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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 59

[Docket No.: 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.

ACTION: Proposed rule.

SUMMARY: The Office of Population Affairs (OPA), in the Office of the Assistant Secretary for Health, proposes to revise its Title X regulations (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. In addition, OPA proposes amendments to the Title X regulations that would, among other things, clarify grantee responsibilities to provide a broad range of family planning methods; to require documented compliance with State and local laws requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking; to provide free or low cost access to family planning services for those women who are unable to obtain employer-sponsored insurance coverage for certain contraceptive services due to their employers' religious beliefs or moral convictions; to provide for the appropriate expenditure of federal Title X funds on family planning services, rather than on lobbying or related

activities; and to appropriately encourage family participation in family planning decisions, all as required by Federal law.

DATES: Comments on this proposed rule are invited. To be considered, comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted to the Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Population Affairs, as specified below. Any comment that is submitted will also be made available to the public.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received. Comments may be submitted anonymously.

Comments, identified by “Family Planning” may be submitted by one of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Mail or Hand Delivery: Office of the Assistant Secretary for Health, Office of Population Affairs, Attention: Family Planning, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Room 716G, 200 Independence Avenue, SW, Washington, D.C. 20201.

Comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Valerie Huber at (202) 690-7694.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Requirements of Title X of the Public Health Service Act and the Title X Appropriations Acts

Title X of the Public Health Service Act (PHS Act or the Act), 42 U.S.C. 300 through 300a-6, was enacted in 1970 by Pub. L. 91-572. 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).” PHS Act sec. 1001(a); 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.¹ 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 determine the number and spacing of children.

¹ Fowler, C. I., Gable, J., Wang, J., & Lasater, B. *Family Planning Annual Report: 2016 National Summary* (Aug. 2017), <https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf>.

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.

The Conference Report described the intent of this provision as follows:

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

H.R. Rep. No 91-1667, at 8-9 (1970) (Conf. Rep.). Later Congresses have, through annual appropriations provisos, reiterated this requirement: “[A]mounts provided to said [voluntary family planning] projects, under such title shall not be expended for abortions.” *See, e.g.*, Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, Title II, 132 Stat. 348, 716 (2018); Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Title II, 131 Stat. 135, 521 (2017); Consolidated Appropriations Act, 2016, Pub. L. 114-113, Div. H, Title II, 129 Stat. 2242, 2602 (2015).

Since it originally created the Title X program in 1970, Congress has, from time to time, imposed additional requirements on it. For example, the annual Title X appropriation includes the provisos that “all pregnancy counseling shall be nondirective”² and that Title X funds “shall not be expended for any activity (including the publication

² *See* Omnibus Consolidated Rescissions and Appropriations Act, 1996, Pub. L. 104-134, Title II, 110 Stat.1321, 1321-221 (1996).

or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.”³ *See, e.g.*, Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, Title II, 132 Stat. 348, 716-717 (2018); Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Title II, 131 Stat. 135, 521 (2017).

Congress has given particular instructions for the services provided under Title X to minors and other vulnerable populations. Congress specifically required that Title