's authority to make particular changes are discussed in more detail in the relevant sections below.

A. General 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, including content in the background, the need for change, and the statutory authorities sections. Those comments are summarized here, together with responses by the Department. Many related comments are addressed in greater detail further below, within the discussion of specific provisions of the regulation.

Comments: Many commenters affirm the accuracy of the historical record summarized by the Department in the proposed rule. This includes the long-standing prohibition on promoting abortion in the Title X program, the Supreme Court's upholding of the 1988 regulations in *Rust* v. *Sullivan,* the Court's reaffirmation of Congress's general intent for Title X to have a preconception focus, the legal precedent for the government to favor childbirth over abortion (for example, *Harris* v. *McRae,* 448 U.S. 297 (1980)), the continued bipartisan support for the Title X statute, and the various supplemental requirements imposed by Congress on the Title X program. Other commenters also contend that, since *Roe* v. *Wade,* 410 U.S. 113 (1973), Title X grantees have unlawfully treated abortion as a method of family planning despite statutory prohibitions and that the 2000 regulations facilitate such activity in violation of the Title X statute. Additional commenters recall the history, purpose, importance, and value of Title X as the sole federal program dedicated to funding family planning services for low income individuals, including the provision of birth control, cancer screening, sexually transmitted disease (STD) testing and treatment, and other preventive care.

The Department received comments expressing diverse and conflicting views on the proposed rule. Many commenters support the language of the rule as proposed, so as to prevent taxpayer dollars from being used to pay for activities related to abortion, contrary to the Title X statute, and to provide the necessary transparency to assure Title X funds are not used for abortion or abortion-related costs. Other commenters assert that proposed changes could reduce access to services, especially for the most vulnerable populations. Some commenters note that the proposed rule closely mirrors the 1988 regulations, while others object to the proposed rule's provisions, particularly on certain abortion referrals, and the similar but broader provisions in the 1988 regulations, and point out that those provisions were never fully implemented. Some commenters support the proposed rule as providing much needed clarification to ensure adherence to the original intent of Title X and to correct the regulations that were issued in 2000. Other commenters contend that the proposed rule is unnecessary, unjustified, unethical, and was proposed without evidence of need.

Some commenters raised legal objections to the rule. Several comments contend the Department's proposed rule is contrary to congressional intent, violative of State sovereignty, and inconsistent with the First Amendment rights of Title X grantees and the Fifth Amendment rights of women. These commenters assert that women have a constitutional right to abortions, and health care workers have a responsibility to counsel individuals on the full scope of family planning options.

Commenters assert that the proposed changes create ethical and legal risks,

[26] This includes attachments and over 40 mass mailing or internet comment generating campaigns, which accounted for more than 480,000 of the comments. The **Federal Register** docket lists only 205,000 comments; however a significant number of comments were submitted in batches to *www.regulations.gov.*

fail to follow professional standards of care for health professionals, and violate conditions associated with federal grant funding under section 330 of the Public Health Service Act.[27] Commenters request clarification on how broadly reporting requirements would apply, specifically regarding referral agencies. They assert that Federally Qualified Health Centers (FQHC), funded under Section 330 of the Public Health Safety Act, are already required to provide significant data reporting, including patient demographics, financial indicators, and clinical quality. Commenters believe that the proposed Title X reporting requirements would be potentially redundant with the existing section 330 reporting requirements. Commenters also argue section 330 requires FQHCs to provide ''voluntary family planning'' services. This rule, they argue, creates a conflict with that requirement by reducing the family planning options, and potentially reduces the performance of FQHCs by restricting their supplementary Title X funding.

Others argue that the proposed rule would make it difficult to meet national performance measures for the Title V Maternal and Child Health Services Block Grant, which serve as a measure of our country's progress on adolescent annual preventive medical visits. Still other commenters argue the proposed rule violates the APA on multiple grounds, including that the rule is arbitrary and capricious, and they assert that the Department has not provided adequate reasons for its rulemaking by examining the relevant data and articulating a satisfactory explanation for its action, including a rational connection between the facts found and the choices made. Several commenters urge the Department to withdraw the proposed rule. Some commenters contend the rule is not legally supportable and that, if the Department finalizes the rule, it will be challenged in court.

In contrast, other commenters argue that the proposed rule closely tracks the 1988 regulations, which were upheld on both statutory and constitutional grounds by the Supreme Court. Those commenters argue that the proposed rule is just as constitutional now as it was then, and observe that many other cases have affirmed the principle that the government is not obligated to fund or facilitate abortions.

Numerous commenters state that the Department has spent much time and effort to craft a solution where there is no problem to be addressed. They claim Title X has never funded abortions, and Title X providers fully understand what the statutes and 2000 regulations require. They state that examples of the misuse of Title X funds are not well founded. Several commenters state that, under the comment filing deadline of July 31, 2018, they were unable to evaluate the full extent of the impacts of the Notice of Proposed Rule Making (NPRM) on affected communities. These commenters requested that the Department extend the comment period an additional 60 days, or to October 1, 2018. They contend this extension would provide the Department more time to hear from impacted populations on changes to Title X. One commenter contends their extension request was due to the Department rushing the publication of the proposed rule, and engaging in insufficient public engagement with stakeholders prior to the release of the rulemaking. Another commenter mentions they were requesting an extension because they experienced issues with submitting their comments electronically.

Response: The Department notes that there is, generally, a common understanding regarding the history and the purpose of the Title X program, together with the sharp diversity of opinion regarding the need for revisions to the 2000 regulations. The Department appreciates the emphasis many comments place on Title X's role in caring for low income individuals by providing a broad range of family planning methods and services. The Department concludes these final rules will contribute to more clients being served, gaps in service being closed, and improved client care that better focuses on the family planning mission of the Title X program. The Department expects these positive outcomes, in part, because the Department believes (1) program parameters will be more clear; (2) new applicants will apply to serve unserved or underserved patients and/or less concentrated population areas because the review and selection criteria will no longer skew in favor of heavily populated areas; (3) new providers who previously were unable to participate in Title X projects due to conscience concerns with the 2000 regulations will be free to apply for a Title X grant or to participate in a Title X project; (4) Title X providers will be more likely to provide comprehensive primary care services or refer to primary health providers who can fulfill non-Title X needs in close proximity to the clinics, furthering overall health care of patients; and (5) the broad and clear definition for ''family planning'' will enable grantees to better provide a broad range of family planning methods and services to meet the needs and desires of more patients.

The Department believes that the final rule represents a better interpretation of the statutory provisions applicable to the Title X program than the 2000 Regulations. The rule permits and will encourage better and closer compliance with these legal obligations on the part of grantees and their subrecipients. The Department agrees with comments stating that the proposed rule is necessary to protect the integrity of the Title X program, and the Department has authority to take such action, as discussed above and supported by case law.[28] The Spending Clause of the Federal Constitution provides Congress authority to spend monies and to impose conditions and requirements with respect to the expenditures of funds,[29] and it has exercised this authority to create the Title X program and impose conditions upon it. The Department has, in turn, exercised its legal authority [30] to issue regulations to guide Title X grantees in carrying out the program. The rule will ensure adherence to the statutory provisions adopted by Congress for the Title X program.

The Department agrees with comments that section 1008 establishes a broad prohibition on funding, directly or indirectly, activities that treat abortion as a method of family planning.[31] The Department also agrees with comments that the 2000 regulations are inconsistent with that interpretation insofar as they require referral for abortion as a method of family planning, allow the use of funds for building infrastructure that could be used for abortion services, and do not require clear physical separation between Title X activities and abortion-related services.[32] The Department

[27] *See* 42 U.S.C. 254b.

[28] *See Rust,* 500 U.S. at 193.

[29] Art. 1, sec. 8, cl. 1.

[30] *See* 42 U.S.C. 300a–4.

[31] *See* 42 U.S.C. 300a–6.

[32] As described in the preamble to the 1988 regulations, 53 FR at 2923, prior to issuance of any regulations pursuant to Title X, the Department had, since 1972, interpreted section 1008 not only as prohibiting the provision of abortion, but also as prohibiting Title X projects from in any way promoting or encouraging abortion as a method of family planning. Further, based on the legislative history, the Department had also, since 1972, interpreted section 1008 as requiring that the Title X program be ''separate and distinct'' from any abortion activities of a grantee. However, in such interpretations, the Department generally took the view that if activity did not have the immediate effect of promoting abortion, or which did not have the principal purpose or effect of promoting abortion, it was permitted in a project. *See* GAO, No. HRD–82–106, Restrictions on Abortion and

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notes that the 2000 regulations also do not ensure transparency and accountability in the use of taxpayer funds since they fail to require grantees to provide the Department with information about subrecipients, to ensure monitoring for potential misuse of funds and for compliance with federal laws (including a Title X-specific appropriations provision) that prohibit the use of taxpayer funds for political activity or lobbying. Finally, the 2000 regulations prescribe inadequate grant application review criteria for selecting grantees of Title X funds who will comply with all of these requirements.

The Department believes that the final rule is a reasonable interpretation of the Title X statute and applicable laws in light of the express statutory terms, legislative history, and case law regarding the implementation and enforcement of provisions such as section 1008. The express terms in section 1008 reasonably support the Department's conclusion that there must be a separation between Title X projects and funds and any project where abortion is a method of family planning. *See* 42 U.S.C. 300a–6. The express terms of section 1008 also reflect the congressional purpose that Title X primarily has a preconception focus and should fund and, thereby, encourage preconception services. *See Rust,* 500 U.S. at 190 (''It is undisputed that Title X was intended to provide primarily prepregnancy preventive services.''). This focus on preconception care generally excludes payment for postconception care and services, though it can allow the provision of information and counseling in a postconception context, or access to postconception services outside the Title X project, if Title X's restrictions concerning abortion as a method of family planning are maintained. It is, thus, no surprise that the Supreme Court concluded that the 1988 regulations' ''program integrity'' requirements, which are substantially similar to the ones adopted in this final rule—including the portions of the regulations mandating separate facilities, personnel, and records—were ''based on a permissible construction of the statute and are not inconsistent with congressional intent.'' *Id.* at 188. The Court noted that, ''if one thing is clear from the legislative history, it is that Congress intended that Title X funds be kept separate and distinct from abortion-related activities. . . . Certainly, the Secretary's interpretation of the statute that separate facilities are necessary, especially in light of the express prohibition of § 1008, cannot be judged unreasonable.'' *Id.* at 190. The Court ''defer[red] to the Secretary's reasoned determination that the program integrity requirements are necessary to implement the prohibition.'' *Id.* The Department now reaffirms that reasoned determination and reaches similar conclusions here.

The Department disagrees with commenters who contend the proposed rule (or this final rule) violates the Constitution and the intent of Title X. The Supreme Court rejected similar constitutional challenges to the 1988 regulations. As an initial matter, it upheld the statutory limitation of Title X funds to programs where abortion is not a method of family planning, concluding that ''[t]here is no question but that the statutory prohibition contained in § 1008 is constitutional'' because Congress ''may 'make a value judgment favoring childbirth over abortion, and . . . implement that judgment by the allocation of public funds.' '' *Id.* at 192 (internal citations omitted; ellipsis in original). The Court further explained that the provisions in the 1988 regulations barring counseling and referral were consistent with the First and Fifth Amendments. *Id.* at 193–94, 203. The Department believes the Court's analysis encompasses, and is equally applicable to, the provisions of this final rule for similar reasons.

The Department disagrees with commenters contending the proposed rule, to the extent it is finalized here, infringes on the legal, ethical, or professional obligations of medical professionals. Rather, the Department believes that the final rule adequately accommodates medical professionals and their ethical obligations while maintaining the integrity of the Title X program. In general, medical ethics obligations require the medical professional to share full and accurate information with the patient, in response to her specific medical condition and circumstance. Under the terms of this final rule, a physician or APP may provide nondirective pregnancy counseling to pregnant Title X clients on the patient's pregnancy options, including abortion. Although this occurs in a postconception setting, Congress recognizes and permits pregnancy counseling within the Title X program, so long as such counseling is nondirective. The permissive nature of this nondirective pregnancy counseling affords the physician or APP the ability to discuss the risks and side effects of each option, so long as this counsel in no way promotes or refers for abortion as a method of family planning. It permits the patient to ask questions and to have those questions answered by a medical professional. Within the limits of the Title X statute and this final rule, the physician or APP is required to refer for medical emergencies and for conditions for which non-Title X care is medically necessary for the health and safety of the mother or child.

The Department appreciates comments expressing concern about administrative reporting burdens on FQHCs who receive funding under both Section 330 and Title X. However, different federal programs often have different reporting and other requirements, depending on the specific statutory requirements and constraints. The fact that some federal grant programs may require more (or less) to qualify for funding is an appropriate reflection of Congressional direction. The Department is mindful of the administrative burden when establishing requirements for federal grant programs and seeks, as possible, to impose substantially the same administrative requirements on grant programs. However, it is under no obligation to impose the same requirements for multiple grant programs; rather, it is guided by the statutory requirements placed by Congress regarding each individual federal grant program. To the extent that requirements overlap, the Department believes that no additional burden results because the information can be readily shared within the grantee organization. Where the Title X program imposes additional requirements, these additional requirements are the result of specific statutory requirements applicable to the Title X program. The Department believes that these additional requirements are reasonable in light of those specific statutory requirements and the Department's need to ensure compliance with such requirements.

The Department also believes that concerns that Title X will conflict with Section 330's voluntary family planning requirements are unfounded. This final rule continues the historical Title X emphasis that family planning must be voluntary—the definition of ''family planning'' adopted by the final rule and, thus, applicable to the Title X program explicitly states that ''family planning methods and services are never to be coercive and must always be strictly voluntary.'' This final rule also confirms the statutorily mandate that a ''broad range'' of family planning methods and services be available under Title X. This requirement also supports the voluntary

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Lobbying Activities in Family Planning Programs Need Clarification, at 22 (Sept. 24, 1982), *https://www.gao.gov/assets/140/138760.pdf.*

nature of family planning by providing a variety of methods and services so that the individual patient can make an informed choice, based on her own lifestyle and needs. To the extent that limitations are imposed on the Title X program (*e.g.,* abortion provisions), the Department has carefully designed these to enforce explicit statutory mandates applicable to Title X. However, the Department intends to continue emphasizing the broad range of family planning methods and services as a way to fulfill the various family planning needs of patients who visit the many Title X clinics across the nation. Thus, the Department finds that section 330 and Title X are complementary in this respect.

The Department does not agree that the final rule will impede the ability of States and jurisdictions to meet the national performance measure (NPM) for annual adolescent preventive well visits for the Title V Maternal and Child Health Services Block Grant. Some commenters contend that any limitation on a patient's ability to access affordable health care at their preferred site of care for family planning services or to meet with the provider of their choice for preventive health care will impede States' ability to meet their goals for the well-woman visit NPM and the adolescent well-visit NPM for Title V. But by encouraging Title X projects to offer either comprehensive primary health care services onsite or have a robust referral linkage with primary health care providers who are in close proximity to the Title X site, the Department believes this final rule should reinforce States' ability to meet their goals for well-woman and adolescent well-visit NPMs. Furthermore, the Department does not believe that the rule will limit the ability of individuals to access affordable health care; thus, achievement of the NPM will remain unaffected by the changes in regulation. The Title X program currently provides services to adolescents and will continue to provide these services.

The Department agrees with comments stating that demonstrated abuses of Medicaid funds do not necessarily mean Title X grants are being abused and did not make that argument in the proposed rule. Rather, the Department believes that examples of abuse in other Federal programs help illustrate the need for clarity with respect to permissible and impermissible activities in connection with the Title X program and Title X funds, especially where the 2000 regulations foster confusion and ambiguity.[33] Title X is a grant program where funds are disbursed before completion of the service, increasing the possibility of intentional or unintentional misuse of funds. Appropriate accountability standards are particularly appropriate in the case of grant programs such as Title X.

The Department's reasons for deciding to revise the 2000 regulations go beyond evidence regarding abuses of Medicaid funds by entities that are also Title X grantees or subrecipients, and are discussed in more detail below. These additional reasons include the Department's view that Title X grantees must be financially transparent and accountable throughout the grant disbursement process, rather than only after the grant is spent. The Department has a compelling interest in ensuring that, from the moment of disbursal, Title X funds are used only for permissible activities under the Title X statute,[34] rather than condoning after-the-fact correction and bookkeeping adjustments. The Department disagrees with some commenters who characterize the government's pursuit of this interest as ''restricting abortion rights''; the Supreme Court rejected similar arguments and challenges to similar provisions in the 1988 regulations. *See Rust,* 500 U.S. at 177–178 (upholding similar Title X ''program integrity'' requirements).

The Department also seeks to remedy the potential for confusion, under the 2000 regulations, about whether Title X funds can be, or are being used, in a project where abortion is a method of family planning. It does so by finalizing the rule to strengthen the requirements for financial separation and to preclude shared physical space and staff with respect to abortion. It also does so by improving grant monitoring, including fiscal and internal controls, to prevent the misuse of taxpayer funds. The Title X program is not unique in the need for such grant monitoring to identify and prevent such misuse. However, particularly because providing abortion as a method of family planning has been statutorily prohibited,[35] and abortion is a source of contentious public debate, the Department believes improved accountability measures are a useful and responsible action that will expand taxpayers' trust in the Title X program.

In response to commenters who contend the rule will be challenged in court, the Department believes the Supreme Court's decision in *Rust* provides broad support for the approach taken in this rule. Although the rule differs in some respects from the 1988 regulations upheld in *Rust,* some of those differences arise from the Department's desire to implement statutory provisions that did not exist at the time the 1988 regulations were adopted. Other differences, such as the permission for nondirective pregnancy counseling—which implements an appropriations rider that was adopted as early as 1996 [36] and has been regularly included in HHS's appropriations through fiscal year 2019—are more permissive than the 1988 regulations and less susceptible to the type of challenges that plaintiffs brought (unsuccessfully) in *Rust.* Other changes concern issues not directly addressed in *Rust,* but plainly supported by the Department's discretion to implement the program as set forth in Title X and applicable statutes. The Department believes that each component of the rule is legally supportable, individually and in the aggregate. To the extent a court may enjoin any part of the rule, the Department intends that other provisions or parts of provisions should remain in effect.

The Department disagrees with commenters who state that the 60-day comment period was insufficient. The APA does not have a minimum time period for comments, and 60-day comment periods are used for large numbers of very significant rules, including rules that contain far more complicated and complex proposed requirements. The comment period closed 60 days after publication of the proposed rule in the **Federal Register** on June 1, 2018, but the proposed rule went on display at the Office of the Federal

[33] ''. . . [A]udits have found overbilling . . . improper practices resulting in significant Title XIX-Medicaid overpayment . . . [and] ''unbundling'' or ''fragmentation'' billing schemes related to pre-abortion examinations, counseling visits, and other services performed in conjunction with an abortion, and improper billing for the abortions themselves.'' *See* Foster, *Profit. No Matter What, 2017 Report on Publicly Available Audits of Planned Parenthood Affiliates and State Family Planning Programs,* Charlotte Lozier Institute Special Report Series 3 (Jan. 4, 2017), *https://lozierinstitute.org/profit-no-matter-what (summarizing evidence from publicly available audits).* These examples of abuse illustrate the need to clarify any confusion or ambiguity that may cause or add to the problems uncovered by the auditors.

[34] 42 U.S.C. 300a–6.

[35] *Id.*

[36] Omnibus Consolidated Rescissions and Appropriations Act of 1996, Public Law 104–134, 110 Stat. 1321, 1321–221 (stating that ''amounts provided to said projects under such title shall not be expended for abortions, that all pregnancy counseling shall be nondirective, and that such amounts shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.''). The 2019 Appropriations Act contains the same directive.

Register on June 1, 2018 and on the Department's website on May 22, 2018. The comment period provided ample time for the submission of over 500,000 comments by a variety of interested parties, including extensive comments by a number of entities. Those comments offer a broad array of perspectives on the full range of issues raised in the proposed rule. After reviewing the public comments and the requests for additional time, the Department does not believe that extending the comment period is or was necessary for the public to receive sufficient notice of, and opportunity to comment on, the proposed rule. Nor is there anything in the statutory provisions governing the Title X program that would have required additional outreach outside of the public notice and comment process and the comment period. Consequently, the Department concludes that the comment period was legally sufficient and is not extending the comment period.

B. To what programs do these regulations apply? (42 CFR 59.1)

Summary of changes: The original language of the 2000 regulations at § 59.1 remains intact. The proposed rule proposed to add that, unless otherwise noted, Title X program requirements and regulations would apply equally to grantees and their subrecipients and that grantees would be responsible for ensuring that the entire project, which includes all subrecipients, complies with the Title X regulations. With certain exceptions, the proposed rule also provided that the regulatory requirements of Title X would apply equally to any contracts established under Section 1001 to carry out a Title X project. The Department finalizes the proposed changes to § 59.1 with slight technical changes to clarify the language regarding the requirements for grantees and subrecipients.

Comments: Some commenters question the need for the proposed changes. They state that the Department is not lacking information about subrecipients, as the Department already publishes a directory listing all subrecipients online. Some commenters contend that previously, the Department's legal relationships have been with Title X grantees concerning project operations only, not with subrecipients.

Several commenters state that the rule gives unprecedented information and regulatory authority to the Department regarding Title X grantees and subrecipients. Some commenters assert that the regulations attempt to give the Department unchecked discretion to disqualify applications. Several commenters contend the proposed rule would impose burdensome and redundant bureaucratic responsibilities on grantees and would limit the participation of certain providers. Some commenters object to the application of the rule to subrecipients, contending it will impose unacceptable burdens on subrecipients and drive qualified providers from Title X projects.

One commenter believes that treating grants and contracts equally will circumvent fair contracting rules, expediting allocation of funds to organizations and programs that do not submit applications as part of a competitive procurement or that will not be required to follow program regulations, including basic eligibility guidelines. The commenter states that, if implemented, this change could drastically alter the landscape of Title X providers, potentially allowing, among other things, for-profit organizations and health care providers that do not meet the highest standards of quality care to be awarded federal funds through a non-competitive process. One commenter states the proposed rule does not adequately discuss the regulatory or economic impact of applying the same requirements of contracts as family planning grants to entities, as contract and grant regulations differ.

One comment states that the proposed rule does not address whether Title X funds used for contracts would offset funds used for grants.

Response: The Department disagrees with commenters who contend that the Department already has sufficient information about subrecipients. Although an online directory lists subrecipients, important information about the grant project is not reported at a granular level. The Department does not know the scope of services provided by individual subrecipients, nor the degree of compliance with statutory and regulatory requirements by individual subrecipients. The Department maintains it is reasonable and appropriate to require additional transparency in these areas to ensure accountability for, and compliance with, the statutory integrity provisions applicable to the Title X program. Moreover, it is quite common for regulatory requirements to flow down from grantees to subrecipients; this final rule simply makes that expectation explicit.

The Department also does not agree with some commenters contending that these regulations are unnecessary, redundant, or overly burdensome. As discussed more below, the Department has a duty to ensure that Title X funds are spent in accordance with statutory requirements; that duty applies equally to Title X funds used by grantees and subrecipients. The final rule helps the Department fulfill that duty and thereby to ensure the proper accounting of Title X funds. The Department believes there has been insufficient transparency and accountability in the use of taxpayer funds because grantees have not been required to provide the Department with sufficient information about subrecipients, to ensure monitoring for potential misuse of funds, or to address express statutory program integrity provisions and limitations (including a Title X specific appropriations provision) that, among other things, prohibit the use of taxpayer funds for political activity or lobbying. The final rule will redress these insufficiencies and improve the transparency and accountability that surrounds the use of Title X funds.

The Department concludes that the final rule appropriately requires that the program integrity provisions of Title X family planning program apply to projects whether they are established by grants or contracts and to any entity receiving Title X funds. The Department disagrees that the application of Title X regulations to the execution of contracts is an exercise of improper or unprecedented regulatory authority. Title X authorizes the Secretary to carry out the Title X program by entering into contracts with, or issuing grants to, public or private nonprofit entities and to promulgate regulations governing grants and contracts issued in the program. 42 U.S.C. 300(a), 300a–4. Thus, the Department has the authority to issue regulations governing the program, including provisions that apply statutory requirements both to grantees and contractors, and subrecipients of Title X funds. With respect to subrecipients, since grantees in most instances do not directly provide Title X services, the only way to ensure compliance with the statutory and regulatory requirements is to require the inclusion of provisions in contracts with, or grants to, subrecipients that require such compliance. Such flow-down requirements are a commonly used mechanism in the Department's grant programs to ensure that the programs are properly implemented. The Department believes that ensuring Title X funds are expended by subrecipients consistent with the statutory and regulatory parameters is a responsibility that all Title X grantees reasonably assume when they extend the financial benefits of the program to another party.

The Department disagrees with commenters that challenge the Department's oversight role in the proposed rule. Title X grantees must ensure adequate oversight of Title X funds, including the use of those funds by subrecipients. The statutory restrictions imposed on the use of Title X funds cannot be avoided by distributing the funds to subrecipients. The Department is committed to ensuring all rules governing Title X funds are applied to both primary grantees and subrecipients. The Department does not agree with commenters who state that the administrative cost of ensuring that subrecipients are compliant with Title X is overly burdensome. Although there may be additional costs involved with these oversight measures, specifying that grantees are responsible for ensuring the compliance of their subrecipients does not add an additional requirement; it merely makes more explicit the fact that grantees are already responsible for ensuring the compliance of their Title X projects with the statutory and regulatory requirements applicable to Title X projects. The specific oversight measures required by this final rule are reasonable and necessary to ensure such compliance with the Title X requirements and proper accountability of Title X funds. The costs associated with those measures are detailed below.

The Department disagrees that the rule will exclude qualified providers from providing Title X services since any eligible organization may apply to provide Title X services, so long as it complies with the requirements set forth in the statute, related regulations, and the funding announcement. The Department disagrees with commenters who suggest oversight will hinder the participation of health centers, except to the extent that they are not compliant with Title X requirements. An organization that qualifies under Title X to provide statutorily appropriate services may also provide non-Title X services, so long as they do so in a manner that complies with the Title X regulations. The Department believes that the provisions of the final rule will result in expanded preconception family planning options available to individuals consistent with the Title X program's explicit mandate.

The Department has considered the comments that express concern about the proposed language that treats Title X contracts and grants equally, but concludes that a plain reading of the statute supports that approach. Title X authorizes the Secretary to award grants and/or enter into contracts to establish and operate voluntary family planning projects—and then authorizes the Secretary to adopt regulations to implement the Title X program.[37] The Department interprets this grant of authority to afford it flexibility in choosing the vehicles to implement the Title X statute, but not to allow funding vehicles that avoid the requirements of the Title X program. Grants and contracts are entered into under different general procedures and are governed by different sets of procedural law. Title X projects, however, whether implemented by grant or contract, must comply with applicable substantive requirements of the Title X statute, which these regulations implement.

Accordingly, regardless of whether the Department enters into a grant or contract, requirements of the Title X program shall apply, except for §§ 59.4, 59.8, and 59.10. For example, the Department interprets section 1008 of Title X to require certain restrictions concerning abortion referrals, and physical and financial separation between Title X activities and activities not permitted under the Title X statute. That interpretation would apply to project activities whether they are undertaken by grant or by contract. This regulatory provision applying certain sections of this rule to contracts is necessary to ensure consistency in the implementation and enforcement of Title X statutory program integrity provisions if a project is implemented through the issuance of a contract.

The Department notes comments that draw distinctions between grants and contracts in the general regulatory system and how they serve different purposes. The Department recognizes these differences exist, but for reasons stated above, believes it necessary to ensure the basic requirements of the Title X program are consistent. Title X authorizes the Secretary to enter into contracts, not just grants, to implement the program.[38] The Department believes it is necessary to treat contracts and grants similarly for both grantees (or, in the case of contracts, contractors) and subrecipients or subcontractors.

The Department disagrees with commenters who contend the proposed rule would circumvent ordinary procurement procedures. The Department's purpose in adding the provision on its ability to carry out a Title X program/project by contract was not to evade or avoid the substantive requirements imposed by Title X or these regulations—the Department, for example, could not contract with a for-profit entity to carry out a Title X program or project because that would be inconsistent with 42 U.S.C. 300(a)—but to confirm that contracts to implement the Title X program must be consistent with, and implement, the substantive requirements entailed in these regulations, including those related to the prohibition on the use of funds for projects where abortion is a method of family planning. If the Department enters into contracts, it would do so based on other rules generally applicable to contracts, except as specified in the Title X statute or these regulations. Thus, for example, any contracts issued under Title X would continue to be competitive to the extent required by law and regulation. To make that clear, the proposed rule would provide that certain sections of part 59 subpart A would not apply to contracts because those sections address processes specifically applicable to grants and grant applications. The substantive requirements of the other sections of the subpart, in contrast, would apply to Title X projects or programs, regardless of whether they are carried out by grant or contract.[39]

Accordingly, the Department expects both grantees and contractors to ensure that Title X funds are spent on statutorily appropriate activities. The proposed rule and this final rule help to ensure that this expectation is met by formalizing those requirements and that process.

One commenter had inquired about how the issuance of a contract to implement a Title X project would affect Title X grants. Since the funds for the program are fixed by appropriations, funds used for contracts in a given fiscal year would not be used for grants, and vice versa. Thus, Title X funds used for contracts would be offset from funds used for grants, as stated in the proposed rule.

C. Definitions (42 CFR 59.2)

1. Definition of Advanced Practice Provider

Summary of changes: The 2000 regulations did not define ''advanced practice provider,'' and the Department had not proposed such a definition in the proposed rule. However, as a result

[37] *See* 42 U.S.C. 300(a), 300a–4(a).

[38] *See* 42 U.S.C. 300(a).

[39] Although the Department had proposed that § 59.3 would not be applicable to contractors carrying out a Title X project, after further consideration, and in light of the public comments, the Department now believes that such contractors should be required to comply with § 59.3. Accordingly, the Department does not include that section in the list of regulatory provisions that would not apply to entities who have contracted with the Department to implement a Title X project. This is discussed in more detail below in response to comments concerning § 59.3.

of comments on the type of medical professional who could provide nondirective counseling and referrals under the proposed rule, as discussed in greater detail below, the Department has determined that, in addition to medical doctors, advanced practice providers (APPs) may provide nondirective counseling and referrals. For greater clarity on the scope of such APPs who can provide such services in Title X projects, the Department defines APPs to include those medical professionals who receive at least a graduate level degree in the relevant medical field and maintain a federal or State-level certification and licensure to diagnose, treat, and counsel patients. The term APP includes physician assistants and advanced practice registered nurses (APRN) who are performing increasingly critical roles within the health care system.[40] Examples of APRNs that qualify as an APP include Certified Nurse Practitioner (CNP), Clinical Nurse Specialist (CNS), Certified Registered Nurse Anesthetist (CRNA), and Certified Nurse-Midwife (CNM).[41] These APPs are qualified, due to their advanced education, licensing, and certification to diagnose and treat patients while advancing medical education and clinical research.[42] The final rule establishes this definition for purposes of Title X in § 59.2.

2. Definition of Family Planning

Summary of changes: The 2000 regulations do not define ''family planning.'' The proposed rule, at § 59.2, proposed to define ''family planning'' as ''the voluntary process of identifying goals and developing a plan for the number and spacing of children and the means by which those goals may be achieved.'' Further, the proposed definition included ''a broad range of acceptable and effective choices, which may range from choosing not to have sex to the use of other family planning methods and services to limit or enhance the likelihood of conception (including contraceptive methods and natural family planning or other fertility awareness-based methods) and the management of infertility (including adoption).'' Family planning services are described in the proposed definition to include ''preconception counseling, education, and general reproductive and fertility health care to improve maternal and infant outcomes, and the health of women, men, and adolescents who seek family planning services, and the prevention, diagnosis, and treatment of infections and diseases which may threaten childbearing capability or the health of the individual, sexual partners, and potential future children).'' Family planning and family planning services are to be voluntary and never coercive. The proposed rule emphasizes that family planning ''does not include postconception care (including obstetric or prenatal care) or abortion as a method of family planning. Family planning, as supported under this subpart, should reduce the incidence of abortion.'' The proposed rule indicates that prenatal referrals are required and medically necessary for the health of the pregnant mother, as well as the unborn baby, and are not included in this prohibition.

The Department finalizes this definition with changes, including clarifying the role of adoption as a family planning activity by permitting Title X providers to provide information about or referrals for adoption as a Title X service; increasing the understanding that family planning must not be coercive and must always be voluntary; and by making technical edits for consistency and readability.

Comments: Some commenters state there is little support for the Department to define family planning. They note that, while the Department says the definition's purpose is to avoid the ''risk of the intentional or unintentional use of Title X funds for impermissible purposes,'' the Department cites no actual violation of Title X requirements in relation to the provision of abortion services.

Some commenters oppose the explicit exclusion of abortion in the definition. One commenter notes that abortion does impact the number and spacing of children and should not be excluded from the meaning of family planning. Such commenters state that couples use abortion as a method of family planning to determine their desired number of children or to space them. They contend that excluding abortion from the definition by labeling it postconception care reflects a failure to consider who may want or need to have an abortion. Additionally, one commenter states that the last sentence of the new definition should be stricken because reducing abortion was not the intent of the enabling legislation. Some commenters suggest the definition creates ambiguity concerning abortion that is not used as a method for family planning.

Many commenters ask the Department to eliminate language that mentions natural family planning and fertility awareness-based methods (FABMs), contending that the definition prioritizes those methods over other contraceptive methods. Such commenters worry that the definition de-emphasizes contraception in favor of abstinence, natural family planning, and fertility awareness-based methods that the agency has long recognized are less-effective methods of family planning. Commenters also contend, for example, that fertility awareness-based methods do not fit everyone's lifestyle and are ineffective for many women; that abstinence programs are ineffective and ignore the needs of participants already engaged in sexual activity; that avoiding sex as a family planning method conflicts with CDC, WHO, and UN definitions of family planning; and directing Title X funds towards natural family planning is unnecessary as 93% of sites report offering it and less than 0.5% of female Title X contraceptive users rely on it.

Some commenters ask, in the alternative, that if the Department does not eliminate language that mentions natural family planning, the Department instead clarify whether it intends to prioritize and promote natural family planning and other FABMs for Title X patients over other contraceptive options, and if so, to provide its justification, and explain why that would not undermine patients' ability to obtain voluntary care free from coercion. Some commenters also state that the proposed language may ''blur the lines'' between choices, methods,

[40] Other Federal Agencies refer to APPs as Mid-Level Practitioners. *See* U.S. Department of Justice Drug Enforcement Diversion Control Division, *Mid-Level Practitioners Authorization by State,* Drug Enforcement Administration, *https://www.deadiversion.usdoj.gov/drugreg/practioners/index.html.* ''Mid-Level Practitioners'' and ''Advanced Practice Provider'' generally describe the same group of individuals; the Department here chooses the latter term in recognition of the increasingly critical and advanced roles that PAs and APRNs play within the clinic environment.

[41] The Department recognizes the wide range of specializations within the nursing profession. These examples were selected as APPs due to their advanced medical degrees, licensing, and certification requirements. *See* National Council of State Boards of Nursing, *APRNS in the U.S, https://www.ncsbn.org/aprn.htm. See also* American Association of Nurse Practitioners, *What's a Nurse Practitioner (NP)?, https://www.aanp.org/about/all-about-nps/whats-a-nurse-practitioner* (stating that ''[a]ll NPs must complete a master's or doctoral program and have advanced clinical training beyond their initial professional registered nurse preparation'' while being regulated by the licensing requirements of each State where the individual practices).

[42] *See,* Catherine S. Bishop, *Advanced Practitioners Are Not Mid-Level Providers,* J Adv Pract Oncol, (Sept. 1, 2012), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4093350/* (noting that Physician Assistants and Advanced Practice Nurses ''have at least a master's degree and many hold doctorates.'') *See also* Jacquelyn Corley, *Advanced-Practice Providers Are Key to America's healthcare Future,* Forbes, (Mar. 16, 2017), *https://www.forbes.com/sites/realspin/2017/03/16/advanced-practice-providers-are-key-to-americas-healthcare-future/#3d25c1f95998.*

and services, and contend this may diminish the range of each provided under the Title X program.

One commenter says the definition of family planning should ensure that women have sufficient access to evidence-based family planning and sexual health information, and the full range of medically accepted forms of contraception, in order to avoid issues that may arise in light of the new definition of family planning. Commenters express concern that the definition would leave many women without access to contraception or the most effective methods to prevent pregnancy. Other commenters oppose the definition of family planning because they contend negative impacts will result, such as driving some providers out of business; increasing the incidence of unintended pregnancy; increasing the incidence of sexually transmitted diseases; leading to grantees offering a more limited scope of services, making it difficult for patients to receive care they need; and leading to increased costs on the health care system as the result of unintended pregnancies.

One commenter supports including only preconception services in the definition of family planning, and states that the definition empowers the Department and Title X providers to provide comprehensive services. Another commenter similarly states that, by placing postconception care beyond the scope of Title X, and by expressly excluding abortion from the definition of family planning, the definition reorients Title X towards its intended purpose.

Other commenters oppose including only preconception services in the definition. One commenter contends that excluding postconception care disrupts the continuity of care for family planning clients. The commenter additionally states the limitation is contrary to national standards that promote early access to prenatal care. Another commenter argues that the government is discriminating against women who seek abortions by defining the practice as postconception care and excluding this type of care from the definition of family planning, but then requiring projects to refer all pregnant woman for prenatal care.

Some commenters request that the Department eliminate language referring to adoption. Commenters assert that the management of infertility, including adoption, exceeds the intent of the program as its inclusion is beyond the language of the Title X statute. Including adoption would put a strain on the program, commenters contend, as it would redirect a large amount of Title X funds. Additionally, commenters contend adoption is a postconception activity, and say its inclusion in the definition contradicts the definition's statement that family planning only includes preconception activities.

Some commenters also argue that excluding abortion is a violation of the First Amendment's religion clauses due to preferring some religious ideas over others and enforcing religion with the power of the government. They contend excluding abortion, and in their view emphasizing natural family planning, is characteristic of particular religious views.

Finally, one commenter states that the rule does not make it clear whether female or male sterilization services are considered within the scope of family planning methods, and contends they are consistent with the goal of determining the number and spacing of one's children.

Response: Title X of the Public Health Service Act confers broad authority on the Secretary of Health and Human Services ''to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents).'' 42 U.S.C. 300(a). Congress placed specific limitations on what constitutes appropriate ''family planning'' for purposes of Title X. In Section 1008, Congress expressly required that ''[n]one of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.'' 42 U.S.C. 300a–6. Congress did not fully define ''family planning'' in the Title X statute. However, section 1006 authorizes the Secretary to promulgate regulations governing grants and contracts in the program. 42 U.S.C. 300(a). Accordingly, the Department has statutory authority to define ''family planning'' for the purposes of the Title X program.

Given the statutory emphasis on family planning, the Department believes defining the phrase is important to ensure a coherent and reliable implementation of Title X, consistent with carefully considered statutory parameters. The Department disagrees with commenters who contend there is little support for creating the definition for family planning because no violations have been identified. The Department does not have to identify violations in order to interpret a statutory term. The Department deems it useful to develop and maintain a definition of family planning, in order to establish the scope of the Title X family planning program, to ensure consistency across the program, and to meaningfully ensure that the family planning projects implemented under Title X grants and/or contracts provide a broad range of family planning methods and services, consistent with the Title X statute. The Department believes it is appropriate to exercise its rulemaking authority to define family planning as a term important to the scope of the Title X projects, the development of grant applications, and the issuance of grants and contracts in the Title X program.

Moreover, the Department notes that the definition will address in part its concern that the requirement for abortion referrals, as provided in the 2000 regulations, violates or leads to violations of section 1008's prohibition on funding Title X projects where abortion is a method of family planning. Concerns about family planning methods being used indirectly to violate requirements of the program dates back at least to the 1988 regulations. There, the Department stated, in § 59.14, that a ''Title X project may not use prenatal, social service or, emergency medical or other referrals as an indirect means of encouraging or promoting abortion as a method of family planning . . .'' 53 FR at 2945. This provision was upheld by the Supreme Court.[43] That the 2000 regulations required certain abortion referrals, in a way the Department, both previously and now, deems inconsistent with the Title X statute, is itself a cause of confusion about what should and should not be included as ''family planning'' under the Title X program, and justifies the Department's decision to establish a definition of family planning in this rule.

The Department disagrees with the many commenters that oppose defining ''family planning'' to exclude abortion and that urge the Department to define the term to include abortion. Such commenters appear to be either unaware of, or confused about (or to have intentionally ignored), the fact that Title X explicitly excludes[44] funding for projects where abortion is a method of family planning. The Department is statutorily required to exclude abortion as a method of family planning for purposes of the Title X program, *see* 42 U.S.C. 300a–6, and has no statutory authority to consider family planning under Title X to include abortion. The

[43] *Rust* v. *Sullivan,* 500 U.S. at 192–195.

[44] *See* 42 U.S.C. 300a–6.

fact that so many commenters are unaware of or confused about this requirement, and ask the Department to include abortion as a method of family planning in violation of the Title X statute, reinforces the Department's view that it is appropriate to define ''family planning'' to clarify the scope of the Title X family planning program, as well as to establish other requirements that separate the Title X family planning program and Title X family planning projects from abortion as a method of family planning.

Some commenters ask how the definition applies to abortions that are not used as a method of family planning. Section 1008 prohibits funding Title X projects where abortion is a method of family planning, but does not preclude referral for services to address health issues or conditions where treatment constitutes a medical necessity. In addition, annual Title X appropriations law has consistently barred the expenditure of Title X funds for abortion. *See* HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat. 2981, 3070 (funds provided to Title X projects ''shall not be expended for abortion''); Consolidated Appropriations Act 2018, Public Law 115–141, Div. H, Title II, 132 Stat. 348, 716 (same); Consolidated Appropriations Act 2017, Public Law 115–31, Div. H, Title II, 131 Stat. 135, 521 (same); Consolidated Appropriations Act 2016, Public Law 114–113, Div. H, Title II, 129 Stat. 2242, 2602 (same). Title X primarily focuses on the provision of certain preconception health care services. Nevertheless, because of certain specific statutory provisions, the Department believes that Title X providers can provide certain counseling and referrals in a postconception setting, if compliance with the Title X statutory and regulatory restrictions concerning abortion is maintained. The Department has interpreted Title X to allow nondirective postconception pregnancy counseling because of an express annual appropriations rider on nondirective pregnancy counseling may be offered. In addition, under the Infant Adoption Awareness grants program, Congress specified that eligible health centers (which includes Title X clinics) should receive training on providing adoption information and referrals, and that the Secretary should encourage the same,[45] therefore expressing its intent that postconception adoption information and referrals be included as part of any nondirective counseling in Title X projects. Thus, adoption counseling and referral is appropriate under Title X, since Congress specified that Title X clinics and providers were eligible health centers to whom adoption related training should be offered.[46] However, this provision differs from the actual provision of adoption services to an interested family, which is outside of Title X health care services. In addition, Title X funds may not be spent on childbirth services or prenatal care, but referrals for prenatal care can be required because it is medically necessary for pregnancy and provides information rather than services.

Taking those provisions, the annual appropriations provision, and section 1008 together, the Department has concluded that Title X projects may allow a physician or APP to provide nondirective counseling on abortion generally as a part of nondirective pregnancy counseling, and may refer for abortion for documented emergency care reasons, but may not refer for abortion as a method of family planning. Similarly, the nondirective pregnancy counseling can include counseling on adoption, and corresponding referrals to adoption agencies. As a consequence, the Department considers it appropriate to define ''family planning'' as (1) excluding abortion, (2) permitting the provision of nondirective pregnancy counseling (including abortion and adoption), and (3) including and requiring Title X projects to refer for prenatal care services.

The Department disagrees with commenters who oppose the last sentence of the definition because, in the commenters' view, Congress's intent in Title X did not include the reduction of abortion.[47] The 1988 regulations, which were upheld by the Supreme Court in *Rust,* contained the same statement, that ''[f]amily planning, as supported under this subpart, should reduce the incidence of abortion.'' *See Rust,* 500 U.S. at 193. The Court stated, ''Here the Government is exercising the authority it possesses under *Maher* and *Harris* v. *McRae,* 448 U.S. 297 (1980), to subsidize family planning services which will lead to conception and childbirth, and declining to 'promote or encourage abortion.' The Government can, without violating the Constitution, selectively fund a program to encourage certain activities it believes to be in the public interest, without at the same time funding an alternative program which seeks to deal with the problem in another way.'' *Id.* In choosing to fund family planning methods, but declaring no Title X project can receive funding where abortion is a method of family planning, Congress decided to encourage certain activities as an alternative to funding abortion. The Court explained such a decision neither infringes upon nor does it constitute State interference in abortion; it represents a legitimate choice by the government to encourage some activities over others. *Id.* Reducing abortion is also commonly identified by the government, researchers, private organizations, and many public commenters here, as being a potential and significant benefit of family planning.[48] The Department, therefore, concludes it is appropriate to define one purpose of family planning, under the Title X family planning program, as being to reduce the incidence of abortion.

Defining family planning, for the purposes of Title X, to exclude abortion, and as being, at least in part, for the purpose of reducing abortion, does not suggest that Title X projects may engage in directive pregnancy counseling to reduce abortion. As discussed below, when a Title X physician or an APP engages in pregnancy counseling, such counseling must be nondirective. But the fact that reducing abortion is not a goal of pregnancy counseling under Title X does not mean that the Department's provision and promotion of family planning in all other contexts cannot be undertaken, in part, for the purpose of reducing the incidence of abortion. When the Department funds Title X projects that provide a broad range of family planning methods and services to prevent pregnancy, the results will likely include, among other things, a decrease in pregnancy and with it, a decrease in the incidence of abortion as a method of family planning.

The Department disagrees with commenters who oppose the

[45] *See* 42 U.S.C. 254c–6 (Congress authorized the Department to make grants ''for the purpose of developing and implementing programs to train the designated staff of eligible health centers in providing adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women.'').

[46] Finalizing the definition of family planning to include adoption information and referrals is also part of the Department's fulfillment of its duties under section 330F, should grants under that section be funded.

[47] The final sentence of the proposed definition of ''family planning'' is that ''[f]amily planning, as supported under this subpart, should reduce the incidence of abortion.''

[48] *See, e.g.,* Guttmacher Institute, *New Clarity for the U.S. Abortion Debate: A Steep Drop in Unintended Pregnancy Is Driving Recent Abortion Declines,* (March 18, 2016), *https://www.guttmacher.org/gpr/2016/03/new-clarity-us-abortion-debate-steep-drop-unintended-pregnancy-driving-recent-abortion* (stating that ''expanding women's access to family planning services not only protects U.S. women's health and rights, it also reduces abortion rates.'')

definition's references to natural family planning, fertility awareness-based methods, and choosing not to have sex (which some commenters refer to as abstinence), or who say the definition emphasizes those methods over contraception or other methods. The definition of ''family planning'' does not emphasize or prioritize those methods over contraception, but mentions them alongside contraception and other family planning methods in a non-exhaustive list of methods of family planning. To the extent many commenters oppose including natural family planning and fertility awareness-based methods in ''family planning'' at all, the commenters are arguing against the Title X statute, not this rule. Title X specifies that the Department fund projects ''which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods . . .).'' 42 U.S.C. 300(a). Congress has, thus, dictated that, for the purposes of Title X, family planning includes natural family planning methods. As a consequence, the Department lacks the authority to exclude natural family planning—or any other family planning method or service mentioned in the Title X statute—from the definition of family planning in Title X. Since Congress explicitly mentions it in Title X as part of family planning services to be provided by a Title X project, the Department declines to delete or deemphasize natural family planning.

The term ''fertility awareness-based methods'' is a more recent term that refers to the same general kind of family planning methods that Congress intended when it included ''natural family planning'' in the Title X family planning program. The science of natural family planning methods, and other family planning methods (including contraceptives), has advanced significantly since Congress enacted Title X in 1970. As explained further below, the term ''fertility awareness-based methods'' includes similar family planning methods and services captured by the term ''natural family planning'' in the statute. But for greater clarity as to the scope of the program, the Department finalizes the definition as proposed to mention fertility awareness-based methods alongside natural family planning.

The Department agrees with commenters who support Congress's inclusion of natural family planning methods in Title X. Some commenters point out that very few women use natural family planning methods within Title X, but there is insufficient information on why this may be the case. It may be that the method is not presented by a clinic as a meaningful option or it may be that staff are not adequately trained in the method. In general, an increasing number of persons are choosing natural family planning methods,[49] at the same time that the scientific basis and approvals for fertility awareness-based methods are also increasing.[50] Requiring projects to provide natural family planning, in addition to contraceptives and other family planning methods and services, does not mandate that such projects provide them in the same quantity, but that natural family planning be meaningfully included in the project.

In response to this and other sections of the proposed rule, some commenters contend natural family planning or fertility awareness-based methods should be excluded from Title X projects because they are not effective. The Department does not find the exclusion of such methods to be consistent with the direction of Congress in section 1001(a), which explicitly includes natural family planning in the range of family planning methods provided through Title X. The commenters also provide no evidence to conclude that natural family planning is categorically ineffective, even if such a conclusion could overcome the statutory language including natural family planning as among the methods of family planning that may be offered in a Title X project. These commenters do not acknowledge that, in the last 40 years, the science behind, and efficacy of, fertility awareness-based methods has improved significantly, leading to FDA approval of certain medical products involving such methods and to increased utilization of these methods.[51] The Department also does not find it consistent with the principle of patient choice categorically to deprive individuals or families of the option of obtaining natural family planning or fertility awareness-based family planning methods within Title X projects.

The Department similarly disagrees with commenters who oppose including choosing not to have sex as a method of family planning. Choosing not to have sex, either for a long period of time or for selected intervals, or choosing not to have sex as often or with as many sexual partners, is clearly a preconception method of family planning for reducing unintended pregnancy. In addition, choosing not to have sex or engaging in sex with a single monogamous partner is protective of preconception health, particularly because it protects an individual from exposure to STDs that may contribute to infertility and negative health outcomes. As a viable method for delaying or avoiding pregnancy altogether, the Department would be remiss if it were to exclude this method, since consistently choosing not to have sex is the most effective way to prevent pregnancy. As with natural family planning, the inclusion of this method within the definition of ''family planning'' does not invalidate other methods within that definition, nor mean that every Title X clinic has to provide counseling services related to this method of family planning.

The Department therefore disagrees with commenters who contend that recognizing these options within the definition of family planning will diminish an individual's ability to choose another form of family planning. Projects must also provide contraception, and can do so in proportion to the demand for such methods. The individual's free and informed choice to select a family planning method is respected by requiring projects to provide the broad range of family planning options that Congress contemplated in the statute, and to allow individuals to freely select the method they prefer. The definition of family planning merely specifies that these methods are included in the broad range of family planning methods available within each Title X project. Projects may comply with the statutory directive when they include natural family planning in the broad range of family planning methods and services that must be provided. The definition also specifies that family planning is never to be coercive and must always be strictly voluntary. This precludes the conclusion, put forth by some commenters, that including natural family planning or choosing not to have

[49] The Guttmacher Institute reported that the percentage of women using natural family planning doubled between 2008 and 2014. Megan L. Kavanaugh and Jenna Jerman, *Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014,* Guttmacher Institute, 97 *Contraception* 1:14–21 (Jan. 2018), *https://www.contraceptionjournal.org/article/S0010-7824(17)30478–X/fulltext.*

[50] *See e.g.,* FDA News Release, *FDA allows marketing of first direct-to-consumer app for contraceptive use to prevent pregnancy,* (Aug. 10, 2018), *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm616511.htm (permitting marketing of a fertility-awareness-based mobile medical application).*

[51] *See, e.g.,* Shawn Malarcher, et. al., *Fertility Awareness Methods: Distinctive Modern Contraceptives,* 4 Global Health: Science and Practice 13, 13 (2016), *available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4807745/pdf/013.pdf* (stating fertility awareness methods of contraception have been tested and proven effective at pregnancy prevention and safe to use).

sex in the definition imposes a requirement on any clients.

The Department also notes that this final rule is consistent with the proposed rule, which explicitly includes contraception in the definition of family planning. Contrary to the suggestion of some commenters, the definition does not place a lower priority on contraception as a method of family planning, nor somehow invite Title X providers to pressure clients to use natural family planning instead of contraception. The rule, both as proposed and finalized, will allow funded projects to provide all acceptable and effective Title X family planning methods, while ensuring that participating entities or service sites that wish to offer only a single method or a limited number of methods may also participate in Title X projects, so long as each Title X project, as a whole, provides a broad range of family planning methods and services, including contraception and natural family planning.

Clarifying that those options fall within the program is well within the purview of the Title X program, and ensures individuals' voluntary and informed access to the family planning option of their choice. The Department does not agree that the definition blurs lines between different family planning options, methods, or choices. Rather, the Department agrees with comments suggesting that the new definition of family planning will expand access to a broad range of family planning methods and services and will ensure patients have the ability to make voluntary and informed family planning choices. To provide clarity and ensure that duplicative terms are not interpreted with different meanings, the Department revises the definition by using the words used in the Title X statute, ''methods and services,'' instead of the word ''choices'' that was used in the proposed rule. The Department further modifies the sentence ''Family planning and family planning services are never coercive and are strictly voluntary'' to read ''Family planning methods and services are never to be coercive and must always be strictly voluntary.'' This clarifies the terms in the sentence and also further aligns the definition with the voluntary requirements set forth in sections 1001 and 1007 of Title X.

The Department acknowledges the concerns of commenters who contend the proposed definition would leave women without access to contraception or other methods of family planning, but believes that these concerns are overstated. The Department is aware of reported success rates regarding various forms of preconception family planning for those engaged in sexual activity. The Department wishes to emphasize that, consistent with the statutory provisions, contraception will continue to be a significant category of family planning methods for Title X projects. This is why the family planning definition specifically mentions contraception among other family planning methods and services and why § 59.5 continues to require a broad range of acceptable and effective family planning methods and services within Title X projects. The Department does not intend to implement or enforce these regulations to have any limiting effect on Title X organizations that offer contraception options if those organizations are otherwise compliant with the Title X grant requirements. The Department believes that the proposed rule broadens access for women seeking preconception family planning options by permitting grantees or subrecipients to provide various or specialized forms of family planning, while also ensuring that projects, as a whole, provide a broad range of family planning methods and services.

The Department finds there is insufficient evidence to support the contention of some commenters that negative impacts will result from the definition, such as driving out some providers, increasing unintended pregnancy, or increasing STDs. The definition encompasses contraception and other methods that these commenters support, and it will not deprive Title X projects of the ability to offer any such methods or services. To the extent commenters believe these negative results will occur because the definition of family planning excludes abortion, and includes natural family planning, both parameters have been mandated by the Title X statute for decades. Any such effect, then, would be attributable to implementing the program as Congress directed.

The Department disagrees with commenters who ask that the definition specify that all family planning methods and services must be ''medically approved.'' The Department also discusses this issue below concerning the change in such language at § 59.5. When Congress specified what family planning methods and services Title X projects must provide, Congress directed that the methods and services be ''acceptable and effective''; it did not specify that they be ''medically approved.'' The Department also does not understand, and commenters fail to explain, what the addition of ''medically approved'' to the definition would mean in practice. Family planning methods and services are often provided through licensed health care professionals. Thus, it is true of all family planning methods or services provided by Title X providers that at least one medical professional or clinic has ''approved'' the method or service, by virtue of providing it to the client. It is not clear what else a requirement of medical approval might mean, or what commenters believe it to mean, if inserted into the family planning definition. For example, would approval by one medical doctor suffice, or would some larger number need to approve, and if so, how many; would certain medical organizations, or governmental organizations, or both, need to approve, and if so, which ones; would a certain level of medical consensus need to exist concerning a particular method or service, and if so, how would the Department measure that consensus; and when doctors and medical organizations disagree either about a family planning method or service, how would that requirement apply? For all of these reasons, the Department does not believe the Title X statute requires the term ''medically approved'' be included in this definition, and does not believe including it is appropriate. The Department instead relies on the statutory language ''acceptable and effective'' as sufficiently ensuring that family planning methods and services are appropriate for clients served in Title X projects.

The Department disagrees with commenters who contend the definition of family planning violates the religion clauses of the First Amendment. As discussed in *Rust,* the Supreme Court has stated many times that the Constitution does not require the government to fund abortion, and it allows the government to encourage alternatives to abortion. *See Rust,* 500 U.S. at 201. The inclusion of natural family planning in the definition of ''family planning'' is a congressional mandate and has existed for decades—there is no legitimate legal reason to believe it violates the First Amendment.

In response to commenters asking whether family planning includes sterilization, the Department clarifies that acceptable and effective methods of sterilization are a preconception means of implementing an individual's or family's decision as to the number and spacing of births.

The Department agrees with commenters that support the limitation in the proposed definition that family planning does not include postconception health care (as distinct from certain types of postconception counseling/information, such as in the

case of congressionally permitted nondirective pregnancy counseling), but does include preconception counseling, education, and health care that can improve maternal and infant outcomes; the health of women, men, and adolescents who seek family planning services; and the prevention, diagnosis, and treatment of infections and diseases that may threaten childbearing capability or the health of the individual, sexual partners, and potential future children. This is consistent with the legislative history of the Title X program, which emphasizes Congress's intent for the program to focus on preconception health services as important to family planning.[52] This Congressional intent is another basis for excluding abortion as a method of family planning from the definition of family planning for the purposes of Title X, because abortion is a postconception service. As discussed further below, Title X projects are not required to provide abortion information or counseling, and if nondirective pregnancy counseling is offered, any abortion counseling also must be nondirective.

The Department finds that a distinction between preconception health care services and postconception services is effective and can be more cost-effective. The Department disagrees with commenters who contend limiting family planning to preconception care is contrary to national standards. For the purposes of the Title X program, the limitation to preconception care is appropriate and consistent with Congressional intent. Any concern with national standards is met and addressed by encouraging Title X projects to offer either comprehensive primary health care services onsite or have a robust referral linkage with primary health care providers who are in close proximity to the Title X site. The Department will administer Title X funds to focus on permissible preventive care and preconception family planning, while promoting robust referral networks to ensure that clients have ready access to non-Title X health care services that they need, including treatment for health conditions that are not provided by Title X and for postconception care (other than abortion as a method of family planning).

The Department appreciates and responds to comments raising concern about the inclusion of adoption in family planning services and clarifies the purpose of the rule in this regard, finalizing a change to the language concerning adoption. Adoption is a method by which families can plan their family size, to either increase it, decrease it, relieve burdens attendant to insufficiently spaced children, or deal with infertility (although infertility management is not the only way in which adoption is a method of family planning, and adoption is not the only method of infertility management). Insofar as adoption is considered a preconception method by which families may plan their family size or respond to infertility, it fits comfortably within the broad range of family methods and services contemplated by Title X. Although many commenters focus on the important role of Title X providers in preventing unintended pregnancy through contraception or not having sex, Congress clearly intended Title X to support family planning through more than preventive services, as evidenced by the emphasis on infertility services in Title X. *See* 42 U.S.C. 300(a) (Title X family planning projects required to ''offer a broad range of acceptable and effective family planning methods and services (including natural family planning, infertility services, and services for adolescents)'').[53] The Department thus found and continues to find that Title X is an important resource for individuals seeking assistance to have children, and adoption is one method by which a Title X client who is not pregnant may seek to have children.[54]

Moreover, Congress has expressed its intent that postconception adoption information and referrals be included as part of any nondirective counseling in Title X projects when it passed the Children's Health Act of 2000, adding section 330F (''Grants Regarding Infant Adoption Awareness'') to the Public Health Service Act on October 17, 2000. Public Law 106–310, 114 Stat. 1101, sec. 1201, codified at 42 U.S.C. 254c–6 (hereinafter ''Infant Adoption Awareness grants''). There, Congress authorized the Department to make grants ''for the purpose of developing and implementing programs to train the designated staff of eligible health centers in providing adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women.'' 42 U.S.C. 254c–6(a)(1). Congress specified that grantees shall offer that training to Title X grantees and the Secretary shall make reasonable efforts to encourage Title X grantees to participate in that training.[55] At least some major organizations ''understood the legislation and the guidelines for the Program to strongly suggest that those working in clinics receiving funds through Title X family planning grants . . . be the principal target for the training.'' [56] If the provision to pregnant women, of nondirective adoption counseling and referral were not appropriate under Title X, Congress would not have specified that Title X clinics and providers were eligible health centers to whom such adoption related training should be offered. This interpretation has been carried into current practice by major adoption organizations, such as The National Council for Adoption.[57]

By contrast, because of Congress's primary focus on funding preconception care in Title X, the Department deems the provision of adoption services themselves to be outside the scope of the Title X program. This clarification should address the concern by some commenters about a potential strain on resources of the Title X program caused by the inclusion of adoption in the family planning definition. Title X providers may provide adoption counseling, information, and referral as a voluntary family planning service for non-pregnant clients as a means of addressing health care issues related to

[52] *See* H.R. Rep. No 91–1667, at 8–9 (1970) (Conf. Rep.) (emphasizing the intent of Congress that Title X funds specifically support preconception family planning, stating ''[i]t is, and has been, the intent of both Houses that funds authorized under this legislation be used only to support preventive family planning services, population research, infertility services and other related medical, information, and educational activities. The conferees have adopted the language contained in section 1008, which prohibits the use of such funds for abortion, in order to make clear this intent.'').

[53] *See* 53 FR at 2922 (the Department historically found ''it is clear that Congress intended the term ''family planning'' to be broader in scope than simply contraception, as infertility services are included as one of the mandatory services listed in section 1001(a) of the Act.'').

[54] *Id.* This interpretation is consistent with the Department's history of enforcing Title X regulations regarding adoption: ''Both approaches [adoption and infertility services] constitute legitimate means of determining family size and spacing, but adoption is simply one means of addressing the broader problem of infertility.'' *Id.*

[55] *See* 42 U.S.C. 254c–6(a)(5) & (6)(A) (adoption organization required to make reasonable efforts to ensure that training is provided to, among others, ''eligible health centers that receive grants under section 1001 (relating to voluntary family planning)''; with respect to eligible health centers that received grants under section 330 or 1001, ''[t]he Secretary shall make reasonable efforts to encourage eligible health centers to arrange for designated staff to participate in such training. Such efforts shall affirm Federal requirements, if any, that the eligible health center provide nondirective counseling to pregnant women.'').

[56] *See* The National Council For Adoption, *NCFA's Infant Adoption Awareness Training Program—A Successful Model,* 193.

[57] Finalizing the definition of family planning to include adoption information and referrals is also part of the Department's fulfillment of its duties under section 330F, should grants under that section be funded.

fertility and reproduction, such as infertility, and as part of nondirective postconception counseling, but may not provide adoption services themselves within the project.

This approach is consistent with the Title X parameters and with the Department's history of implementing Title X. In the 1981 Title X program guidelines, ''Program Guidelines for Project Grants for Family Planning Services,'' the Department allowed nondirective counseling on, and referral for, adoption and foster care when a woman with an unintended pregnancy requested information on her options. The 1988 regulations continued this support for encouragement of counseling on and referral for adoption. The 2000 regulations required both counseling and referral on adoption, if the client requested such assistance. Given this history and Congress's expressed intent, the Department concludes that Title X funds may facilitate access to adoption through nondirective adoption counseling and referral as a part of the nondirective counseling offered to pregnant clients.

Congress's express intent to include adoption information and referral in Title X projects can be contrasted with its express intent to exclude Title X funding from any projects where abortion is a method of family planning. The Title X statute contains no similar prohibition on funding projects where adoption is a method of family planning, and section 330F requires the Secretary to encourage the inclusion of adoption information and referrals in the Title X program. Similarly, the Title X statute contains no similar prohibition on funding projects that include postconception referrals for prenatal care, which is necessary for pregnancy as a medical condition. Thus, the Department disagrees with commenters contending that the definition improperly discriminates by treating adoption more favorably than abortion. Simply put, abortion is prohibited as a method of family planning within a Title X project and adoption is not. Given Congress's explicit differential treatment of adoption and abortion throughout the applicable statutes, the definition is an appropriate exercise of the Department's authority to promulgate regulations to implement the Title X family planning program.

For all these reasons, the definition of family planning appropriately includes adoption information and referral as a family planning method. To clarify this, in response to questions from commenters about this issue, the Department modifies this aspect of the family planning definition in the final rule by changing ''the management of infertility (including adoption)'' to ''the management of infertility, including information about or referrals for adoption.''

3. Definition of Grantee

Summary of changes: The 2000 regulations did not define a ''grantee'' under Title X. The proposed rule, at § 59.2, proposed to define ''grantee'' as ''the entity that receives Federal financial assistance by means of a grant, and assumes legal and financial responsibility and accountability for the awarded funds, for the performance of the activities approved for funding and for reporting required information to the Office of Population Affairs.''

There were no substantive comments regarding this definition.

The Department finalizes the definition of ''grantee'' in § 59.2 without change, except for minor grammatical corrections.

4. Definition of Low Income Family

Summary of changes: The 2000 regulations at § 59.2 defined ''low income family'' by income and allowed the project director to determine ''good reasons'' where an individual may qualify even if income exceeded the defined amount. Pursuant to an example in the definition, minors who wish to receive services on a confidential basis are considered on the basis of their own resources. The proposed rule, at § 59.2, proposed to modify the existing definition of ''low income family'' relating to minors by requiring the program to document its efforts to encourage the unemancipated minor to involve his/her family in the decision to seek family planning services, in order to ensure compliance with the applicable Title X and appropriations law provisions on the issue. In addition, the proposed rule included a provision whereby the project director may consider a woman as a low income family when her employer-sponsored health insurance does not cover certain contraceptives because of her employer's religious or moral objection to such contraceptives. The Department recognizes that a woman's insurance coverage may relate to her ability to pay for family planning services. The Department finalizes the proposed modifications with no substantive changes to the definition with respect to unemancipated minors, but with some minor grammatical corrections. However, in response to public comments, the Department also finalizes paragraph (2) under the definition for low-income family for cases involving ''payment for contraceptive services only,'' where the woman's employer ''does not provide the contraceptive services sought by the woman because the employer has a sincerely held religious or moral objection to providing such coverage.'' This final rule clarifies that, in these cases, the project director may exercise discretion under the existing ''good reason'' exception to ''consider her insurance coverage status as a good reason why she is unable to pay for contraceptive services.'' In making this determination, the project director ''must also consider other circumstances affecting her ability to pay.'' This final rule then provides mechanisms by which a director may determine whether the woman is from a ''low income family'' or is eligible for a discount for contraceptive services on the schedule of discounts provided for in § 59.5.''

Comments: Some commenters support the proposed changes to the definition of low income family. Some of these commenters support the encouragement of family participation in the family planning decisions of minors. Some also support the definition's clarification about how women may be eligible to receive contraceptive services where health insurance from their employers does not cover those services due to their employers' religious or moral objections. Some commenters support the change because they say it assists the Department in not requiring employers to violate their religious or moral beliefs, while protecting the ability of women to receive family planning services.

Commenters support the encouragement of family participation in the family planning decisions of minors, noting that it does not block access to family planning services. Rather, as comments explain, family participation should be the standard for any health care service provided to minors because they do not always know their family history and certain contraceptives are contraindicated for females with certain health conditions. In addition, parents are better able to direct health care decisions for their children if they are aware of other health care services and products that their children are receiving.

Some commenters oppose the definition's requirement that emancipated minors be charged based on their own income only if there is documentation of specific actions taken with respect to each minor to encourage such family participation. Such commenters are concerned this would threaten the confidentiality of these patients, as well as the patient-provider

relationship. Commenters state that providers typically use their expertise and judgment when deciding whether or not to encourage family involvement in the care of patients who are minors, and they identify situations in which family involvement should not be encouraged, such as in cases of neglect, coercion, or abuse. Some commenters are worried that the definition could cause strain on the patient-provider relationship and could lead to patients omitting information that would impact their care. Other commenters are concerned the definition would increase barriers for minors receiving low cost or free, confidential care. Such commenters conclude the revision runs counter to congressional intent, by including services for adolescents in the Title X statute, and exceeds the Department's authority under Title X. One commenter asks the Department to include additional language in the rule to ensure confidentiality for such minors; confidentiality of the information received about minors' circumstances; that the encouragement of family involvement is not coercive; and, that the minor's decision to involve his or her family is strictly voluntary.

Many commenters also oppose revising the definition of low income family to include women who are unable to obtain certain family planning services under their employer-sponsored health insurance policies due to their employer's sincerely held religious or moral objections. Many such commenters assert that Title X is already underfunded, and this revision would result in a large number of new Title X patients and could reduce services for actual low income patients, due to limited funds. Many stated that, if the Department does revise the definition, there must be increased Title X funding to account for the new patients.

Commenters who are health care providers note that the Department did not discuss the impacts this change would have on Title X patients and providers. Such commenters stated that the proposed rule did not provide evidence to support the conclusion that the Title X network can absorb the new patient population, nor address how the change would impact current patients. They also contend that the proposed rule did not discuss any financial impacts, operational impacts on projects, or corresponding costs. For example, commenters contend the Department did not explain how women are to show they are in an employer plan with a religious or moral objection to contraceptive coverage. Some Title X providers comment that requiring projects to verify that status would be cumbersome and involve administrative costs. Some commenters ask whether newly eligible patients would be able to obtain other services (*e.g.,* STD testing or Pap test) during a contraceptive visit and whether these services would also be free, and request guidance on that question.

Many commenters object to the new definition on the ground that previous interim final rules concerning contraceptives issued by the Department and the Departments of Labor and of the Treasury in October 2017 are not in effect based on court orders. Such commenters also contend the definition applies to women who are the policyholders of employer-sponsored insurance but not to other beneficiaries of such plans. Commenters further object that the definition does not guarantee coverage for such women but only states the project director may consider her as being from a low income family if good reasons exist under the definition. And commenters object that some women with insurance sponsored by an employer that objects to contraceptive coverage for religious or moral reasons might not have access to a Title X provider.

Some commenters assert that the Secretary does not have the legal authority to deem women as ''low income'' if their employer-sponsored plans have religious or moral objections to contraceptive coverage. Some commenters object that the definition only encompasses women, not men, whose employer-sponsored plans have religious or moral objections to contraceptive coverage, and they believe the definition does not encompass transgender men. One commenter contends the definition constitutes impermissible government subsidy of religious objections under the Establishment Clause of the First Amendment.

Response: The Department agrees with commenters generally supporting the revised definition concerning minors and women with employer-sponsored health insurance that does not cover contraceptive services based on the employer's religious or moral objections. Nevertheless, the Department has carefully considered all the comments, including comments opposing the changes, and is finalizing the definition with changes in response to those comments.

The Department disagrees with the suggestion of some commenters that its revised definition of low income family threatens the confidentiality of unemancipated minors. The revised definition explains that, if a project director seeks to consider only an unemancipated minor's own resources to determine whether the minor seeking confidential services qualifies as a low income family, the project director must document efforts to encourage family participation in the unemancipated minor's decision to seek family planning services. As discussed more fully below, such encouragement is specifically required by Congress and would occur within the context of the provider-patient relationship. Communications in that relationship are already confidential, and communications in which the provider encourages family participation in the minor's decision to seek family planning services would be subject to the same confidentiality requirements.

The Department similarly disagrees with the suggestion that this documentation requirement infringes on the judgment of medical professionals or threatens minors who are in abusive home circumstances. As discussed below, this final rule does not require a Title X provider to encourage family involvement ''if the Title X provider has documented in the medical record: (i) That it suspects the minor to be the victim of child abuse or incest; and (ii) That it has, consistent with, and if permitted or required by, applicable State or local law, reported the situation to the relevant authorities.'' Situations exist where confidentiality is important, and the Department incorporated those into the proposed rule. Moreover, the rule does not require family participation, but merely the encouragement of such participation. Inserting references to that general requirement in the definition of ''low income family'' concerning unemancipated minors simply reinforces the already existing statutory requirement—and ensures that Title X providers are actually complying with such requirements. To the extent that there were any infringement on the judgment of medical professionals, it would be the result of requirements imposed on the Title X program by Congress, requirements that the Department merely seeks to faithfully implement.[58]

Some commenters contend the Department lacks statutory authority to include as ''low income'' patients women who have employer-sponsored health insurance that does not cover contraceptive services based on the employer's religious or moral

[58] For additional responses to similar comments, please see the discussion of § 59.17, in which the Department responds more fully to similar objections.

objections, but this argument appears to be premised on a misunderstanding of the Department's proposal. Section 1006 gives the Secretary of HHS the authority to promulgate regulations governing grants and contracts issued under the Title X statute. 42 U.S.C. 300a–4. Section 1006 further specifies that projects receiving Title X grants or contracts must assure the Department that ''priority will be given in such project or program to the furnishing of such services to persons from low income families'' and that ''no charge will be made in such project or program for services provided to any person 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 or is under legal obligation to pay such charge.'' 42 U.S.C. 300a–4(c)(2). Section 1006 does not define ''low income family,'' but instead declares that the Secretary has discretion to define ''the term 'low income family'. . . in accordance with such criteria as he may prescribe so as to insure that economic status shall not be a deterrent to participation in the programs. . . .'' 42 U.S.C. 300a–4(c). Consequently, Congress granted the Secretary discretion to decide what constitutes a ''low income family'' for the purpose of giving priority of services to persons from such families, so as to ensure that economic status is not a deterrent to participating in Title X programs. *Id.*

For decades, the Department has implemented such regulations by defining ''low income family'' to mean a family whose total income does not exceed 100% of the Poverty Level guidelines,[59] along with individuals in families whose income does exceed that level but for whom the project director determines—based on unenumerated factors—that there are ''good reasons'' to conclude is ''unable'' to pay for family planning services. 42 CFR 59.2. The 2000 regulations provide the example of unemancipated minors who desire to receive services on a confidential basis. 42 CFR 59.2. The proposed addition to the definition maintains the same standard and simply specifies that one factor relevant to the ''good reasons'' standard is a woman's insurance status –which may affect her financial/economic status—with respect to the provision of contraception because of her employer's religious or moral objection to contraceptive coverage. Project directors already have this discretion under the 2000 regulations. The text of the proposed rule simply makes it explicit that a project director may rely on this factor in such circumstances. Some commenters are under the mistaken impression that the proposed rule requires project directors to consider women as being from a low income family if they have this insurance status, but the proposed rule said the project director ''may'' reach that conclusion, not that the director ''must'' do so.

This clarification does not, as some commenters contend, contradict the text or intent of the Title X statute. Congress authorized the Secretary to decide what constitutes a ''low income family'' in the program, and the Department's decades-old decision has allowed project directors to deem families ''low income'' even if their income exceeds 100% of the Poverty Guidelines. Thus, project directors might conclude based on a particular prospective client's insurance, income, and financial situation that the individual is unable to pay for family planning services. The proposed definition clarifies that a project director may—but is not required to—allow the same treatment for women with health insurance from an employer with a religious or moral objection to contraceptive coverage. And the definition instructs the project director to consider the woman's income in assessing her ability to pay. Thus, under the definition, if a project director concludes that a woman with that insurance status who has an income above 100% of the Poverty Guidelines[60] can afford to pay for family planning, the project director should conclude that she is not from a low income family. But the project director is also free to conclude, taking into account the particular circumstances, that a woman with that insurance status who has an income above 100% of the Poverty Guidelines cannot, in fact, afford to pay for family planning and should qualify as ''low income.'' That flexibility makes sense, as a woman's ability to obtain contraceptive services through an insurance plan may be relevant to her ability to pay for family planning services, and Congress has long directed that ''low income family'' be defined ''so as to insure that economic status shall not be a deterrent to participation in the programs assisted under this title.'' 42 U.S.C. 300a–4(c).

Some commenters correctly read the proposed definition to mean the project director may, or may not, deem a particular woman who lacks insurance coverage for contraception because of her employer's religious or moral objection as being from a ''low income family,'' and they object to the Department giving the director that discretion. They seem to ask that the Department require the project director to deem such women as being from a ''low income family,''[61] regardless of her family's total annual income, or other factors contributing to her ability to pay for family planning.

The Department rejects that suggestion. It is true that the Department has required, in the ''low income family'' definition, that a project director ''must'' consider only an unemancipated minor's own resources if the minor seeks confidential services to determine whether the minor is from a ''low income family.'' In that way, the Department has previously exercised its regulatory authority to define ''low income family'' to include some persons who potentially have ability to pay for family planning—namely, minors from families who may have access to funds to pay for family planning services even if they are not employed. But in this case, the Department declines to finalize the definition to require project directors to consider a woman as being from a ''low income family'' based solely on her employer's religious or moral objection to contraceptive coverage. Some women in such circumstances may be unable to pay for family planning, but others may be able to pay. For example, some may be from families with total incomes well above the poverty level, and their other circumstances may reflect that they are able to pay. The Department wishes to leave this discretion with the project director.

The Department disagrees with commenters who contend the definition is confusing and leaves project directors with insufficient guidance. For decades, the definition of ''low income family'' has given project directors discretion to determine whether good reasons exist as to why a person cannot pay for family planning. The definition being finalized here provides more guidance, not less, for the project director's exercise of that discretion in the given scenario.

Some commenters object that projects will not be able to determine whether a woman's employer-sponsored insurance omits contraceptive coverage, or does so on the basis of religious or moral objections, but the Department believes

[59] *See* 42 U.S.C. 9902(2).

[60] The poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2). *See* Office of the Assistant Secretary for Planning and Evaluation, *U.S. Federal Poverty Guidelines Used to Determine Financial Eligibility for Certain Federal Programs* (Nov. 15, 2018, 9:51 a.m.), *https://aspe.hhs.gov/poverty-guidelines.*

[61] *See* 42 U.S.C. 300a–4.

this concern is overstated. This task is not fundamentally different from the task that projects face in determining what a person's income is, or whether, despite their income being above the poverty level, good reasons exist for considering them unable to pay for family planning. Guidance has set forth a variety of ways to seek information of this kind, including that set forth in the 2014 Title X program requirements.[62] Projects are also generally required to obtain third party payment or contribution for services that persons receive for free or at a sliding scale discount. All of these types of information are similar to the types of information that might demonstrate to a project that a woman has employer-sponsored health insurance that does not provide certain contraceptive coverage because the employer has a religious or moral objection to providing such coverage. A pay stub may demonstrate where a person works. Proof of insurance may demonstrate the person has coverage. A plan's summary of benefits and coverage would also indicate whether the plan covers the contraceptive services a woman seeks. And just as projects contact third party payers to obtain payment or contributions, projects could contact a woman's insurer to inquire whether the plan covers the particular contraceptive services and could ask if the lack of coverage is due to a religious or moral objection on the part of the plan sponsor. Where a woman wants to obtain the coverage confidentially, the project may not be able to make such contact, but in those cases, the same difficulty would be presented under the definition from the 2000 regulations, with respect to whether to deem those persons as having good reasons for their inability to pay for family planning services. The revised definition does not add uncertainty that is not already inherent in the good reasons discretion afforded to project directors. Rather, it adds clarity concerning one good reason that can form the basis of that good reason determination.

The Department understands the objection that project directors may seek more specific instructions on how to implement the definition, and also understands the concerns of some commenters who believe that women should automatically be deemed as being from a ''low income family'' if her employer-sponsored insurance coverage omits contraceptive services on the basis of a religious or moral objection. Such comments reflect that, for some women, not having contraceptive coverage may affect their ability to pay and, thus, their economic status. In light of this concern, and the desire to provide more specific direction sought by commenters, the Department is finalizing the definition with the modification that a project director may exercise discretion to consider such women as being from a ''low income family'' or eligible for a discount for contraceptive services on the schedule of discounts provided for in § 59.5, based on the impact that not having contraceptive coverage may have on their ability to pay for contraceptives.

Under the women's preventive services guidelines issued by the Department, certain plans (or issuers or plan administrators) are required to cover all FDA-approved contraceptives with no cost-sharing, unless an exemption applies to the plan based on sincerely held religious beliefs or moral convictions. *See* 45 CFR 147.132 (religious exemption criteria); 45 CFR 147.133 (moral exemption criteria); *see also* 45 CFR 147.131 (religious or moral accommodation criteria). In addition, various entities with religious or moral objections have obtained permanent injunctions from federal courts, entitling them to exemptions from the federal contraceptive coverage requirement.[63] Where a woman has health insurance coverage through an employer that does not provide the contraceptive services she seeks from a project, because her employer has a sincerely held religious or moral objection to providing such coverage, the project director may approximate the net effect on the woman's economic status by the average annual cost of the contraceptive services that would have been covered if her employer did not object. For example, if she seeks oral contraceptives, and her employer had covered oral contraceptives without cost-sharing, she would incur no out-of-pocket cost for oral contraceptives. If her employer omits oral contraceptives on the basis of a religious or moral objection, her annual cost as the result of that decision can be approximated by the annual out-of-pocket cost she would bear for oral contraceptives.

Consequently, in the final rule, the Department modifies the example involving a woman whose employer-sponsored health insurance does not cover contraceptives because of a religious or moral objection on the part of the employer. In such a situation, in determining whether such a woman's income is more than 100% of poverty level, or whether she is subject to sliding scale discounts for contraceptive services under § 59.5, the project director may reduce the woman's annual income by the annual out-of-pocket cost she would pay for the desired contraceptive services. The project director may estimate the annual cost based on the project director's expertise regarding the costs of contraceptive services, or reduce the woman's estimated total income by an estimated [64] average of $600 per year. This gives the project director additional discretion and guidance in considering the income status of a woman whose employer omits contraceptives from her insurance plan on the basis of a religious or moral objection.

The Department disagrees with commenters who assert that the example is discriminatory because it only refers to women. As discussed more fully below, the definition does not preclude men from seeking to establish good reasons for which they are unable to pay for family planning services. This specific example simply refers to women because it has mainly arisen in a context related to coverage for women's contraceptive services. A section of the PHS Act added by the Affordable Care Act,[65] specifies that certain group health plans and issuers shall provide coverage, with no cost sharing, of women's preventive services as provided by guidelines supported by the Health Resources and Services Administration (HRSA), a component of the Department. Section 2713(a)(4) does not apply to men and does not provide for cost-free coverage of men's contraceptive services. Where a woman's plan omits contraceptive coverage on the basis of religious or moral objections, it falls into an exemption to the guidelines set forth at 45 CFR 147.131 and 147.133. That exemption does not apply to men's contraceptive coverage, because the

[62] Office of Population Affairs, *Program Requirements for Title X Funded Family Planning Projects,* Health and Human Services, 12 (April 2014), *https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf* (''Although not required to do so, grantees that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients self-report.'').

[63] *See, e.g., Catholic Benefits Ass'n LCA* v. *Hargan,* No. 5:14–cv–00240–R (W.D. Okla. order filed Mar. 7, 2018), and *Dordt Coll.* v. *Burwell,* No. 5:13–cv–04100 (N.D. Iowa order filed June 12, 2018).

[64] *See* 83 FR 57536, 57551 (Nov. 15, 2018) (estimating the average annual cost of contraceptives at just under $600 per year).

[65] *See* 42 U.S.C. 300gg–13(a)(4) as added by the Affordable Care Act, Public Law 111–148, 124 Stat. 119, 131, sec. 1001 (adding new PHS Act section 2713).

underlying requirement of section 2713(a)(4) does not encompass preventive services for men. Given these circumstances, the Department deems it appropriate to illustrate how the project director could apply the discretion embodied in the existing low income family definition when a woman's employer-sponsored insurance plan omits contraceptive coverage on the basis of a religious or moral objection.

The Department notes that the definition maintains the decades-old discretion granted to the project director to deem a person as having good reasons why he or she cannot pay for family planning and therefore deem him or her as being from a ''low income family.'' Consequently, project directors may also consider a man's lack of access to insurance coverage for contraceptive services as potentially constituting a good reason why the project will consider the man as being from a low income family. The definition has required, and continues to require, project directors to take into consideration such indicia of ability to pay. This final rule mentions one specific context involving women who may not have access to contraceptive coverage as one possible application of the ''good reasons'' determination, but does not do so in an exclusive way, nor does it negate the applicability of the project director's pre-existing discretion to any person seeking services from the project.

Some commenters ask the Department to clarify whether a woman, who is considered as being from a low income family based in part on the lack of contraceptive coverage in her plan due to her employer's religious or moral objection, then qualifies to receive just the contraceptive services that her plan omits, or qualifies to receive all family planning services provided by the project, such as pap smears and STD testing. The Department clarifies that a project director may consider the woman with this insurance status as being from a low income family, or as qualifying for sliding scale discounts, for the purposes of her payment for the contraceptive services she seeks that are not covered by her insurance plan. The revision does not specify that such a woman will be deemed as being from a low income family for the purpose of receiving other services from the Title X project. Presumably, the woman would have insurance coverage for such other services, and the Title X provider could bill her health insurance company for them. Nevertheless, as noted above, the definition retains the decades-old discretion given to the project director to make a ''good reasons'' determination to deem a person as being from a ''low income family'' for the purposes of receiving all the services offered in the Title X project. The example specifies and clarifies how the project director's discretion could be applied in a particular situation, but it does not add limitations to the project director's discretion in other hypothetical cases raised by commenters.

Many commenters express concern that implementation of the example would cause a financial strain on the program. The Department disagrees. As noted above, the example does not mandate that project directors must consider a woman as being from a ''low income family'' based on her employer's religious or moral objection to contraceptive coverage in her insurance plan. The example simply affirms the project director's discretion to take that fact into consideration. Project directors are aware of long-standing flexibility when defining ''low income,'' since the 2000 regulations do not preclude project directors from deeming women who do not have contraceptive coverage because of their employer's religious or moral objection to contraceptive coverage in their insurance plans to be ''low income.'' Because the project director already has that discretion under the 2000 regulations, the Department disagrees that merely making this discretion even more explicit will result in a significant number of women being granted low income status to receive free or low cost contraceptive services from Title X projects. Commenters did not provide data from which the Department could reliably estimate how many women will seek to obtain free or low cost contraceptives from Title X providers as a result of this change and how many will then be granted ''low income family'' status by project directors.

To the extent that commenters base this objection on estimates in rules concerning religious and moral exemptions to the contraceptive coverage guidelines, the Department notes that such estimates were speculative. The Department, along with the Departments of Labor and of the Treasury, attempted to set forth various estimates concerning the number of women who would use the exemptions, but noted that they lacked adequate data to know whether those estimates were accurate. 83 FR 57536, 57550 (Nov. 15, 2018). The Departments made several assumptions that they noted were likely too high. *Id.* at 57581. And they emphasized that the estimate was not the number of women that they believed would be affected by use of the exemptions by sponsors of health insurance plans.

Even if those estimates of the women affected by the religious and moral exemption rules were accurate, the Department could not simply assume that all of those women would obtain contraceptive services from a Title X project. As noted above, the proposed additional example in this definition does not require a project director to consider a woman to be from a low income family on this basis. Project directors might conclude that women seeking to use the clarifying example have incomes that, despite their lack of contraceptive coverage, render them able to pay for contraceptive services. Moreover, it is unlikely that all women affected by the exemption rules will seek services from Title X projects. Some of those women may have family incomes under which they can afford the services. Some may choose, for other reasons, not to seek contraceptive services from Title X projects. For example, some may share their employers' objections to such contraceptives.

The Department is not aware of data from which to reliably estimate how many women will seek contraceptive services from Title X projects because the sponsors of their health plans have religious or moral objections leading them to omit contraceptive coverage from their insurance plans, but believes that any overall cost to the Title X program will be slight. With regard to low income women in general, the Department is aware that significantly less than half of such women receive services from Title X projects. In 2017, Title X projects served more than 4 million persons of whom 90% were low income persons.[66] The official poverty rate in 2016 was 12.7%,[67] therefore encompassing more than 41 million persons.[68] Thus, fewer than 10% of persons eligible for low income status in Title X projects sought and obtained Title X services. The Department estimates that an even smaller fraction of women would be affected by the exemptions provided for entities with religious and moral objections to providing contraceptive coverage. And

[66] Christina Fowler et al., *2017 Family Planning Annual Report,* Health and Human Services, (2008), *https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2017-national-summary.pdf.*

[67] Jessica Semega et al., *Income and Poverty in the United States: 2016,* U.S. Census Bureau, (Sept. 12, 2017), *https://www.census.gov/library/publications/2017/demo/p60-259.html.*

[68] U.S. Census Bureau, *Annual Estimates of the Resident Population: April 1, 2010 to July 1, 2016,* (2017), *https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk.*

the Department does not expect that the sliding scale discount discussed above would lead to a significantly greater number of women obtaining discounted contraceptives than would otherwise receive them. Their incomes will only be reduced by the cost of contraceptives, which, on average, is about $600 per year (*see* 83 FR at 57551), but the Title X sliding scale discounts span several thousand dollars between ranges. Women could thus be deemed to receive less income and still not be eligible for discounts. Finally, Title X projects pay only a fraction of the retail costs for contraceptive services discussed in the religious and moral exemption final rules.

Consequently, the Department concludes that the number of women whose employers have religious or moral objections leading them to omit contraceptive coverage from their insurance plans is small compared to the number of low income women served by Title X projects; at most, a small minority of such women will seek contraceptive services from Title X projects; the revision to the definition allows project directors to consider deeming those women as being from low income families, but it is likely that only a fraction of them will be deemed unable to pay for family planning; and the cost to the projects of contraceptive services provided or discounts offered is only a fraction of the retail costs of contraceptive services. In light of these factors, even assuming that the use of this example would lead more women to seek to use the existing ''good reasons'' exception than had previously, the Department does not believe it will lead to an unreasonable strain on the Title X program.

Even if there is an economic impact on the program, it is supported by the Title X statute. Where women are actually deemed to be from a ''low income family'' after the project director's consideration of their insurance status, the Title X statute provides for low cost or discounted contraceptive services. As discussed above, insurance status is one factor that may affect a woman's overall economic status or ability to pay for family planning services. The Department concludes it is appropriate to clarify the ''low income family'' definition through the proposed example, so that project directors may appropriately extend eligibility to such women. This helps fulfill the purposes of the Title X statute to ensure that women are not prevented from participating in the program due to their economic status.

The Department disagrees with commenters contending these revisions in the definition violate the Establishment Clause of the First Amendment. The proposed example clarifies the discretion that a project director has long had under the rules concerning good reasons why some persons may be deemed from a low income family. Specifying that a project director may consider a woman's lack of contraceptive coverage as a result of a religious exemption exercised by the sponsor of her health plan from contraceptive coverage into consideration does not violate the Establishment Clause. The example also allows the project director to consider a woman's lack of contraceptive coverage from a sponsor's non-religious moral objection, or to take any number of other non-religious factors into account as a good reason that the woman may be unable to pay for family planning services. The Department also disagrees with a commenter who argues that project directors should consider whether a woman's health plan covers abortion. Title X precludes considering abortion as a method of family planning.

Accordingly, the Department finalizes the definition of ''low income family'' without change to the prefatory text or paragraph (1), but with changes to paragraph (2) to emphasize that the project director may exercise discretion under the existing ''good reason'' exception to ''consider her insurance coverage status as a good reason why she is unable to pay for contraceptive services'' when her employer has a sincerely held religious or moral objection to providing such coverage. The final rule in paragraph (2) is also finalized with guidance for the project director in making this determination.

5. Definition of Program or Project

Summary of changes: The 2000 regulations did not define a Title X ''program'' or ''project.'' The proposed rule, at § 59.2 proposed to define ''program'' and ''project'' as interchangeable and mean ''. . . a plan or sequence of activities that fulfills the requirements elaborated in a Title X funding announcement . . .'' The proposed definition indicated that implementation of a Title X ''program'' or ''project'' may be completed by grantees, subrecipients, or partnering providers working under grantees or subrecipients who deliver comprehensive family planning services.

The Department finalizes this definition as discussed below in response to public comment by stating ''*Program* and *project* are used interchangeably and mean a plan or sequence of activities that is funded to fulfill the requirements elaborated in a Title X funding announcement; it may be comprised of, and implemented by a single grantee or subrecipient(s), or a group of partnering providers who, under a grantee or subrecipient, deliver comprehensive family planning services that satisfy the requirements of the grant within a service area.''

This clarification establishes the Department's finding that any organization receiving Title X funds is responsible to adhere to Title X requirements.

Comments: One commenter asked the Department to alter the definition of ''Program or Project'' because many of the prohibitions against using Title X funding for abortion only legally apply to the program or project, so the commenter asked the Department to reexamine the definition to be sure that entities cannot use the definition to escape compliance with the rule's requirements. In addition, the commenter suggested that the phrase ''and may be comprised of'' does not form part of the working definition but only describes how a program or project, as defined, may be comprised. That leaves the legally operative definition in the proposed rule of ''program'' and ''project'' as being ''a plan or sequence of activities that fulfills the requirements elaborated in a Title X funding announcement.''

At the same time, the commenter expresses concern that if an entity does not fulfill all or some of the requirements of the announcement, the program or project could argue that it does not meet this definition, and thus can avoid the requirements of the rule. Instead, the commenter suggests restating the definition as ''[a]n enterprise, scheme or venture carried out or proposed to be carried out by a grantee, subrecipient(s) or a group of partnering providers pursuant to a Title X award granted by the Secretary.''

Response: The Department appreciates the commenter's observations concerning whether aspects of the program and project definition might inadvertently allow entities to avoid compliance with the requirement of the rule. The 1988 regulations stated that '''[p]rogram' and 'project' are used interchangeably and mean a coherent assembly of plans, activities and supporting resources contained within an administrative framework.'' The proposed definition was similar in referencing plans and activities. The Department agrees with the commenter that the definition should include not only a plan or sequence of activities that fulfills Title X requirements, but those that seek to

fulfill them. A program or project is one that receives Title X funding, as distinct from applications and proposed projects that are not awarded funding. In response to the commenter, the Department clarifies that, when it stated in the proposed rule that a program or project ''may be comprised of, and implemented by a single grantee or subrecipient(s), or a group of partnering providers who, under a grantee or subrecipient, deliver comprehensive family planning services that satisfy the requirements of the grant within a service area,'' it intended those parameters to be, and those parameters will be, treated as operative parts of the definition. The Department intends to enforce all requirements of the Title X program with respect to any entity receiving a Title X grant. If an applicant cannot sufficiently show that the program will meet all the Title X requirements, then it will not qualify for a Title X grant. Consequently, the Department finalizes this definition by changing the word ''fulfills'' to ''is funded to fulfill,'' and by changing the phrase ''and may'' to '', and it may''.

6. Definition of Subrecipient

Summary of changes: The 2000 regulations do not define subrecipient. The proposed rule, at § 59.2, proposed to define ''subrecipient'' as ''any entity that provides family planning services with Title X funds under a written agreement with a grantee or another subrecipient. These entities may also be referred to as ''delegates'' or ''contract agencies.'''

There were no substantive comments under this section that are not already discussed elsewhere in the preamble to this rule. The Department finalizes this definition without change, except for minor grammatical corrections.

D. Who is eligible to apply for a Family Planning Services Grant or contract? (42 CFR 59.3)

Summary of changes: The proposed rule at § 59.3 proposed to delete the provision that was rendered void by means of the CRA joint resolution of disapproval that was signed by the President, and would make corresponding changes to the heading of the section. The Department finalizes this section with changes in response to comments concerning the applicability of this section to contracts. As revised, the section would specify that ''[a]ny public or nonprofit private entity in a State may apply for a family planning grant or contract under this subpart.''

Comments: One commenter supports the proposed language to nullify the provisions of the 2016 regulation and believes it will help improve the Title X program by making it permissible to fund organizations that do not provide artificial contraceptives. Another commenter thinks the federal government should directly fund national family planning organizations.

Response: The Department appreciates the support for the revocation of the nullified 2016 regulation. Regarding the commenter who calls for direct funding of entities that provide natural family planning, the Title X regulations already permit, and this final rule allows, such entities to be participating entities in Title X projects. For projects to receive a grant, they must provide a broad range of family planning methods and services. The Department does not prioritize providers of one specific family planning method over another. Accordingly, the Department believes the Title X program works most efficiently with grantor and grantees as defined in this rule.

As discussed above in section II.B concerning § 59.1, the proposed rule would not apply § 59.3 to contracts, and some commenters asked whether § 59.3 and other sections should apply to contracts. Section 1001 of the Title X statute specifies that, ''in the establishment and operation of voluntary family planning projects,'' the Secretary ''is authorized to make grants and to enter into contracts with public or nonprofit private entities.'' To conform § 59.3 to the scope of the statute, the Department finalizes § 59.3 with changes to the title of that section to read ''Who is eligible to apply for a family planning services grant or contract?'' Likewise, the text of § 59.3 is finalized with change to read: ''Any public or nonprofit private entity in a State may apply for a family planning grant or contract under this subpart.''

E. What Requirements Must be Met by a Family Planning Project? (42 CFR 59.5)

In the proposed rule, the Department proposed a number of revisions and additions to § 59.5(a)(1), (5), and (10) and (b)(1) and (8). Each is discussed in turn.

1. Broad Range of Acceptable and Effective Family Planning Methods (42 CFR 59.5(a)(1))

a. Acceptable and Effective Methods and Services

Summary of changes: The 2000 regulations required that Title X programs provide a broad range of acceptable and effective family planning methods that were medically approved. The proposed rule proposed to revise § 59.5(a)(1) by removing the language, ''medically approved'' and by clarifying the acceptable and effective family planning methods and services under Title X.

Comments: Many commenters oppose the proposed language because it removes the phrase ''medically approved'' as a description of the broad range of acceptable and effective family planning methods a project must provide. Some commenters state the language could reduce access to the safest, effective, and medically approved contraceptive methods, increase risks associated with promoting medically unreliable methods, place political ideology over science, and undermine recommendations jointly issued by OPA and the CDC on Quality Family Planning. Many commenters feel that the proposed language is misleading to patients and could negatively impact the quality of care provided to patients, especially to adolescents and young adults who may require hormonal contraceptive methods which have been associated with decreased rates of teen and unintended pregnancies.

Some commenters, however, support the proposed rule and point out that it will increase choices for persons served by Title X projects, allowing the government to choose the most qualified applicants instead of the applicants who happen to provide the most services.

Response: Section 1001(a) of the PHS Act requires Title X projects to ''offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods . . .).'' 42 U.S.C. 300(a). The final rule at § 59.5(a)(1) ensures that the regulatory language is consistent with the statutory language.

The Department disagrees with comments that oppose removal, from the regulatory text, of the phrase ''medically approved,'' leaving ''acceptable and effective'' to describe the family planning methods and services to be provided by Title X projects. As noted above, the Title X statute does not contain the phrase ''medically approved'' and it is far from clear what that undefined phrase requires. The Title X statute provides that Title X projects ''shall offer a broad range of acceptable and effective family planning methods and services . . . .'' 42 U.S.C. 300. That language was sufficient when Congress drafted the Title X statute, and the Department concludes that it is sufficient today. As such, the revision is clearly within the Department's statutory authority. The Department disagrees with commenters

who contend removing this language causes the regulations (or the Title X statute) to promote medically inaccurate information, or Title X to be administered based on a political ideology.

The ''medically approved'' language risked creating confusion about what kind of approval is required for a method to be deemed ''medically approved.'' Family planning methods offered by Title X projects are already offered by health care professionals, so, to that extent, those methods are already medically approved. But different medical doctors and professional organizations may differ on which methods of health care they approve, including different methods of family planning. Some family planning methods cannot be medically approved by a government agency, such as the Food and Drug Administration, because they do not fall within its jurisdiction.[69] This does not mean that such methods of family planning are unacceptable or ineffective in the view of medical sources.[70] Moreover, various medical sources may view a particular method differently, based on different criteria, and it is not clear what the ''medically approved'' standard would mean in a circumstance where medical authorities differ regarding a particular method. The statutory language of ''acceptable and effective family methods or services,'' without the phrase ''medically approved'' provides sufficient guidance to Title X projects in considering the types of family planning methods and services that they provide.

The Department does not believe that the final language of the first two sentences of § 59.5(a)(1), as finalized here, would limit access to family planning services or other necessary health care, nor lead to an increase in unintended pregnancies.

b. Projects Required To Provide a Broad Range of Family Planning Methods and Services, but Participating Entities May Offer a Limited Number of Family Planning Methods and Services

Summary of changes: The Department proposed to specify in the proposed rules that participating entities within a project would not be required to provide every method or service. The Department further proposed that, projects as a whole provide a ''broad range of such family planning methods and services,'' but not be required to provide every acceptable and effective method or service. The Department finalizes these sentences in § 59.5(a)(1) without change.

Comments: Some commenters agree with the Department that not every project or participating entity should be required to provide all Title X services, so long as the overall Title X project offers a broad range of family planning methods and services. They believe that allowing participating entities that do not offer all services will increase the pool of potential applicants, allow projects to offer a broader range of services by utilizing specialty providers, and allow the government to choose the most qualified applicants.

Many commenters express concern with the language describing the broad range of family planning methods and services that projects must provide. Some commenters say the proposed language would reduce the methods offered within a project by stating, ''projects are not required to provide every acceptable and effective family planning method or service . . . as long as the entire project offers a broad range of such family planning methods and services.'' Commenters express concern that projects will not be required to provide every acceptable and effective family planning method or service, and contend the language seems to encourage projects to not offer every acceptable and effective family planning method or service. Many commenters state that the proposed rules are inconsistent with the original intent of Title X to establish as a national goal the provision of adequate family planning services and to all those who want them but cannot afford them. Many commenters oppose the proposed language because they believe it will limit access to family planning services and other necessary health care. One commenter states that the definition will limit access to comprehensive reproductive health services, and therefore adversely impact women's ability to attain positive economic outcomes for themselves and their families. A commenter requests that the Department clarify that, even if a Title X project need not provide every acceptable and effective family planning method or service, a project must provide a broad range of contraceptive methods. Some commenters assert that the proposed rule may cause more abortions by encouraging low-efficacy methods of family planning and decreasing access to contraception and, therefore, increasing unintended pregnancies.

Many commenters express concern regarding the language specifying that participating entities within a project may offer a single method, or a very limited number of methods, of family planning. Some of these commenters suggest that this weakens the Title X program, undermining its status as a program offering comprehensive services, and prevents patients from making the best decisions about their health due to lack of information or options.

Many commenters suggest that allowing participating entities that offer limited services would divert scarce family planning dollars away from entities that provide effective and preferred methods of contraception and instead provide grants to entities that provide few, if any, methods that patients find acceptable. One commenter expresses concern that inexperienced entities might participate in the Title X program, making navigation more challenging as patients struggle to find providers that offer desired services. Some commenters contend that the proposed rule opens the potential for what they call ''fake'' women's health care facilities to receive funding from Title X, and that the proposed rule deemphasizes the importance of contraception and the full range of family planning methods.

Some commenters express concern that the language might allow for or encourage coercion, and might undermine the standard of health care service delivery and outcomes. Many commenters express concern that the rule will remove a person's choice in the selection of family planning method.

[69] *See* FDA, *Birth Control* (March 6, 2018), *https://www.fda.gov/ForConsumers/ByAudience/ForWomen/FreePublications/ucm313215.htm. See also,* FDA, *Enforcement Story Archive* (August 7, 2003), *https://www.fda.gov/iceci/enforcementactions/enforcementstory/enforcementstoryarchive/ucm106947.htm* (''Warning Letter Issued for ''Fertility Awareness Kit''). *But see* FDA, *FDA allows marketing of first direct-to-consumer app for contraceptive use to prevent pregnancy* (August 10, 2018), *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm616511.htm.*

[70] For example, pursuant to a contract with HRSA, in March 2016, the American College of Obstetricians and Gynecologists (ACOG) launched the ''Women's Preventive Services Initiative.'' In its ''Clinical Recommendations,'' ACOG recommended that instruction in fertility awareness-based methods of family planning, and counseling, initiation of use, follow-up care, management, and evaluation of the same, be provided with no cost-sharing in health coverage. *See* Women's Preventive Services Initiative, *Clinical Recommendations Contraception,* American College of Obstetricians and Gynecologists (2018), *https://www.womenspreventivehealth.org/recommendations/contraception.* The Health Resources and Services Administration (HRSA), a component of HHS, adopted this recommendation on December 20, 2016, and added coverage of fertility awareness-based methods of family planning to its women's preventive services guidelines, issued pursuant to Section 2713(a)(4) of the Affordable Care Act (42 U.S.C. 300gg-13(a)(4)). *See* HRSA, *Women's Preventive Services Guidelines,* Health Resources & Services Administration (October 2017), *https://www.hrsa.gov/womens-guidelines-2016/index.html.* On that basis, fertility awareness-based methods of family planning could be said to be ''medically approved.''

Some commenters believe the proposed rule presents a potential threat to reverse decades of progress in reducing unintended and teen pregnancy, citing that natural family planning methods require a regular menstrual cycle to be effective, which adolescents rarely have.

Other commenters, however, assert that there is no requirement for each participating entity to provide all family planning services and that this flexibility is in line with our Nation's longstanding commitment to protecting freedom of conscience and comports with the First Amendment.

Response: The Department finalizes without change the language specifying that participating entities within a project ''may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services.'' Neither the Title X statute nor the proposed rule would permit a Title X project as a whole to provide only one (or a limited number of) family planning methods and services. The Department is finalizing this rule which continues to require Title X projects to offer a broad range of family planning methods and services.

The Department appreciates concerns of commenters who believe the proposed language that says projects are not required to provide every acceptable and effective family planning method or service would reduce the range of family planning methods that Title X projects must provide, but does not believe that this is a reasonable interpretation of the proposed rule. To clarify, projects would continue to be required to offer a broad range of family planning methods and services, consistent with the statutory mandate. However, neither the plain language of the statutory requirements, nor the 2000 regulatory text, requires that Title X projects provide every acceptable and effective family planning method or service. Thus, the proposed rule and this final rule merely clarify, and make explicit, that the requirement for a broad range of acceptable and effective family planning methods and services does not mean every acceptable and effective family planning method or service. Furthermore, neither the plain language of the statute, nor the 2000 regulatory text, requires participating entities within a project to provide every acceptable and effective family planning method or service, or even a broad range of such methods or services. It is permissible under the 2000 regulations for a subrecipient within a funded project to offer only a single or limited number of family planning methods or services. *See* 42 CFR 59.5(a)(1) (''If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.''). The same is true under this final rule. This is permissible only if the project as a whole provides a ''broad range'' of such methods and services. The final rule merely acknowledges and clarifies this reality.

The Department disagrees that requiring a broad range of family planning methods and services, while recognizing that some projects may not offer every method or service, would lead to an increase in unintended pregnancies. Similar to the 2000 regulations, this rule requires the project as a whole to offer a broad range of acceptable and effective family planning methods and services, which includes contraceptives. While the rule clarifies the broad range of family planning methods and services permissible under Title X, it also ensures Title X patients are free, without coercion, to select any of the broad range of family planning methods and services offered in a project. The Title X statute has always provided as much, and the 2000 regulations did too.

The Department disagrees with commenters opposing the language allowing participating entities to offer one or few family planning methods. The 2000 regulations explicitly permits this, stating ''[i]f an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services''; this language has been included in regulations since at least 1988. To the extent the commenters opposing this language do not find fault with the 2000 regulations, the Department sees no cause for concern over this provision. About four million patients are annually served with the current provision that allows organizations that offer only a single family planning method to participate in a Title X project. The Department now merely confirms this practice by stating that ''[a] participating entity may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services.'' Therefore, the Department disagrees with the concerns expressed about including this sentence in the final rule.

The Department also disagrees that the proposed rule weakens the standing of Title X programs as comprehensive sources for family planning. The rule does not prohibit projects or providers from offering every acceptable and effective family planning method or service, so long as abortion is not considered a method of family planning. The rule simply reflects, as stated in the 2000 regulations, that Title X projects are required to provide a broad range of acceptable and effective family planning methods and services (not every such method or service), and that participating entities are permitted to participate in a Title X project even if not all of them offer every method—and, indeed, even if some participating entities within a project offer only one family planning method. The range of available family planning methods has significantly increased over the last few decades. The Department believes it may be unreasonably difficult or expensive to add a new requirement that all projects and all participating entities must offer all acceptable and effective forms of family planning. It may also be difficult for clients to access certain methods in which not all participating entities have specific training and expertise. This rule enhances the ability of individual Title X projects to offer, and clients to access, such methods, while preserving the requirement that individual Title X projects offer a broad range of family planning methods and services. The Department disagrees with some commenters who say the rule is misleading to Title X clients. This rule is substantially similar to the 2000 regulations rule in that it permits single method providers to participate in the Title X program and includes natural family planning methods as those that qualify under the ''broad range.''

The Department disagrees that the proposed and final rules authorize Title X funding for what some commenters call ''fake'' women's health care facilities. It is not clear what such commenters deem to be ''fake'' facilities, but nothing in the rule authorizes projects to use clinics that engage in fraud or allow the practice of medicine without a license. Title X projects are subject to quality oversight by the Department and are also subject to relevant State laws in the operation of health clinics.

The Department believes that permitting entities to provide services for which they have particular expertise allows greater access to family planning methods in Title X projects and contributes to quality care for patients. The final rule does not require projects to include participating entities that offer only one or just a few methods, but it continues to allow them to do so, if they deem it appropriate and consistent with offering a broad range of family planning methods and services.

The final rule, thus, clarifies and reframes, but does not create or invent the ability of a single-method entity to participate in a Title X project. The Department believes that continuing to allow such entities to participate will give people served under Title X access to specialized expertise in certain methods. Increasing client choices among family planning clinics and methods in a project is likely to decrease unintended pregnancies, not increase them, because clients are more likely to visit clinics that respect their views and beliefs and to use methods that they desire and that fit their individual circumstances.

The Department also agrees with commenters that say the final rule is consistent with principles of the First Amendment and laws that protect freedom of conscience. By allowing projects to use entities that offer a single method or limited methods—including providers that might do so for reasons of conscience—the language being finalized will, among other things, both protect the ability of health care providers and facilities with conscientious objections to providing certain types of family planning methods and services to participate in Title X projects and maintain Title X projects that offer a broad range of family planning methods and services.

c. Listing Particular Services in the Broad Range of Family Planning Services That May Be Provided

Summary of changes: The 2000 regulations recognized natural family planning and services for adolescents as some of the broad range of acceptable and effective family planning methods. The proposed rule proposed to clarify that natural family planning and other fertility-awareness based methods qualify as acceptable methods, as do contraceptives. In addition, as a mechanism for addressing infertility, the Department proposed to add adoption as a family planning service. Therefore, the Department finalizes § 59.5(a)(1) with changes to replace the word ''and'' with the word ''or'' before the phrase ''other fertility-awareness based methods.''

Comments: The Department received several comments about the listing of particular services in the broad range of family planning services that may be provided. Some commenters objected to references to natural planning or fertility awareness-based methods because fertility awareness-based methods are already offered at 93% of Title X clinics and natural family planning is already a method included in the Quality Family Planning Guidelines provided by CDC. Others object to these methods because they assert that the methods are ineffective, or at least among the least effective forms of family planning.

Other commenters object to language specifying adoption as a type of family planning service. They contend that the management of infertility, including adoption, is beyond the language and intent of the Title X statute. They also believe that including adoption would put a strain on the program, as it would redirect a large amount of Title X funds. And they assert that including adoption in the definition is contradictory because adoption is a postconception activity and the new definition states that family planning only includes preconception activities. Some commenters also assert that the Department improperly redefines the meaning of a reproductive life plan.

Response: The Department disagrees with commenters who say the rule should not mention natural planning or additional fertility awareness-based methods, and who contend the rule emphasizes those methods over other forms of family planning. As discussed in the context of the definition of family planning in § 59.2, the Title X statute itself requires projects to offer a broad range of family planning methods and services, and specifies that those methods ''includ[e] natural family planning methods, infertility services, and services for adolescents.'' 42 U.S.C. 300(a). The Department concludes that Title X projects (although not necessarily each provider or site within a project) must offer both contraception and natural family planning in order for the Department faithfully to implement Title X's ''broad range'' requirement. The proposed and final rules, far from over-emphasizing natural family planning or emphasizing it to the exclusion of contraceptives, add contraceptives to this non-exclusive list of examples of family planning methods that projects must provide. The proposed rule at § 59.5(a)(1) also includes the phrase ''and other fertility awareness-based methods'' alongside ''natural family planning.'' As discussed concerning the ''family planning'' definition, ''natural family planning'' is not defined in the Title X statute, and scientific advances have occurred in natural family planning methods in the last 40 years, so that some medical professionals now refer to related methods as ''fertility awareness-based methods.'' [71] The final rule does not emphasize natural family planning over other forms of family planning.

The definition of family planning at § 59.2 uses the word ''or'' before the phrase ''other fertility awareness-based methods,'' whereas the text at § 59.5(a)(1) uses the word ''and.'' The Department considers the word ''or'' to be more appropriate in both instances. This clarifies that by ''other fertility awareness-based methods,'' the Department is not referring to methods that are not ''natural family planning,'' nor is it requiring projects to offer natural family planning and other fertility awareness-based methods as if those are two different kinds of categories. Instead, by using the word ''or,'' the Department intends for projects to have flexibility in deciding which types of natural family planning or fertility awareness-based methods they will offer in meeting their obligation to offer natural family planning methods within the project. Therefore, the Department finalizes § 59.5(a)(1) with a change to replace the word ''and'' with the word ''or'' before the phrase ''other fertility-awareness based methods.''

The language specifying that participating entities may offer only a single method does not mention natural family planning or any other single method. Therefore, it does not emphasize natural family planning over other methods as some commenters contend. Under the final rule, single-method providers are permitted in projects whether their single method is a natural family planning method, a contraceptive method (for example, an implant), or some other family planning method. The Department disagrees with commenters' concerns that allowing single or limited method entities to participate in a Title X project limits family planning to natural family planning methods, limits what individuals may choose, or deprives individuals of methods they may choose. Those results have not occurred under the 2000 regulations, which already allow for single method participating entities.

The Department also disagrees with commenters who oppose the inclusion of adoption information as a type of infertility services offered by Title X providers. As discussed with respect to the proposed definition of family planning, the Title X statute does not define ''family planning,'' and the Department has always read the

[71] *See, e.g.,* Shawn Malarcher, et. al., *Fertility Awareness Methods: Distinctive Modern Contraceptives,* 4 Global Health: Science and Practice 13, 13 (2016), *available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4807745/pdf/013.pdf* (stating fertility awareness methods of contraception have been tested and proven effective at pregnancy prevention and safe to use).

examples it gives of family planning methods and services as being a non-exclusive list; otherwise, Title X could fund nothing but ''natural family planning methods, infertility services, and services for adolescents.'' Adoption is a method of planning the size of one's family and the spacing of children raised in one's family, and it can be used to enlarge one's family or to plan one's family in the context of infertility.

In addition, under Infant Adoption Awareness grants program, Congress specified that eligible health centers (which includes Title X clinics) should receive training on providing adoption information and referrals, and that the Secretary should encourage the same.[72] Accordingly, Title X projects may provide adoption information and referrals as a preconception family planning method, especially in the context of providing infertility services, and may provide adoption information and referrals during postconception pregnancy counseling as long as the pregnancy counseling satisfies the statutory requirement that it be nondirective. Therefore, the Department considers it appropriate to include adoption information in the non-exclusive list of services mentioned among a possible broad range of family planning methods and services a Title X project might offer. But consistent with the change finalized in the definition of ''family planning,'' the Department modifies the phrase contained in the proposed rule, ''including infertility services, including adoption, and services for adolescents'' to provide ''including infertility services, information about or referrals for adoption, and services for adolescents''.

Importantly, the proposed language in no way limits the choices of Title X clients or infringes on their views of what services to choose. The final rule does not require any Title X client to pursue adoption, natural family planning, or any other particular family planning method or service. On the contrary, as discussed above, the definition of family planning is finalized to specify that ''[f]amily planning methods and services are never to be coercive and must always be strictly voluntary.''

[72] *See* 42 U.S.C. 254c–6 (Congress authorized the Department to make grants ''for the purpose of developing and implementing programs to train the designated staff of eligible health centers in providing adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women'').

2. Projects Shall Not Provide, Promote, Refer for, or Support Abortion as a Method of Family Planning (42 CFR 59.5(a)(5))

Summary of changes: The 2000 regulations prohibited Title X projects from providing abortion as a method of family planning. They also specified that Title X projects must provide information on, counseling regarding, and referral for, a variety of services for pregnant women, including abortion. The proposed rule, at § 59.5(a)(5), instead proposed to emphasize the duty of Title X providers to ''[n]ot provide, promote, refer for, support or present abortion as a method of family planning.'' The proposed rule would allow nondirective pregnancy counseling, but would delete the current language in that paragraph (including (i) and (ii)), which stated that ''[a] project must . . . [o]ffer pregnant women the opportunity to be provided information and counseling regarding . . . [p]renatal care and delivery; [i]nfant care, foster care, or adoption; and [p]regnancy termination'' and that a project must, ''[i]f 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 woman indicates she does not wish to receive such information and counseling.'' *See* 42 CFR 59.5(a)(5).

At §§ 59.14 and 59.16, the proposed rule proposed more specific parameters to implement the requirement in § 59.5(a)(5) that ''[a] Title X project may not perform, promote, refer for, support, or present abortion as a method of family planning . . .'' and to implement the requirement that any pregnancy counseling provided by Title X projects must be nondirective. The proposed rule addressed in this section relates to the proposal to remove the requirement for nondirective pregnancy counseling and referral (including the obligation to counsel on, and refer for, abortion), and replace it with a prohibition in § 59.5(a)(5) on the use of Title X funds to perform, promote, refer for, support, or present abortion as a method of family planning. Comments discussing pregnancy counseling are discussed in a distinct part of this preamble, as are comments discussing the deletion of the requirement to refer for abortions. Comments discussing the prohibition on abortion referrals, and permissible referral activities in general, are discussed with regard to section §§ 59.14 and 59.16.

The Department finalizes the proposed rule in § 59.5(a)(5) with one change to make it clear that providers are allowed to provide nondirective pregnancy counseling about abortion, by removing ''present'' from the proposed list of prohibitions regarding abortion as a method of family planning.

Comments: Many commenters support eliminating the requirement that Title X family planning providers counsel for, provide information about, and refer for abortion, citing protections found in health care conscience laws and principles. Such commenters contend that the requirement in the 2000 regulations of abortion referrals, information and counseling is inconsistent with section 1008 of Title X, and with the conscience protections provided for in laws such as the Church, Coats-Snowe, and Weldon Amendments. Commenters also contend the proposed language appropriately protects and recognizes the importance of religious freedom and freedom of speech.

Other supportive commenters note that the 2000 regulations stand in the way of some organizations applying for Title X funds, or participating in Title X projects, due to the requirement for abortion referrals and information. Such commenters contend the 2000 regulations limit choice for patients, especially those who live in rural or remote areas, where faith-based and local community organizations would be more likely to apply if the abortion counseling and referral requirement were lifted.

Some commenters express concerns related to federal conscience protections, including the Weldon, Coats-Snowe, and Church Amendments, that may apply to Title X grantees and subrecipients. The Church Amendments prohibit grantees from discriminating in ''the employment, promotion, or termination of employment of any physician or other health care personnel'' or ''the extension of staff or other privileges to any physician or other health care personnel'' because ''he performed or assisted in the performances of a lawful sterilization procedure or abortion. . . .'' 42 U.S.C. 300a–7(c). One commenter asks that the final rule include similar conscience protections for health care personnel who refuse to engage in family planning research or services that are contrary to their religious beliefs or moral convictions. A commenter also requests clarification on whether this provision would require religious or pro-life groups who receive Title X funds to hire someone who disagrees with their religious and moral convictions

regarding abortion. Other commenters seek clarity on whether Title X projects must hire personnel who disagree with certain family planning methods. Some commenters state there is no need for further regulatory review to protect the rights of those who decline to participate in abortion-related services, but rather, contend there is a need to protect the rights of those who conscientiously provide and seek abortion-related services.

Several commenters disagree with the proposed rule's elimination of the abortion information, counseling, and referral requirements. Such commenters argue that withholding information about pregnancy options interferes with the patient-provider trust relationship, is contradictory to patient-centered care, and compromises the health of the patient, as well as the ability of the patient to make timely and fully informed decisions. One commenter states that some patients are surprised to hear abortion is legal and have other misconceptions about the procedure, making it imperative that comprehensive information about abortion be shared with those patients.

Some commenters contend that restricting counseling for and information about abortion in Title X projects would encroach on physicians' codes of ethics and responsibilities to patients. Many commenters state that prohibitions on abortion counseling and referral would directly conflict with the requirements or codes of ethics of medical professional associations, including the American College of Physicians and the American College of Obstetricians and Gynecologists. These associations state that patients should receive full and accurate information to inform their health care decisions. For example, commenters refer to the American Medical Association Code of Medical Ethics that providers should ''present relevant information accurately and sensitively, in keeping with the patient's preferences'' and that ''withholding information without patient's knowledge or consent is ethically unacceptable.'' Some commenters contend that the restriction on referral, and on directive abortion counseling, may put providers at risk of medical liability since a delay or failure to diagnose is one of the top three liability allegations cited by ob-gyns, who are already at an elevated liability risk compared to their colleagues.

One commenter takes the view that the rule should prohibit Title X from offering nondirective counseling on abortion altogether. The commenter proposes instead that providers should provide only life-affirming counseling to pregnant clients who consent to receive such counseling. The commenter says this approach would protect the conscience rights of certain organizations and their employees.

Response: The Department believes the requirement to provide information, counseling, and referral for abortion in the 2000 regulations is incorrect and inconsistent with a number of federal conscience protection statutes and, at least with respect to referral, with section 1008's prohibition on funding Title X projects where abortion is a method of family planning. As described in the preamble to the 1988 regulations, prior to issuance of any regulations pursuant to Title X, the Department had, since 1972, interpreted section 1008 not only as prohibiting the provision of abortion but also as prohibiting Title X projects from in any way promoting or encouraging abortion as a method of family planning. *See* 53 FR 2922, 2923. Based on the legislative history, the Department has also, since 1972, interpreted section 1008 as requiring that the Title X program be ''separate and distinct'' from any abortion activities of a grantee. Although the Department had generally permitted activities that did not have the immediate effect of promoting abortion, or the principal purpose or effect of promoting abortion, the Department also provided in its 1988 Title X regulations that ''a Title X project may not provide counseling concerning the use of abortion as a method of family planning or provide referral for abortion as a method of family planning.'' The 1988 regulations added that ''[a] Title X project may not use prenatal, social service, emergency medical, or other referrals as an indirect means of encouraging or promoting abortion as a method of family planning.'' 53 FR at 2945.

Since that time, however, Congress has contemplated that nondirective pregnancy counseling may be offered in Title X projects. The HHS fiscal year 2019 appropriations act provides that ''amounts provided to said projects under such title shall not be expended for abortions, that all pregnancy counseling shall be nondirective. . . .'' [73] Similarly, the statute establishing the Infant Adoption Awareness program directed the Department to include ''nondirective counseling to pregnant women.'' 42 U.S.C. 254c–6.

The Department has carefully considered the provision of counseling and information about abortion in the Title X context in light of Section 1008, the appropriations riders in place since 1996 that all counseling be nondirective, public comments, policy considerations, and the Department's historical positions. As a result, the Department concludes that:

- Title X projects will not be required to refer for abortion (and, as discussed in regard to § 59.14, referrals for abortion as a method of family planning are prohibited).
- Physicians or APPs within Title X projects may offer pregnancy counseling, including counseling that addresses the option of abortion among other options, so long as the counseling is nondirective and does not include referrals for abortion as a method of family planning.
- Title X projects will not be required to offer nondirective pregnancy counseling in general, or abortion information and counseling specifically.

In stating that ''all pregnancy counseling shall be nondirective,'' Congress did not explicitly require pregnancy counseling, nor prohibit such counseling from discussing abortion if the counseling is nondirective. Unlike abortion referral, nondirective pregnancy counseling would not be considered encouragement, promotion, support, or advocacy of abortion as a method of family planning, which would be prohibited by the Title X statute and this final rule. Therefore, the approach of this final rule is more permissive than the 1988 regulations, which prohibited any counseling concerning the use of abortion as a method of family planning, but predated Congress's directive that all pregnancy counseling in the program be nondirective. Therefore, the Department finalizes without change the proposed rule's deletion of the language in § 59.5(a)(5) requiring pregnancy options information and counseling, including requiring information, counseling and referrals for abortion. Consistent with that rescission of § 59.5(a)(5)(i) and (ii), there is no requirement in the final rule that a project offer nondirective counseling or information about abortion. The rule does not, however, prohibit nondirective pregnancy counseling by physicians or APPs, even if that counseling discusses abortion.

Some commenters urge the Department to prohibit nondirective counseling concerning abortion in a way similar to the 1988 regulations. The Department acknowledges that it has the

[73] HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat. 2981, 3071. This provision has been inserted into various HHS appropriations acts since first adopted in the 1996 Appropriations Act. *See, e.g.*, Consolidated Appropriations Act 2018, 115 Pub. L. 141, Div. H., 132 Stat 348, 717; Consolidated Appropriations Act 2017, 115 Pub. L. 31, Div. H, 131 Stat. 135, 521.

discretion to interpret section 1008 as it did in the 1988 regulations, but it disagrees that it must prohibit discussion of abortion in nondirective pregnancy counseling. Instead, the Department interprets Congress's directive that all pregnancy counseling be nondirective as permitting the Department to allow nondirective pregnancy counseling even if such counseling includes abortion among other options. Nevertheless, the Department also agrees, to take a phrase from the 1988 regulations, that Title X projects should not use the permission to provide pregnant patients certain information through nondirective counseling ''as an indirect means of encouraging or promoting abortion as a method of family planning.'' Title X projects and service providers must be careful that nondirective counseling related to abortion does not diverge from providing neutral, nondirective information into encouraging or promoting abortion as a method of family planning, or into referral for abortion as a method of family planning. The Department anticipates that it may provide further guidance to grantees on this issue.

Some commenters contend this rule will deprive women of the information they need about abortion or where to obtain one, but the purpose of Title X is not to provide such information. To the contrary, Congress expressly restricted the Department from funding Title X projects where abortion is a method of family planning. Title X programs, accordingly, may offer information about abortion only as part of nondirective pregnancy counseling. The primary focus of Title X remains on preconception family planning methods and services. In implementing section 1008, moreover, the Department has a history of establishing prohibitions on abortion referral, even if at other times it has allowed or required such referrals. The 1988 regulations, for example, prohibited Title X projects from providing abortion information, counseling or referrals. The 2000 regulations took a different approach by requiring information, counseling and referrals for abortion as a method of family planning in certain cases. The Department has now reconsidered this issue and believes the approach taken in this final rule is a better interpretation of section 1008, consistent with the subsequent Congressional directive that all pregnancy counseling be nondirective. Further, in the Department's view, it is not necessary for women's health that the federal government use the Title X program to fund abortion referrals, directive abortion counseling, or give to women who seek abortion the names of abortion providers. Information about abortion and abortion providers is widely available and easily accessible, including on the internet.

The Department disagrees with commenters who assert that prohibiting referrals or directive counseling about abortion violates the First Amendment rights of grantees or subrecipients. The Supreme Court explicitly rejected this claim in *Rust,* upholding the provisions of the 1988 regulations ''prohibiting counseling, referral, and the provision of information regarding abortion as a method of family planning.'' *Rust,* 500 U.S. at 193. The Court explained that the challenged provisions are permissible because they ''are designed to ensure that the limits of the federal program are observed. . . . This is not a case of the Government 'suppressing a dangerous idea,' but of a prohibition on a project grantee or its employees from engaging in activities outside of the project's scope.'' *Rust,* 500 U.S. at 193–94. The Court rejected the argument that the restrictions constitute impermissible viewpoint discrimination, and instead held the government may ''choose[] to fund a program dedicated to advance certain permissible goals,'' even when ''in advancing those goals necessarily discourages alternative goals.'' *Id.* at 194. The same principles would sustain this rule under the First Amendment. In fact, this rule is more permissive of speech than the regulations upheld by *Rust,* because this rule allows physicians or APPs to provide nondirective pregnancy counseling even if it discusses abortion, as long as the project does not promote, encourage, or refer for abortion as a method of family planning.

The Department appreciates comments that discuss how conscience laws such as the Church, Coats-Snowe, and Weldon Amendments apply in the context of the Title X program. In deciding to rescind the requirement that Title X projects counsel, provide information on, and refer for abortion, the Department concludes those requirements in the 2000 regulations are not consistent with federal conscience laws. As explained in the preamble to the proposed rule, the Department had already acknowledged this problem in the preamble to the 2008 regulations implementing these conscience protections. 73 FR 78087. There, the Department observed, ''[w]ith regards [sic] to the Title X program, commenters are correct that the current regulatory requirement that grantees must provide counseling and referrals for abortion upon request (42 CFR 59.5(a)(5)) is inconsistent with the health care provider conscience protection statutory provisions and this regulation. The Office of Population Affairs, which administers the Title X program, is aware of this conflict with the statutory requirements and, as such, would not enforce this Title X regulatory requirement on objecting grantees or applicants.'' *Id.* Although those 2008 conscience statute regulations were partially repealed in 2011, 76 FR 9968 (Feb. 23, 2011), the underlying statutes remain valid and in place, and the reasoning in the preamble to the 2008 regulations on this point remains persuasive.[74]

The Department continues to conclude that the abortion referral and counseling requirements in the 2000 regulations cannot be enforced against objecting grantees or applicants, and that such requirements cannot be used to deny participation in the Title X program or a Title X project comprised of objecting family planning providers. The 2000 regulations required that projects provide information about abortion, counsel a client about abortion if she asks for it, and refer her for abortion. However, the Weldon Amendment prohibits the federal government from engaging in discrimination against a health care entity on the basis that it does not, among other things, refer for abortion. The Coats-Snowe Amendment also prohibits the federal government and State and local governments that receive federal financial assistance—such as State and local health departments that receive Title X funds—from discriminating against a health care entity on the basis that it refuses to ''provide referrals'' for abortion or refuses to ''make arrangements for'' providing referrals for abortion. To ensure compliance with these and other federal conscience laws, this final rule does not require Title X projects to provide any nondirective counseling, information, or referral for abortion. In order to ensure compliance with section 1008, the Department affirmatively prohibits referrals for abortion. The Department thus concludes that these federal conscience protection laws, along with its interpretation of section 1008, support its decision to finalize the rescission of the requirement in the

[74] As noted in the proposed rule, the Department has issued a proposed rule that would expand the Department's enforcement ability with respect to federal conscience protection and related anti-discrimination laws. Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 FR 3880 (Jan. 26, 2018).

2000 regulations that projects provide abortion information, counseling, and referral in § 59.5(a)(5).

The Department appreciates the concerns of commenters about other ways in which federal conscience laws might apply in Title X projects, for example, whether they require Title X providers to hire personnel with certain views or objections, or prohibit entities from firing an individual willing to perform an abortion, or who has done so in the past. The Department intends to operate the Title X program consistent with federal conscience laws, the First Amendment, the Religious Freedom Restoration Act, and similar federal laws. The Department also notes that the Title X statute itself explicitly prevents programs from receiving Title X funds where abortion is a method of family planning. Accordingly, any Title X project must ensure compliance with this final rule to receive Title X funds. The Title X statute has coexisted with federal conscience laws for over 40 years. The limitation on referral for abortion as a method of family planning in this final rule, along with the removal of the abortion counseling, information, and referral requirements, is consistent with these statutory provisions. Just as *Rust* affirmed the government's right to place such limits on the Title X program, the Department concludes that it can fully achieve the goals of the Title X program while faithfully enforcing federal conscience laws.

The Department declines the invitation of a commenter to expand these final rules to further address the protection of conscience in the Title X program. First, because the Department did not propose such provisions in the proposed rule and did not expressly request comment on the issue, it does not have the benefit of extended comment on the issue. Second, the Department does not believe further clarification of this issue is necessary in this final rule, when the federal health care conscience laws are already the subject of separate rulemaking. The Department also will not address in this rule individual qualifications for staff hiring by a Title X program for services performed before or outside the Title X program, nor accept one commenter's invitation to add provisions to implement the Religious Freedom Restoration Act as it may apply to personnel who work for entities participating in Title X projects. Rather, the Department simply notes that the Office of Population Affairs bears the responsibility for holding grantees responsible for complying with federal conscience laws in the Title X program. In addition, the HHS Office for Civil Rights has been designated to receive complaints of conscience law violations and to coordinate with the relevant program office with respect to such complaints.

The Department does not agree with the commenter who proposes that Title X providers provide prenatal care. While the Department agrees that prenatal care is important to maternal and infant outcomes, the primary purpose of the Title X program is to provide preconception family planning services. Nondirective counseling and referrals for postconception services—although not the provision of postconception health care services themselves—are the appropriate approach in the context of pregnancy, so long as they do not include referral for abortion as a method of family planning. Within a Title X project, Title X providers may not provide prenatal care because it is outside the scope of the project, but must refer for prenatal care as pregnancy makes such referral medically necessary. However, the Department encourages Title X grantees either to offer comprehensive primary health services onsite (although outside the scope of the Title X project) or to have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site.

The Department agrees with commenters that say the Department should offer more guidance concerning how projects that provide nondirective pregnancy counseling should do so consistent with applicable Title X statutory requirements. The proposed rule set boundaries on Title X projects concerning referral for, encouragement of, promotion of, advocacy for, support for, and assistance with, abortion as a method of family planning, and those boundaries would also apply to any nondirective pregnancy counseling that physicians or APPs provide within the Title X project. The proposed rule did not further specify the parameters of such counseling, for example by defining ''nondirective.'' Nevertheless, projects must comply with Congress's requirement that pregnancy counseling be nondirective, and the Department must enforce that requirement.

Therefore, the Department offers the following guidance on the requirement of nondirective pregnancy counseling. When a woman is confirmed to be pregnant, a physician or APP may provide nondirective pregnancy counseling. While all pregnancy counseling must be nondirective, in compliance with Congress's consistent direction through the HHS appropriation laws, this rule permits the physician or APP to exercise discretion on whether to offer such counseling.[75] Nondirective counseling is designed to assist the patient in making a free and informed decision. In nondirective counseling, abortion must not be the only option presented by physicians or APPs; otherwise the counseling would violate not only the Congressional directive that all pregnancy counseling be nondirective, but also the prohibitions in this rule on encouraging, advocating, or supporting abortion as a method of family planning, which the Department prohibits in order to implement, among other provisions, section 1008. Each option discussed in such counseling must be presented in a nondirective manner. This involves presenting the options in a factual, objective, and unbiased manner and (consistent with other Title X requirements and restrictions) offering factual resources that are objective, rather than presenting the options in a subjective or coercive manner. Physicians or APPs should discuss the possible risks and side effects to both mother and unborn child of any pregnancy option presented, consistent with the obligation of health care providers to provide patients with accurate information to inform their health care decisions.

Title X projects should not use nondirective pregnancy counseling, or referrals made for prenatal care or adoption during such counseling, as an indirect means of encouraging or promoting abortion as a method of family planning. They should not use such counseling or referrals to steer clients to abortion or to specific providers because those providers offer abortion as a method of family planning. Referrals for abortion as a method of family planning may not be offered. If the patient is provided a list or the contact information of licensed, qualified, comprehensive primary health care service providers (including providers of prenatal care), the list—and the Title X staff—must not identify to the woman which, if any, providers on the list offer abortion.

Referrals for abortion for emergency care purposes are not prohibited.[76]

[75] While the decision to offer nondirective counseling is subject to the discretion of physicians and APPs, this rule requires referral for prenatal care in these situations because it is a medically necessary care for all pregnant women. In any case, all pregnancy counseling must be nondirective.

[76] Similarly, in cases involving rape and/or incest, it would not be considered a violation of the prohibition on referral for abortion as a method of family planning if a patient is provided a referral to a licensed, qualified, comprehensive health service provider who also provides abortion,

Continued

Permitted referrals under this scenario include one in which a medical emergency is revealed, such as when a woman has a suspected ectopic pregnancy.[77] Because prenatal care is medically necessary for pregnancy, prenatal care referral is required and does not, under this final rule, render any pregnancy counseling impermissibly directive.

Referrals for, and information about, adoption are also permitted, as long as the counseling remains nondirective. Title X projects are not required to offer nondirective counseling or information on abortion.

Referring for adoption or prenatal care, but not for abortion, does not, in the Department's view, make pregnancy counseling directive in light of Congress's legislative directives applicable to the Title X program. Where care is medically necessary, as prenatal care is for pregnancy, referral for that care is not directive because the need for the care preexists the direction of the counselor, and is, instead, the result of the woman's pregnancy diagnosis or the diagnosis of a health condition for which treatment is warranted. Moreover, seeking prenatal care is not the same as choosing the option of childbirth. Regarding adoption referrals, in Infant Adoption Awareness grants and the Infant Adoption Awareness Training Act, Congress made clear that the provision of adoption information and referrals do not necessarily render pregnancy counseling directive.[78] By contrast, Congress has prohibited funding projects where abortion is a method of family planning. That disparate treatment in Congress's legislative directives makes it appropriate to prohibit referrals for abortion as a method of family planning, including during nondirective pregnancy counseling, while permitting (and in some instances, mandating) referrals for other purposes.

The Department disagrees with commenters who contend the rule will require health care professionals to violate medical ethics, regulations concerning the practice of medicine, or malpractice liability standards. In *Rust,* the Supreme Court upheld the prohibition in the 1988 regulations on both referral for, and counseling about, abortion in the Title X program. The Department does not believe the Court in *Rust* upheld a rule that required the violation of medical ethics, regulations concerning the practice of medicine, or malpractice liability standards. Federal and State conscience laws, in place since the early 1970s, have protected the ability of health care personnel to not assist or refer for abortions in the context of HHS funded or administered programs (or, under State law, more generally). Indeed, in *Roe* v. *Wade,* 410 U.S. 113 (1973), the Court favorably quoted the proceedings of the American Medical Association House of Delegates 220 (June 1970), which declared ''Neither physician, hospital, nor hospital personnel shall be required to perform any act violative of personally-held moral principles.'' *See Roe,* 410 U.S. at 144, n.38. And in *NIFLA* v. *Becerra,* the Supreme Court upheld conscience objections to making certain statements, despite objections from professional medical organizations that similarly asserted medical ethics standards. *Nat'l Inst. of Family & Life Advocates* v. *Becerra,* 138 S. Ct. 2361, 2371–76 (2018).[79] The restrictions on referral for, encouragement of, promotion of, advocacy for, support of, and assistance of, abortion in Title X only apply to abortion as a method of family planning, not for any other reason that might give rise to malpractice liability, and the final rule has a specific provision in § 59.14(c), allowing referrals in case of emergencies.

As the Supreme Court affirmed, section 1008 and its implementing regulations are simply a matter of Congress's choice of what activities it will fund, not about what all clinics or medical professionals may or must do outside the context of the federally funded project. The Department believes that medical ethics, regulations concerning the practice of medicine, and malpractice liability standards are not inconsistent with this final rule. The Supreme Court upheld similar conditions and restrictions in *Rust* as a constitutionally permissible exercise of Congress's Spending Power. As federal law, these requirements apply to federal grantees, notwithstanding any potential State law to the contrary.

3. Removal of the Requirement for Consultation (42 CFR 59.5(a)(10))

Summary of changes: The 2000 regulations, at § 59.5(a)(10)(i), ''[p]rovide 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.'' The proposed rule would remove that requirement and paragraph. The proposed rule would redesignate the provision that existing or potential subrecipients be given an opportunity for maximum participation in the ongoing policy decisions of the project, from § 59.5(a)(10)(ii) to § 59.5(a)(10). The Department finalizes this part of the rule without change.

Comments: Many commenters are concerned that this change would open the door for multiple projects in one region, uncoordinated care, and a disruption in the currently successful Title X network by excluding current providers that have the expertise to provide quality services. Some commenters recommend that the language in § 59.5(a)(10) remain unchanged to preserve opportunities for local stakeholder input.

Response: The Department disagrees with commenters who challenge removing the consultation requirement at § 59.5(a)(10). Title X requires the Department to issue grants that provide a broad range of acceptable and effective family planning methods and services. Encouraging competition among applicants is conducive to achieving the goals of the Title X statute. The Department concludes that it is not necessary, and is potentially counterproductive, to require new applicants to first consult with pre-existing providers, as currently required by § 59.5(a)(10)(i), although they may choose to do so. New applicants bring fresh ideas and innovative approaches to serving patients with their family planning needs. Requiring new applicants to consult with previous or current grantees could have the

provided that the Title X provider has complied with any applicable State and/or local laws requiring reporting to, or notification of, law enforcement or other authorities and such reporting or notification is documented in the patient's record.

[77] However, as with nondirective pregnancy counseling on abortion, Title X projects and service providers must ensure that they do not, under the cover and pretext of providing such abortion referral, actually refer for abortion as a method of family planning. This is an area in which Title X projects can expect OPA monitoring and oversight and should maintain appropriate records to support such referrals.

[78] The Act calls for Title X project staff to have access to training on including adoption information and referrals ''in nondirective counseling to pregnant women'', where Infant Adoption Awareness grants are in operation. 42 U.S.C. 254c–6(a)(6)(A).

[79] *See e.g. U.S. Supreme Court Amici Curiae Brief of the American Academy of Pediatrics,* California, the American College of Obstetricians and Gynecologists, et al., *NIFLA,* No. 16–1140 (U.S. Ct) (filed Feb. 27, 2018).

unintended consequence of quashing new ideas in favor of maintaining a potentially sub-par status quo in a given locale. The Department agrees it is important that new applicants build robust community partnerships in order to expand the reach of Title X services. In some cases, awareness of a region's existing services might strengthen an application, so applicants might continue to be incentivized to consult existing grantees. But the Department will not require consultation with previous grantees as a prerequisite to application. The Department will continue to review applications based on their quality and to fund those best positioned to achieve the goals of the Title X statute and the criteria set forth in the final rule.

The Department disagrees with commenters who contend current Title X providers will necessarily be shut out as future Title X providers. Removal of this consultation requirement does not prejudge whether current grantees will continue to receive Title X grants, nor whether new applicants will receive grants. The Department, likewise, does not believe that the removal of the consultation requirement will lead to uncoordinated care. Of course, applicants may voluntarily choose with whom they partner and with whom they consult, and such coordination may strengthen an applicant's proposal. However, the Department believes the removal of this as a requirement encourages a broader range of applicants and permits innovative approaches that may not have been envisioned or supported in the past.

The Department finds no evidence to support the assertion that the final rule will drive current providers from the Title X program. Under the final rule, the government will choose from the most qualified applicants in order to achieve the statutory goals of the program. The fact that some applicants received funding in the past is not a guarantee of future funding, but neither is it a guarantee that their funding will end in the future. Encouraging new applicants in the program could improve both the quality and breadth of service within the Title X program; it does not reflect a preference for new applicants over previous grantees.[80]

[80] The removal of the requirement for consultation likewise does not violate the requirement in Title X section 1001(b) that ''[l]ocal and regional entities shall be assured the right to apply for direct grants and contracts . . ., and the Secretary shall by regulation fully provide for and protect such right'', which only addresses the right of certain entities to apply for direct grants and contracts. 42 U.S.C. 300(b).

4. Promotion of Access to Comprehensive Primary Health Services (42 CFR 59.5(a)(12))

Summary of changes: The proposed rule included a new § 59.5(a)(12), which stated, ''In order to promote holistic health and provide seamless care, Title X service providers should offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site.'' The Department finalizes this provision with only stylistic changes to improve readability.

Comments: Many commenters state that providing comprehensive primary care onsite or through a robust referral linkage is not conducive or appropriate for Title X service providers, as many patients prefer to have their reproductive health managed by a specialist. Many commenters express that specialists have the most up-to-date knowledge of their specialty, and this is why many primary care providers in turn refer out to those specialists. Many commenters additionally indicate that this rule would create an administrative burden and result in less primary care. Many commenters state that the Department's proposed primary care requirement, including regarding a robust referral linkage, is unclear, and the regulatory text would fail to give sufficient notice to Title X grantees about the obligations under the rule.

A commenter supports the new text and expresses the view that the rule would amend the criteria for grants and increase competition to encourage a broader, more diverse, applicant pool.

Response: The Department concludes that it is appropriate to encourage Title X service providers to have comprehensive primary health services onsite (although such services cannot be billed to the Title X program, unless it serves the goals of the program) or to build a robust referral linkage with primary health providers who are in close physical proximity to the Title X site. The 2000 regulations have similar provisions at § 59.5(b)(2) and (8), requiring projects to provide ''referral to and from other social and medical services agencies'' and ''coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.'' Like the 2000 regulations, the final rule allows for a referral linkage if projects do not offer comprehensive health services onsite. The final rule adds, however, that such referral entities should be in close proximity to the service site, and places additional emphasis on projects providing services onsite. The Department considers this change appropriate to help minimize the difficulty of patients receiving needed health care outside of Title X services.

The Department believes that the connection between Title X services and comprehensive primary care decreases the overall cost and transportation challenges to obtain needed health care services identified as a result of routine family planning screening and consultation. A 2013 Child Trends Research Brief, ''The Health of Women Who Receive Title X supported Family Planning Services,'' found that 60% of women receiving care at Title X clinics report that the clinic is their primary source for health care, yet many fear they cannot address other health concerns with their family planning provider, making the need for a linkage to comprehensive primary care providers essential for women's health.[81] The report also found that women who receive care at Title X clinics generally have worse health status than women who receive services elsewhere, and that, of such women, (1) over 25% report at least 3 health concerns; and (2) one-third are obese, with an additional 29% being overweight.[82] The placing of Title X services in the context of a comprehensive primary care setting or with strong referral networks to such care is consistent with Congress's expectation. In the 1975 Title X reauthorization, the Senate Report stated: ''The Committee believes that Family Planning Services under Title X generally are most effectively provided in a general health setting and thus encourages coordination and integration into all programs offering general healthcare.'' S. Rep. No 63, 94 Cong., 1st Sess. 65–66 (1975), reprinted in 1975 US Code Cong. & Admin News 469, 528.

Since Title X family planning services are primarily limited to preconception services, it is important that Title X sites assist clients with onsite care outside of the Title X project itself, or at least with referrals to local providers, to achieve optimal preconception and general health outcomes. Since any sexually active woman of childbearing age could become pregnant, the inclusion of preconception health screenings in the continuum of family planning care is

[81] Elizabeth Wildsmith et al., *The Health of Women who Receive Title X-Supported Family Planning Services,* Child Trends, 1 (Dec. 1, 2013), *https://www.childtrends.org/publications/the-health-of-women-who-receive-title-x-supported-family-planning-services.*

[82] *Id.*

important for clients, whether or not seeking pregnancy. Access to comprehensive preconception health care is also important to family planning outcomes because pregnancy may stress and affect extant health conditions. Linkages to comprehensive primary health care may be critical to ensure that pregnancy does not negatively impact such conditions. In addition, the greatest risks affecting the health of a baby occur early in a pregnancy—often before a woman realizes she is pregnant—such that helping women achieve optimal preconception health is important to ensure healthy pregnancies (as well as healthy babies) should conception occur.

The Department disagrees with commenters who contend this language concerning the proximity of comprehensive primary health care cannot be implemented by Title X service providers that specialize in family planning. First, as part of providing comprehensive primary health care, clinic may employ, among other providers, health care providers who specialize in family planning. Second, the primary care provision presents two options, onsite comprehensive primary care and referrals; it does not require the provision of onsite comprehensive primary care by Title X service providers. The Department believes this clarification addresses some concerns of commenters who feared that specialized providers could not provide all the services that an individual may need. The final rule also does not permit primary care to be subsidized by Title X funds, unless it serves the goals of the program. Thus, the requirement for Title X service providers to provide onsite, or have a robust referral linkage with, comprehensive primary health services does not move Title X outside of its scope of services. Instead, the final rule makes it easier to ensure that Title X clients, particularly low income clients, have access to necessary medical services and related educational and nondirective counseling services; that screening, diagnosis, and treatment can be provided within close proximity to the clinic; and that the most needy have access to care.

5. Title X Transparency (42 CFR 59.5(a)(13)

Summary of changes: The proposed rule proposed to add § 59.5(a)(13), to require that projects ''[e]nsure transparency in the delivery of services'' by reporting certain information ''in grant applications and all required reports.'' It then outlined three types of information that would be reported: ''(i) Subrecipients and referral agencies and individuals by name, location, expertise and services provided or to be provided; (ii) Detailed description of the extent of the collaboration with subrecipients, referral agencies and individuals, as well as less formal partners within the community, in order to demonstrate a seamless continuum of care for clients; and (iii) Clear explanation of how the grantee will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients and those who serve as referrals for ancillary or core services.''

The Department adopts this provision in the final rule with four changes. First, in § 59.5(a)(13)(i), the Department replaces ''referral agencies'' with simply ''agencies'' who are ''providing referral services''. Second, the Department removes the phrase ''as well as less formal partners within the community'' from § 59.5(a)(13)(ii) and replaces it with any individuals ''providing referral services''. Third, the Department removes the phrase ''and those who serve as referrals for ancillary or core services'' from § 59.5(a)(13)(iii). Fourth, the Department makes stylistic changes to improve clarity.

Comments: Many commenters contend the transparency requirements would add administrative burden and costs to projects, stating that programs lack familiarity with policies, referral practices, or services offered by their subrecipients. Some commenters contend that these requirements will discourage qualified entities from applying for Title X grants and will put Title X grantees, in particular programs with larger referral networks, in the overly burdensome position of providing oversight for programs that provide non-Title X services. One commenter suggests that this rule would limit grantees' referral networks and clients' health care choices and would pose a special burden to larger grantees. Many commenters state the new reporting requirements for grantees would take time away from staff who might otherwise be engaged in patient care. Commenters also state that the Department already has a level of transparency in place, complete with access to subrecipient information, and that the proposed language creates a disincentivized and burdensome outcome for providers to continue collaborations.

The Department also received comments on whether and how to include referral agencies in these requirements. One commenter states that the Department should require documentation from referral agencies to ensure that referrals are not used to promote abortion. Other commenters state that the referral agencies, which receive no Title X funding, should not be subject to these reporting requirements.

Some commenters state that the regulatory text is unclear and inconsistent, and fails to provide sufficient notice of obligations under the rule. They point out that it does not define ''less formal partners'' and does not express a distinction between ''ancillary'' and ''core'' services. They contend the rule unreasonably assumes an individual physician would know the myriad revenue streams that a large system receives.

Response: The Department disagrees that the rule will impose an inappropriate administrative burden or cost on projects. The reporting requirements would expand transparency surrounding Title X services. The proposed rule would require applicants to provide certain information in their applications, required reports, and in response to performance measures. The information required would include the name, location, expertise and services provided or to be provided by the subrecipient/referral agency/individual; a detailed description of the extent of the collaboration with subrecipient/referral agency, in order to demonstrate a seamless continuum of care for clients; and a clear explanation of how the grantee will ensure adequate oversight of, and accountability for quality and effectiveness of outcomes by, subrecipients. This information is necessary to ensure that Title X projects are achieving the goals of the program and expending grant funds properly.

The Department also disagrees with the suggestion that the transparency requirements disincentivize collaborations. The fact that grantees need to describe subrecipient and agencies or individuals providing referral services by name, location, expertise and services provided or to be provided does not deter those collaborations. Grantees should already know the details of those collaborations if they are important to the success of their projects. Understanding and being able to describe the details of collaborations is important to ensure the collaborations help the project achieve the goals of the program and comply with all applicable program requirements.

The Department appreciates the responses to its request for comment specifically on whether a referral agency should be subject to the same reporting requirements as a grantee and/or

subrecipient.[83] After carefully considering the comments on this issue, the Department concludes that the regulations should apply differently to referral agencies than to subrecipients of funding. A subrecipient ''provides family planning services with Title X funds under a written agreement with a grantee or another subrecipient.'' As such, the subrecipient functions as a part of the Title X program in providing preconception family planning services. Referral agencies do not receive Title X funds to provide Title X services. The Department, thus, has concluded it will not use these rules to hold referral agencies to the same requirements that are expected of grantee and subrecipient entities. Grantees and subrecipients must provide certain information regarding their referral network, as described elsewhere in this rule, but since referral entities do not receive Title X funding, they are not required to comply with the requirements of this final rule.

The Department also concurs that the phrase ''ancillary or core services'' may not have been clear. Therefore, the Department does not include the phrase ''and those who serve as referrals for ancillary or core services'' in § 59.5(a)(13)(iii) of the final rule. The Department also agrees with commenters who say it is difficult to understand what is meant by ''less formal partners.'' The Department believes it is sufficient to include subrecipients and referral agencies and individuals in the explanation of collaborations, so the phrase ''as well as less formal partners within the community'' will likewise not be included in § 59.5(a)(13)(ii) of the final rule.

6. Encouragement of Family Participation (42 CFR 59.5(a)(14))

Summary of changes: The proposed rule would add § 59.5(a)(14), a new requirement that projects ''[e]ncourage family participation in the decision of minors to seek family planning services and ensure that the records maintained with respect to each minor document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).'' The Department adopts this language with changes to clarify that family participation is encouraged for all patients, including, but not exclusive of, minors in the final rule.

Comments: Many commenters express concern that this language undermines patient confidentiality and access to care by placing increased pressure on adolescent patients to involve their family, and may possibly cause patients to avoid seeking care. Many commenters state this requirement creates barriers for young people to obtain care by imposing several new, but in their opinion, antiquated requirements on providing care to minors, especially through screening the adolescents for STDs or pregnancy.

Many commenters express concern that providers will be confused about their obligations. They assert this requirement is not responsive to the CDC/OPA Quality Care Guidelines, and state that it runs afoul of the Title X regulations that require providing services in a manner that protects patients dignity and ensures patient choices are entirely voluntary. Many commenters suggest that involving family members is not always advisable or realistic, and could cause conflict with some State statues or regulations that allow minors to make decisions about their health care, including contraception. One such commenter suggests that this paragraph be stricken or at least clarified further.

Many commenters feel that clinicians should not be required to take specific actions to document attempts to involve family members, as this would undermine patient-provider relationships and is unnecessary and excessively burdensome. Alternatively, commenters recommend that the efforts and funds from Title X programs would be better used to support training for providers on the best methods to encourage family involvement consistent with minor patient's confidentiality rights, health needs, and best interests.

Some commenters support the language requiring, and documenting, the encouragement of family participation, saying it is an appropriate clarification of the Congressional mandate for the program. Several commenters state that the requirement is consistent with the statutes and Supreme Court jurisprudence on parental rights. One commenter states that the encouragement of family participation and other reporting requirements provide an appropriate layer of protection for children to ensure Title X agencies are considering circumstances in which minors may be suffering abuse. One commenter states that the language does not have a chilling effect on access to Title X health services. Other commenters commend the Department's proposed language and suggest that encouraging parental involvement should always be the standard for any health care services provided to a minor.

Response: The Department realizes that the Title X statute is clear that family participation should be encouraged for all patients who access family planning services, and not merely minors. Congress requires that ''[t]o the extent practical, entities which receive grants or contracts under this subsection shall encourage familiy [sic] participation in projects assisted under this subsection.'' 42 U.S.C. 300(a). However, pursuant to annual appropriations provisions, Congress directs additional specific requirements with respect to the encouragement of family participation in the decisions of minors to seek family planning services: ''None of the funds appropriated in this Act may be made available to any entity under title X of the PHS Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services . . . .'' [84] To ensure compliance with these requirements, the final rule requires Title X service providers to encourage family participation in the decision of minors and others to seek family planning services. It also requires providers to document, in the records maintained with respect to each minor patient, the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).[85] The Department believes that the rule clarifies the steps the Title X providers must take, consistent with governing law, to encourage family participation, especially with respect to minors.

The Department disagrees that the rule causes conflict with State statutes and other Title X regulations. As noted above, the rule specifically implements several federal statutory requirements by requiring encouragement of family participation in family planning decisions while making allowance for instances where such encouragement would not be appropriate. Requiring

[83] The Department proposed to define ''subrecipient'' as ''any entity that provides family planning services with Title X funds under a written agreement with a grantee or another subrecipient. These subrecipients have entered into binding agreements or other financial relationships with Title X grantees to provide Title X services in a given State or community. A ''[s]ubrecipient'' may also be referred to as a ''delegate'' or ''contract agency.'' These entities receive Title X funds to provide Title X services, and are subject to the Title X statute and regulations.

[84] HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090.

[85] As noted below, suspecting child abuse, child molestation, incest, or the like and reporting it to the appropriate authorities, consistent with State or local reporting or notification laws, would constitute a good reason not to encourage family participation.

Title X projects to encourage family participation in the decision of unemancipated minors to seek family planning services does not require, and is not the equivalent of, parental notification or family participation. Rather, the ordinary meaning of Congress's requirement would be for a provider to converse with a minor (or other) patient in the course of care, and in an appropriate way, encourage family participation in the patient's consideration of family planning methods and services. This requirement is consistent with the ordinary understanding that communication between health care providers and patients is essential to providing quality and effective care. Congress is not required to fund projects where minors (or other patients) are given subsidized family planning but not encouraged to involve their families in their family planning decisions. To the extent that there is conflict between the Title X statutory (and regulatory) requirements and any requirements of State law, the federal requirements would apply to the recipients (and subrecipients) of Title X funds.

The Department understands some commenters' concerns about the need to maintain patient confidentiality. The Department agrees that Title X providers must continue to comply with laws concerning patient confidentiality, including those specifically pertaining to the confidentiality of minors with respect to Title X services. Health care providers already have conversations with their patients and document those discussions in patient records, while maintaining patient confidentiality. More broadly, such health care providers in the Title X program are also already required to encourage family participation where practical by the statutory directives adopted by Congress. This provision merely implements that requirement. With respect to minors, the Department believes that Title X projects and participating entities can comply with the rule's requirement to encourage family participation and to document such encouragement, or to note the reason why that was not appropriate, without infringing on patient confidentiality.

To those commenters who contend that encouraging family participation imposes barriers to the care of minors, the Department would point out that Congress made a different judgment. Congress requires that, ''[t]o the extent practical'', Title X grantees ''shall encourage familiy [sic] participation in projects assisted under this subsection.'' 42 U.S.C. 300(a). Similarly, specifically with respect to minors, Congress has made it a condition of funding that an applicant for a Title X award ''certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services.'' HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090; Consolidated Appropriations Act 2018, Public Law 115–141, Div. H, sec. 207, 132 Stat. 348, 736. Congress clearly did not anticipate a meaningful barrier when it enacted these requirements. Moreover, encouraging family participation is not the same as requiring family participation. The rule also allows appropriate discretion for health care professionals with respect to the requirement to encourage family participation where, for example, family participation may present a serious risk to the minor, such as when child abuse or incest is suspected. The rule simply requires Title X providers to document, in the patient's records, the reasons why family participation was not encouraged and, consistent with applicable local law, to report any suspected abuse to the relevant authorities.

The Department disagrees with those who contend the rule may compromise the provision of patient-centered care or the protection of the patient's dignity. The Department believes that involving parents in general, and in family planning decision-making in particular, can improve behavioral consistency with health recommendations for an adolescent. There is evidence that parent-child communication about family planning decisions increases the likelihood that the adolescent will consistently make healthier choices.[86]

For all these reasons, the Department considers it appropriate to finalize the proposed rule concerning encouragement of family participation, with the clarification noted above.

7. Provide for Medically Necessary Services (42 CFR 59.5(b)(1))

Summary of changes: The proposed rule would amend § 59.5(b)(1) to require that any referrals to other medical facilities be made consistent with § 59.14(a), which would bar referral for abortion as a method of family planning. The department finalizes 42 CFR 59.5(b)(1) with stylistic changes and to change the phrase ''when medically indicated'' to ''when medically necessary.'' The finalized provision requires Title X projects to:

Provide for medical services related to family planning (including physician's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) and referral to other medical facilities when medically necessary, consistent with § 59.14(a), and provide for the effective usage of contraceptive devices and practices.

All comments concerning this section are addressed in the section of this preamble that discusses new § 59.14(a).

8. Provide for Coordination and Referral, Consistent With Prohibition on Referral for Abortion (42 CFR 59.5(b)(1))

Summary of changes: The 2000 regulations state that projects must ''[p]rovide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.'' The proposed rule would amend this provision by requiring that any referrals be consistent with § 59.14(a), which would bar referral for abortion as a method of family planning.

The Department's discussion of and response to other comments relevant to this language are incorporated in the section of the preamble discussing proposed § 59.14(a).[87]

The Department finalizes this language without change, except for corrections in punctuation.

F. Criteria for Selection of Grantees (42 CFR 59.7)

Summary of changes: At § 59.7 of the proposed rule, the Department proposed to revise the criteria for the selection of grantees set forth in the 2000 regulations. The 2000 regulations set forth seven criteria for the Department to take into account, including the four criteria established in PHS Act section 1001(b). Those four criteria are included in the 2000 regulations and are similar to the PHS Act wording: (1) ''The number of patients to be served, and, in particular, the number of low-income patients,'' (2) ''the extent to which

[86] Patricia Dittus et al., *Parental Monitoring and Its Associations with Adolescent Sexual Risk Behavior: A Meta-analysis,* 136 Pediatrics e1587–99 (2015).

Tianji Cai et al., *The School Contextual Effect of Sexual Debut on Sexual Risk-Taking: A Joint Parameter Approach,* J Sch Health. 2018; 88: 200–207 (2018). *library.nih.gov/pubmed/29gov.ezproxyhhs.nihlibrary.nih.gov/pubmed/29399838* or *https://www.ncbi.nlm.nih.gov/pubmed/29399838.*

[87] As discussed above, in § 59.5(a)(12) the Department is finalizing requirements concerning the relationship between Title X service providers and comprehensive primary health services. The Department is also maintaining the requirement for coordination and use of referral arrangements in in § 59.5(b)(8), but qualifying that requirement with the more specific requirements set forth in in § 59.14(a).

family planning services are needed locally,'' (3) ''the relative need of the applicant,'' and (4) an applicant's ''capacity to make rapid and effective use of such assistance.'' The 2000 regulations also added three additional criteria not listed in the PHS Act: (5) The ''adequacy of the applicant's facilities and staff,'' (6) the ''relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project,'' and a catch-all criterion considering (7) ''the degree to which the project plan adequately provides for the requirements set forth in these regulations.'' The proposed rule would restructure these requirements into five parts: first, in paragraph (b), a consideration of whether the applicant proposes to satisfy the requirements set forth in the regulations, and then, in paragraph (c), the four criteria set forth in section 1001(b), elaborating on each one to indicate how the Department would implement them. The proposed rule would delete the remaining two paragraphs of the 2000 regulations discussing cost allocations for projects as determined by the Secretary.

The Department finalizes this section with changes in § 59.7(c)(2) to address concerns raised by certain comments regarding an applicant's ability to procure a broad range of diverse subrecipients. In the final rule, the Department also retains § 59.7(b) and (c) of the 2000 regulations, which the proposed rule would have deleted, but redesignates them as § 59.7(d) and (e). Finally, several stylistic changes are made to improve clarity and readability of the application review criteria.

Comments: Several commenters state the rule significantly alters the existing program grant review criteria, undermining the usefulness of the criteria for the purpose of differentiating the best applications and best uses of Title X funds. Some commenters state that the new, shorter list of criteria contributes to greater Department leeway in making decisions about awards that do not focus on the effectiveness of the family planning care. One commenter contends that the new criteria will limit the number of qualified and experienced health care providers who can compete for funding. One commenter states the Department provides no justification or rationale for the requirement for new and inexperienced partners. The commenter laments that the wording of the rule appears to require projects to partner with new organizations each year—an unworkable proposition because the pool of new providers is limited.

Some commenters state the rule will unconstitutionally give an advantage to religious groups due to the second factor of the grant review process criteria stating that preference will be given ''especially among a broad range of partners and diverse subrecipients and referral individuals and organizations, and among non-traditional Title X partnering organizations.'' Some of these commenters express concern that the ''diverse'' and ''non-traditional'' organizations the Department is referring to are faith-based providers or religious entities that oppose abortion and some or all forms of contraception. The commenters state that these organizations have been previously ineligible to receive Title X funds but would now be eligible under the new criteria. One commenter argues the rule provides no evidence supporting the idea that there are many ''non-traditional'' organizations and different kinds of new subrecipients that could cycle into Title X projects and improve low income patients' access to high-quality family planning services.

Some commenters state the rule will not increase competition and rigor among applicants, encourage broader and more diverse applicants, or better ensure quality applicants are selected. Rather, they contend the rule will curtail the current wide reach of Title X by allowing funding to organizations that do not provide comprehensive pregnancy counseling. A few commenters state that there was no evidence that a change in the application review process or additional diversity among applicants is necessary.

Some commenters note that the existing network of Title X primary grantees and subrecipients has been relatively stable over time and has developed deep expertise and experience in family planning that profoundly benefits the communities they serve. They believe the rule will jeopardize the existence of well-developed, proven-effective programs that are based on the best clinical standards, scientific evidence, and care. One commenter asserts that, although the Department states there will be increased competition for funding, the changes set forth in the proposed rule will only change the types of entities applying for these funds, inviting organizations to apply that have no interest in fulfilling the statutory program mandate to provide a broad range of effective family planning methods and services.

Some commenters express concern regarding how much weight will be allocated to each criterion, and whether preferences may be established for Title X projects that do not provide a full scope of scientific, medically based care, citing providers of natural family planning and other fertility awareness-based methods. One commenter expresses a belief that sites providing abortion services will be disqualified and other sites that offer natural family planning and fertility awareness-based methods will be preferred.

One commenter supporting the proposed rule describes the process for evaluating applicants as thorough, and is in favor of requiring applicants to demonstrate their ability to comply with regulations, especially in terms of separation of funds and transparency of activity. The commenter adds that this requirement likely would reduce the potential for misuse of funds. One commenter argues grant applicants should be required to provide written assent to all relevant statutory and regulatory requirements, and should submit all relevant organizational documents, such as personnel manuals, client guidelines and protocols, in order to demonstrate that the organization has a pervasive policy framework and organizational culture consistent with the law and the final rule.

Several commenters state the Department will have unchecked discretion to prevent applications from reaching the objective review process that now governs the awarding of grants, putting the Department in complete unfettered control of which applications will be a part of the objective review process. Such commenters state that, historically, the process has hinged on the evaluation of objective review panels, but the new assessment would be subjective and non-transparent, and would give the Department discretion to block any applicant from reaching the competitive review process, perhaps for political purposes. Several commenters state the criteria are unclear and vague, and ask the Department to specifically and clearly state the criteria with which it will review applicants before they reach the objective panel review. One commenter contends the Department is bypassing the regulatory process to add new criteria, and says the rule will include a subjective standard without oversight.

A few commenters state that, in applying these criteria retroactively to grantees with current grants at the time the final rule goes into effect, the rule would undermine the fairness of the funding opportunity announcement (FOA) and thwart the award process in which applicants were scored on criteria about which they were aware at the time of their applications. The commenters contend that imposition of

these measures well after the application due date of the previous FOA would create a fundamentally unfair scoring process with respect to that FOA and would unjustly provide funding to organizations not capable of providing the full range of comprehensive services that has long been the benchmark of Title X care.

Response: The Department generally agrees with commenters who support the proposed language of § 59.7 as providing a thorough process to ensure applicants demonstrate their ability to comply with regulations and avoid misuse of funds.

Proposed § 59.7(b) would require Title X applicants to clearly address how their proposal will satisfy the requirements of this regulation, in order to proceed to the competitive grant review process. As a result of confusion by some commenters, the Department provides additional clarity with further detail related to the requirements for compliance with this initial screening. An applicant would be required to describe its plans for affirmative compliance with each requirement of the Title X regulations, as explicitly defined by the Department in the funding announcement. For example, this would include not only demonstrating physical and financial separation from abortion as a method of family planning (when compliance with such requirement becomes required), but also explaining how the applicant will provide a broad range of acceptable and effective family planning methods and services. The funding announcement will clearly describe how applicants should address this requirement, including any documentation that is necessary to demonstrate affirmative compliance with each of the regulation requirements. The Department will implement these requirements to better direct Title X funds for family planning projects, to prevent misuse of funds, and to save taxpayer dollars by only sending qualified applications to the costly and time consuming competitive review committee. Once the applicant successfully demonstrates affirmative compliance with the Title X regulations (a yes/no issue), the Department will consider each applicant competitively according to the criteria set forth in the regulation.

In response to a commenter suggesting that applicants be required to submit additional documentation such as personnel guidelines and documents regarding the organizational structure of applicants, the Department agrees that submission of such documents may be included to support an application, but will not require it. The Department concludes that such a requirement may be overly burdensome. Applicants will be required to demonstrate they will achieve the goals of the program and meet the statutory and regulatory criteria, but the Department declines to add the additional documentation requirements suggested by the commenter.

The Department acknowledges the confusion expressed by commenters on the meaning of the phrase ''a broad range of partners and diverse subrecipients and referral individuals and organizations, and among non-traditional Title X partnering organizations'' in § 59.7(c)(2) of the proposed rule. Although most such commenters objected to the need for new partners, the Department notes that it does not intend that grant funds be designated to referral individuals or referral organizations, since such referrals are made without any monetary exchange. Grant funds would only be provided to ''non-traditional Title X partnering organizations'' if they are subrecipients in a Title X project. The Department further clarifies that it does not intend that grantees must change subrecipient relationships each year, but that grantees make ongoing efforts to expand the network of partners throughout the service area, especially with respect to nontraditional partnering organizations. The Department additionally clarifies that it does not expect grantees who plan to provide all family planning services themselves, to now designate that these services be provided by subrecipients. The Department wishes to spur innovation and more extensive service, but does not wish to limit grantees' flexibility. However, if grantees implement a model in which they partner with subrecipients for services, the Department wants to emphasize that a broad range of subrecipients be partners, including those who are nontraditional organizations, but this does not necessarily mean that such subrecipients will be new providers in the Title X program. Finally, the Department adds the phrase ''as applicable'' following the ''broad range of diverse subrecipients in recognition of and to allow for grantees, such as community health centers, who may choose to directly provide services and not use any subrecipients. To clarify this provision and resolve the concerns of many commenters, the Department modifies the language of § 59.7(c)(2) in the final rule to read as follows: ''The degree to which the relative need of the applicant for federal funds is demonstrated in the proposal, and the applicant shows capacity to make rapid and effective use of grant funds, including its ability to procure a broad range of diverse subrecipients, as applicable, in order to expand family planning services available to patients in the project area.''

The Department rejects the claim by some commenters that the criteria set forth in the rule gives an unconstitutional advantage to religious groups. Neither the proposed language, nor the language of the final rule (including § 59.7(c)(2)), mentions religious groups nor expresses a preference in favor of them. The Department's focus in implementing Title X is on providing and expanding the provision of services to low income, unserved or underserved patients in a timely manner. The Department welcomes applications from faith-based organizations as well as secular non-profit entities. With respect to the criteria in § 59.7(c)(2), the Department would favor those applicants that can meet the needs of patients, especially those who are unserved and underserved, seeking family planning services, while complying with the statutory and regulatory requirements of the Title X program. The Department encourages Title X applicants to develop innovative strategies to meet the family planning needs of the various populations in their proposed service areas. Diversity in the range of partners included in applicants' proposals is but one factor among many that the Department will consider in reviewing applications.

The Department disagrees with commenters who contend the criteria in § 59.7 will diminish the program's effectiveness. Rather, these criteria will assist the Department in ensuring that the statutory requirements of the Title X program are met, the program is serving patients as Congress intended, gaps in services (or populations served) are closed, and providers are free to explore and test new ways to better provide service to patients.

The Department similarly disagrees with commenters who fear the rule, and the review criteria in particular, will exclude some applicants, especially those who provide abortion or those who have long experience with the program. No provision in Title X or in the proposed or final rule prevents abortion-providing organizations from applying for, and receiving, Title X funding, so long as the organization meets this rule's requirements with respect to the proposed Title X project, including physical and financial separation, and not providing,

promoting, or referring for abortion as a method of family planning in the Title X project. Nothing in § 59.7 excludes experienced Title X providers from continuing to compete on a level playing field for Title X funds. In fact, some review criteria might be more easily met by applicants with experienced and established networks. The Department intends for all funded applicants, both new and those who are experienced Title X providers, to improve or expand the quality and scope of overall service to clients, as a result of following the criteria set forth in these final rules.

The Department also disputes the assertion by some commenters that an emphasis will be placed on natural family planning over other methods. In the final rule at § 59.7(c)(1), the Department clearly and specifically requires every Title X project 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).'' The Department emphasizes that Section 1001 of the Title X statute includes natural family planning in its non-exclusive list of family planning methods and services. *See* 42 U.S.C. 300(a). The Department's definition of family planning recognizes the broad range of statutorily acceptable services by ''including contraceptive methods, and natural family planning or other fertility awareness-based methods.'' Accordingly, nothing in the criteria set forth in § 59.7 expresses a preference for applicants that offer natural family planning or other fertility awareness-based methods methods—they simply require each project to offer both contraceptives and natural family planning or other fertility-awareness based methods.

Consistent with the Department's historic processes, the weight attached to each criterion is not established in this rule. This is not only consistent with how the Department has operated, but also with the process of most other grant funding programs. The Department reserves the discretion to set forth more specific weights for each criterion in funding opportunity announcements.

The Department has not given itself unchecked discretion to disqualify applications in this rule. First, the Department is bound to maintain the integrity of the program and to implement the program in such a manner as to ensure compliance with statutory requirements. All provisions in this rule seek to achieve that purpose. The 2000 regulations afforded the Department significant flexibility in determining criteria for awards. In the revised version of § 59.7, paragraph (b) sets forth an overarching requirement that each applicant clearly address how the proposal will satisfy the requirements of the regulations and describe the applicant's plans for affirmative compliance. That paragraph, far from giving the Department unconstrained discretion, ensures that projects will comply with the provisions of the applicable statutes (which are embodied in the regulation) and the regulations themselves. It also increases the efficiency of the review process by only expending Department resources for the competitive review panel to review applications that meet the minimum requirements for the program.

Second, paragraph (c) of § 59.7, as revised, does not set forth any novel flexibility or discretion not already provided by the Title X statute and available under the Title X regulations. The 2000 regulations, like section 1001(b) of Title X, simply state the Department shall ''take into account'' those factors. The statutory list of factors is not exclusive. And the Department has periodically described, in funding opportunity announcements and its grants policy, other criteria applicable to proposals, paying due attention to consistency with the Title X statute and regulations. Section 59.7(c) of this final rule states that applicants ''will be subject'' to those criteria, again leaving the Department some discretion to describe additional criteria. But in all events, the Department recognizes that such criteria must be consistent with any applicable statutes and regulations. And here, the new regulatory criteria are consistent with the requirements set forth in the Title X statute.

Third, as is true throughout the Department, Title X grants are awarded through a merit-based grantmaking process consistent with the Department's grants policy, and in accordance with the Executive Branch's Uniform Administrative Requirements and the Department's own grants regulations. In this competitive process, eligible applications are reviewed by a panel of independent reviewers and evaluated based in part on criteria in the Title X program regulations, and published in the funding opportunity announcement. In addition to the independent review panel, Federal staff review each application for programmatic, budgetary, and grants management compliance. Finally, applications recommended for funding are evaluated, in accordance with 45 CFR 75.205, for risks before an award is issued.[88]

The Department does not agree with commenters that it will assert unchecked discretion to arbitrarily dismiss applications before reaching the independent review panel. For example, as stated in paragraph (b) of the final rule, the Department has committed to ''explicitly summarize each requirement of the Title X regulations . . .'' or provide the entire regulation with which the applicant must demonstrate compliance, and has explained that applicants must ''describe its plans for affirmative compliance with each requirement.'' These requirements, which focus on regulatory provisions with which grantees must comply, provide meaningful parameters to the Department's discretion. Failure by an applicant to clearly demonstrate compliance with Title X regulations would constitute a fatal flaw to an application for Title X funds.

The Department also notes that broad discretion is granted to it by the Title X statute when selecting between potential grantees. The 2000 regulations acknowledged this discretion when they stated that ''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.'' 42 CFR 59.7(a). Requiring applicants to establish compliance with Title X regulatory provisions is important to providing the Department with an informed baseline for exercising this discretion. As noted above, these regulatory provisions ensure compliance with the statutory framework and, thus, provide useful information for assessing applications both before and within the competitive grant review process. The Department believes that receiving this information will enable the Department to more efficiently and effectively review the significant number of applications for Title X funding, as well as provide important information to the independent review panel. Accordingly, the Department finds that the final rule reflects a proper and effective exercise of the Department's grant discretion bound by the statutory and regulatory text.

[88] 45 CFR 75.204 (''HHS funding agency review of merit of proposals'', provides that ''[f]or competitive grants or cooperative agreements, unless prohibited by Federal statute, the HHS awarding agency must design and execute a merit review process for applications. This process must be described or incorporated by reference in the applicable funding opportunity (*see* appendix I to this part.) *See also* § 75.203.'')

In sum, the Department believes the final rule functionally and appropriately limits the Department's discretion by requiring that applicants be subject to the criteria set forth in § 59.7(c), and that the discretion the Department retains under § 59.7 to consider other factors is not fundamentally different from the non-exclusive lists of factors set forth in the 2000 regulations. The Department believes that this final rule will help ensure reliability and certainty in the grant selection process, while maintaining an open process similar to the selection process for other grants at the Department. In pursuing these ends, the Department continues to focus on ensuring compliance with the statutory Title X requirements,[89] including the program integrity provisions referenced throughout this preamble; expanding the type and nature of the Title X providers and ensuring the diversity of such providers so as to fill gaps and expand family planning services offered through Title X; and using review criteria as a meaningful instrument to assess the quality of the applicant and the application. The Department believes that these goals, which are consistent with the Title X statute and similar to the approach taken in the 2000 regulations, are best achieved by finalizing § 59.7 as set forth in this final rule.

In response to a commenter who requests that an additional criterion be added to § 59.7(c) to consider whether there is a family planning gap in the community, the Department appreciates the concern. But, as part of the final rule, § 59.7(c)(4) already states the Department will consider ''[t]he extent to which family planning services are needed locally. . .'' and whether the applicant proposes innovative ways to provide services to unserved or underserved patients. The Department believes that the community's need—including any family planning gaps in the community—is already adequately addressed in that criterion. Furthermore, in response to comments cited earlier that emphasize the value of Title X as the sole federal program dedicated to funding family planning services for low income individuals, the Department adds a reference to low-income patients to the criterion in § 59.7(c)(3) in order to accentuate the obligation of Title X projects to serve low-income patients and populations.

The Department agrees with the concerns of commenters who ask that the application criteria not be effective with regard to a FOA that has already been published, and where applications have already come due, prior to the effective date of this final rule. The Department agrees that applicants should know the criteria on which review of their applications will be based. Therefore, the Department will establish compliance dates for these provisions so that § 59.7 and the criteria set forth therein will be applied only to future FOAs issued after the effective date of this final rule, consistent with the effective dates and compliance dates established in this final rule. To the extent these criteria are relevant to applications for continuation awards under previously awarded grants, § 59.7 will also apply if those continuation award applications are due after the effective/compliance date, *i.e.,* more than 60 days after the publication date of the final rule. As discussed below, the Department is establishing compliance dates for other provisions of the final rule in the transition provision, § 59.19, so language clarifying the compliance date for § 59.7 is set forth in that provision.

The proposed rule would have deleted current § 59.7(b) and (c) from the Title X regulations. These provisions concern the amount of an award with respect to a project's estimated costs. The Department did not receive comments concerning the proposal to delete these paragraphs. Upon further consideration, however, the Department has determined that it is appropriate to retain these two paragraphs from the 2000 regulations. In section 1006(a), Title X provides that, while the Secretary shall determine the amount of any grant, no grant may generally be made for less than 90% of its costs. The Department believes that these current provisions in the Title X regulations—which reiterates this requirement and provides that no grant may be made for an amount equal to 100% of the project's estimated costs—express statutory requirements for the Title X program. The Department believes explicitly maintaining these statutory parameters in the Title X regulations provide helpful clarity for Title X grantees. Therefore, the Department is not finalizing the proposal to delete these two paragraphs from the 2000 rule, and this final rule will retain the paragraphs, redesignated as paragraphs (d) and (e).

G. Confidentiality (42 CFR 59.11)

Summary of changes: The 2000 regulations required that all information obtained by project staff about individuals must be held confidential and not disclosed without the individual's documented consent, with limited exceptions required by law. The proposed rule, at § 59.11, would clarify that confidentiality concerns cannot be the basis for failure to comply with legal requirements to report or provide notice of certain criminal activity. With the proposed amendment, section 59.11 would specify that ''[a]ll information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and 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; concern with respect to the confidentiality of information, however, may not be used as a rationale for noncompliance with laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.''

The Department adopts the modification to this section without change, except for corrections in punctuation.

Comments: Many commenters assert that medical professionals are deeply committed to protecting patients who may be victims of abuse or other criminal activity, and their commitment is reflected in their ongoing compliance with State and local reporting laws. Commenters emphasize the importance of confidentiality in the care of adolescents, with commenters characterizing Title X providers as access points for youth autonomy. Commenters argue that, without assurances of confidentiality, young people would not seek family planning services. They contend that the proposed changes to confidentiality protections would hinder access to contraception and information for young people, both of which have contributed to lower instances of teen pregnancy.

Response: The Department agrees with commenters who stress that Title X providers must continue to comply with laws concerning patient confidentiality, including those specifically pertaining to the confidentiality for minors with respect to Title X services. For this reason, the Department does not change the current regulatory provision that requires that all information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and

[89] *See* 42 U.S.C. 300–300a–6; HHS Appropriations Act 2019, Public Law 115–245, Div. B, secs. 207–208 132 Stat. at 3090.

not be disclosed without the individual's documented consent, except as necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. The Department also does not change the further specification in the rule that, in any other case, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals. The rule will, thus, continue to protect the confidentiality of patient information subject to these well-established exceptions and limitations. The only change is to clarify that the concerns for ''appropriate safeguards for confidentiality'' may not be used as a rationale for noncompliance with State or local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar criminal activity.

The Department believes the final rule is consistent with standard health care confidentiality practices, in which providers already have conversations with their patients, document those discussions in patient records, and comply with State and local reporting requirements, while otherwise maintaining the confidentiality of that information. Although the Department understands the challenge of balancing protection for victims, complying with State reporting laws, and maintaining trust in the patient-provider relationship, the Department's annual appropriations law requires that Title X projects comply with such State reporting requirements. Moreover, the Department believes that Title X programs can best serve minors and other vulnerable populations by ensuring Title X providers have a plan for reporting abuse as required by State and local reporting laws. Title X projects and participating entities can comply with these reporting requirements and document the measures taken to comply, much as health care providers do in other contexts, without infringing in any way on patient confidentiality.

H. Standards of Compliance With Prohibition on Abortion (42 CFR 59.13)

Summary of changes: The proposed rule would add § 59.13, which would specify that ''[a] project may not receive funds under this subpart unless it provides assurance satisfactory to the Secretary that, as a Title X grantee, it does not provide abortion and does not include abortion as a method of family planning. Such assurance must also include, at a minimum, representations (supported by documentary evidence where the Secretary requests it) as to compliance with this section and each of the requirements in §§ 59.14 through 59.16. A project supported under this subpart must comply with such requirements at all times during the project period.''

The Department finalizes this definition with changes in response to comments that emphasize the grantee's responsibility to provide satisfactory assurance to the Secretary that the project complies with the statutory and regulatory Title X requirements.

Comments: One commenter states that the definitions of ''grantee'' and ''project'' are unclear and create confusion. Specifically, the commenter states that, under § 59.13, ''[a] project may not receive funds under this subpart unless it provides assurance satisfactory to the Secretary that, as a Title X grantee, it does not provide abortion and does not include abortion as a method of family planning.'' Project, however, is defined to ''mean a plan or sequence of activities that fulfills the requirements elaborated in a Title X funding announcement and may be comprised of, and implemented by a single grantee or subrecipient(s), or a group of partnering providers who, under a grantee or subrecipient, deliver comprehensive family planning services that satisfy the requirements of the grant within a service area.'' The commenter contends that § 59.13 treats ''grantee'' and ''project'' interchangeably, and therefore causes confusion, as well as risking the interpretation that, under § 59.13, the grantee may not provide abortion or include abortion as a method of family planning both inside and outside the project. The commenter contends this ambiguity fails to give applicants a sufficient understanding of how the rule works, and what conditions apply to applicants for grants.

Commenters also assert that the regulations do not articulate how compliance should be demonstrated under § 59.13, and what documentary evidence would be necessary to provide this assurance.

Other commenters raise general concerns discussed elsewhere in this preamble.

Response: The Department agrees with the commenter that there is a lack of clarity with respect to the use of the terms ''grantee'' in § 59.2 and ''project'' in § 59.13. The Department intends the compliance standards in § 59.13 to apply to a grantee's activities within a Title X project, not to a grantee's activities outside of a project. The Department recognizes that an entity that serves as a Title X grantee may provide abortion or include abortion as a method of family planning separate from, independent of, and outside, the Title X project for which the grantee has been selected. Such an entity may still qualify for a Title X grant, so long as it meets each of the requirements in §§ 59.13 through 59.16 with respect to the project, including but not limited to the physical and financial separation, and ensures compliance with those requirements by its subrecipients with respect to the project. This recognition is consistent with *Rust* v. *Sullivan* [90] and the 1988 regulations.[91] The Department believes that the lack of clarity in the proposed rule was not due to the definition of ''grantee'' in § 59.2, but the use of the terms ''grantee'' and ''project'' in § 59.13.

The Department addresses this confusion by modifying a phrase and adding further clarity with regard to where responsibility for compliance lies.[92] Consequently, the Department finalizes § 59.13 to state: ''A project may not receive funds under this subpart unless the grantee provides assurance satisfactory to the Secretary that the project does not provide abortion and does not include abortion as a method of family planning. Such assurance must also include, at a minimum, representations (supported by documentary evidence where the Secretary requests it) as to compliance with this section and each of the requirements in §§ 59.14 through 59.16. A project supported under this subpart must comply with such requirements at all times during the project period.'' The Department believes this change addresses the confusion raised by the commenter concerning how the definition of grantee applies in § 59.13.

The Department disagrees with commenters who contend the proposed rule at § 59.13 gives improper or unprecedented regulatory authority to the Department beyond the concern addressed above. Title X authorizes the Secretary to promulgate regulations governing grants and contracts issued in the program. 42 U.S.C. 300a–4. Thus, the Department is authorized, and in many cases required to, apply requirements both to primary grantees and to subrecipients of Title X funds. This includes the requirements set forth in section 1008.

[90] 500 U.S. 173.

[91] 42 CFR 59.1–59.12 (1988 ed.), 53 FR 2922 (Feb. 2, 1988).

[92] As discussed above, the Department believes the concern raised by the commenter does not require a change to the definitions of ''grantee'' and ''project'' in § 59.2, since they are clear, and not the subject of the commenter's concern.

The Department disagrees with commenters who assert that the regulations do not articulate how compliance should be demonstrated under § 59.13, and what documentary evidence would be necessary to provide this assurance. The plain text in proposed § 59.13 would require that the grantee provide representations of compliance with the section and each of the requirements in §§ 59.14 through 59.16, and be prepared to support the representations with documentary evidence of compliance if requested by the Department. Proposed § 59.17(b) similarly requires the establishment and documentation of certain protocols, plans and training related to knowledge of and compliance with certain State or local notification or reporting requirements. The grantee would provide a representation or assurance that it has adopted the required protocols and conducted/provided the required training. The types of documentary evidence that might be required could include (1) copies of the protocols or plans that have been adopted and implemented; (2) copies of the training materials; (3) training session sign in sheets; and (4) notations in patients' records as to reporting, notification, or in the case of minors, screening for abuse or victimization. To the extent that additional documentation is required by the Secretary at a later date, future guidance will be communicated to grantees.[93]

I. Requirements and Limitations With Respect to Post-Conception Activities (42 CFR 59.14)

Summary of changes: The proposed rule would add § 59.14, which would provide guidance to grantees regarding the requirements and limitations of the Title X program with respect to the post-conception activities of projects and clinics. Sections 59.5(a)(5) and 59.16(a) contain related provisions. Because many comments on these related sections overlap, some comments (and responses) in this section are also applicable to those sections as well.

Comments concerning the prohibition on providing or performing abortion as a method of family planning are addressed above in the discussion of the definition of ''family planning'' in § 59.2 and in the discussion of the prohibition on providing, promoting, referring for, or supporting abortion as a method of family planning in § 59.5(a)(5).

Comments concerning the rescission of the requirement in the 2000 regulations to provide abortion counseling, information, and referrals, and concerning nondirective pregnancy options counseling under this rule, are addressed above in the discussion of § 59.5(a).

Comments concerning the prohibition on referral for abortion as a method of family planning, on the promotion, or support of abortion as a method of family planning, and on taking affirmative action to assist a patient to secure an abortion, are considered here, and relate to § 59.14 as well as parts of §§ 59.5(a)(5) and 59.16(a).

The Department finalizes the language at § 59.14 with changes in response to public comments, as discussed below.

1. Prohibition on Referral for, and Encouragement, Promotion, Advocacy, Support, and Assistance of, Abortion as a Method of Family Planning (42 CFR 59.14(a), Inclusive of Pertinent Portions of §§ 59.5(a)(5), and 59.16(a))

Summary of changes: The first sentence of proposed § 59.14(a) would provide that ''[a] Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion.'' This sentence remains unchanged in the final rule. The remaining language in § 59.14(a) would permit doctors to provide a list of licensed, qualified, comprehensive primary health care providers (some of which may also provide abortion services) and guidance on circumstances when the list could be provided. The Department now finalizes language in the first sentence without change. In response to comments, the Department has updated the remaining language of § 59.14(a), regarding the list of comprehensive health service providers and has updated the examples listed at the end of § 59.14. Further discussion of these changes regarding the list is included in the subsection below, entitled ''Information About Prenatal Care, Use of Permitted Information To Refer For Abortion, and Examples (42 CFR 59.14(b), (c), and (e)).'' A further discussion of this prohibition is also included in the discussion of § 59.16, which contains a related provision.

Comments: Many commenters strongly support the proposed language to prohibit Title X projects from referring for abortion as a method of family planning and from promoting, supporting, encouraging, advocating for, or assisting abortion as a method of family planning. They contend these prohibitions are consistent with Congressional intent for Title X, including in section 1008 of the PHS Act. Some commenters note that, in *Rust,* 500 U.S. at 17892, the Supreme Court upheld a prohibition on abortion referrals in the 1988 regulations as being both constitutionally valid and a permissible implementation of the statutory restrictions on the program. Another commenter states that the government is permitted to direct how Title X funds are spent, consistent with the Title X statute, and that this sustains the prohibition on referrals. The commenter contends the proposed rule would ensure not only that program funds are not used to directly provide abortions, but also that program funds do not support loopholes by which some providers abuse the system to refer for abortion as a method of family planning. Another commenter supports the proposed rule because it will be consistent with a number of State laws that prohibit Title X providers from referring for abortions.

Other commenters oppose the prohibition on abortion referrals. A significant number of commenters call the prohibition a gag rule, arguing it restricts providers from speaking freely with their patients about every health concern they may have. They state that this prohibition violates ethical standards and undermines the patient-provider relationship, noting that a health care provider should not fail to provide certain services, namely those associated with abortion, because of private religious beliefs. Some commenters also contend the proposed changes disregard the consciences of providers who support ensuring patient access to information related to abortion and abortion-related services, including providing abortion referrals. And some commenters state that the abortion referral prohibitions in the proposed rule regulate activities outside the Title X program and are, therefore, illegal.

A commenter supporting the proposed rule disputes the characterization of the prohibition on abortion referrals and promotion as a gag rule. The commenter contends the language merely implements what the law already requires and does not prevent physicians or APPs from providing nondirective counseling as long as it is done in a manner consistent with the Title X statute. In addition, the commenter notes that abortion referral prohibitions do not prevent a doctor from making medical determinations on behalf of a patient that require services

[93] Grantees are already required to affirm that neither they nor any of their subrecipients provide abortion as a method of family planning. At the present time, the Department contemplates a narrow compliance requirement where the grantee assures the Department of compliance and provides adequate representations to bolster that assurance, such as those discussed above.

outside of the scope of the Title X program.

Response: Having examined its past rules governing the Title X program, the public comments on this issue, and the Department's interpretations of section 1008's prohibition on funding Title X programs ''where abortion is a method of family planning,'' the Department concludes that the requirement in the 2000 regulations for abortion referral is inconsistent with the Department's current interpretation of section 1008.[94] The language of Section 1008 goes beyond merely prohibiting the funding of abortion (which is addressed in the Title X appropriation provision), or of projects that perform abortion. The Title X statute prohibits spending Title X funds on programs where abortion is treated as a method of family planning. This prohibition impacts Title X projects in a variety of ways. If a Title X project refers for, encourages, promotes, advocates, supports, or assists with, abortion as a method of family planning, it is a program ''where abortion is a method of family planning'' and the Title X statute prohibits Title X funding for that project. For this reason, the Department agrees with commenters who support the language prohibiting such activities in the proposed rule as legally permissible and appropriate.

The Supreme Court has already recognized the reasonableness of this interpretation. In *Rust,* the Supreme Court upheld the provisions in the 1988 regulations that a Title X project may not ''provide counseling concerning the use of abortion as a method of family planning or provide referral for abortion as a method of family planning,'' provisions implementing that prohibition, and provisions stating a Title X project may not ''encourage, promote, or advocate abortion as a method of family planning'' or ''assist women to obtain abortions.'' *See* 53 FR 2923–2924; *Rust,* 500 U.S. at 179–80. The Supreme Court held that ''[t]he broad language of Title X plainly allows the Secretary's construction of the statute'' to prohibit abortion referral, counseling, and advocacy, and the Secretary ''amply justified his changed interpretation.'' *Rust,* 500 U.S. at 184–87. The Court further concluded ''[t]here is no question but that the statutory prohibition contained in § 1008 is constitutional,'' because Congress ''may 'make a value judgment favoring childbirth over abortion, and . . . implement that judgment by the allocation of public funds.' '' Id. at 192 (internal citations omitted; ellipses in original). The court explained that the challenged provisions of the 1988 regulations were also consistent with the First Amendment:

> The challenged regulations implement the statutory prohibition by prohibiting counseling, referral, and the provision of information regarding abortion as a method of family planning. They are designed to ensure that the limits of the federal program are observed. The Title X program is designed not for prenatal care, but to encourage family planning. A doctor who wished to offer prenatal care to a project patient who became pregnant could properly be prohibited from doing so because such service is outside the scope of the federally funded program. The regulations prohibiting abortion counseling and referral are of the same ilk. . . . This is not a case of the Government 'suppressing a dangerous idea,' but of a prohibition on a project grantee or its employees from engaging in activities outside of the project's scope.

Id. at 193–94.

The Department disagrees with the view of some commenters that the prohibitions on referral for, encouragement of, promotion of, advocacy for, support of, or assistance with, abortion as a method of family planning regulate non-Title X activities. The Department intends these prohibitions to apply only to the Title X project. The Supreme Court, in *Rust* rejected a First Amendment claim in which the challengers contended that similar regulations apply outside the Title X project, stating that ''[t]he Secretary's regulations do not force the Title X grantee to give up abortion-related speech; they merely require that the grantee keep such activities separate and distinct from Title X activities. . . . The regulations govern the scope of the Title X project's activities, and leave the grantee unfettered in its other activities.'' *Rust,* 500 U.S. at 196. Furthermore, the Court stated that an entity that receives Title X funds ''can continue to perform abortions, provide abortion-related services, and engage in abortion advocacy; it simply is required to conduct those activities through programs that are separate and independent from the project that receives Title X funds.'' *Id.*

The Department also disagrees with commenters who contend that prohibiting referring for, promoting, supporting, encouraging, advocating for, or taking any other affirmative action to assist a patient to secure, abortion as a method of family planning in Title X projects violates the Church Amendment rights of Title X projects or their employees. Although paragraph (c)(1) of the Church Amendments protects personnel on the basis that they ''performed or assisted in the performance of a lawful . . . abortion,'' [95] those are not inconsistent with the clear statutory prohibition that funds may not be provided to Title X projects where abortion is a method of family planning. Projects can comply with this prohibition on the use of Title X funds without discriminating against personnel in a way that violates the Church Amendments.

The Department, thus, finalizes the first sentence of § 59.14(a).

2. Information About Prenatal Care, Use of Permitted Information To Refer for Abortion, and Examples (42 CFR 59.14(b)(1), (c), and (e))

Summary of changes: The proposed rule would provide in § 59.14(b) that, once a Title X client is diagnosed as pregnant, she must be referred for appropriate prenatal and/or social services. The proposed rule also would have required that the project provide any information necessary to protect her health and the health of the unborn child until the referral appointment is kept, including referral for emergency medical services when appropriate. In § 59.14(c), the proposed rule would have acknowledged the duty of a physician to promote patient safety in allowing a doctor to provide a list, if asked, of licensed, qualified, comprehensive health service providers, some of which may provide abortion in addition to comprehensive prenatal care. In paragraph (e), the Department would set out several examples to illustrate the application of the requirements of paragraphs (a) through (d).

The Department finalizes § 59.14(b)(1) with changes, including to permit the provision of a single list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) to pregnant clients. In addition, the final rule requires referral for prenatal care since such care is medically necessary to maintain or improve the health of both the mother and the unborn baby. The Department simplifies and clarifies the description of pregnancy health information in this final rule to read ''[i]nformation about maintaining the health of the mother and unborn child during pregnancy.''

The Department also finalizes provisions addressing the permissive nature of nondirective pregnancy counseling and the provision of information about pregnancy health.

[94] As discussed *supra* at I(A)(2)(c) Nondirective Pregnancy Counseling Permitted, Not Required and elsewhere in this preamble, such a requirement also raises issues under the Church, Coats-Snowe, and Weldon Amendments.

[95] 42 U.S.C. 300a–7.

The Department is simplifying this language and separating the requirements into enumerated subparagraphs of paragraph (b)(1) for clarity. The final rule, thus, specifies that referrals for prenatal care are required, because of its medical necessity due to pregnancy. Further, the Title X provider may also choose, but is not required to, provide nondirective pregnancy counseling, referrals to social services or adoption agencies, and information consistent with Section 1008 and appropriate post-conception activities under Title X regulation.

As discussed below, the Department also finalizes, as proposed, the final sentence in proposed paragraph (b) concerning cases that require emergency care as paragraph (b)(2).

The Department finalizes § 59.14(c) with changes in response to comments, including the consolidation of the two lists of comprehensive health care providers (from paragraphs (a) and (c) of the proposed rule) into one list and the addition of the requirement that the list and project staff not identify which providers on the list, if any, perform abortion.

The Department finalizes § 59.14(e), which sets forth examples illustrating the rules described in paragraphs (a) through (d), with changes consistent with the changes to those subsections.

Comments: Many commenters oppose the list of providers that may be shared with pregnant patients who request abortion. Commenters believe the list lacks necessary detail, may be difficult to understand for some patients, and difficult to implement for some providers because of the lack of comprehensive service providers who also provide abortion in their community.

Other commenters oppose the fact that the list may include some health providers that perform abortions, contending that Title X projects should not provide women seeking abortion with any list of providers that perform abortion. They contend providing such a list, or any information a woman may use to obtain an abortion, would violate section 1008 as it would make the project one ''where abortion is a method of family planning.'' Such commenters also contend providing such a list would constitute a referral for abortion. They point to the proposed rule, published by the HHS Office for Civil Rights in January 2018 to implement conscience laws such as the Weldon Amendment, defining referral as providing information that could provide assistance in obtaining a particular health care service. *See* 83 FR 3880, 3924 (Jan. 26, 2018).[96]

Several commenters contend that rule's description of two lists—one that may include abortion providers to be given to pregnant patients who want an abortion (described in § 59.14(a) and (c)), and another (described at the end of § 59.14(a)) that does not include abortion providers and that would be given to all other pregnant patients—is confusing and cumbersome for both the patient and the provider.

Other commenters object to the requirement that only doctors are permitted to give the list of providers to a woman seeking abortion described in § 59.14(a) and (c).

Some commenters assert that requiring referrals for pregnant patients to obtain prenatal and/or social services, regardless of the patient's wishes, violates the Congressional requirement that all Title X counseling be nondirective.

Many commenters present objections to the examples set forth in subsection (e) consistent with their objections to the requirements of subsection (a) that those examples illustrate.

Response: The Department agrees that it is appropriate to implement section 1008 to prohibit referrals for, and encouragement, promotion, advocacy, support, and assistance of abortion. The Department also agrees that, while nondirective pregnancy counseling is permissible in Title X projects by physicians or APPs, even if nondirective abortion counseling is provided among other options (so long as the counseling falls within parameters of the Title X statute and this regulation), abortion referral is inconsistent with the prohibition against funding Title X projects where abortion is a method of family planning.

The Department's approach to counseling is somewhat different than in the 1988 regulations, which, in addition to prohibiting abortion referrals, also prohibited ''counseling concerning the use of abortion as a method of family planning.'' In subsequent years, Congress has indicated that nondirective postconception counseling would be permissible, without requiring that any such counseling occur. It has done so through appropriations law provisions requiring that any pregnancy counseling offered in Title X projects be nondirective.[97] The Department believes these enactments make it appropriate for the Department to allow nondirective pregnancy counseling in Title X projects by physicians or APPs, even if the counseling includes nondirective counseling on abortion. Although Congress did not require projects to offer pregnancy counseling, a permissible interpretation of the statutory provision requiring that any such counseling be nondirective is that abortion may be discussed in a nondirective way. The Department believes that it would also be a permissible interpretation to conclude that, even without discussion of abortion, other nondirective counseling should be presented to the pregnant woman. In the absence of more specific direction from Congress in the nondirective counseling provision, the Department concludes that it is permissible to interpret the various statutory requirements for Title X so as to permit projects to provide nondirective pregnancy counseling, even if it involves counseling on abortion, as long as that counseling is truly nondirective.

As clarified by the direction given by Congress, nondirective counseling is consistent with the provision as analyzed in *Rust.* The 1988 regulations upheld in *Rust* stated a Title X project may not, among other things, ''provide counseling concerning the use of abortion as a method of family planning,'' ''provide referral for abortion as a method of family planning,'' ''encourage, promote or advocate abortion as a method of family planning,'' or ''use prenatal, social service or emergency medical or other referrals as an indirect means of encouraging or promoting abortion as a method of family planning, such as by weighing the list of referrals in favor of health care providers which perform abortions, by including on the list of referral providers health care providers whose principal business is the provision of abortions, by excluding available providers who do not provide abortions, or by 'steering' clients to providers who offer abortion as a method of family planning.'' *Rust,* 500 U.S. at 179–80 (*citing* 42 CFR 59.8(a)(1)–(3) (ed. 1988)). In upholding those provisions, the Supreme Court added that the Department may also prohibit ''abortion-related speech'' and ''abortion advocacy'' in a Title X project. *Rust,* 500 U.S. at 175. The language of this final rule, which at §§ 59.14(a) and 59.16(a) similarly prohibits a Title X project from referring for, promoting, supporting, encouraging, advocating for, or taking any other affirmative action to assist a patient to secure, abortion as a method

[96] That proposed rule has not yet been finalized.

[97] *See* Omnibus Consolidated Rescissions and Appropriations Act of 1996, Public Law 104–134, sec. 104, 110 Stat. 1321; HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat. 3070.

of family planning, is consistent with the provisions of the 1988 regulations that the Supreme Court upheld in *Rust.* Thus, the Supreme Court's conclusions upholding these provisions of the 1988 regulations would be equally applicable to this final rule and the permissions surrounding nondirective pregnancy counseling.

The Department has seriously considered the many comments offered regarding the two lists referenced in proposed § 59.14(a) and (c): One list required for pregnant clients generally, and another list permitted in the more specific circumstance where pregnant clients have decided to seek an abortion and request an abortion referral. The Department agrees that the proposal for two lists to be provided in two different and specific circumstances was potentially confusing and/or burdensome for projects which might be confused or unclear about how to develop and implement the lists. The proposed rule's duplicative description (in both paragraphs (a) and (c)) of the more specific list allowed when a client requests abortion may also have been confusing. And although the proposed rule attempted to describe, in more detail, how a project would respond to requests for abortion or abortion referrals, the Department concludes that description was also potentially confusing and is unnecessary in the final rule.

The Department is finalizing § 59.14(b)(1)(ii) to allow Title X providers to give a single list of providers to any pregnant woman. This list will contain licensed, qualified, comprehensive primary health care providers (including providers of prenatal care). At § 59.14(c), the Department consolidates and finalizes the description and requirements applicable to such list. The Department permits, but does not require, some providers on the list of comprehensive primary health care providers (including providers of prenatal care) to be providers that also provide abortion. The Department believes this will enable some projects to create a single list of comprehensive primary health care providers (including providers of prenatal care). For example, some service sites might find that the main provider of comprehensive primary or prenatal health care services is a hospital that also performs some abortions. At the same time, projects cannot create or distribute a list in which every provider (or a majority) on the list provides abortion. Projects, however, may compile their list so that no providers of abortion are on the list.

Because referrals for abortion as a method of family planning are prohibited, the list of comprehensive primary health care providers (including providers of prenatal care) that Title X projects and providers may provide to pregnant clients (and which may include abortion providers) cannot be used to indirectly refer for abortion or to identify abortion providers to a client. Thus, in the circumstance where a pregnant woman asks for an abortion or an abortion referral for family planning purposes, the project's response would be to say it does not refer for abortions, and then to offer her, if she desires, a list of comprehensive primary health care providers (including providers of prenatal care); that list could include (but not identify) such providers that also perform abortions.

The Department believes these limitations on the list of comprehensive primary health care providers (including providers of prenatal care), as well as the context in which the list would be provided, prevents distribution of that list from violating section 1008, even if some providers on the list also provide abortions. There are many potential reasons or purposes for a Title X provider to provide the list to a pregnant patient. If provision of the list is for a referral purpose, it must be for a permissible purpose, such as to refer the patient for prenatal care or for care of pre-existing maternal health conditions, not for the purpose of referring for abortion as a method of family planning. The final rule prohibits the list and project staff from identifying which, if any, providers on the list provide abortions. The Department, therefore, disagrees with some commenters who contend that including any abortion providers on a list of comprehensive primary and/or prenatal health care providers would render the project one ''where abortion is a method of family planning.''

In response to comments, the Department has decided to eliminate the requirement that a list provided specifically to women seeking abortion referrals be provided only by a doctor. Some commenters object to this requirement and note that the proposed rule did not require the list of prenatal care referrals, which was to be provided to all pregnant women, to be provided only by a doctor. Upon consideration of these comments, the Department has decided not to finalize any restriction on which personnel may provide the list to a pregnant patient. Any member of the Title X staff may provide the list, but only physicians and APPs may provide any nondirective pregnancy counseling.

In light of section 1008 and federal conscience laws, the Department has concluded it will not require Title X projects to offer nondirective counseling or information about abortion. The Department similarly will not require projects to offer nondirective pregnancy counseling on other subjects if they choose not to do so. Congress did not require that projects offer pregnancy counseling, but only that such counseling be nondirective, when/if offered. The Department concludes that the final rule should take a similar approach. Accordingly, this rule does not require a Title X project to offer abortion-related pregnancy counseling (or pregnancy counseling at all). When a project chooses to offer such pregnancy counseling, it must be nondirective. The clinic may offer referral services except that, given the statutory parameters set forth in Section 1008, a project is not permitted to provide referrals for abortion as a method of family planning.[98] As noted above, with respect to § 59.5(a)(5), this final rule rescinds the requirement of pregnancy options counseling from the 2000 regulations. This final rule neither requires nor prohibits pregnancy counseling (although pursuant to Congressional mandate, if such counseling occurs, it must be nondirective). Consistent with federal law (including the requirements of this final rule), Title X projects and providers must comply with all applicable laws concerning the practice of medicine and the offering of medical advice, as they may apply to the Title X project or provider that provides pregnant clients with nondirective pregnancy counseling, a list of comprehensive primary and prenatal health care providers, prenatal care referrals, assistance with setting up referral appointments, or information about pregnancy health.

Some commenters contend that providing prenatal care referrals violates Congress's requirement that pregnancy counseling be nondirective. The Department responds to this comment above in its discussion of referrals for prenatal care and adoption in § 59.2. Prenatal care is medically necessary for any patient who is pregnant, so referrals for such care do not render counseling directive. Moreover, the Department notes that low income women are more likely to deliver low birthweight babies

[98] Projects may permit each Title X clinic to make the decision whether it will provide each aspect of permissible counseling. The Department notes, however, that clinics, providers, and staff cannot be required to counsel on abortion if, for example, such activity would be contrary to their religious beliefs or moral convictions.

and to deliver before term, and less likely to access adequate prenatal care services. Yet prenatal care is one of 14 mandatory categories of Medicaid services and is deemed medically necessary for pregnant women. Because prenatal care is essential in order to optimize the health of the mother and unborn child, and to help ameliorate the current health inequality as it relates to low income women,[99] referring low income pregnant women for prenatal care is of increased importance.[100] Therefore, the Department adds additional clarity regarding referrals for prenatal care in an example in § 59.15(e)(1). The Department continues to believe that Title X projects are well situated to provide such referrals.

The Department does not, however, agree with the commenter who proposes that Title X providers are responsible for prenatal care. While the Department agrees that prenatal care is important to maternal and infant outcomes, and encourages Title X providers to provide comprehensive health care services onsite or through robust referral networks, the provision of postconception and pregnancy services (as distinct from information and referrals for them) are outside the scope of Title X.

Accordingly, the Department is finalizing this section as discussed to simplify and clarify the approach set forth in the proposed rule. Consequently, § 59.14(a) is finalized to prohibit Title X projects from referring for abortion, which includes ''any affirmative action to assist a patient to secure such an abortion.'' Section 59.14(b)(1) is also finalized to only require Title X projects to refer pregnant clients to a ''health care provider for medically necessary prenatal health care.'' Subsection (b)(1) also establishes that the Title X provider may also provide certain specified counseling and/or information to the pregnant woman. Finally, subsection (b)(2) establishes that, in cases requiring emergency care, referral is required ''to an appropriate provider of medical services needed to address the emergency.'' [101] Section 59.14(c) is finalized to establish that a Title X project may not use lists, referrals, or counseling ''as an indirect means of encouraging or promoting abortion as a method of family planning.'' Subsection (c) further establishes that while the list may include some providers who provide abortion services, ''[n]either the list nor project staff may identify which providers on the list perform abortion.''

The Department is finalizing the changes described above to reduce confusion, facilitate implementation of the rule, provide pregnant clients with counseling and information for prenatal care and information to promote the health of the mother and unborn child, and implement section 1008 to ensure Title X does not fund projects where abortion is a method of family planning. The Department also finalizes the examples in paragraph (e), with changes corresponding to the changes made in paragraphs (a) through (d).

3. Emergency Care and Medically Necessary Information (42 CFR 59.14(b)(2) and (d))

Summary of changes: In the last sentence of § 59.14(b), the proposed rule would require that, ''[i]n cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of emergency medical services.'' The Department finalizes § 59.14(b)(2), in response to comments discussed below, by replacing ''an appropriate provider of emergency medical services'' with ''an appropriate provider of medical services needed to address the emergency.''

At § 59.14(d), the proposed rule would provide: ''Provision of medically necessary information. Nothing in this subpart shall be construed as prohibiting the provision of information to a project client that is medically necessary to assess the risks and benefits of different methods of contraception in the course of selecting a method, provided that the provision of such information does not otherwise promote abortion as a method of family planning.'' The Department finalizes § 59.14(d) without change.

Comments: Some commenters object that the proposed rulemaking does not allow for medically necessary, but non-emergency, referrals for abortion. These commenters state that when maternal and child health outcomes will be compromised if a pregnancy is continued, or if appropriate treatment and services are delayed, referral for abortion is needed.

Several commenters express concern that the proposed language would allow providers to refer patients who need emergency care only to an emergency room, which may not be the best place for the patient. They assert that this will increase unnecessary emergency room use. Commenters ask the Department to clarify in the rulemaking that providers be allowed to refer the pregnant woman to the provider that is clinically appropriate for the patient.

Several other commenters request that the Department clarify the language in the proposed rulemaking regarding women who experience ectopic pregnancies and other life-threatening conditions related to pregnancy. They contend that the exception for ''danger of death'' should be included in the discussions of the Hyde Amendment. They contend this would assure that Title X providers have accurate information to be compliant and consistent among federal agencies.

Response: The Department disagrees with commenters contending that restrictions in the rule on referral and directive counseling affect situations concerning emergency or medically necessary care. Section 1008 prohibits funding for Title X projects where abortion is a method of family planning, and the final rule's restrictions on referral, promotion, or encouragement of abortion are similarly limited to abortion as a method of family planning. Referral for abortion because of an emergency medical situation does not fall into restrictions concerning abortion as a method of family planning. Paragraph (b)(1) of § 59.5 of the final rule makes clear that Title X grantees and subrecipients not only may, but must, provide for ''referral to other medical facilities when medically necessary.'' *See also* § 59.5(b)(8).[102]

The Department appreciates commenters who suggest that the final sentence in proposed § 59.14(b) limits referral to emergency rooms. The Department agrees with a commenter who stated that a hospital emergency room may not always be the most appropriate referral location and that the referral should be commensurate with the medical need. Because the text of the proposed rule would require only referral to ''an appropriate provider of emergency medical services,'' the Department finalizes this language with clarification to avoid confusion and to emphasize, ''[i]n cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of medical services needed to

[99] Tanya Nagahawatte and Robert L. Goldenberg, *Poverty, Maternal Health, and Adverse Pregnancy Outcomes,* 1136 Ann. N.Y. Acad. Sci. 80, 81 (2008), *https://www.ncbi.nlm.nih.gov/pubmed/17954684.*

[100] Rita Hamad and David H. Rehkopf, Poverty, Pregnancy, and Birth Outcomes: Earned Income Tax Credit, 29(5) Paediatr Perinat Epidemiol 444–452, Jul. 24, 2015. PMCID: PMC4536129.

[101] This sentence in § 59.14(b) is addressed in the immediately below section.

[102] As noted above, Title X projects and service providers must ensure that they do not, under the cover and pretext of providing such abortion referral, actually refer for abortion as a method of family planning. This is an area in which Title X projects can expect OPA monitoring and oversight, and should maintain appropriate records to support such referrals.

address the emergency.'' This language is intended to emphasize that it does not require that such referral be to an emergency room.

It is also not the intent of the regulatory provisions at § 59.14(b)(2) or § 59.5(b)(1) to restrict the ability of health professionals to communicate to a patient any information they discover in the course of physical examination (or otherwise) about her medical condition, such as an extant condition that might make her pregnancy high risk; to communicate an assessment of the urgency of the need for treatment; or to ensure that a patient is referred to the appropriate specialist for treatment of the condition, consistent with the exercise of his or her professional judgment and the parameters of the Title X program. The restrictions in these provisions solely concern abortion as a method of family planning. For this reason, the Department disagrees that these provisions of the final rule will increase medical liability, or will prohibit Title X projects from providing the factual information necessary to assess risks of a particular family planning or contraceptive method as set out in the patient package inserts.

As noted, at § 59.14(c), the final rule will also provide that a Title X project may not use emergency medical or other referrals as an indirect means of encouraging or promoting abortion as a method of family planning.

J. Maintenance of Physical and Financial Separation (42 CFR 59.15)

The proposed rule, at § 59.15, would require physical and financial separation of a Title X project or facility from prohibited activities (*e.g.,* abortion as a method of family planning).

The Department finalizes this section without change. The Department finalizes the compliance date for this section, as set forth in § 59.19, with changes in response to public comments, as discussed below.

Comments: Many commenters express support for the proposed financial and physical separation provisions and the Department's efforts to enforce the restrictions. These commenters agree that the proposed separation provisions will ensure statutory compliance with section 1008, eliminate potential confusion, and reduce the use of Title X funds for non-Title X services. One commenter adds that maintaining separate funds is a common requirement for federal grants and contracts. Another commenter states that, as upheld in *Rust* v. *Sullivan,* the Secretary is entitled to interpret Title X to include ''separate facilities.'' Several commenters point out that the proposed separation amendments are consistent with numerous State laws.

Many other commenters contend that the proposed financial and physical separation requirements and reduced flexibility of funds are illegal, not intended by Congress, burdensome, and unworkable. To begin, commenters claim that the Department fails to adequately justify why the change is necessary and argue that concerns about fungibility or possible co-mingling of funds are flawed. They assert that Title X already prohibits clinics from using federal funds to provide abortions and requires that funds used for abortion be kept separate, and that regular, extensive, and comprehensive audits currently are already used to enforce the existing rule. They contend that the 2000 regulations have successfully ensured separation compliance and that no additional measures are needed. They also contend that improving public education efforts so the public understands Title X funds cannot be used for abortion, would make physical separation unnecessary. These commenters urge the Department to withdraw the new separation requirement, or at a minimum, to provide clearer justifications for the requirement.

Some commenters focus on the possible burden and workability of the rule. They contend that the Department lacks evidence that the rules are feasible, particularly because the separation requirements in the 1988 regulations, which were nearly identical to the proposed rule here, were never fully implemented. They assert that the Department neglected to do adequate research and analysis of how the proposed changes would interact with various State laws, including laws that govern medical licensure and scope of practice. Some commenters state that a Department notice (Provision of Abortion-Related Services in Family Planning Projects, 65 FR 41281, 41282 (July 3, 2000)) allows Title X service sites to use common waiting rooms, staff, filing systems, and other resources and argue that changes to this approach would impair the family planning network by constraining certain providers' ability to participate in the Title X program. They state, for example, that many Title X grantees are hospitals that must be able to perform abortions in emergency situations and would not be able to afford separate infrastructure. Other commenters contend that the financial separation provisions would increase the cost of medical supplies and reduce grantees' ability to make cost-effective bulk purchases. Some commenters contend that 60 days from the date the final rule is published is insufficient time to accomplish the requirement of separate electronic health records. One commenter urges the Department to consult with a diverse group of Title X providers to calculate the monetary and time costs to comply with the proposed changes.

Some commenters contend that the rule will harm patient care. They state that, for women seeking both Title X services and abortion, the rule would require two separate visits to separate facilities because of effects of the restrictions on same-day post-abortion contraception. They claim that the need for two separate visits would create unnecessary costs and obstacles to care. Other commenters express concern that the new provisions would exacerbate health inequalities in terms of sexually transmitted diseases (STDs) among low income people affected by the loss of Title X providers. Some commenters state that the separation provisions undermine the objectives of integrated care and health systems. Similarly, many commenters argue that the requirement for separate electronic medical records (EHR) contradicts the principles of integrated, patient-centered medical care. They contend the financial separation requirement could lead to instances of missing or incomplete patient data and increased costs, as the same patient must have two separate medical records—one for Title X services and another for abortion services.

Some commenters raise other objections. One commenter, for example, expresses concern that the mandated physical separation would reinforce the notion that abortion is not a normal and legal part of health care. One commenter states that if the separation provisions force clinics that perform abortions to close, it would impede training for residents in obstetrics and gynecology. Another commenter expresses concern that requiring physical separation serves to highlight locations where abortion services are provided, which may increase the risk of those locations being the target of violent crime or protest. Several commenters object to the proposed signage requirements. Many other commenters object to the rule because, in their view, it gives the Department unrestricted authority to determine how to apply the separation requirements, while leaving Title X programs with insufficient guidance.

Finally, some commenters argue that mere physical and financial separation is not enough to ensure program integrity. They recommend Title X

clinics have distinctive names from clinics that offer abortions, distinct organizational entities, organizational headquarters, or unique signage and labeling on all Title X materials and service sites.

Response: The Department agrees with the commenters who support the rule and the Department's legal authority to require physical and financial separation. The rule is nearly identical to the policy set forth in the 1988 regulations, which was upheld by the Supreme Court in *Rust* v. *Sullivan.* 500 U.S. 173. After having reconsidered this issue, the Department's interpretation of section 1008 in the 1988 and 2000 regulations, and the public comments, the Department reaffirms its conclusions and its approach in the 1988 regulations with respect to physical and financial separation, as set forth in the proposed rule. The Department finds that the approach outlined in the proposed rule is in line with the Congressional mandate to separate Title X funds from those where abortion is a method of family planning. The Department finalizes that provision, with some changes discussed below.

In the 1988 regulations, the Department noted that it was requiring physical and financial separation because it found the regulations inadequate without that requirement, stating that the Department found, ''as a matter of experience with Title X, its responsibility to administer the program as provided by Congress, and its general administrative discretion, that the provisions of the current guidelines do not faithfully or effectively maintain the prohibition contained in section 1008.'' 53 FR at 2923. The 1988 regulations had several key features to address this deficiency and required compliance with the statutory prohibition. Among those, the regulations required grantees to separate their Title X project—physically and financially—from any abortion activities.

Those regulations were upheld on both statutory and constitutional grounds in *Rust.* 500 U.S. 173. The Supreme Court first rejected the claim that the regulations violated the Administrative Procedure Act. The Court concluded that—although the language of section 1008 did not directly prescribe physical and financial separation—the ''broad language of Title X plainly allows the Secretary's construction of the statute.'' *Id.* at 184. The Court declined to view the regulations skeptically merely because the agency had changed its view and reaffirmed the legal principle that ''[a]n agency is not required to 'establish rules of conduct to last forever,' but rather 'must be given ample latitude to 'adapt [its] rules and policies to the demands of changing circumstances.' '' *Id.* at 186–87 (internal citations omitted). The Court held the portions of the regulations mandating separate facilities, personnel, and records were ''based on a permissible construction of the statute and are not inconsistent with congressional intent.'' *Id.* at 188. On the contrary, the Court noted, ''if one thing is clear from the legislative history, it is that Congress intended that Title X funds be kept separate and distinct from abortion-related activities. . . . Certainly, the Secretary's interpretation of the statute that separate facilities are necessary, especially in light of the express prohibition of [section] 1008, cannot be judged unreasonable.'' *Id.* at 190. Accordingly, the Court ''defer[red] to the Secretary's reasoned determination that the program integrity requirements are necessary to implement the prohibition.'' *Id.*

The Court similarly rejected constitutional challenges to the regulations. As an initial matter, it upheld the statutory limitation of Title X funds to programs where abortion is not a method of family planning, concluding that ''[t]here is no question but that the statutory prohibition contained in [section] 1008 is constitutional'' because Congress ''may 'make a value judgment favoring childbirth over abortion and . . . implement that judgment by the allocation of public funds.' '' 500 U.S. at 192–93 (internal citations omitted; ellipsis in original). The Court explained that the requirement of physical and financial separation was also consistent with the First Amendment:

> By requiring that the Title X grantee engage in abortion-related activity separately from activity receiving federal funding, Congress has, consistent with our teachings . . . not denied it the right to engage in abortion related activities. Congress has merely refused to fund such activities out of public fisc, and the Secretary is simply requiring a certain degree of separation from the Title X project to ensure the integrity of the federally funded program.

Id. at 198. The Court held that the regulations did not violate any Fifth Amendment rights because the ''Government has no constitutional duty to subsidize an activity merely because the activity is constitutionally protected and [Congress] may validly choose to fund childbirth over abortion and 'implement that judgment by the allocation of public funds' for medical services relating to childbirth but not to those relating to abortion.'' *Id.* at 201 (internal quotations omitted). The Court, thus, held that the regulations ''are a permissible construction of Title X and do not violate either the First or Fifth Amendments to the Constitution.'' *Id.* at 203.

The Department carefully considered the issue of physical and financial separation in light of the statutory guidance of section 1008 and notes that it is similar to the 1988 regulations, which were upheld by the Supreme Court. The Department has reconsidered the 2000 regulations, which allowed the sharing of physical space so long as certain financial separation was maintained. The Department continues to hold with the 2000 regulations, to the degree it requires financial separation, that financial separation is a necessary condition to implementing section 1008, but it no longer believes financial separation is sufficient without physical separation. For the reasons discussed below, financial separation without physical separation does not sufficiently address the Congressional mandate that Title X funds be separate and distinct from abortion-related services.

The Department disagrees with commenters who contend it has not provided sufficient reasons or evidence to justify the physical and financial separation requirements. In *Rust,* the Supreme Court upheld imposing those requirements as a legitimate interpretation of the Congressional mandate in section 1008, and the Department continues to believe that the physical and financial separation requirements are in line with that mandate. 500 U.S. at 203. But the Department also believes that such separation would appropriately address certain concerns it has with the current arrangements in which physical separation is not required. First, under the current arrangement, it is often difficult for patients, or the public, to know when or where Title X services end and non-Title X services involving abortion begin. As the Department explained in the proposed rule, shared facilities create a risk of the intentional or unintentional use of Title X funds for impermissible purposes, the co-mingling of Title X funds, the appearance and perception that Title X funds being used in a given program may also be supporting that program's abortion activities, and the use of Title X funds to develop infrastructure that is used for the abortion activities of Title X clinics. Even with the strictest accounting and charging of expenses, a shared facility greatly increases the risk of confusion and the likelihood that a violation of the Title X prohibition will occur.

This concern is particularly acute in light of more recent evidence that abortions are increasingly performed at sites that focus primarily on contraceptive and family planning services—sites that could be recipients of Title X funds. A 2014 report from the Guttmacher Institute provides detail about the various types of facilities at which abortions are performed.[103] It notes that ''nonspecialized clinics''—*i.e.,* ''nonhospital sites in which fewer than half of patient visits are for abortion services,'' including physicians' offices—may provide 400 or more abortions per site per year.[104] The report notes that, ''[w]hile many of these [nonspecialized] clinics primarily serve contraceptive and family planning clients, about half provided 400 or more abortions per year.'' [105] It defines ''abortion clinics'' as ''nonhospital facilities in which half or more of patient visits are for abortion services, regardless of annual abortion caseload.'' [106] According to the Guttmacher Institute, nonspecialized clinics accounted for 24% of all abortions in 2008; [107] 31% in 2011; [108] and 36% in 2014.[109] In addition, nonspecialized clinics represented 26% of abortion providers in 2008; [110] 30% in 2011; [111] and 31% in 2014.[112] Further, despite a 3% drop in the total number of abortion facilities between 2011 and 2014, the number of abortion clinics dropped by 17%, while the number of nonspecialized clinics performing abortions remained stable.[113] The performance of abortions at nonspecialized clinics that also may provide Title X services increases the risk and potential both for confusion and for the co-mingling or misuse of Title X funds.

Together, these circumstances create a risk of intentional or unintentional misuse of Title X funds and have created public confusion over the scope of Title X services, about whether Title X projects provide abortion services, and about whether federal taxpayers fund abortion services provided by organizations that are grantees (or subrecipients) of Title X grants/funds. The Department believes that such potential co-mingling and confusion provides sufficient supporting evidence, in addition to the Department's rationale for physical and financial separation upheld in *Rust* (which the Department also adopts now), that the 2000 Regulations neither adequately reflect nor ensure compliance with the text and purpose of section 1008. It is generally the Department's view that, if it is difficult to distinguish Title X activities from non-Title X activities, then adequate physical separation has not been achieved.

As discussed above, the Department interprets section 1008 to require Title X project activities to be separate and distinct from prohibited activities (*e.g.,* abortion as a method of family planning). Thus, the Department finalizes the proposed text of § 59.15 so that, when a grantee or subrecipient conducts abortion activities that are not part of the Title X project, and would not be permissible if they were, the grantee must ensure that the Title X-supported project is separate and distinguishable from those other activities.

The Department disagrees with comments opposing the requirement of physical separation on the basis that other means exist to achieve same goals of the proposed rule while still allowing the Title X project and a program engaged in prohibited activities to occupy the same physical space. The Department considered other alternatives to physical separation. For example, it considered whether signs or brochures could be posted to indicate distinctions between the Title X project and Title X prohibited activities, or whether separate staff and examinations rooms within the same area in the facility could sufficiently delineate a separation between the Title X project and abortion-related services. The Department has determined, however, that a shared reception area with materials available on both Title X family planning services and abortion-related services would not resolve the confusion, but could allow it to continue. Signage is often not read, and the segregation of staff or staff responsibilities would not, in the Department's view, provide sufficient distinction to end confusion. Single facilities often have staff fulfilling distinct roles without making the program itself separate. Patients might not be aware of the distinction made between different examination rooms if the entrance and reception area is shared in common, especially in a smaller facility. The optics and practical operation of two distinct services within a single collocated space do not sufficiently create the separation Congress intended when it said Title X funds cannot be spent ''where'' abortion is a method of family planning. As in its 1988 regulations, the Department interprets section 1008 to require clear physical separation between Title X projects and places ''where'' abortion is offered as a method of family planning.

The Department agrees that educational efforts to help the general public understand the services provided by Title X as well as those not provided by Title X, would be beneficial and will be considered by the Department. The Department believes that public educational efforts could augment the requirement for physical separation and contribute to more accurate public perception. But such efforts do not negate the need for clear and understandable separation between Title X services and abortion services at the clinic level. Physical separation assists with statutory compliance, in addition to improving public perception, by ensuring that both intentional and unintentional comingling of resources, activities, and services do not take place in ways that are exacerbated when both services are housed in the same space.

The final rule seeks to reduce, and potentially eliminate, any confusion—actual or potential—as to the scope of services supported by Title X funds by requiring funded projects to maintain clear physical and financial program separation from programs that use abortion as a method of family planning. The Department believes the rule will create a clearer and more transparent system of separation and accountability, similar to that established by the 1988 regulations and affirmed in *Rust.* It will also help assure fidelity to the text and purpose of section 1008 and facilitate auditing and enforcement of program requirements. The rule does not, however, restrict the use of non-Title X funds outside the Title X program, nor does it impose restrictions on funds provided by other federal programs.

The Department disagrees with commenters who contend that, because the Department did not have sufficient

[103] Rachel K. Jones and Jenna Jerman, *Abortion incidence and service availability in the United States, 2014,* 49 Guttmacher Institute Perspectives on Sexual and Reproductive Health 17, 19 (2017), *https://www.guttmacher.org/journals/psrh/2017/01/abortion-incidence-and-service-availability-united-states-2014.*

[104] *Id.* at 19.

[105] *Id.* at 20.

[106] *Id.* at 19.

[107] Rachel K. Jones and Kathryn Kooistra, *Abortion incidence and access to services in the United States, 2008,* 43 Guttmacher Institute Perspectives on Sexual and Reproductive Health 41, 46 (2011), *https://www.guttmacher.org/sites/default/files/pdfs/pubs/psrh/full/4304111.pdf.*

[108] Rachel K. Jones and Jenna Jerman, *Abortion incidence and service availability in the United States, 2011,* 46 Guttmacher Institute Perspectives on Sexual and Reproductive Health 3, 6 (2014), *https://www.guttmacher.org/sites/default/files/article_files/abortion_incidence_in_the_united_states_2011.pdf.*

[109] *See* Jones 2017, supra at 20.

[110] *See* Jones 2011, supra at 46.

[111] *See* Jones 2014, supra at 6.

[112] *See* Jones 2017, supra at 20.

[113] *See* Jones 2017, supra at 20.

opportunity after several years of litigation to put the 1988 regulations into effect before a new administration chose not to implement them, the Department may not implement essentially the same rules now. When the Supreme Court upheld the 1988 regulations, the Court held it was legally permissible for the Department to put them into effect. Nothing in the Administrative Procedure Act precludes the Department from re-adopting regulatory provisions that it had previously adopted, successfully defended in court, and then rescinded.

Commenters contend that the Department should have conducted more research regarding State laws, and regulation implementation costs by interviewing Title X providers. However, the number or administrability of State laws cannot take precedence over the statutory requirements of the federal Title X grant program. Additionally, the large volume of responses submitted within the 60-day comment period verifies that this process was sufficient for organizational and State stakeholder responses, both of which the Department received and carefully considered.

With respect to the contention of some commenters that the physical and financial separation requirements will destabilize the network of Title X providers, the Department disagrees. The rule continues to allow organizations to receive Title X funds even if they also provide abortion as a method of family planning, as long as they comply with the physical and financial separation requirements. The rule also allows case-by-case determinations on whether physical separation is sufficiently achieved to take the unique circumstances of each program into consideration. As is true for all program requirements, the Department welcomes regular interaction with grantees and subrecipients, should they have questions. Project officers are available to help grantees successfully implement the Title X program in compliance with both the statute and the regulation. The Department encourages grantees to contact the program office with questions, discuss ways to comply with the physical separation requirement, and put a workable plan in place to meet the compliance deadline. Moreover, the Department will not require compliance with the physical separation requirements of § 59.15 until one year after this final rule is published in the **Federal Register**. This will give grantees and subrecipients time to make arrangements to comply with physical separation requirements if they choose to seek Title X funds (or to participate in a Title X project) and also offer abortions as a method of family planning. Other provisions of the rule encourage additional entities to apply for Title X grants and additional individuals and institutions to participate in the Title X program. If certain grantees and/or subrecipients choose not to continue in the Title X program because they elect not to comply with the physical separation requirements in § 59.15 in one year, the Department will be in a position to continue to fulfill the purpose of Title X by funding projects sponsored by entities that will comply with the physical separation requirement and provide a broad range of family planning methods and services to low income clients. In several locations, there are already competing applicants to serve the same region. The Department believes that, overall, the final rule will contribute to more clients being served, gaps in services being closed, and improved client care that better focuses on the family planning mission of the Title X program.

Commenters' insistence that requiring physical and financial separation would increase the cost for doing business only confirms the need for such separation. If the collocation of a Title X clinic with an abortion clinic permits the abortion clinic to achieve economies of scale, the Title X project (and, thus, Title X funds) would be supporting abortion as a method of family planning. Put differently, the abortion clinic would be benefiting from the presence of the Title X project in the same location. Moreover, it would be the participation of the Title X project in bulk purchases and other economies of scale that enables the abortion clinic to achieve economies of scale. Such an argument makes the case that comingling of funds between Title X and abortion services is difficult to avoid without a physical and financial separation between the two.

The final rule does not prevent a woman from seeking and obtaining an abortion. It simply draws a bright line between permissible services provided with Title X funds and prohibited abortion services. The Department, thus, disagrees with commenters who contend the rule should not be finalized because women might need to make separate visits if they seek both Title X services and abortions from a Title X provider. Congress chose to restrict the use of Title X funding in section 1008, and the Supreme Court held in *Rust* that the requirement of physical and financial separation is not an impermissible imposition on any Fifth Amendment right concerning abortion.

Moreover, for the reasons discussed above, the Department does not anticipate any loss of Title X providers that will exacerbate health inequalities or harm patient care. The Department anticipates that the rule, overall, will contribute to more clients being served and gaps in services being closed. In response to commenters who contend more time is needed than the proposed 60 days to implement aspects of § 59.15 other than physical separation, such as factors concerning separate signs and other forms of identification in paragraph (d), or factors concerning the requirement for separate electronic health care records in paragraph (c), which commenters say would require separate Electronic Health Record (EHR) systems, the Department disagrees. The Department notes that EHR systems would be considered part of the physical separation requirement. The Department found that approximately 80% of the 4,000 Title X sites were using an electronic practice management system in 2016, with about 70% using the more advanced EHR system.[114] For those with an EHR system, the implementation of a new site within the same system should take significantly less time than the one year provided in the final rule. In addition, depending upon the EHR system, it may not be necessary to acquire a new EHR license at all. While some EHR systems include integrated administrative or financial accounting systems, that is not the universal practice. Moreover, although some EHR systems can generate separate financial reports, as well as a variety of other useful information for the Title X program, current grantees should already maintain financial separation, so whether such separation is accomplished through an EHR system or another means, this rule should not impose additional burden on the provider.

Although the proposed rule does not identify these factors as such, factors (b)–(d) are factors that help determine whether there is physical separation (the degree of separation from facilities; existence of separate personnel, electronic or paper-based health records, and workstations; and the extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent). Accordingly, the 1-year compliance date applicable to physical separation will apply to them. Factor (a) (separate, accurate accounting records)

[114] OPA, 2016 Sustainability Assessment: The Title X program (Feb. 2017).

relates to financial separation. In light of those concerns, the Department is finalizing § 59.19's transition provisions so that the physical separation requirements of § 59.15 will have a compliance date (by which covered entities must comply with the physical separation requirements of the section) of one year after publication in the **Federal Register**. The financial separation requirements of § 59.15 will have a compliance date of 120 days after publication in the **Federal Register**. During that transition period, Title X projects will still be required to comply with the financial separation requirements of the 2000 regulations, and accompanying guidance that the Department has published concerning financial separation. Title X projects may transition to compliance with the physical and financial separation requirements of § 59.15 prior to the respective compliance dates if they choose to do so.

Regarding the remaining comments, the Department rejects the comment that it should not finalize the rule because physical separation reinforces the notion that abortion is not a normal part of health care. It is Congress that singled out abortion as an impermissible activity for Title X projects when it specified that it will not fund Title X projects where abortion is a method of family planning.[115] The Department is merely implementing that determination by Congress in a legally permissible manner by determining that there should be physical separation between Title X projects and abortion as a method of family planning.

The Department likewise rejects the suggestion that the rule will impede training for residents in obstetrics and gynecology because the rule will force abortion clinics to close. This final rule does not require clinics that perform abortions to shut down; it only requires that Title X programs maintain physical and financial separation from any provision of abortion. Residents in obstetrics and gynecology will be able to continue their training on family planning methods and services in Title X clinics or at other clinics that provide abortion services. Such training is not impeded by this final rule.

Although the Department takes seriously the concerns raised about potential violence to locations where abortion services are provided, the Department views those concerns as misplaced objections to this rule. Congress chose not to use Title X funds to support programs where abortion is a method of family planning, and the Department has determined that a clear separation between Title X projects and locations offering abortion services is the most appropriate means of implementing that requirement. In order to comply with statutory program integrity provisions to separate Title X funds from facilities where abortion is a method of family planning, the Title X project should not be intermixed with such abortion services. The Department believes that having signs and other forms of materials referencing or promoting abortion present together with Title X materials will confuse the patient regarding what Title X allows. In addition, the Department believes clinic signs must be clear in identifying Title X services versus abortion services. All such requirements avoid confusion regarding what are Title X services and what are not Title X services. Congress has separately provided protections for locations offering abortion services. *See, e.g.,* 18 U.S.C. 248.

Title X authorizes the Secretary to promulgate regulations governing the program. 42 U.S.C. 300a–4. The Department has exercised this authority through regulations to guide Title X grantees in carrying out the program. The Department disagrees with commenters who assert that Title X programs have insufficient guidance on how to apply the physical and financial separation requirements. The Department has included the factors it considers for physical and financial separation of Title X project or facility from prohibited activities in § 59.15. The Department will also take individual circumstances into consideration. For example, a Title X service site might be a hospital that also performs some abortions. However, there is likely less chance of confusion between the hospital's family planning services and abortion services. There are many and diverse centers within the hospital, often in different locations within the hospital building or complex, with different entrances, signage, waiting rooms, and protocols. In addition, it is highly unlikely that a Title X clinic and abortion facilities would be collocated within a hospital building or complex. As long as the Title X clinic and the hospital facilities where abortions are performed are not collocated or located adjacent to each other within a hospital building or complex, it is highly likely that the hospital is not violating the requirement that there be physical separation between the Title X funded activities and activities related to abortion as a method of family planning. By contrast, in a free-standing clinic, physical separation might require more circumstances to be taken into account in order to satisfy a clear separation between Title X services and abortion services. A free-standing clinic would likely present greater opportunities for confusion between Title X and abortion services, including, for example, the same entrances, waiting rooms, signage, examination rooms, and the close proximity between Title X and impermissible services.

The Department does not believe that the physical and financial separation requirement will lead to the mishandling of patient data, as some commenters suggest. Separate EHR systems may lead to two separate electronic medical records, but that is no more burdensome than if the clinic only offers specific services and the patient needs to go to a separate clinic for other needed health care services. It is not uncommon for people to have different health care providers for different health care needs. If Title X services and abortion services are separate, it is no more difficult for Title X providers to maintain two electronic records, one for Title X services and another for abortion services, than to keep abortion services and other services separate within the same EHR system. Moreover, because of growing interoperability of EHRs and other health IT, it is a simpler matter for one provider to share a patient's EHR with another provider—thus, any risk associated with mishandling or missing patient data should be minimized.

Finally, the Department has considered comments on whether the rule should also require, not just physical and financial separation between Title X projects and programs where abortion is a method of family planning, but also organizational separation, and/or provisions such as a requirement that a Title X clinic must operate under a distinct name from a facility that provides abortion as a method of family planning. After considering all the comments and balancing the Department's need to transition to and implement the proposals it is finalizing in this rule, the Department has concluded that, at this time, it will not finalize this rule to add a requirement of organizational separation or name separation, beyond the requirement for physical and financial separation.

[115] It is also Congress that prohibits the use of Title X funds to pay for any abortions and the use of other federal funds to pay for abortions, except in cases of rape, incest, or where the life of the mother is endangered unless an abortion is performed.

K. Prohibition on Activities That Encourage, Promote or Advocate for Abortion (42 CFR 59.16)

Summary of changes: In the first two sentences of proposed § 59.16(a), the proposed rule would require that ''[a] Title X project may not encourage, promote or advocate abortion as a method of family planning. This restriction prohibits actions to assist women to obtain abortions or to increase the availability or accessibility of abortion for family planning purposes.'' The Department finalizes the title and first two sentences of proposed § 59.16(a) as § 59.16(a)(1), with a change to clarify, in response to comments, that the prohibitions apply in the Title X project, not to a grantee's or subrecipient's activities outside of the Title X project and with respect to abortion as a method of family planning, as explained above in response to comments discussed in the section of the preamble addressing § 59.14(a).

The proposed third sentence, and paragraphs (a)(1) through (6), of § 59.16 would specify that the prohibitions include various activities. Paragraph (b) gives examples to illustrate how the proposed prohibitions and specific items listed in § 59.16(a) would apply.

The Department finalizes the third sentence, and paragraphs (a)(1) through (5), of § 59.16 without change, except for formatting changes to improve readability, as § 59.16(a)(2)(i) through (v). The Department finalizes paragraph (a)(6) of the proposed rule in § 59.16(a)(2)(vi), as modified in response to comments. The Department finalizes § 59.16(b)(2) and (3) with changes for clarity in response to comments, as discussed below, and otherwise finalizes § 59.16(b) without change.

Comments: In the discussion of § 59.14(a), the Department addressed comments concerning prohibitions on referral for, and encouragement, promotion, advocacy, support, and assistance of abortion. The Department does not repeat those comments and responses here to the extent they overlap with the comments concerning the specific actions listed in paragraphs (a)(1) through (6) of § 59.16, or the examples explained in paragraph (b).

The Department received various and conflicting comments about its legal authority to enact this section. Some commenters argue the Department is exceeding its statutory authority by impermissibly limiting providers' non-Title X activities and by limiting speech and activities by defining such activities as lobbying. Some of these commenters assert the Department does not adequately explain why the prohibitions on advocacy, lobbying and political activities are justified, stating that it is unreasonable to impose the cost of complying with the proposed rule with no justification. Other commenters contend the proposed rule sufficiently protects free speech by prohibiting the encouragement, promotion or advocacy of abortion by Title X projects but not outside of those projects. These commenters further defend the proposed rule on First Amendment grounds by supporting the Department's rescission of the paragraph in § 59.5 that required Title X providers to counsel on, and refer patients for, abortion.

Some commenters state that the proposed language in § 59.16 is vague, making it difficult to discern what is permissible under the proposed rule, causing confusion, and leading to a prohibitory effect on activities paid for with non-Title X funds. Some of those commenters state that the vagueness may lead to decreased participation in the program or the exclusion of qualified providers, reducing access to care for many patients. Some commenters contend that, to comply with the restriction not to pay affiliation dues or disseminate materials with non-Title X funds, grantees would need separate facilities, and this would lead to the isolation of family planning centers that receive Title X funding, limitations on access, and decreases in the quality of care.

Other commenters oppose the section as unnecessary, arguing that Title X grantees already receive sufficient guidance on what is and is not a permissible use of funding, and that the Department has power without this rule to remedy any findings of noncompliance.

Still other commenters support the proposed rule, and assert that the Department should add additional activities to § 59.16, activities that would be considered as promoting abortion. They ask the Department to provide a wider list of prohibited activities in order to avoid confusion. One commenter provided a list of additional activities that should be prohibited.

Multiple commenters express concern about the proposed rule's impact on State law. For example, commenters write that § 59.16 is not consistent with California's Reproductive Privacy Act and Healthy Youth Act. Some commenters contend that, in New York, organizations that can apply for funding through Title X are already prohibited from funding or engaging in any kind of lobbying activities, rendering this section unnecessary.

Response: As noted above, the Department has slightly modified § 59.16(a) to more clearly explain it applies to actions undertaken within the Title X project, not actions and speech undertaken by Title X grantees (and subrecipients) outside the Title X project. This, and the discussion above, of the Supreme Court's rejection of First Amendment challenges to the 1988 regulations, which had substantially the same provisions, adequately addresses commenters concerns that § 59.16 fails to adequately protect free speech. The Department clarifies again that nothing in this rule restricts the use of non-Title X funds.

In *Rust* v. *Sullivan,* the Supreme Court upheld similar regulations ''broadly prohibit[ing] a Title X project from engaging in activities that 'encourage, promote or advocate abortion as a method of family planning.'' *Rust,* 500 U.S. at 180. As in this rule, the general prohibition was followed by a list of prohibited activities that included, with respect to abortion as a method of family planning, ''lobbying for legislation that would increase [its] availability,'' ''developing or disseminating materials advocating'' it, ''providing speakers to promote'' it, ''using legal action to make [it] available in any way,'' and ''paying dues to any group that advocates'' it. *Id.* The Court concluded a prohibition on such activities is within the Secretary's discretion in implementing section 1008. *Id.* at 184–87. The Court further concluded such conditions did not violate either free speech principles under the First Amendment, or women's rights under the Fifth Amendment. *Id.* at 192–200, 200–203.

The Department concludes that § 56.16 of the final rule does not violate the First Amendment's protections for the same reasons that the Supreme Court held that the 1988 regulations withstood First Amendment challenges in *Rust.* Both this rule and the rule upheld in *Rust* entail the same basic prohibition on encouraging, promoting, and advocating abortion as a method of family planning within the scope of the Title X project, while leaving Title X providers free to undertake any activity they desire outside the scope of the Title X project. This rule contains many of the same illustrations of activities that fall within the prohibition. The list of activities included in the 1988 regulations was non-exclusive, using the same language set forth in this final rule that ''[p]rohibited actions include'' various specific activities. The proposed rule adds some additional examples to those set forth in the 1988 regulations, namely the development of materials

that promote a favorable attitude towards abortion, a reference to web-based materials in that context, and the addition of ''educators'' to the prohibition on ''speakers'' that promote abortion as a method of family planning. Those examples are well within the reasoning of *Rust,* and indeed within the broad prohibition of the 1988 regulations. However, the Department is removing the phrase regarding a prohibition on the use of Title X funds for the production of materials that ''promote a favorable attitude towards abortion.'' The Department makes this change in acknowledgement of some of the commenters who contend the section is vague and subjective, so that it would be difficult for grantees to know what would be a permitted activity and what would constitute an impermissible activity. The Department agrees that the phrase is vague, and believes that prohibiting materials that promote abortion as a method of family planning is clear and sufficient. This final rule also includes some examples prohibiting project funds from being used on lobbying, specifically the use of project funds for attendance at events and conferences where the grantee or subrecipient engages in lobbying, and the restriction on payment of dues to a group that does not separately collect and segregate funds used for lobbying purposes. These clauses implement the specific Congressional prohibition that Title X project funds ''shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.'' [116] As proposed, § 59.16(a)(4) would prohibit ''[p]aying dues to any group that, as a more than insignificant part of its activities, advocates abortion as a method of family planning and does not separately collect and segregate funds used for lobbying purposes.'' The Department considers this provision concerning lobbying to be an appropriate measure to implement Congress's prohibition on the use of Title X funds ''in any way'' for lobbying. [117] As noted above, the Department finalizes this text, and makes corresponding changes to the examples in § 59.16(b)(2) and (3).

The Department appreciates commenters' suggestions of additional activities that should be included in § 59.16(a) as actions that cannot be undertaken in Title X projects, but declines to add to the list of actions in § 59.16(a). The regulatory text indicates that the list is non-exhaustive and that prohibited actions ''include'' the actions listed; it does not indicate that those actions listed are the only actions that fall under the prohibition on encouragement, promotion, or advocacy of abortion as a method of family planning.

The Department disagrees with commenters who contend the provisions will have the effect of pushing providers out of the Title X program, and, therefore, that § 59.16 will have a negative impact on access to care. Much of § 59.16 merely implements the applicable appropriations law provisions; thus, Title X projects should not currently be using Title X funds to engage in such activities. To the extent that § 59.16 incorporates new requirements, the Department concludes that the articulation of those requirements in rulemaking after notice and public comment is an appropriate approach to ensure consistency and compliance with the parameters applicable to Title X. But in any event, nothing in the final rule precludes entities that encourage, promote, or advocate abortion from being grantees or subrecipients, if such activities are undertaken outside the scope of the project and consistent with the physical and financial separation requirements of these rules. Because section 1008 precludes projects where abortion is a method of family planning, if entities are encouraging, promoting, or advocating such abortions within a project, they are diverging from the goals of Title X. By ensuring that Title X project funds are not diverted to activities that encourage, promote or advocate abortion as a method of family planning, or that assist women to obtain abortions for family planning purposes or to increase the availability or accessibility of abortion, the Department anticipates that more project funds will be available to provide the family planning services that Congress intends in its focused approach to Title X's scope.

The Department does not agree that this rule inadequately considers the requirements of State laws. The rule represents implementation of a clear choice by Congress not to fund certain activities in Title X projects. Applicants for Title X funding will need to maintain an awareness regarding State and local laws to which they are subject, as well as the requirements to which they are subject under this final rule.

The Department finalizes the example in § 59.16(b)(2) with a clarifying change. The proposed rule provided a proposed example that established a Title X project violates paragraph 59.16(a) if it makes an appointment with an abortion clinic for a pregnant client. The Department clarifies this example to be more consistent with section 1008 of the PHS Act, which prohibits funding a Title X project where abortion ''is a method of family planning.'' Consistent with that language, as noted above and in the second sentence of § 59.16(a), the provisions of this rule implementing section 1008 apply to ''abortion for family planning purposes.'' Therefore the Department finalizes the example listed in § 59.16(b)(2) to specify that the scenario in question is one where ''[a] Title X project makes an appointment for a pregnant client for an abortion for family planning purposes . . .'' The Department also makes a change to the example in § 59.16(b)(3), so that it illustrates more directly the activity prohibited in § 59.16(a)(2)(iv), by incorporating into the example information about whether the lobbying funds were separately collected and segregated.

L. Compliance With Reporting Requirements (42 CFR 59.17)

Summary of changes: The proposed rule would add § 59.17, which imposes requirements concerning compliance with State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence (IPV) or human trafficking. The Department finalizes this section with changes in response to public comments to clarify notification, screening of minors, and recordkeeping relating to minors; and to expand related topics to be covered in annual staff training.

Comments: Some commenters express support for increased compliance requirements of § 59.17(a) and contend that providing evidence of compliance with all State and local laws would strengthen protection for minors and vulnerable adult populations. Some argue that some Title X entities enable sexual exploitation by failing to institute compliance procedures with State and local laws that would help victims, and they request an investigation into Title X entities to determine the extent of failed abuse reporting. Several commenters favor expanding reporting requirements to include reporting of general criminal conduct unrelated to acts of sexual abuse.

[116] *See* Omnibus Consolidated Rescissions and Appropriations Act, 1996; HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat at 3071.

[117] Title X funds ''shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.'' HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat. at 3071.

Many commenters state that the proposed rule wrongly gives the Department compliance oversight over State and local reporting laws. Several commenters contend that mandated reporting of intimate partner violence (IPV) would prevent patients from speaking candidly with health care providers for fear that their abuse will be reported before they have had the opportunity to protect themselves (and their children, if applicable) financially, legally, and physically from their abusers. Commenters mention that medical records documenting IPV and other abuse issues can be used in legal contexts, putting patients at risk for further violence.

Many commenters note the complexity and variety of State and local reporting laws. Several commenters emphasize that there must be a balance between the protection for victims of abuse, complying with State laws, and trust in the patient-provider relationship. Several commenters note that State laws already include specific requirements that provide clear direction to health professionals regarding their obligations to report and their responsibility to exercise discretion. One commenter argues that federal and state laws should support physicians in their clinical judgment. Other commenters contend that allegations of providers avoiding reporting responsibilities are without evidence and should not be a basis for policy-making.

In reply to the Department's request for comment on whether a referral agency (to which a Title X project refers) should be subject to the same reporting requirements as a grantee or subrecipients subject to § 59.17, some commenters state there is no need for a referral agency to be subject to the same reporting requirements as a grantee or subrecipient. Several commenters state that community partners and referral agencies are not Title X funded entities, are often overburdened and additional requirements may cause referral agencies to terminate collaborative relationships rather than comply with the new reporting requirements, thereby reducing patients' access to health care.

Some commenters contend that Department enforcement of the provisions of § 59.17(b), including the threat of revocation of funding based on whether providers comply with State and local reporting requirements, would increase pressure on Title X projects to over-report abuse and to engage in ''excessive policing,'' thus traumatizing patients through interrogative questioning. They also contend the rule would erode patient-provider trust, put patients at risk for serious harm, re-victimize patients that have experienced trauma, stigmatize patients that are sexually active, and negate personal agency for adolescents.

Many commenters contend that mandatory screening raises issues regarding confidentiality for adolescents and minors, noting that the Title X protections for patient confidentiality are some of the strongest under current law.

A few commenters mention that the proposed rule would result in increased cost for screening and reporting, specifically noting the transition to electronic health record templates. A few commenters note that this would lead to decreased care and family planning options for patients, resulting in increased costs for unintended pregnancies.

Many commenters fear, in particular, that screening minors with a sexually transmitted disease (STD), pregnancy, or suspicion of abuse would be harmful to patients and detrimental to the provider-patient relationship, compromising trust and honesty in consultations. Many argue that mandated screening would shift the provider role to that of an interrogator, making young people less likely to reveal abuse, and making them less likely to return to the Title X facility. One commenter argues that the age of a teenager's sexual partner does not have bearing on family planning services. Others contend that mandatory screening would deter patients from seeking family planning services and treatment for STDs, resulting in increased pregnancy and STDs.

Other commenters assert that screening should only be required for patients that show signs of abuse. Commenters argue that the screening is unnecessary, as Title X grantees already are mandated to adhere to Federal and State notification requirements. Some commenters note that the proposed rule may conflict with Medicaid coverage, which permits confidential family planning services for individuals of childbearing age, suggesting that it creates confusion as to who must be screened.

Several commenters support a commitment to confidentiality, but also support the new rules as an important safeguard for minors who may be the victims of sexual abuse. One commenter recommends that projects be required, rather than permitted, to diagnose, test for, and treat STDs.

Finally, some commenters describe instances in which they claim the language of the proposed rule is confusing. For example, they contend that required screening for patients ''under the age of consent in the State'' is inconsistent with the requirement for Title X projects to implement a plan committing to preliminary screening of teenagers with a sexually transmitted disease (STD), pregnancy, or any other suspicion of abuse. Such commenters suggest the language be re-written to clarify the intent.

Response: The Department agrees with commenters who voice support for § 59.17 to ensure those vulnerable to abuse are protected in Title X projects. The Department takes seriously the duty of Title X grantees and subrecipients to comply with State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking. Congress has specifically emphasized the importance it attaches to compliance with such laws by Title X funding recipients. As stated in the most recent appropriations act, ''[n]ot withstanding 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.'' [118] The Department interprets that direction to include State or local laws respecting intimate partner violence (IPV) and human trafficking. In addition, the Secretary has authority under section 1006 of Title X to issue regulations governing grants and contracts in the Title X program. Thus, to ensure compliance with this Congressional mandate, the Department believes it is appropriate to include specific regulatory requirements with respect to the care and treatment of survivors of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence and human trafficking within the context of the provision of family planning services, and the reporting or notification of such criminal acts under State and local notification laws in § 59.17. The Department disagrees with commenters who assert that the Department does not have the authority to oversee compliance with reporting the listed crimes by Title X providers in Title X projects.

The Department understands the sensitivity that comes with IPV, but concludes that, if a State or local jurisdiction has enacted laws to require reporting of IPV by entities that are Title X grantees or subrecipients, it is appropriate for the Department to ensure that such entities comply with

[118] HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 208, 132 Stat. at 3090.

those laws as a condition of receiving Title X funds. Title X providers may be the first health care touchpoint for the survivors of IPV. As such, they should be prepared and trained not only to treat such individuals with dignity and care in addressing such individuals' family planning needs, but also to refer them for other needed health care and to report such IPV to the appropriate authorities. State and local reporting laws that include IPV do so, among other reasons, because of its connection to poverty, because most IPV victimizes women, and because intimate partner homicides make up 40% to 50% of all murders of women in the United States.[119] Moreover, IPV may include rape, sexual abuse, and/or other crimes expressly addressed in the Title X appropriations provision. The Department considers these reasons sufficient to include IPV in the reporting requirements of this rule.

The Department acknowledges that complying with State and local laws may be complicated, and for that reason Title X grantees and subrecipients must have in place a plan that ensures that the grantee and any subrecipients are aware of what specific reporting requirements apply to them in their State (or jurisdiction), and provide adequate training for all personnel with respect to these requirements and how such reports are to be made. The complexity of those laws is not an excuse for non-compliance, and the Department will not tolerate Title X grantees and subrecipients failing to comply with the reporting requirements that State and local governments have seen fit to enact as binding legal requirements. The proposed rule at § 59.17 defers to State and local jurisdictions on what reporting requirements apply, and in this way fully respects Federalism and the proper jurisdiction over such crimes that is exercised by State and local governments. The proposed rule does not add any substantive reporting requirement that State and local jurisdictions do not already impose; the rule simply ensures that the Title X grantees and subrecipients are in compliance with federal law by ensuring that such grantees and subrecipients are in compliance with State and local reporting requirements.

As several commenters note, State and local laws can be vital resources in crafting protocols since they often provide direction to health professionals regarding how to balance their obligations for reporting with the exercise of discretion to best protect the safety of the victim. As part of prevention, protection, and risk assessment efforts, grantees and subrecipients should include compliance protocols to identify individuals who are victims of sexual abuse or who are targets for underage sexual victimization, as well as to ensure that every minor who presents for treatment is provided counseling on how to resist attempts to coerce them into engaging in sexual activities (as required by appropriations law applicable to Title X).

The Department believes that increased compliance requirements strengthen protection for minors and other vulnerable populations. The proposed rule, and this final rule, at § 59.17 explicitly address the requirement for Title X projects to comply with all State and local laws regarding the notification or reporting of crimes involving sexual exploitation, child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking (collectively, ''State notification laws''). The Department's Office of Inspector General (OIG) issued a 2005 report revealing that even though OPA informs and periodically reminds Title X grantees and subrecipients of their responsibilities regarding State child-abuse and sexual-abuse reporting requirements, it could not determine the extent to which grantees actually comply with these requirements.[120] The Department believes that minors and other vulnerable communities are better served if Title X providers are accountable for complying with these State and local laws.

The Department is also sensitive to concerns raised by commenters that victims of abuse are sometimes repeatedly victimized after abuse is reported. Therefore, the Department expects grantees and subrecipients to include additional training in their protocols to assist counselors with their interactions with a victim of abuse and to ensure that they are equipped to make referrals that increase the safety of the patient. The regulatory text is updated to reflect this additional component of training for Title X staff in paragraph (b)(1)(ii) of § 59.17. The final rule adds that the policies will include training regarding State notification laws and ''appropriate interventions, strategies, and referrals to improve the safety and current situation of the patient. . . .''

The Department has considered the request of some commenters to broaden the reporting requirements even further. The Department concludes, however, that the proposed language is consistent with language that has been included in appropriations acts for the Department since fiscal year 1999.[121] Additionally, the Department has considered some commenters' requests to further investigate the specific entities which the commenters allege have misappropriated Title X funds. The Department believes that the clarification of reporting requirements found in the rule will remedy any confusion about the use of Title X funds. The Department will investigate any credible report of fiscal abuse or misuse of funds and take appropriate action, if found.

Having considered the comments about whether to broaden the reporting requirements to include entities that are not grantees or subrecipients, such as referral agencies, the Department agrees with commenters who state that referral partners should not be subject to the same reporting requirements. Referral agencies do not receive Title X funds, therefore, the Department declines to make changes in § 59.17 that would expand the provision to impose reporting requirements on entities that are neither recipients nor subrecipients of Title X funds.

The Department disagrees with commenters who say the training and reporting requirements in the proposed rule will lead to over-reporting or erode patient trust and confidentiality. Title X grantees and subrecipients are already subject to State and local reporting laws, and Congress has made it clear that the receipt of Title X funds does not permit Title X grantees and subrecipients to avoid such obligations. In addition, § 59.11 of the 2000 regulations permits the use of confidential information obtained by project staff to comply with State and local reporting requirements. The Department will not second guess the determinations of States or local governments that these reporting requirements do not erode patient trust and confidentiality, but protect vulnerable persons. The Department is not aware of compelling evidence to the contrary from commenters. The Department also hopes that victims of

[119] Office of Justice Programs, *Causes and Consequences of Intimate Partner Violence,* National Institute of Justice (Oct. 24, 2007), *https://www.nij.gov/topics/crime/intimate-partner-violence/Pages/causes.aspx.*

[120] HHS OIG, OEI–02–03–00530, *Letter on Federal Efforts to Address Applicable Child Abuse and Sexual Abuse Reporting Requirements for Title X Grantees* (Apr. 25, 2005), *https://www.hhs.gov/opa/sites/default/files/child-abuse-reporting-requirements.pdf.*

[121] *See, e.g.,* Department of Health and Human Services Appropriations Act, 1999, Public Law 105–277, Title II, sec. 219, 112 Stat. 2681, 2681–363 (1998).

abuse will feel increased trust with Title X providers as a result of the training required in the final rule, not only with respect to compliance with State and local reporting laws, but also how to offer strategies to improve the victim's current situation, including the patient's safety.

The Department disagrees with commenters who assert the regulations will abrogate confidentiality for minors, stigmatize them, cause them to lose their personal agency, or violate their informational privacy rights. All recordkeeping, except that which must be submitted as a result of mandatory reporting, is subject to the same confidentiality requirements as other medical services rendered by the clinic. If a minor is a suspected victim of abuse, the Title X provider has the obligation to report suspected abuse,[122] make appropriate referrals if needed, and empower the minor with skills to build self-efficacy and the self-confidence to resist any future sexual coercion.[123]

The Department disagrees with some commenters who contend the age of a minor's sexual partner has no relevance for Title X grantees. State and local reporting laws concerning sexual abuse or child abuse often have elements concerning the age of the minor and the minor's sexual partner. Title X exempts neither Title X providers nor Title X health care providers from their responsibility to comply with State and local reporting laws. Child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking are crimes that affect individuals, families, and communities. Title X projects should be the exemplar of an appropriate model for protecting those who are vulnerable to sexual abuse, rape, and assault; in developing protocols to identify clients who may be at risk for sexual abuse; in counseling teens on, and in producing programs and materials that assist teens in, resisting sexual exploitation, abuse, and coercion; [124] and in assuring appropriate support and management of teens (and women and men) who have been exploited, abused or coerced into unequal sexual partnerships. The Department believes asking the right questions can identify victims of abuse for mandatory reporting purposes, protect them from continued victimization, and help them access services to increase their health and safety in the future. With regard to comments concerning the requirement in § 59.17(b)(2)(ii) to maintain records including those which ''[i]ndicate the age of the minor client's sexual partners where required by law,'' the Department clarifies what is meant by that paragraph by finalizing it to read, ''[i]ndicate the age of the minor client's sexual partners if such age is an element of a State notification law under which a report is required. . . .'' The Department does not believe that conforming to the reporting requirement will result in a regulatory burden or increased costs for reporting to State and local authorities, since grantees and subrecipients should already be complying with this mandate.

The Department disagrees that required sexual abuse/victimization screenings are harmful to patients. Similar to typical components of a medical history, Title X projects are already required to conduct a preliminary screening of any teen who presents with an STD, pregnancy, or suspicion of abuse in order to rule out victimization of a minor. Such screening is required with respect to any individual who is under the age of consent in the jurisdiction in which the individual receives Title X services. If positively diagnosed, projects are permitted to treat STDs as an appropriate preconception service. The requirement in the final rule is more explicit in the age parameters in order to offer consistency from State to State and to ensure that this requirement consistently applied throughout all Title X services areas. This requirement is responsive to both State notification laws as well as the appropriations rider related to sexual coercion of minors. The Department does not believe, as some commenters suggest, that Title X providers should be required to diagnose, test for, and treat STDs, although testing and treatment would be an appropriate referral service, if not offered onsite. Sites must offer a variety of family planning services, but are not required to provide all such services. As an important component of the screening process, staff would sensitively converse with patients and build trust, while obtaining the information needed to comply with the screening and reporting requirements.

The Department disagrees with commenters who assert the rule conflicts with Medicaid coverage confidentiality requirements. The rule requires screening for minors who are pregnant or test positive for STDs. The preliminary screening is used to determine whether the minor is a likely victim of sexual coercion, a concern of Congress, as evidenced by its specific mandate that Title X projects provide ''counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.'' [125] While Medicaid and Title X both allow family planning services to be provided confidentially to individuals of childbearing age, providers serving patients who use Medicaid must still do their due diligence to ensure they are complying with all State and local reporting requirements, and if Title X grantees, with the appropriations riders applicable to the program. In light of State and local laws against incest and laws regulating age-specific requirements for permitting sexual relations with minors, the Department believes that mandatory screening of minors ensures that Title X providers are adequately assessing their legal requirements under State and local law, the protection to minors sought in the appropriation rider, and the patient's overall health. The Department is specifically directed to focus Title X grantees on these issues: Appropriations law provisions requires Title X applicants to certify that it ''provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities'' [126] and requires Title X providers to comply with State notification or reporting laws on child abuse, child molestation, sexual abuse, rape, or incest. The confluence of these two separate, but related, mandatory provisions are addressed in this Section.

The Department disagrees with commenters who assert only those with visible signs of abuse should be screened or that screening is unnecessary. Pregnancy, or the presence of an STD, can be evidence of abuse or a predictive sign of abuse, especially among younger minors. Often victims

[122] As Representative Ernest Istook said during the debate regarding the provision: ''It says, if there is a situation, such as I described, involving an underage child, Title X providers must report that and comply with State law the same as anyone else who deals with services to our young people.'' 143 Cong. Rec. H7053 (daily ed. Sept. 9, 1997).

[123] HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090.

[124] As noted above, the annual appropriations laws also impose on Title X grantees the obligation to provide ''counseling to minors on how to resist attempt to coerce minors into engaging in sexual activities.'' *See* HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090.

[125] Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1998, Public Law 105–78, sec. 212, 111 Stat. 1467, 1495; HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090.

[126] Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1998, Public Law 105–78, sec. 212, 111 Stat. 1467, 1495; HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090.

do not self-identify and may have no obvious indicators at all, elevating the necessity of screening. The Department believes that a confidential and empathetic screening process will enable a program to better serve those individuals who have been victimized and to identify those instances where state or local law requires notification of certain crimes.

The Department agrees with some commenters who observe that the language of the proposed rule is inconsistent in referring to a ''minor'' several times, an individual below the ''age of consent'' in another place, and to a ''teen'' in the first part of the first sentence of § 59.17(b)(1)(iv). The Department intended the rule to refer to ''minors'' in all such instances, and finalizes § 59.17(b)(1)(iv) to change the word ''teen'' to ''minor;'' and to remove the sentence referencing ''age of consent'' in relation to State laws, since preliminary screening for minors would be separate from, but inclusive of, ages included in individual State notification laws.

Although § 59.17(a) defines the term ''State notification laws'' for the purposes of the section to refer collectively to ''all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking'', the prefatory text of § 59.17(b)(1) mistakenly uses the phrase ''State laws'' instead of ''State notification laws.'' The Department therefore finalizes § 59.17(b)(1) prefatory text to change the phrase ''State laws'' to ''State notification laws,'' consistent with the intent of the proposed rule.

M. Appropriate Use of Funds (42 CFR 59.18)

The 2000 regulations required that any Title X funds must be expended solely for the purposes for which the funds were granted. The proposed rule would add § 59.18, which clarifies this language by detailing the prohibited uses of Title X funds, including their use for abortion-related infrastructure building, lobbying activities, and any other possible misuse of funds. The Department finalizes the section without change, except to make technical edits that improve understanding and readability.

Comments: Many commenters that object to § 59.18's proposed prohibition on uses for Title X funds, including limits on infrastructure building, and raise objections that overlap with their objections to the proposed requirements of § 59.15 for physical and financial separation of Title X projects and prohibited activities. The Department's response to those comments above encompasses those objections.

Some commenters support the proposed language of § 59.18 prohibiting the use of Title X funds for building infrastructure that supports a Title X grantee's abortion-related activities. Commenters state that the proposed changes will help ensure that Title X funds are correctly appropriated. Others believe the rule should go further and require grantees or subrecipients to demonstrate that they do not fund abortion services with Title X funds.

Some commenters contend it is unnecessary for the Department to prohibit the use of Title X funds to support abortion services, infrastructure building for that purpose, or lobbying. They contend current accounting, reporting, and auditing requirements already ensure that each Title X project fully accounts for and justifies charges against the Title X grant.

Response: The Department agrees with commenters who support the proposed language at § 59.18.

The Department disagrees with commenters who suggest that there have been no concerns raised regarding improper use of Title X funds. The Department believes that, even if the extent of such misuse of funds is not fully known, the Department is still legally obliged to ensure funds are not misused, so it is appropriate for the final rule to identify what constitutes such misuse of Title X funds. Increased transparency will ensure greater accountability for the use of Federal funds and will mitigate confusion about what services the federal government supports and funds.

As explained in the proposed rule, the flexibility in the use of Title X funds under the 2000 regulations raises concerns about the fungibility of assets that could be used to build infrastructure for abortion services. By law, Title X providers must secure other sources of revenue to leverage Title X grants. 42 CFR 59.7(c) (''No grant may be made for an amount equal to 100 percent for the project's estimated costs.''). Medicaid providers are reimbursed by States for allowable expenditures. By their very nature, grants afford considerably greater latitude and versatility to grantees on how funds are used. If an organization receives both Medicaid and Title X funding, for example, Medicaid reimbursement payments might be used to cover many family planning services, freeing up Title X funds to be used for infrastructure-building and support. In its *Moving Forward: Family Planning in the Era of Health Reform* report, the Guttmacher Institute reported that providers do in fact use Title X funds in this way:

> Up-front funding helps supply a cash-flow cushion for providers who are often operating on tight and uncertain budgets. More specifically, Title X grantees use the program's flexible grant funding in a variety of ways to address staff-related issues, including hiring individuals capable of meeting communities' need for linguistic or culturally appropriate care, training staff on the latest medical techniques or to provide tailored counseling for clients with special needs, maintaining sufficient staff to operate outside regular business hours and paying sufficient wages to staff at all levels to reduce high turnover rates that often plague health centers. Providers may also use Title X funds for operational investments, such as utilizing advanced technologies and facilitating more accessible and efficient client care . . . . Finally, Title X undergirds the infrastructure and general operations of the health centers themselves in ways that Medicaid and private insurance simply cannot. Title X funds go to centers up front as grants, rather than after the fact as reimbursement for services centers have provided to individual enrollees. Providers have long relied on that flexibility to hire, train and maintain their staff to meet the diverse needs of their clients and community. They have also depended on these grants to keep their lights on and their doors open, to adapt to unexpected budget shortfalls and to make improvements to their facilities. Such versatility is even more vital in the era of health reform. The up-front investments in staffing, training and infrastructure needed to work effectively with health plans—and to thereby draw in new revenue to serve more clients—are substantial, and flexible funds like those provided through Title X are ideal for such investments. Those expenses include upgrading health information technology systems and training staff on their use, training clinicians and front-line staff to properly code and bill for services provided, obtaining the appropriate credentials to ensure third-party reimbursement, and devoting time and resources to researching available health plans and negotiating contracts with them. They may also include expenses related to outsourcing some administrative functions to private contractors or as part of collaborations with other health care providers.[127]

In a 2007 report, Guttmacher expanded upon the infrastructure support afforded by Title X funding:

> Title X can subsidize the intensive outreach necessary to encourage some individuals to seek services. Furthermore, by paying for everything from staff salaries to utility bills to medical supplies, Title X funds provide the essential infrastructure support that enables clinics to go on and claim

[127] Sonfield, A., Hasstedt, K., Gold, R.B., Moving forward. Family planning in the era of health reform, Guttmacher Institute 30 (March 2014), *https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform.*

Medicaid reimbursement for the clients they serve.[128]

Infrastructure building may include securing physical space, developing or acquiring health information technology systems (including electronic health records), bulk purchasing of contraceptives or other clinic supplies, clinical training for staff, and community outreach and recruiting. An anecdotal story [129] from the 2007 report reinforces the point:

> Ibarra of California's Venice clinic says her agency sends street outreach teams into the community with backpacks of condoms and basic educational materials, while other teams make regular visits to homeless shelters. Often, it will take multiple visits to a shelter or street-corner conversations until someone feels safe enough to come to a clinic. According to Ibarra, Title X will fund and train the outreach workers, purchase the condoms and often even develop the educational materials they distribute. Only when a client actually comes to the clinic is reimbursement available (through Medicaid or any other source), and then only if the client qualifies. According to Annette Amey, director of program evaluation for CFHC, ''it's all about getting people to the inside of the clinic door, and for that Title X dollars are indispensable.''

The Department is concerned about this infrastructure building on both statutory and policy grounds. As a statutory matter, the use of Title X funds to build infrastructure that can be used for purposes prohibited with these funds, such as support for the abortion business of a Title X grantee or subrecipient, clearly violates section 1008. As a policy matter, Title X is the only discrete, domestic, Federal grant program focused solely on the provision of cost-effective family planning methods and services. As the number of Americans at or below the poverty level has increased, the need to prioritize the use of Title X funds for the provision of family planning services has as well.

The Department concludes it is appropriate to implement the statutory requirements applicable to Title X by imposing the § 59.18 restrictions addressing the use of Title X funds for infrastructure purposes related to abortion, particularly in combination with the § 59.15 requirement of physical and financial separation of Title X projects from prohibited activities (*e.g.,* abortion as a method of family planning). Because Title X projects would not share any infrastructure with abortion-related activities, direction of Title X funds toward such infrastructure would no longer threaten to divert funds to impermissible activities. That separation would thus ensure that Title X funds are used for the purposes expressly mandated by Congress, that is, to offer family planning methods and services—and that any infrastructure built with Title X funds would not be used for impermissible purposes.

N. Transition Provisions (42 CFR 59.19)

Summary of changes: The proposed rule would add § 59.19, which specifies the effective dates and compliance dates of the provisions of the proposed rule. The Department finalizes this provision with changes to the compliance dates in response to public comments, and makes some minor formatting and technical edits to improve readability.

Comments: Many commenters contend transition periods by which covered entities must comply with the rule are not long enough. Some recommend lengthening the physical separation transition period from one to two years, while many recommend extending the period to three years. Some contend they do not know how long would be needed for compliance, but at least an additional year is needed. Various commenters worry that many Title X recipients would be unable to receive care while clinics are in the process of separating after the proposed one year time period expires.

One commenter asks that the changes be scheduled to take effect at the end of the project period during which the rule is finalized in order to limit confusion for current grantees. One commenter suggests that Title X create different transition requirements for different Title X providers based on resource-level, location revenue, and client population.

Additionally, one commenter notes the cost of establishing new Electronic Health Record (EHR) systems would include the costs for new hardware and infrastructure for these systems. In New York State, providers may not purchase equipment in the final year of a grant cycle. Since 2019 is the final year of the grant for New York State Family Planning projects, the commenter contends that these providers would be unable to comply with the new requirements until a new grant is issued.

One commenter requests that the financial transition period be lengthened from 60 days to six months, stating that, according to businesses that provide modification and implementation of EHR systems, six months, at minimum, is needed. The majority of commenters recommended changing the transition period to one year for financial separation.

Response: The effective date for all sections of the final rule is 60 days after publication of this rule in the **Federal Register**, as set forth in the Dates section of this notice. Except with respect to the provisions for which the Department establishes a separate compliance date, covered entities will be expected to comply with the requirements of this final rule by that date.

The Department extends some of the compliance dates of certain sections or paragraphs in the rule, by which covered entities must comply with those sections after their effective date, in response to public comments as follows.

The Department maintains the compliance date of one year for the physical separation requirements of § 59.15. The Department disagrees with commenters who contend one year is an insufficient time period for covered entities to comply with the physical separation requirement of the rule. The Department believes one year is an ample and generous amount of time for an entity to rearrange locations, find new locations, comply with related State requirements, or even make changes to a facility to physically separate Title X services from abortion services. These rules might be satisfied by placing Title X projects (or the abortion services) in a different location without changing any physical or facility space. It is not uncommon for health care providers to change locations, change their physical space, or even add new service delivery locations. As a result, the Department disagrees with commenters who assert that patients will lose service because of the physical separation requirement would apply beginning one year after the publication of the final rule.

The Department agrees with commenters who contend some other components of § 59.15, such as those pertaining to electronic health records, should also be subject to the one-year separation requirement. The Department considers the electronic health records to pertain to physical separation and, thus, subject to the one-year compliance deadline. However, the Department will require that Title X projects and providers comply with the requirement of financial separation by July 2, 2019. The Department therefore finalizes paragraph (a) of the transition rule specifying the compliance date for the physical separation requirements contained in § 59.15, by which covered entities must comply with such requirement, as March 4, 2020. Title X projects may comply with the physical

[128] Gold, R.B., *Stronger Together: Medicaid, Title X Bring Different Strengths to Family Planning Effort,* Guttmacher Institute 15 (May 17, 2007), *https://www.guttmacher.org/gpr/2007/05/stronger-together-medicaid-title-x-bring-different-strengths-family-planning-effort.*

[129] *Id.* at 17.

separation requirements of § 59.15 earlier than the one year compliance date if they choose, and may comply with the financial separation requirements of § 59.15 earlier than the 120 day compliance date if they choose. Prior to the compliance date for the financial separation requirements of this final rule, the Department expects that grantees will comply with the ''Separation'' section of the guidance at 65 FR 41281, 41282, or with the financial separation requirements of § 59.15.

Various parts of the final rule impact applications for grants, namely § 59.7, the removal of § 59.5(a)(10)(i), and § 59.5(a)(13) as it applies to grant applications. The Department intends that these requirements will apply prospectively to applications for competitive or continuation awards, but not to applications that have been submitted before publication of the final rule or that are due in a time period soon after publication of the final rule. The Department intends that these provisions will apply to applications for which the Department has informed the applicant these provisions will apply. Therefore, the Department finalizes paragraph (b) of the transition section to establish that the compliance date for covered entities regarding § 59.7, the deletion of § 59.5(a)(10)(i), and § 59.5(a)(13) as it applies to grant applicationswill be the date on which competitive or continuation award applications are due, where that date occurs after July 2, 2019.''

The Departments have carefully reviewed comments seeking more time for implementation of requirements for reporting, submitting assurances, and providing certain services. These sections include §§ 59.5(a)(12), 59.5(a)(13) as it applies to all required reports, 59.5(a)(14), (b)(1) and (8), 59.13, 59.14, 59.17, and 59.18. In response to the request by commenters that more than 60 days is needed for compliance with such requirements, the Department has concluded that it will finalize the transition section to allow 120 days for compliance with this section. The Department believes this provides sufficient time for grantees and subrecipients to comply with these requirements. Therefore, the Department finalizes paragraph (c) of the transition section to establish the compliance date for covered entities regarding § 59.5(a)(12), § 59.5(a)(13) as it applies to all required reports, § 59.5(a)(14), § 59.5(b)(1), § 59.5(b)(8), § 59.13, § 59.14, § 59.17, and § 59.18is July 2, 2019.''

The Department concludes that the remaining requirements of the final rules, that is, all requirements not specified above, can be satisfied within 60 days of publication of the final rules in the **Federal Register**, that is, by the effective date. For example, Title X projects can comply with the prohibition on referrals for abortion as a method of family planning within 60 days. Therefore, the Department does not establish a separate compliance date for such provisions of this final rule.

III. Economic/Regulatory Impact and Paperwork Burden

A. Introduction and Summary

The Department examined the impacts of the final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993); Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011); the Regulatory Flexibility Act, 5 U.S.C. 601 (RFA); Unfunded Mandates Reform Act, 1995, Public Law 104–4, Title II, sec. 202(a), 109 Stat. 48, 64 (1995); Executive Order 13132 on Federalism (August 4, 1999); the Congressional Review Act, 5 U.S.C. 804(2); section 654, 5 U.S.C. 601 (note), on the Assessment of Federal Regulation and Policies on Families; E.O. 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017); and the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520.

In addition, the Department carefully reviewed the public comments, and as a result, has updated the estimated costs for implementing the final rule in some cases. Those changes are described below and reflected in the narrative and calculations represented later in this section.

1. Executive Orders 12866 and 13563 and the Congressional Review Act

Comments: Commenters contend that the Administration failed to solicit public input on the proposed rule, citing E.O. 12866, noting that the proposed rule was not included in the Spring 2018 Unified Regulatory Agenda and that public input was not permitted prior to final review.

Commenters contend that the proposed rule qualifies as a ''significant regulatory action'' under E.O. 12866 and E.O. 13563, and maintain that the Economic Impact Analysis performed by the Department failed to address the potential cost to patients and providers. Commenters contend that the Department focused on the benefits and protections of the proposed rule, but failed to adequately address potential problems. For example, commenters contend that the Department did not accurately estimate costs associated with the physical separation requirement, the new definition of ''low income family,'' and unintended births that will result from the regulation.

Response: Although some commenters claimed that this rule would increase unintended pregnancies, the Department disagrees, for the reasons set forth above, and believes this rule will lead to a better or wider distribution of family planning services. In any event, the Department is not aware, either from its own sources or from commenters, of actual data that could demonstrate a causal connection between the type of changes to Title X regulations contemplated in this rulemaking and an increase in unintended pregnancies, births, or costs associated with either, much less data that could reliably calculate the magnitude of that hypothetical impact. Therefore, the Department concludes that those are not likely or calculable impacts for the purpose of the Executive Order.

The Department's impact analysis provides its best thinking on the effects of the proposed rule. It acknowledges that it is difficult to forecast all of its effects, and acknowledges uncertainty regarding the estimates. However, the Department believes that this proposed rule will result in better outcomes for people interested in utilizing Title X family planning services and does not believe that public comments provided substantive evidence of negative effects of the proposed rule.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Under Executive Order 12866, the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs determines whether a regulatory action is significant and, therefore, subject to the requirements of the Executive Order and review by OMB. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule that (1) has an annual effect on the economy of $100 million or more, or adversely affects in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as economically significant); (2) creates serious inconsistency or otherwise interferes with an action taken or

planned by another agency; (3) materially alters the budgetary impacts of entitlement grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. OMB has determined that this final rule is a significant, but not economically significant, regulatory action under section 3(f) of Executive Order 12866.

2. Regulatory Flexibility Act (RFA)

The RFA requires agencies that issue regulations to analyze options for regulatory relief of small entities, businesses, 501(c)(3) entities, as well as government entities if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. (States and individuals are not included in the definition of ''small entity.'') The Department considers a rule to have a significant economic impact on a substantial number of small entities if at least 5% of small entities experience an impact of more than 3% of revenue. The Department does not believe that the rule will have a significant economic impact on a substantial number of small entities. Supporting analysis is provided below.

3. Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies 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.'' Public Law 104–4, Title II, sec. 202(a), 109 Stat. 48, 64 (1995). The current threshold after adjustment for inflation is $150 million. The Department does not expect this rule to result in expenditures that would exceed this amount.

4. Federalism

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.

Comments: Commenters contend that the Department is preempting State law (without approval from Congress) by eliminating abortion referral and counseling requirements for Title X projects. Commenters assert that the Department failed to obtain State and local government input on the proposed rule, and failed to provide a comprehensive analysis for the Federalism implications of the proposed rule, which would have included a summary of the concerns expressed by State and local government officials. Commenters note that the Department included a federalism impact statement in a 2016 effort to revise Title X eligibility funding and argued that one should be required for this rule as well. Commenters recommend that an analysis be conducted that will assess how to address potential conflicts between the rule and State law. Commenters assert that State and local entities qualify as Title X grantees or subrecipients and would incur increased costs associated with providing access to services no longer provided by Title X, as well as costs associated with reduced access to those services for the public.

One commenter stated that the Department did not adequately assess the impact of the NPRM on individuals' health and well-being, as is required under Public Law 105–277. According to the commenter, the Department provided no details of an assessment in the NPRM, but only stated that the proposed rule would not negatively impact health and well-being. The commenter requests that the Office of Management and Budget (OMB) look into this issue.

Response: The Department disagrees with commenters who suggest the proposed rule preempts State law by removing the requirement for abortion counseling and referral. This regulation only impacts the Title X program and has no impact on State laws that may, in other venues or circumstances, require State or local entities to counsel and/or refer for abortion. And to the extent that any State laws requiring referral for abortion cannot be carried out in a Title X project, it is due to Congress's restriction on the use of Title X funds in projects where abortion is a method of family planning.

The Department also disagrees with comments suggesting that federalism requires the Department to permit Title X projects to provide directive counseling and information about abortion, or referrals for abortion. As the Supreme Court held in *Rust* v. *Sullivan,* the federal government is not required to fund Title X projects that promote or refer for abortion. 500 U.S. at 193–94. Regardless of the status of State laws that some commenters say require the provision of directive counseling, information, or referrals for abortion, neither the principle of federalism nor the Constitution requires the federal government to fund Title X programs or projects—or any other program—that include directive counseling, information, or referrals for abortion as a method of family planning. And the Department believes it would be inconsistent with restrictions on the Title X program to allow (or require) Title X projects to provide directive counseling about abortion. The Department has determined that the final rule will not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. The changes in the rule represent the Federal Government regulating its own program.

The Department disagrees with comments that suggest the inclusion of a federalism impact statement in the 2016 Title X regulation demands the same for this rule. The 2016 regulation was a regulatory change to the status quo of the 2000 regulations that limited the ability of states and other grantees to choose their own subrecipients; the Department specifically stated that its reason for issuing the rule was to respond to new approaches to competing or distributing Title X funds that were being employed by several States. As a result, the 2016 regulation had a federalism impact. This final rule, however, removes a provision that Congress has already legislatively repealed through the Congressional Review Act. That regulatory provision was nullified as a matter of law when the President signed the repeal. This rule simply conforms the text of the Title X regulations to what Congress has already done. Consequently, there is no federalism impact of the removal of this provision.

Additionally, States are free to apply or not apply for Title X funding and so are only required to comply with regulations in this Federal program if they decide to apply for a grant under the discretionary Title X program and, thereby, voluntarily agree to follow the statutory program integrity provisions, the regulation provisions, and those requirements communicated in the funding announcement. Should they agree that the Title X program is a good fit for their State government

application, this regulation establishes the program's core requirements to maintain statutory program integrity, but States (or other grantees) have the freedom to implement their own programs, select their own subrecipients, establish their own referral networks, and test approaches within this framework to identify the most effective and innovative means to serve Title X patients in their States.

The Department disagrees with comments suggesting that State and local entities will incur additional costs to provide services that were once part of Title X, but are no longer permitted. Commenters fail to provide convincing evidence of these costs and also fail to provide evidence that there will be reduced access to Title X services as a result of this rule. Accordingly, the Department concludes that the final rule does not contain policies that have federalism implications, as defined in Executive Order 13132 and, consequently, a federalism summary impact statement is not required.

5. Summary of the Final Rule

This final rule amends the regulations governing the Title X program to ensure programmatic compliance with statutory program integrity provisions. Specifically, the rule:

(1) Aligns the regulation with the statutory requirements and purpose of the Title X program, the appropriations provisos and riders addressing the Title X program, and other obligations and requirements established under other Federal law;

(2) Expands the scope of enforcement and auditing mechanisms available to the Department to enforce such program requirements; and

(3) Requires individuals and entities covered by this proposed rule to adhere to certain procedural and administrative requirements that aim to improve client care and increase transparency.

The Department evaluated the effects of this rule over 2019–2023. As a result of comments, it has increased estimated costs. Costs are estimated to be $69.2 million in 2019 and $14.8 million in subsequent years. Present value costs of $110.4 million and annualized costs of $26.4 million are estimated using a 3% discount rate; present value costs of $91.1 million and annualized costs of $27.2 million are estimated using a 7% discount rate. The quantified and non-quantified benefits and costs are summarized in Table 1.

TABLE 1—ACCOUNTING TABLE OF BENEFITS AND COSTS OF ALL PROPOSED CHANGES

	Present value over 5 years by discount rate (Millions of 2016 dollars)		Annualized value over 5 years by discount rate (Millions of 2016 dollars)	
	3 Percent	7 Percent	3 Percent	7 Percent
Benefits:				
Quantified Benefits	0	0	0	0
Non-quantified Benefits (see below):				
Program integrity of Title X, especially with respect to ensuring that projects and providers do not fund, support, or promote abortion as a method of family planning. Enhanced compliance with statutory requirements and appropriations riders and provisos. Expanded number of entities interested in participating in Title X, including by the removal of abortion counseling and referral requirements that potentially violate federal health care conscience protections. Enhanced patient service and care.				
Costs:				
Quantified Costs	110.4	91.1	26.4	27.2
Non-quantified Costs:				
None				

B. Analysis of Economic Impacts

1. Need for Regulatory Action

This final rule addresses two categories of problems:

(1) Insufficient compliance with the statutory program integrity provisions and the purpose and goals of the Title X program (especially those related to section 1008), the appropriations provisos and riders addressing the Title X program, and other obligations and requirements established under other Federal law; and

(2) Lack of transparency regarding the provision of services (with respect to both the identity of the providers and the services being provided by such entities). Each of the issues fall into one or more of these categories.

While the 2000 regulations state that Title X projects must not provide abortion as a method of family planning, they do not provide sufficient guidance to ensure that Title X projects comply with section 1008 by not encouraging or promoting abortion as a method of family planning. Limiting section 1008's prohibition to only ''direct'' facilitation of abortion is not consistent with the best reading of that provision, which was intended to ensure that Title X funds are also not used to encourage or promote abortion. For example, the 2000 regulations:

- Mandate that providers provide counseling on and referral for abortion, if requested by the client;
- Permit shared locations, facilities, personnel, file systems, phone numbers, and websites between Title X clinics and abortion clinics, creating confusion regarding the scope of Title X services and whether the Federal government is funding abortion services; and
- Permit a fungibility of assets that can be used to free funds and build infrastructure for abortion services, including physical space, health information technology systems, community recruitment, and bulk purchase of contraceptives and other clinic supplies.

The lack of clear operational guidance on the abortion restriction in section 1008 has created confusion as to what activities are proscribed by section 1008. With abortions increasingly performed at nonspecialized clinics primarily serving contraceptive and family planning clients, it is critical that the Department ensure that Federal funds are not directly or indirectly supporting, encouraging, or promoting abortion as a method of family planning and that there is a clear demarcation between Title X services and abortion-related services for which Title X funds cannot be used.

The 2000 regulations suffer from additional deficiencies. They are inconsistent with the conscience

protections embodied in the Church, Coats-Snowe, and Weldon Amendments; do not address the statutory requirement that Title X projects encourage family participation in minors' decisions to seek family planning services; do not address the statutory requirement that Title X projects provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities; do not expressly address the obligation of Title X grantees and subrecipients to comply with State sexual abuse reporting or notification requirements; and do not expressly prohibit the use of Title X funds to encourage, promote, or advocate for abortion, to support any legislative proposal that encourages abortion, or to support or oppose any candidate for public office. In addition, the 2000 regulations do not communicate that Title X providers should either offer comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site. And the 2000 regulations fail to require grantees to provide the Department sufficient information about the subrecipients with which they (or their subrecipients) contract or other partners to whom Title X funds may flow, thus hindering OPA from exercising appropriate oversight of the activities of its program and project subrecipients.

This final rule addresses each of the foregoing problems. First, to assist the Department in ensuring compliance with, and enforcement of, the section 1008 prohibition, the final rule will 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; and provide clarification on the appropriate use of funds in regard to the building of infrastructure.

To assist the Department in ensuring compliance with, and enforcement of, appropriations provisos and riders addressing the Title X program, the final rule also reiterates the voluntary, non-coercive nature of Title X services; requires Title X facilities to encourage family participation in a minor's decision to seek family planning services; requires Title X facilities to provide minors with counseling on how to resist attempts to coerce them into engaging in sexual activities; prohibits the use of Title X funds for any activity that in any way tends to promote public support or opposition to any legislative proposal or candidate for office; clarifies the duty of projects to comply with State and local laws requiring notification and reporting of criminal sexual exploitation; explains that confidentiality of information may not be used as a rationale for noncompliance with such notification or reporting laws; and requires assurances of compliance and maintenance of records.

To assist the Department in ensuring compliance with conscience protections embodied in the Church, Coats-Snowe, and Weldon Amendments, the final rule eliminates the requirement that Title X projects provide abortion counseling and referral. These changes will also add clarity to extant conscience protections, making it easier for entities to participate who may have felt unable to do so in the past. In addition, though already permitted in the 2000 regulations, the final rule clarifies that participating entities within a project may offer only a single method or a limited number of methods as components of a Title X family planning project, so long as the overall project provides a broad range of acceptable and effective family planning methods and services throughout the service area.

Second, to ensure that the Title X program places an adequate emphasis on holistic family planning services that recognize the need for linkages with comprehensive primary health care providers, the final rule clarifies the definition of family planning; provides for the referral of pregnant patients for appropriate prenatal services; encourages the provision of comprehensive primary health services onsite or through a robust referral linkage; and updates the application review criteria, including to expand provision of family planning service in under- and un-served areas and populations.

Third, to ensure transparency regarding the provision of services, the final rule requires additional information from applicants and grantees regarding subrecipients, requires a clear explanation of how grantees ensure adequate oversight and accountability for compliance and quality outcomes among subrecipients and requires each project supported under Title X to fully account for, and justify, charges against the Title X grant. The Department believes these changes will ensure that OPA has the information necessary to determine whether Title X projects, grantees, and subrecipients are complying with the statutory provisions of the program. Title X grantees and subrecipients must comply with the Federal laws that are the subject of this proposed rulemaking. In addition to conducting outreach and providing technical assistance, OPA has the authority to initiate compliance reviews and take appropriate action to assure compliance with the provisions in this final rule.

2. Affected Entities

This rule would affect the operations of entities which receive Title X grants or are subrecipients of such entities at some point in time. According to the 2016 Family Planning Annual Report (FPAR), there were 91 Title X grantees and 1,117 Title X subrecipients in 2016.[130] These entities operated at 3,898 service sites, and provided services to 4,007,552 people.[131] For purposes of this analysis, the Department assumes that these numbers will remain the same across time. Title X services were delivered by 3,550 clinical services provider full-time equivalent employees (FTEs), which include 780 physician FTEs, 258 registered nurse FTEs, and 2,512 combined FTEs from physician's assistants (PAs), nurse practitioners (NPs), and certified nurse midwives (CNMs).[132] These FTEs are associated with 1,403 Title X family planning encounters per FTE, for 5.0 million total Title X family planning encounters across these providers in 2016.[133] Title X services are also delivered by other types of service providers, who were involved with 1.7 million Title X family planning encounters in 2016.[134] Providers in these categories include registered nurses, public health nurses, licensed vocational or licensed practical nurses, certified nurse assistants, health educators, social workers, and clinic aides. The Department assumes that there are 1,403 encounters per FTE for individuals in these categories, which implies approximately 1,219 FTEs in this category in 2016.[135] To convert FTEs reported in the FPAR to the number of individuals in these categories, the Department assumes that each individual works an average of between 0.5 FTEs and 1.0 FTEs delivering Title X services, with 0.75 FTEs as its central estimate, uniformly

[130] Fowler et al., *Family Planning Annual Report: 2016 National Summary* 7 (Aug. 2017), *https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.*

[131] *Id.* at 8.

[132] *Id.* at 49–51.

[133] *Id.* at 51.

[134] *Id.* at 24.

[135] *Id.* at 49.

across occupation categories. This implies that there are approximately 4,733 clinical service providers and 1,625 other service providers associated with the provision of Title X family planning services. The Department will use these estimates as its estimate of service providers affected by this rule.

The Department estimates the hourly wages of individuals affected by this proposed rule using information on hourly wages in the May 2016 National Occupational Employment and Wage Estimates provided by the U.S. Bureau of Labor Statistics [136] and salaries from the U.S. Office of Personal Management.[137] It uses the salary of registered nurses as a proxy for ''other clinical service providers'' and ''other types of service providers'' described above. In FPAR, PAs, NPs, and CNMs are not distinguished. Since wages in these three categories are very similar, the Department uses the average wage across this group when discussing impacts affecting the group. The Department uses the wages of Medical and Health Services Managers as a proxy for management staff, and the wages of Lawyers as a proxy for legal staff throughout this analysis. To value the time of potential Title X service grantees, the Department takes the average wage across all occupations in the U.S. The Department assumes that federal employees affected by the proposed changes to the Title X regulation are Step 5 within their GS-level and earn locality pay for the District of Columbia, Baltimore, and Northern Virginia. It divides annual salaries by 2,087 hours to derive hourly wages. It assumes that the total dollar value of labor, which includes wages, benefits, and overhead, is equal to 200% of the wage rate. Estimated hourly rates for all relevant categories are included below.

Throughout, estimates are presented in 2016 dollars. When present value and annualized values are presented, they are discounted relative to year 2016. Finally, the Department estimates impact over five years starting in 2019. Please note that the list includes staff that the Department assumes will be impacted by the final rule and is inclusive of those positions which are included in the APP category.

[136] Bureau of Labor Statistics, *Occupational Employment and Wage Statistics,* (May 2016), *https://www.bls.gov/oes/2016/may/oesnat.htm.*

[137] Office of Personnel Management, *Salary Table 2016–DCB,* (Jan. 2016), *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DCB.pdf.*

TABLE 2—HOURLY WAGES

Physician	$101.04
Physician Assistant	49.08
Nurse Practitioner	50.30
Certified Nurse Midwife	49.23
Registered Nurse	34.70
Medical and Health Services Managers	52.58
Lawyers	67.25
Federal employees in the District of Columbia, Baltimore, and Northern Virginia (2016)	
GS–13 Step 5	50.04
GS–14 Step 5	59.13
GS–15 Step 5	69.56

3. Estimated Costs

a. Learning the Rule's Requirements

To comply with the regulatory changes proposed in this final rule, affected entities must learn the rule's requirements, review their policies in the context of these new requirements, and determine how to respond. Affected entities here would include not only existing grantees and subrecipients, but also potential grantees and subrecipients. Consistent with our view that this proposed rule would increase competition for Title X funding, the Department estimates that potential grantees and subrecipients range from between 100% and 300% of their 2016 values, with a central estimate of 200%. This implies 182 potential grantees and 2,234 potential subrecipients. The Department estimates that learning the final rule's requirements and determining how to respond would require an average of 20 hours for potential grantees and an average of 10 hours for potential subrecipients, divided evenly between managers and lawyers, in the first year following publication of the final rule. As a result, using wage information provided in Table 2, this implies costs of $3.11 million in the first year following publication of the final rule.

b. Training

Individuals involved with delivering family planning services would need to receive training on the requirements of the final rule. To convert FTEs reported in FPAR to the number of individuals who would receive training, the Department assumes that each individual works an average of between 0.5 FTEs and 1.0 FTEs delivering Title X services, with 0.75 FTEs as its central estimate. This implies that there are approximately 4,733 clinical service providers and 1,625 other service providers who will need training in order to ensure compliance with these regulations. The Department estimates that these individuals would require an average of 4 hours of training in the first year following publication of this rule. In subsequent years, it assumes that this new information would be incorporated into existing training requirements, resulting in no incremental burden. As a result, using wage information provided in Table 2, this would imply costs of $2.71 million in the first year following publication of a final rule in this rulemaking.

In addition, training materials would need to be updated to reflect changes made by this rulemaking. Training materials for Title X providers are currently developed by contract. The Department estimates that these updates would cost approximately $200,000. In addition, changes to training materials would require interaction with OPA employees in order to ensure that the materials are suitable for Title X providers. The Department estimates that this would require half of an FTE at the GS–13 level and half of an FTE at the GS–14 level. It estimates that all of these costs would be incurred in the first year following publication of the final rule. Using wage information provided in Table 2, this would imply costs of $0.43 million in the first year after publication of the final rule.

c. Assurance Submissions

Title X grantees and subrecipients face new assurance requirements because of this final rule. The Department estimates that these new requirements would require a lawyer to spend an average of 3 hours reviewing the assurances and 3 hours reviewing organizational policies and procedures or taking other actions to assess compliance, and a medical and health services manager to spend 2 hours total for the same tasks the first year of the final rule for each grantee and subrecipient. In subsequent years, the Department estimates that these new requirements would require a lawyer to spend an average of 1 hour reviewing the assurances, 3 hours reviewing organizational policies and procedures or taking other actions to assess compliance, and a medical and health services manager to spend 2 hours total for the same tasks at each grantee and subrecipient. Using wage information provided in Table 2, this would imply costs of $1.2 million in the first year following publication of the final rule, and $0.9 million in subsequent years.

d. Documentation of Compliance

Title X grantees and subrecipients need to document their compliance

with new requirements because of this final rule. First, Title X grantees are required to encourage minors to involve family in their decisions to seek family planning services. Actions taken to satisfy this requirement must be documented in a minor's medical record. The Department estimates that each occurrence would require a physician assistant to spend an average of 2 minutes to make appropriate documentation in a minor's medical records. Approximately 20% (800,000) of the 4 million Title X clients are adolescents. The Department estimates that complying with the requirement to encourage family participation will result in 75% (600,000) of adolescent patients' medical records requiring appropriate documentation. Using wage information provided in Table 2, this would imply costs of $2.0 million in each year following publication of this rule.

In addition, the rule requires Title X projects to report certain crimes in compliance with State notification laws, and to counsel minors on how to resist sexual coercion, but the Department does not include cost estimates for compliance with these provisions because grantees are already required to comply with these congressional mandates. However, while Congress encourages family participation, especially related to minors, this rule requires an additional compliance step that grantees document that they encourage family participation with each minor—and to so document this conversation in each minor's patient file.

Second, grantees must generate reports with information related to subrecipients involved in the grantee's Title X project. The Department believes that this will impose direct and indirect costs. It estimates that these new requirements would require a health services manager to spend an average of 4 hours in each year following publication of the final rule at each grantee and subrecipient. Using wage information provided in Table 2, this would imply costs of $0.5 million in each year following publication of a final rule in this rulemaking.

In addition, based on public comment, the Department also believes that these documentation requirements will result in indirect costs. In particular, it believes that affected entities may update systems to facilitate newly required documentation and reporting. It estimates that between 25% and 75% of service sites, with a central estimate of 50%, will make changes along these lines in response to these new requirements. These changes could range from very minor tweaks to existing systems to more comprehensive overhauls. The Department estimates that an average of between $1,000 and $5,000, with a central estimate of $3,000, would be incurred at these sites in the first year following publication of this proposed rule. This would imply costs of $11.69 million in the first year following publication of a final rule.

e. Monitoring and Enforcement

This final rule will result in additional monitoring of Title X grantees and subrecipients in order to ensure compliance with new regulatory and existing statutory requirements.

Some commenters contend that requiring grantees to provide information concerning their subrecipients will be burdensome because of limited funding and the magnitude of oversight required and will prohibit them from freely selecting subrecipients. Commenters contend that these requirements will be prohibitive to providing comprehensive care and continuing partnerships with referral agencies. Other commenters contend that many clinics will be forced to close as a result of the burdensome requirements and that this is evidence of a departmental agenda to discourage participation in the Title X program. Commenters request a response as to whether the Department has studied the costs to subrecipients and referral agencies associated with data collection, training and oversight. Commenters also note that other programs with comparable federal funding are not required to submit to the same requirements.

HHS does not agree with commenters who say that providing the Department with information regarding subrecipients is unduly burdensome or prohibitive, since grantees already are responsible for ensuring that all partners who receive funding as a part of the grant project are providing services that are responsive and compliant with the purposes of Title X. The Department is only requiring that compliance and appropriate service provision be documented and submitted to HHS. Grantees may relieve reporting burdens by requiring subrecipients to draft compliance reports that grantees can submit to HHS after certifying their accuracy. Commenters provided no documentation to support the assertion that such certification of subrecipient compliance would be unique among federal programs. In addition, as a result of comments, HHS is only requiring monitoring and oversight of subrecipients, not referral agencies, because only grantees and subrecipients receive Title X funds for their services. Requirements regarding referral agencies will be limited to the grantee providing information that they should already have available, such as the name of the referral agency, the services it provides, and the extent of the referral partnership. For all of these reasons, the Department does not find this objection compelling.

Similarly, the Department does not agree with the concern expressed by some commenters regarding the effect of this rule on quality and accessibility of Title X services. These commenters did not provide evidence that the rule will negatively impact the quality or accessibility of Title X services. And the Department believes that this rule will likely improve quality and accessibility for Title X services.

For example, the Department expects that honoring statutory protections of conscience in Title X may increase the number of providers in the program. If health care providers or entities know they will be protected from discrimination on the basis of conscience with respect to counseling on, or referring for, abortion, they might seek to participate in programs as a subrecipient where they may previously have been deterred from doing so under the current regulations because of concerns that they would be forced to violate their religious belief or moral conviction. This may also lead to an increase in the number of health care providers who apply and receive funding under the Title X program, thus decreasing current gaps in family planning services in certain areas of the country. For example, under the 2000 regulations, some individuals and entities may have chosen not to apply to provide Title X services because they anticipated they would be pressured to counsel or refer for abortions. One public commenter supporting finalization of the proposed rule on behalf of religiously affiliated health care organizations cited polling data and organizational comments suggesting that protecting conscience in the Title X program would prevent medical providers or students from refraining from participation in the program due to concerns about being forced to violate their consciences.[138]

[138] See comment of Jonathan Imbody (posted July 23, 2018), available at *https://www.regulations.gov/document?D=HHS-OS-2018-0008-69125* (citing a Christian Medical Association and Freedom2Care poll conducted on May 3, 2011, which found that 91 percent of physicians who practiced medicine based on the principles of their faith said they would be forced to leave medicine if coerced into violating the faith tenets and medical ethics principles that guide their practice of medicine). Freedom2Care and The Christian Medical

Similarly, a certain proportion of decisions by currently practicing health providers to leave the profession are presumably motivated by such pressure.[139] With the final rule's added emphasis on protecting rights of conscience, more individuals may enter the Title X family planning program, helping to meet that unmet need for care.

This effect may also occur at the macro scale in the health industry. For example, hospitals or other facilities that will not refer for abortion as a method of family planning may view the final rule as granting Title X participants greater freedom to provide family planning services consistent with their beliefs and may find it worthwhile to apply for Title X funds, or seek to participate in a Title X project as a subrecipient, in order to serve more people or new populations, or underserved communities, including urban or rural, consistent with their calling to serve the health care needs of the poor and underserved.

As a result, the rule will not impede access to care in areas with fewer providers, such as rural communities, but enhance it. Indeed, because patients may seek out health care providers that reflect their own religious beliefs or moral convictions, service delivery should be improved because opportunities for conflict may be limited and the cultural competency of providers may be increased.[140] Another way this effect may manifest itself is that, if the number of family planning providers were to remain constant, the average provider would have more highly qualified staff, because the Title X grantees and their subrecipients would be selecting from a larger pool of medical and health professionals. Ultimately, the Department believes that this final rule will result in more Title X applicants, which will likely translate into more diverse grantees and subrecipients. In addition, the Department closely monitors the performance of the Title X program, including through the Family Planning Annual Report, which should allow the Department to quickly identify and respond to any problems in order to maintain high quality standards within the program.

The Department estimates that addressing additional monitoring and enforcement activities would require management staff for each grantee to spend an average of an additional 40 hours each year, and would require an average of an additional 10 hours for each Title X service provider each year. Finally, additional monitoring and enforcement require additional time by Federal staff. The Department estimates this would require 3 FTEs at the GS–13 level, 2 FTEs at the GS–14 level, and 2 FTEs at the GS–15 level. As a result, using wage information provided in Table 2, this would imply costs of $8.53 million every year following publication of this rule.

f. Physical Separation

As a result of this final rule, Title X providers would be required to provide Title X services at facilities that are physically separate from facilities at which abortion as a method of family planning is provided. A Congressional Research Service [141] report estimates that 10% of clinics that receive Title X funding offer abortion as a method of family planning in addition to their Title X-funded activities. In addition, Title X providers may share resources with unaffiliated entities that offer abortion as a method of family planning. As a result, the Department estimates that between 10% and 30% of service sites, with a central estimate of 20%, would need to be evaluated to determine whether they comply with the proposed physical separation requirements. Commenters contend that the Department underestimated the costs related to new physical separation requirements, but themselves did not provide sufficient data to estimate these effects across the Title X program. Commenters also provided extremely high cost estimates based on assumptions that they would have to build new facilities in order to comply with the requirements for physical separation from abortion as a method of family planning. The Department does not anticipate that entities will necessarily engage in construction of new facilities to comply with the new requirements, rather that entities will usually choose the lowest cost method to come into compliance. The Department expects that the lowest cost method will vary across covered entities depending on their circumstances, and that covered entities will make the decision which best suits their circumstances in light of the new requirements, and therefore that entities will likely choose the lowest cost method, given their circumstances. For example, Title X providers which operate multiple physically separated facilities and perform abortions may shift their abortion services, and potentially other services not financed by Title X, to distinct facilities, a change which likely entails only minor costs. Other Title X providers, with different circumstances, will have different options and therefore may have a more or less costly lowest cost method. Furthermore, as stated above, the Department estimates that between 10% and 30% of service sites, with a central estimate of 20%, would be subject to physical separation requirements, because their Title X services and abortion services are currently collocated. Accordingly, the Department believes that enforcing the physical separation requirements as interpreted through Section 1008 should have minimal effect on the majority of current Title X providers. The Department has updated quantitative estimates in response to these comments, while acknowledging that there is substantial uncertainty regarding the magnitude of these effects. The Department estimates that evaluation of sites would require an average of an additional five hours by management staff at each of these affected service sites in the first year following publication of the final rule. Similarly, it estimates that this evaluation would affect between 10% and 30% of grantees, with a central estimate of 20%. The Department estimates that this would require an average of an additional forty hours, divided evenly between lawyers and management staff, for each affected grantee, in the first year following publication of a final rule. It estimates that these evaluations would determine that between 10% and 20% of service sites, with a central estimate of 15%, do not comply with physical separation requirements. At each of these service sites, the Department estimates that an average of between $20,000 and

Association, *National Poll Shows Majority Support Healthcare Conscience Rights, Conscience Law* (May 3, 2011), *https://docs.wixstatic.com/ugd/809e70_7ddb46110dde46cb961ef3a678d7e41c.pdf.*

[139] The Christian Medical Association and Freedom2Care poll of May 3, 2011, found that 82% of medical professionals ''said it was either 'very' or 'somewhat' likely that they personally would limit the scope of their practice of medicine if conscience rules were not in place. This was true of 81% of medical professionals who practice in rural areas and 86% who work full-time serving poor and medically-underserved populations . . . 91% agreed, 'I would rather stop practicing medicine altogether than be forced to violate my conscience.' '') Freedom2Care and The Christian Medical Association, *National Poll Shows Majority Support Healthcare Conscience Rights, Conscience Law* (May 3, 2011).

[140] In a 2011 poll, 88% of adults said it was very or somewhat important that they share moral beliefs with their health care providers. *See* Freedom2Care and The Christian Medical Association, *National Poll Shows Majority Support Healthcare Conscience Rights, Conscience Law* (May 3, 2011).

[141] Angela Napili, *Title X (Public Health Service Act) Family Planning Program,* Congressional Research Service 22 (Aug. 31, 2017), *https://fas.org/sgp/crs/misc/RL33644.pdf.*

$40,000, with a central estimate of $30,000, would be incurred to come into compliance with physical separation requirements in the first year following publication of a final rule in this rulemaking. This estimate is an increase from an averaged estimate between $10,000 and $30,000 in the proposed rule. Using wage information provided in Table 2, this would imply costs of $36.08 million in the first year following publication of a final rule, an increase from an estimated cost of $24.38 million in the proposed rule.

The Department does not anticipate that these requirements will have a significant impact on access to services. Although some facilities may relocate in response to the new requirement, the Department does not anticipate that there will be a decrease in the overall number of facilities offering services, since it anticipates other, new entities will apply for funds, or seek to participate as subrecipients, as a result of the final rule. Further, the Department cannot calculate or anticipate future turnover in grantees. Various entities may change their decision to apply to be a grantee or sub-grantees or may change the way in which they provide services, affecting the viability of their applications. Such calculations would be purely speculative, and, thus, very difficult to forecast or quantify. Based on the Department's best estimates, it anticipates that the net impact on those seeking services from current grantees will be zero, as any redistribution of the location of facilities will mean that some seeking services will have shorter travel times and others seeking services will have longer travel times to reach a facility. Additionally, as a result of this final rule, the Department anticipates expanded competition that will engender new and/or additional grantees who will serve previously unserved or underserved areas, likely expanding coverage and patient access to services.

g. Encouraging Parental Involvement in Family Planning Services

Title X providers are already required by the Title X statute to encourage minors to involve their parents in family planning services, but this rule would ensure that actions are taken to satisfy this requirement and require such actions be documented in a minor's medical record. As noted previously, the Department estimates that complying with the requirement to document the encouragement of family participation will result in 600,000 adolescent patients' medical records requiring documentation each year. The Department estimates that an additional 0–50% of these adolescents, with a central estimate of 25%, would receive additional encouragement to involve parents each year. It estimates that this would require an average of an additional ten minutes spent by a registered nurse and ten minutes spent by the service recipient in each case. These impacts would occur each year upon publication of this final rule. Using wage information provided in Table 2, this would imply costs of $2.93 million in each year upon publication of this final rule.

The Department does not include costs associated with compliance with State reporting requirements or the requirement that minors receive counseling to avoid sexual coercion because these Congressional requirements should already be satisfied by grantees.

4. Estimated Benefits

This final rule is expected to offer benefits to taxpayers and stakeholders who want assurance that their tax dollars are being used in compliance with the requirements of the Title X program. It is also 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. Third, because of the clarifying language, as well as the new provisions within this rule, the Department expects the quality of service to improve. Finally, the rule would clarify the role of the Title X program within communities across the nation, expand and diversify the field of medical professionals who serve individuals and families, and build a better appreciation for the important services offered as a result.

a. Upholding and Preserving the Purpose and Goals of the Title X Program

As discussed throughout this rule, the statutory prohibition on the use of Title X funds in programs/projects where abortion is a method of family planning has been in existence as long as the program. This final rule is expected to provide the Department with tools to ensure compliance with those statutory requirements. It is also expected to increase transparency and assurances that taxpayer dollars are being used as Congress intended. The Title X program, too, would benefit, as the requirement of physical and financial separation and the prohibition on infrastructure building for non-Title X purposes will ensure greater accountability for the use of Federal funds and mitigate confusion about what services the Federal government supports and funds.

b. Patient/Provider Benefits and Protections

The Department expects that the final rule will have additional benefits for patients and providers. Benefits for patients are significant. First, as noted above, the new regulation will encourage Title X service providers to offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site. This will promote seamless care and services for patients while expanding the breadth of services available within the States, territories, and throughout the regions.

Second, the final rule will protect certain patients from coercion or further victimization. It will require Title X facilities to counsel minors on how to resist attempts to coerce them into engaging in sexual activities. Such consulting would serve to help minors resist coercion and exercise self-determination. In addition, the final rule will protect certain Title X patients from further victimization by requiring Title X grantees and subrecipients to comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking; to develop a plan for such compliance and provide adequate training for all personnel on the subject; and to maintain records identifying the age of any minor clients served, the age of their sexual partner(s) where required by law, and the reports or notifications made to appropriate State or local law enforcement or other authorities, in accordance with such laws. These provisions would protect patients, especially minor children, from further victimization, and promote the identification and bringing to justice of those who would prey on women, men, and children.

For providers, the final rule is expected to create benefits through respect for conscience. It will do so by better aligning the Title X regulations with the statutory prohibitions on discrimination against health care entities, including individual health care providers, who refuse to participate in abortion-related activity such as counseling on, and referral for, abortion. Potential grantees and subrecipients that refuse to provide abortion counseling and referrals will clearly be eligible to participate in the Title X program and to apply to provide family planning

services as grantees or subrecipients. And the expansion of provider and family planning options would have salutary benefits for patients, including for patients who seek providers who share their religious beliefs or moral convictions.

As the Department has stated with regard to other conscience protection actions, open communication in the doctor-patient relationship would foster better over-all care for patients. While the benefit of open and honest communication between a patient and her doctor is difficult to quantify, one study showed that even ''the quality of communication [between the physician and patient] affects outcomes . . . [and] influences how often, and if at all, a patient would return to that same physician.'' [142] Facilitating open communication between providers and their patients helps to eliminate barriers to care. Because positions of conscience are often grounded in religious influence, ''[d]enying the aspect of spirituality and religion for some patients can act as a barrier. These influences can greatly affect the well-being of people. These influences were reported to be an essential element in the lives of certain migrant women which enabled them to face life with a sense of equality.'' [143] It is important for patients seeking care to feel assured that their faith, and the principles of conscience grounded in their faith, would be honored, especially in the area of family planning. This would ensure that patients with such religious beliefs or moral convictions feel they are being treated fairly and that their religious beliefs or moral convictions are respected.[144]

C. Analysis of Regulatory Alternatives

The Department considered a variety of options to ensure that it is clear to grantees, the general public, and patients who depend upon Title X services, that Title X programs do not fund, support, or promote abortion as a method of family planning. Specifically, the Department considered:

(1) Maintaining the status quo, where only line-item, pro-rated financial separation from activities that treat abortion as a method of family planning is required. However, such financial accounting separation leaves too much ambiguity surrounding abortion activities that may be a part of the overall services of the organization or facility, although not a part of Title X-funded family planning services. The Department considered utilizing programmatic guidance and funding opportunity announcements (FOAs, also known as notices of funding opportunities) to address that problem, but such actions would not be able to fix the requirement that Title X providers provide counseling on, and referral for, abortion upon request, a requirement inconsistent with federal conscience laws, and at least in terms of abortion referrals, is also inconsistent with section 1008 and that could be discouraging to potential grantees and subrecipients that refuse to counsel on, or provide referrals for, abortion. The maintenance of this requirement, as noted above, is potentially inconsistent with the Coats-Snowe Amendment and the Weldon Amendment. Moreover, part 59 as it currently exists, affords no mechanisms by which the Department would be able to verify whether grantees and their subrecipients are complying with the statutory program integrity, education, and reporting requirements. In addition, the Department would still be required to use application review criteria that the Department now believes fail to ensure that applicants comply with the statutory requirements of the Title X program. As detailed earlier, application review criteria must serve as a meaningful instrument to assess the quality of the applicant and the application. While the Department had discretion under the 2000 regulations to strengthen the selection criteria through FOA requirements, such an approach does not give the public notice of the long term commitment of the program.

(2) Requiring signage, brochures or separate staff and examination rooms within the same physical space to delineate a separation between Title X and abortion-related services. The Department considered that this less restrictive option might serve the same goal as physical separation in erasing, or mitigating, the current confusion between Title X and abortion-related services. But the Department determined that a shared reception area with materials available on both Title X family planning services and abortion-related services would continue the confusion, rather than mitigate it. Signage is often not read, and the segregation of staff or staff responsibilities within the same reception area likely would not provide sufficient distinction to end confusion. If the same physical space provides both Title X and abortion-related services, signs and separate receptionists may only diminish, but not eliminate, the public perception and confusion. Different examination rooms would likely have little impact because patients would be unaware that the purpose of a suite of examination rooms differs by funding stream, if the entrance and reception area is shared in common. The optics and practical operation of two distinct services within a single collocated space are difficult, if not impossible to overcome.

Commenters contend that the Department neglected to fully address the economic impact of proposed regulatory provisions, maintain that there are more cost-effective alternatives, and present three regulatory alternatives that would not substantively change the status quo and which were not considered in the analysis: (1) Provide exemptions to those with objections to providing information about abortion; (2) improve public education efforts, so the public understands Title X funds cannot be used for abortion; and (3) permit longer time frames between finalization of, and required compliance to, the final rule in order to lower costs associated with implementation.

The Department appreciates these suggestions, but does not accept these as meaningful alternatives to the changes proposed by the rule. While cost is an important consideration in any rulemaking, compliance with statutory program integrity provisions is of greater importance and none of the alternatives suggested by commenters guarantees such program integrity. The first alternative, the provision of exemptions to those who object to providing information concerning abortion, is unnecessary with the elimination of the requirement for abortion counseling and referral. Also, the Department's approach obviates the need for a burdensome process, involving the expenditure of additional time and resources by both the provider and the federal government associated with proposing, processing, and investigating each request for exemption. The elimination of the requirement for abortion counseling and referral, coupled with the regulatory permission for nondirective pregnancy counseling, achieves the same objective without the need for such a burdensome process. In addition, the mere existence of the requirements—even with a process to apply for exemptions—may serve to discourage organizations with religious or moral objections to

[142] Fallon E. Chipidza, F. E. *et al.,* Impact of the Doctor-Patient Relationship, *The Primary Care Companion for CNS Disorders* 17(5) (Oct. 22, 2015), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4732308.*

[143] Scheppers, E. *et al.,* Potential Barriers to the Use of Health Services Among Ethnic Minorities: A Review, *Family Practice* (23):325, 343 (June 1, 2006), *https://academic.oup.com/fampra/article/23/3/325/475515.*

[144] *Id.*

counseling on, or referring for, abortion from applying. Moreover, that alternative does not address the fact that the Department believes that the current requirement to provide abortion referrals upon request is inconsistent with PHS Act § 1008's prohibition on funding projects where abortion is a method of family planning. Second, the Department agrees that educational efforts to help the general public understand the services provided by Title X would be beneficial, but this alternative does not negate the need for clear and understandable separation between Title X services and abortion services at the clinic level. Physical separation assists with statutory compliance, in addition to improving public perception, by ensuring that both intentional and unintentional comingling of resources, activities, and services do not take place in ways that are exacerbated when both services are housed in the same space. Finally, the Department considered longer implementation periods and has updated and extended transition periods and compliance dates for the provisions of this final rule, in response to comments, but the Department is not convinced that extending the time period for compliance with the final rule in any way decreases the overall cost.

The Department, therefore, concludes that no other alternative would adequately address the two categories of problems it seeks to address: (1) Insufficient compliance with the statutory requirements and the purpose and goals of the Title X program (especially those related to section 1008), the appropriations provisos and riders addressing the Title X program, and other obligations and requirements established under other Federal laws; and (2) lack of transparency regarding the provision of Title X family planning services.

Thus, for these reasons and other stated reasons for our decision to propose both physical and financial separation, the Department determines that all of these options would be insufficient to ensure statutory compliance and clarity regarding such compliance.

D. Executive Order 13771

Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This final rule is considered an Executive Order 13771 regulatory action. The Department estimates that this rule generates $15.0 million in annualized costs at a 7% discount rate, discounted relative to fiscal year 2016, over a perpetual time horizon.

E. Regulatory Flexibility Analysis

As discussed above, the RFA requires agencies that issue a regulation to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. The Department considers a rule to have a significant economic impact on a substantial number of small entities if at least 5% of small entities experience an impact of more than 3% of revenue.

In the public comments, some commenters contend that implementing the new requirements within the first year after publication of the final rule will require transitioning to electronic health records, allocating staff to perform additional documentation, recruiting new staff/consultants, engaging legal support, and allocating training time (requiring facility closure). Commenters argue that these changes would incur costs much higher than the Department's estimated cost to implement the new requirements. Commenters express concern that these requirements will result in decreased provider participation in the Title X program, reducing services for the communities they serve.

In most cases, the Department does not find these comments compelling, since commenters do not provide sufficient detail and explanation. The Department accordingly does not find comments that predicted a large impact more reliable than the estimates set forth in the proposed rule. But the Department made some amendments to this final rule, particularly with respect to extending compliance dates and clarifying what requirements fall under each date of compliance. These amendments are described in other parts of the final rule and those germane to the RIA are detailed throughout this section.

The Department calculates the costs of the changes per service site over 2019–2023. The estimated average annualized cost of the final rule per service site is approximately $6,761 using a 3% discount rate, accounting for comments received. This represents an increase from $5,423 in the proposed rule. The Department notes that this figure includes all costs and that relatively large entities are likely to experience proportionally higher costs. The U.S. Small Business Administration establishes size standards that define a small entity. According to these standards, family planning centers with revenues below $11.0 million are considered small entities. Since the estimated costs of the final rule would be a small fraction of the standard by which a family planning center entity is considered a small entity, the Department anticipates that this final rule will not have a significant economic impact on a substantial number of small entities.

F. Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999, Public Law 105–277, sec. 654, 112 Stat. 2681 (1998), requires Federal departments and agencies to determine whether a policy or regulation could affect family well-being.[145]

Agencies must assess whether the regulatory action: (1) Impacts the stability or safety of the family, particularly in terms of marital commitment; (2) impacts the authority of parents in the education, nurture, and supervision of their children; (3) helps the family perform its functions; (4) affects disposable income or poverty of families and children; (5) if the regulatory action financially impacts families, are justified; (6) may be carried out by State or local government or by the family; and (7) establishes a policy concerning the relationship between the behavior and personal responsibility of youth and the norms of society.[146] If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law.

Some commenters contend that the proposed rule fails to address the impact of unplanned births on families, arguing that unplanned births are a known factor in familial instability and dysfunction, decreased disposable income, and decreased relationship satisfaction. Commenters contend that the Department has incorrectly concluded that the proposed rule will not pose negative effects to family well-being, and noted a lack of evidence and/or justification for this conclusion. Commenters contend that increased

[145] This section discusses the assessment required in Executive Order 12606, The Family, which was revoked on April 21, 1997. Office of Management and Budget, Memorandum from Jacob Lew, Dir., To Heads of Executive Departments, Agencies, & Independent Establishments Assessment of Federal Regulations and Policies on Families (Jan. 26, 1999), *https://www.fws.gov/policy/library/rglew.pdf*.

[146] Treasury and General Government Appropriations Act, 1999, Public Law 105–277, sec. 654, 112 Stat. 2681, 2681–528 to 2681–530 (1998).

unintended pregnancies decrease Quality Adjusted Life Years (QALYs), and therefore the proposed rule would result in increased costs. Commenters contend that access to contraceptives has several benefits including the pursuit of higher education and increased earning power for unmarried women, leading to more enduring relationships in the future; and enabling couples to plan the number of children in their family, increasing parents' ability to invest in their children, and in turn improving children's development and ability to succeed in school.

The Department does not change from its opinion that the action taken in this final rule cannot be carried out by State or local government or by the family because the rule pertains to the enforcement of certain Federal laws and the administration of a Federal program. While the Department agrees that family planning is important, it does not agree that the final rule will negatively impact access to family planning. On the contrary, more patients could have access to services because of changes to the program. Commenters offer no compelling evidence that this rule will increase unintended pregnancies or decrease access to contraception.

Other commenters note that the Department previously has supported legislation that increases access to family planning care and provides necessary referrals. Commenters contend that the Department has supported the personal agency of families and individuals over Federal involvement in family activities in the past. Commenters contend that the Department should be required to explain its change in position.

The Department is perplexed by these comments, since the Department supports increased access to family planning services, promotes informed care for patients, and encourages family participation in family planning decisions. The final rule is designed to increase access to family planning and referrals to maintain the health of the patient. In fact, providing health care services to patients is of such importance to the Department that it encourages grantees to either provide comprehensive health services or maintain a close relationship with those who do. The Department therefore rejects the premise of this set of comments and concludes that it is not necessary to prepare a Family Policymaking Assessment.

The Secretary certifies that this final rule has been assessed in accordance with section 654 of the Treasury and General Government Appropriations Act of 1999, Public Law 105–277, sec. 654, 112 Stat. 2681 (1998), and will not negatively affect family well-being.

G. 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, 44 U.S.C. 3501–3520. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 3. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA), the Department solicited comment on the following issues:

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

The Department solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA. The collections of information required by the final rule relate to § 59.2 (Definitions), § 59.5 (What requirements must be met by a family planning project?), § 59.7 (What criteria would the Department of Health and Human Services use to decide which family planning services projects to fund and in what amounts?), § 59.13 (Standards of compliance with prohibition on abortion), § 59.17 (Compliance with reporting requirements), and § 59.18 (Appropriate use of funds).

Section 59.2 would apply to situations where an unemancipated minor wishes to receive services on a confidential basis and be considered on the basis of her/his own resources, as would § 59.5(a)(14). In such cases, the Title X provider would be required to document in the minor's medical records the specific actions taken by the provider to encourage the minor to involve her/his family (including her/his parents or guardian) in her/his decision to seek family planning services. This documentation requirement would not apply if the Title X provider (1) believes that the minor is a victim of child abuse or incest and (2) has, consistent with applicable State or local law, reported the situation to the relevant authorities. The reporting requirement must be documented in the medical record.

Section 59.5 requires Title X providers to report, in grant applications and in all required reports, information regarding subrecipients and referral agencies and individuals, including a detailed description of the extent of collaboration and a clear explanation of how the grantee will ensure adequate oversight and accountability; and to maintain records with respect to minors on the specific actions taken to encourage family participation (or the reason why such family participation was not encouraged).

Section 59.7 requires Title X grant applicants to describe, within their applications, their affirmative compliance with each provision of the regulations governing the Title X program.

Section 59.13 requires Title X grantees to provide assurance satisfactory to the Secretary that, as a Title X grantee, it does not provide abortion and does not include abortion as a method of family planning. This assurance will include, at a minimum, representations (supported by documentary evidence where the Secretary requests it) as to compliance with § 59.13 and each of the requirements in § 59.14 through § 59.16.

Section 59.17 requires Title X grantees to provide appropriate documentation or other assurance satisfactory to the Secretary that it has in place and has implemented a plan to comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking. It also requires Title X grantees to maintain records to demonstrate compliance with the requirements of § 59.17, and makes continuation of funding for Title X services contingent upon demonstrating to the Secretary that the criteria have been met.

Lastly, § 59.18 requires Title X grantees to give a detailed accounting of use related to grant dollars, both in their applications for funding, and within any annually required reporting, and to fully account for, and justify, charges against the Title X grant.

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 grantees to sign. The Department anticipates two separate burdens of response: (1) Assurance of compliance; and (2) documentation of compliance.

The burden for the assurance of compliance is the cost of grantee and/or subrecipient staff time to (a) review

the assurance language as well as the underlying language related to stated requirements; (b) to review grantee and/or subrecipient policies and procedures or to take other actions to assess grantee and/or subrecipient compliance with the requirements to which the grantee and/or subrecipient is required to assure compliance.

The labor cost would include a lawyer spending an average of 3 hours reviewing all assurances and a medical and health service manager spending an average of one hour reviewing and signing the assurances at each grantee and subrecipient. The Department estimates the number of grantees and subrecipients at 1,208, based on 2016 number of Title X grantees and subrecipients, as represented in Title X FPAR data. The mean hourly wage (not including benefits and overhead) for these occupations is $67.25 per hour for the lawyer and $52.58 for the medical and health service manager, as noted in the table above. The labor cost is $307,000 in the first year (($67.25 × 3 + $52.58 × 1) × 1,208 grantees and subrecipients). The Department estimates that the cost, in subsequent years, would be $145,000, which would represent an annual allotment of one hour for the lawyer and one hour for the medical and health service manager (($67.25 × 1 + $52.58 × 1) × 1,208 grantees and subrecipients).

The Department estimates that all grantees and subrecipients will review their organizational policies and procedures or take other actions to self-assess compliance with applicable Title X requirements each year, spending an average of 4 hours doing so. The labor cost is a function of a lawyer spending an average of 3 hours and a medical and health service manager spending an average of one hour. The labor cost for self-assessing compliance, such as reviewing policies and procedures, is a total of $307,000 each year (($67.25 × 3 + $52.58 × 1) × 1,208 grantees and subrecipients).

The burden for the documentation of compliance is the cost of grantee and/or subrecipient staff time to (a) document in a minor's medical records actions taken to encourage the minor to involve parents in family planning services and (b) complete reports regarding information related to subrecipients, referral agencies and individuals involved in the grantee's Title X project. The Department assumes that a physician assistant would be used to document such compliance. The mean hourly wage (not including benefits and overhead) for this occupation is $49.08 per hour. The labor cost would require spending an average of 10 minutes to make appropriate documentation in a minor's medical records. Approximately 20% (800,000) of the 4 million Title X clients are adolescents. The Department estimates that complying with the requirement to encourage family participation will result in 75% (600,000) of adolescent patients' medical records requiring appropriate documentation. The labor cost will be $982,000 each year ($49.08 per hour × 2 minutes × 600,000 adolescents).

The labor cost would also include a medical and health services manager spending an average of four hours each year to complete reports regarding information related to subrecipients involved in the grantee's Title X project at each grantee and subrecipient. The labor cost will be $254,000 each year ($52.58 per hour × 4 hours × 1,208 grantees and subrecipients).

TABLE 3—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS OR BURDEN OF RESPONSE IN YEAR ONE/SUBSEQUENT YEARS UPON PUBLICATION OF THE FINAL RULE

Regulation burden	OMB control No.	Respondents responses	Hourly rate ($)	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)
Assurance of Compliance	NEW	1,208/1,208	63.58/62.36	8/6	9,664/7,248	614,000/452,000
Documentation of Compliance	NEW	1,208/1,208	52.58/52.58	4/4	4,832/4,832	254,000/254,000
Documentation on Minor's Medical Records.	NEW	600,000/600,000	49.08/49.08	.03/.03	20,000/20,000	982,000/982,000
Total Cost						1,850,000/1,688,000

The Department asked for public comment on the information collection including what additional benefits may be cited as a result of this rule. Where warranted, changes were made in the preceding calculations of cost.

The Department has submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

List of Subjects in 42 CFR Part 59

Family planning, Grant programs—health, Grant programs—social programs, Health professions, Reporting and recordkeeping requirements, Youth, Health, Abortion, Birth control, Title X, Contraception, Natural family planning, Infertility, Fertility awareness.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 42 CFR chapter I, subchapter D, part 59, as set forth below:

PART 59—GRANTS FOR FAMILY PLANNING SERVICES

■ 1. The authority citation for part 59 is revised to read as follows:

Authority: 42 U.S.C. 300 through 300a–6.

■ 2. Revise § 59.1 to read as follows:

§ 59.1 To what programs do these regulations apply?

(a) 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. Unless otherwise specified, the requirements imposed by these regulations apply equally to grantees and subrecipients, and grantees shall require and ensure that subrecipients (and the subrecipients of subrecipients) comply with the requirements contained in these regulations pursuant to their written contracts with such subrecipients.

(b) Except for §§ 59.4, 59.8, and 59.10, the regulations of this subpart are also applicable to the execution of contracts 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, and will be applied in accordance with the

applicable statutes, procedures and regulations that generally govern Federal contracts. To this extent, the use of the terms ''grant'', ''award,'', ''grantee'' and ''subrecipient'' in applicable regulations of this subpart will apply similarly to contracts, contractors and subcontractors, and the use of the term ''project'' or ''program'' will also apply to a project or program established by means of a contract.

■ 3. Amend § 59.2 by:
■ a. Adding in alphabetical order definitions for ''Advanced Practice Provider'', ''Family Planning'' and ''Grantee'';
■ b. Revising the definition of ''Low income family''; and
■ c. Adding in alphabetical order definitions for ''Program and project'', and ''Subrecipient''.

The additions and revision read as follows:

§ 59.2 Definitions.

* * * * *

Advanced Practice Provider means a medical professional who receives at least a graduate level degree in the relevant medical field and maintains a license to diagnose, treat, and counsel patients. The term Advanced Practice Provider includes physician assistants and advanced practice registered nurses (APRN). Examples of APRNs that are an Advanced Practice Provider include certified nurse practitioner (CNP), clinical nurse specialist (CNS), certified registered nurse anesthetist (CRNA), and certified nurse-midwife (CNM).

* * * * *

Family planning means the voluntary process of identifying goals and developing a plan for the number and spacing of children and the means by which those goals may be achieved. These means include a broad range of acceptable and effective family planning methods and services, which may range from choosing not to have sex to the use of other family planning methods and services to limit or enhance the likelihood of conception (including contraceptive methods and natural family planning or other fertility awareness-based methods) and the management of infertility, including information about or referrals for adoption. Family planning services include preconception counseling, education, and general reproductive and fertility health care, in order to improve maternal and infant outcomes, and the health of women, men, and adolescents who seek family planning services, and the prevention, diagnosis, and treatment of infections and diseases which may threaten childbearing capability or the health of the individual, sexual partners, and potential future children. Family planning methods and services are never to be coercive and must always be strictly voluntary. Family planning does not include postconception care (including obstetric or prenatal care) or abortion as a method of family planning. Family planning, as supported under this subpart, should reduce the incidence of abortion.

Grantee means the entity that receives Federal financial assistance by means of a grant, and assumes legal and financial responsibility and accountability for the awarded funds, for the performance of the activities approved for funding and for reporting required information to the Office of Population Affairs.

Low income family means a family whose total income does not exceed 100% of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). The project director may find that ''Low income family'' also includes members of families whose annual 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:

(1) Unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources, provided that the Title X provider has documented in the minor's medical records the specific actions taken by the provider to encourage the minor to involve her/his family (including her/his parents or guardian) in her/his decision to seek family planning services, except that documentation of such encouragement is not to be required if the Title X provider has documented in the medical record:

(i) That it suspects the minor to be the victim of child abuse or incest; and

(ii) That it has, consistent with, and if permitted or required by, applicable State or local law, reported the situation to the relevant authorities.

(2) For the purpose of considering payment for contraceptive services only, where a woman has health insurance coverage through an employer that does not provide the contraceptive services sought by the woman because the employer has a sincerely held religious or moral objection to providing such coverage, the project director may consider her insurance coverage status as a good reason why she is unable to pay for contraceptive services. In making that determination, the project director must also consider other circumstances affecting her ability to pay, such as her total income. The project director may, for the purpose of considering whether the woman is from a ''low income family'' or is eligible for a discount for contraceptive services on the schedule of discounts provided for in § 59.5, consider her annual income as being reduced by the total annual out-of-pocket costs of contraceptive services she uses or seeks to use. The project director may determine those costs, or estimate them at $600.

* * * * *

Program and *project* are used interchangeably and mean a plan or sequence of activities that is funded to fulfill the requirements elaborated in a Title X funding announcement; it may be comprised of, and implemented by, a single grantee or subrecipient(s), or a group of partnering providers who, under a grantee or subrecipient, deliver comprehensive family planning services that satisfy the requirements of the grant within a service area.

* * * * *

Subrecipient means any entity that provides family planning services with Title X funds under a written agreement with a grantee or another subrecipient. These entities may also be referred to as ''delegates'' or ''contract agencies.''

■ 4. Revise § 59.3 to read as follows:

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

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

■ 5. Amend § 59.5 by:
■ a. Revising paragraphs (a)(1) and (5);
■ b. Removing paragraph (a)(10)(i);
■ c. Redesignating paragraph (a)(10)(ii) as (a)(10);
■ d. Adding paragraphs (a)(12), (13), and (14); and
■ e. Revising paragraphs (b)(1) and (8).

The revisions and additions read as follows:

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

(a) * * *

(1) Provide a broad range of acceptable and effective family planning methods (including contraceptives, natural family planning or other fertility awareness-based methods) and services (including infertility services, information about or referrals for adoption, and services for adolescents). Such projects are not required to provide every acceptable and effective family planning method or service. A participating entity may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services.

* * * * *

(5) Not provide, promote, refer for, or support abortion as a method of family planning.

* * * * *

(12) Should offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity, to the Title X site, in order to promote holistic health and provide seamless care.

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

(i) Subrecipients and agencies or individuals providing referral services by name, location, expertise and services provided or to be provided;

(ii) Detailed 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) Clear explanation of how the grantee will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients.

(14) Encourage family participation in the decision to seek family planning services; and, with respect to each minor patient, ensure that the records maintained document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).

(b) * * *

(1) Provide for medical services related to family planning (including physician's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) and referral to other medical facilities when medically necessary, consistent with § 59.14(a), and provide for the effective usage of contraceptive devices and practices.

* * * * *

(8) Except as provided in § 59.14(a), provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.

* * * * *

■ 6. Amend § 59.7 by:

■ a. Revising paragraph (a);

■ b. Redesignating paragraphs (b) and (c) as paragraphs (d) and (e); and

■ c. Adding new paragraphs (b), and (c).

The revisions and additions read as follows:

§ 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 statutory provisions applicable to the Title X program, and ensure that no Title X funds are used where abortion is a method of family planning.

(b) Any grant applications that do not clearly address how the proposal will satisfy the requirements of this regulation shall not proceed to the competitive review process, but shall be deemed ineligible for funding. The Department will explicitly summarize each requirement of the Title X regulations or include the Title X regulations in their entirety within the Funding Announcement, and shall require each applicant to describe its plans for affirmative compliance with each requirement.

(c) If the proposal is deemed compliant with this regulation, then applicants will be subject to criteria for selection within the competitive grant review process, including:

(1) The degree to which the applicant's project plan adheres to the Title X statutory purpose and goals for the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents), while meeting all of the statutory and regulatory requirements and restrictions, including that none of the funds shall be used in programs where abortion is a method of family planning.

(2) The degree to which the relative need of the applicant for Federal funds is demonstrated in the proposal, and the applicant shows capacity to make rapid and effective use of grant funds, including its ability to procure a broad range of diverse subrecipients, as applicable, in order to expand family planning services available to patients in the project area.

(3) The degree to which the applicant takes into account the number of patients, particularly low-income patients, to be served while also targeting areas that are more sparsely populated and/or places in which there are not adequate family planning services available.

(4) The extent to which family planning services are needed locally and the applicant proposes innovative ways to provide services to unserved or underserved communities.

* * * * *

■ 7. Revise § 59.11 to read as follows:

§ 59.11 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and 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; concern with respect to the confidentiality of information, however, may not be used as a rationale for noncompliance with laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

■ 8. Add § 59.13 through § 59.19 to subpart A to read as follows:

Sec.

* * * * *

59.13 Standards of compliance with prohibition on abortion.
59.14 Requirements and limitations with respect to post-conception activities.
59.15 Maintenance of physical and financial separation.
59.16 Prohibition on activities that encourage, promote, or advocate for abortion.
59.17 Compliance with reporting requirements.
59.18 Appropriate use of funds.
59.19 Transition provisions; compliance.

§ 59.13 Standards of compliance with prohibition on abortion.

A project may not receive funds under this subpart unless the grantee provides assurance satisfactory to the Secretary that the project does not provide abortion and does not include abortion as a method of family planning. Such assurance must also include, at a minimum, representations (supported by documentary evidence where the Secretary requests it) as to compliance with this section and each of the requirements in §§ 59.14 through 59.16. A project supported under this subpart must comply with such requirements at all times during the project period.

§ 59.14 Requirements and limitations with respect to post-conception activities.

(a) *Prohibition on referral for abortion.* A Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take

any other affirmative action to assist a patient to secure such an abortion.

(b) *Information about prenatal care.* (1) Because Title X funds are intended only for family planning, once a client served by a Title X project is medically verified as pregnant, she shall be referred to a health care provider for medically necessary prenatal health care. The Title X provider may also choose to provide the following counseling and/or information to her:

(i) Nondirective pregnancy counseling, when provided by physicians or advanced practice providers;

(ii) A list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care);

(iii) Referral to social services or adoption agencies; and/or

(iv) Information about maintaining the health of the mother and unborn child during pregnancy.

(2) In cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of medical services needed to address the emergency.

(c) *Use of permitted lists or referrals to encourage abortion.* (1) A Title X project may not use the provision of any prenatal, social service, emergency medical, or other referral, of any counseling, or of any provider lists, as an indirect means of encouraging or promoting abortion as a method of family planning.

(2) The list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) in paragraph (b)(1)(ii) of this section may be limited to those that do not provide abortion, or may include licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), some, but not the majority, of which also provide abortion as part of their comprehensive health care services. Neither the list nor project staff may identify which providers on the list perform abortion.

(d) *Provision of medically necessary information.* Nothing in this subpart shall be construed as prohibiting the provision of information to a project client that is medically necessary to assess the risks and benefits of different methods of contraception in the course of selecting a method, provided that the provision of such information does not promote abortion as a method of family planning.

(e) *Examples.* (1) A pregnant client of a Title X project requests prenatal health care services. Because the provision of such services is outside the scope of family planning supported by Title X, the client is referred for prenatal care and may be provided a list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care). Provision of a referral for prenatal health care is consistent with this part because prenatal care is a medically necessary service.

(2) A Title X project discovers an ectopic pregnancy in the course of conducting a physical examination of a client. Referral arrangements for emergency medical care are immediately provided. Such action complies with the requirements of paragraph (b) of this section.

(3) After receiving nondirective counseling at a Title X provider, a pregnant woman decides to have an abortion, is concerned about her safety during the procedure, and asks the Title X project to provide her with a referral to an abortion provider. The Title X project tells her that it does not refer for abortion, but provides the following: A list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), which is not presented as a referral for abortion, but as a list of comprehensive primary care and prenatal care providers that does not identify which providers perform abortion, and the project staff member does not identify such providers on the list; and information about maintaining her health and the health of her unborn child during pregnancy. Such actions comply with paragraphs (a) through (c) of this section.

(4) A pregnant woman asks the Title X project to provide her with a list of abortion providers in the area. The project tells her that it does not refer for abortion, and provides her a list that consists of hospitals and clinics and other providers, all of which provide comprehensive primary health care (including prenatal care), as well as abortion as a method of family planning. Although there are several licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) in the area that do not provide abortion as a method of family planning, none of these providers is included on the list. Provision of the list is inconsistent with paragraphs (a) and (c) of this section.

(5) A pregnant woman requests information on abortion and asks the Title X project to refer her for an abortion. The counselor tells her that the project does not consider abortion a method of family planning and, therefore, does not refer for abortion. The counselor offers her nondirective pregnancy counseling, which may discuss abortion, but the counselor neither refers for, nor encourages, abortion. The counselor further tells the client that the project can help her to obtain prenatal care and necessary social services and offers her the list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), assistance, and information for pregnant women described in paragraph (b) of this section. None of the providers on the list provide abortions. Such actions are consistent with paragraphs (a) through (c) of this section.

(6) Title X project staff provide contraceptive counseling to a client in order to assist her in selecting a contraceptive method. In discussing oral contraceptives, the project counselor provides the client with information contained in the patient package insert accompanying a brand of oral contraceptives, referring to abortion only in the context of a discussion of the relative safety of various contraceptive methods and in no way promoting abortion as a method of family planning. The provision of this information is consistent with paragraph (d) of this section and this section generally and does not constitute an abortion referral.

§ 59.15 Maintenance of physical and financial separation.

A Title X project must be organized so that it is physically and financially separate, as determined in accordance with the review established in this section, from activities which are prohibited under section 1008 of the Act and §§ 59.13, 59.14, and 59.16 of these regulations from inclusion in the Title X program. In order to be physically and financially separate, a Title X project must have an objective integrity and independence from prohibited activities. Mere bookkeeping separation of Title X funds from other monies is not sufficient. The Secretary will determine whether such objective integrity and independence exist based on a review of facts and circumstances. Factors relevant to this determination shall include:

(a) The existence of separate, accurate accounting records;

(b) The degree of separation from facilities (*e.g.,* treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites) in which prohibited activities occur and the extent of such prohibited activities;

(c) The existence of separate personnel, electronic or paper-based health care records, and workstations; and

(d) The extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent.

§ 59.16 Prohibition on activities that encourage, promote, or advocate for abortion.

(a) *Prohibition on activities that encourage abortion.* (1) A Title X project may not encourage, promote or advocate abortion as a method of family planning. This restriction prohibits actions in the funded project that assist women to obtain abortions for family planning purposes or to increase the availability or accessibility of abortion for family planning purposes.

(2) Prohibited actions include the use of Title X project funds for the following:

(i) Lobbying for the passage of legislation to increase in any way the availability of abortion as a method of family planning;

(ii) Providing speakers or educators who promote the use of abortion as a method of family planning;

(iii) Attending events or conferences during which the grantee or subrecipient engages in lobbying;

(iv) Paying dues to any group that, as a more than insignificant part of its activities, advocates abortion as a method of family planning and does not separately collect and segregate funds used for lobbying purposes;

(v) Using legal action to make abortion available in any way as a method of family planning; and

(vi) Developing or disseminating in any way materials (including printed matter, audiovisual materials and web-based materials) advocating abortion as a method of family planning.

(b) *Examples.* (1) Clients at a Title X project are given brochures advertising a clinic that provides abortions, or such brochures are available in any fashion at a Title X clinic (sitting on a table or available or visible within the same space where Title X services are provided). Provision or availability of the brochure violates paragraph (a)(2)(vi) of this section.

(2) A Title X project makes an appointment for a pregnant client for an abortion for family planning purposes. The Title X project has violated paragraph (a)(1) of this section.

(3) A Title X project pays dues with project funds to a State association that, among other activities, lobbies at State and local levels for the passage of legislation to protect and expand the legal availability of abortion as a method of family planning. The association spends a significant amount of its annual budget on such activity and does not separately collect and segregate the funds for such purposes. Payment of dues to the association violates paragraph (a)(2)(iv) of this section.

(4) An organization conducts a number of activities, including operating a Title X project. The organization uses non-project funds to pay dues to an association that, among other activities, engages in lobbying to protect and expand the legal availability of abortion as a method of family planning. The association spends a significant amount of its annual budget on such activity. Payment of dues to the association by the organization does not violate paragraph (a)(2)(iv) of this section.

(5) An organization that operates a Title X project engages in lobbying to increase the legal availability of abortion as a method of family planning. The project itself engages in no such activities, and the facilities and funds of the project are kept separate from prohibited activities. The project is not in violation of paragraph (a)(2)(i) of this section.

(6) Employees of a Title X project write their legislative representatives in support of legislation seeking to expand the legal availability of abortion, in their personal capacities and using no project funds to do so. The Title X project has not violated paragraph (a)(2)(i) of this section.

(7) On her own time and at her own expense, a Title X project employee speaks before a legislative body in support of abortion as a method of family planning. The Title X project has not violated paragraph (a)(2)(i) of this section.

(8) A Title X project uses Title X funds for sex education classes in a local high school. During the course of the class, information is distributed to students that includes abortion as a method of family planning. The Title X project has violated paragraph (a)(2)(vi) of this section.

§ 59.17 Compliance with reporting requirements.

(a) 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'').

(b) A project may not receive funds under this subpart unless it provides appropriate documentation or other assurance satisfactory to the Secretary that it:

(1) Has in place and implements a plan to comply with State notification laws. Such plan shall include, at a minimum, policies and procedures that include:

(i) A summary of obligations of the project or organizations and individuals carrying out the project under State notification laws, including any obligation to inquire about or determine the age of a minor client or of a minor client's sexual partner(s);

(ii) 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 provider 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.

(iii) Protocols to ensure that every minor who presents for treatment is provided counseling on how to resist attempts to coerce them into engaging in sexual activities; and

(iv) Commitment to conduct a preliminary screening of any minor who presents with a sexually transmitted disease (STD), pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor. Projects are permitted to diagnose, test for, and treat STDs.

(2) Maintains records to demonstrate compliance with each of the requirements set forth in paragraph (b)(1) of this section, including which:

(i) Indicate the age of minor clients;

(ii) Indicate the age of the minor client's sexual partners if such age is an element of a State notification law under which a report is required; and

(iii) Document each notification or report made pursuant to such State notification laws.

(c) Continuation of grantee or subrecipient funding for Title X services is contingent upon demonstrating to the satisfaction of the Secretary that the criteria have been met.

(d) The Secretary may review records maintained by a grantee or subrecipient for the purpose of ensuring compliance with the requirements of this section, the requirement to encourage family participation in family planning decisions, or any other section of this rule.

§ 59.18 Appropriate use of funds.

(a) Title X funds shall not be used to build infrastructure for purposes prohibited with these funds, such as support for the abortion business of a Title X grantee or subrecipient. Funds shall only be used for the purposes, and in direct implementation of, the funded project, expressly permitted by this regulation and authorized within section 1001 of the Public Health Service Act, that is, to offer family planning methods and services. Grantees must use the majority of grant funds to provide direct services to clients, and each grantee shall provide a detailed plan or accounting for the use of grant dollars, both in their applications for funding, and in any annually required reporting. Any significant change in the use of grant funds within the grant cycle shall not be undertaken without the approval of the Office of Population Affairs.

(b) Title X funds shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for office.

(c) Each project supported under Title X shall fully account for, and justify, charges against the Title X grant. The Department shall put additional protections in place to prevent possible misuse of Title X funds through misbilling or overbilling, or any other unallowable expense.

§ 59.19 Transition provisions; compliance.

(a) *Compliance date concerning physical and financial separation.* The date by which covered entitites must comply with the physical separation requirements contained in § 59.15, is March 4, 2020. The date by which covered entities must comply with the financial separation requirements contained in § 59.15 is July 2, 2019.

(b) *Compliance date concerning applications.* The date by which covered entities must comply with § 59.7 and 59.5(a)(13) (as it applies to grant applications), is the date on which competitive or continuation award applications are due, where that date occurs after July 2, 2019.

(c) *Compliance date concerning reporting, assurance, and provision of service requirements.* The date by which covered entities must comply with §§ 59.5(a)(12), 59.5(a)(13) (as it applies to all required reports), 59.5(a)(14), (b)(1) and (8), 59.13, 59.14, 59.17, and 59.18gg is July 2, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–03461 Filed 2–26–19; 4:15 pm]

BILLING CODE 5140–34–P

Decl
2/23/88

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 88-Z-158

PLANNED PARENTHOOD FEDERATION OF AMERICA, et al.,

Plaintiffs,

v.

OTIS BOWEN, M.D., individually and in his capacity as Secretary of the United States Department of Health and Human Services,

Defendant.

FILED

PRELIMINARY INJUNCTION

Pursuant to Federal Rule of Civil Procedure 65(a), this Court finds and orders as follows:

1. This action was brought by Planned Parenthood Federation of America, Planned Parenthood of the Rocky Mountains, Planned Parenthood Association of Utah, Boulder Valley Women's Health Center, Marilyn Foelski, Philip Freedman, and Kirtly Jones. Planned Parenthood Federation of America sued on its own behalf and on behalf of its affiliates who receive funds under Title X of the Public Health Service Act, 42 U.S.C. § 300 et seq., and who have not sued elsewhere. A list of these affiliates is attached to this Preliminary Injunction as Exhibit A. Collectively, all of the entities and persons identified in this paragraph and Exhibit A shall be referred to in this Order as "Plaintiffs and Affiliates."

2. Plaintiffs have moved for a preliminary injunction to enjoin defendant Otis Bowen from implementing or enforcing certain regulations promulgated under Title X of the Public Health Service Act. At the hearing on that motion, held on Monday, February 15, 1988, this Court found that the Plaintiffs had satisfied the standards for granting a preliminary injunction set forth in Lundgrin v. Claytor, 619 F.2d 61, 63 (10th Cir. 1980). Those findings are incorporated into this Order by reference.

3. Accordingly, this Court orders that defendant Otis Bowen is enjoined from taking any action, directly or indirectly, to condition grants under Section 1001 of Title X on compliance

with or otherwise implementing or enforcing against the Plaintiffs and Affiliates the regulations published at 52 Fed. Reg. 2944-2946 (February 2, 1988), including without limitation those regulations appearing at 42 C.F.R. §§ 59.7, 59.8, 59.9, and 59.10, and the related definitions appearing at Section 59.2.

4. This injunction shall bind defendant Otis Bowen in his capacity as Secretary of the Department of Health and Human Services, his officers, agents, servants, employees, and attorneys, and all persons in active concert or participation with them who receive actual notice of this injunction.

5. Defendant Bowen shall provide a copy of this injunction to all persons responsible for implementing or enforcing the regulations with respect to the Plaintiffs and Affiliates.

BY THE COURT:

Zita L. Weinshienk

ZITA L. WEINSHIENK
DISTRICT COURT JUDGE

Dated: February 25th, 1988,
nunc pro tunc to February 15, 1988.

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of June, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Alan E. Schoenfeld
ALAN E. SCHOENFELD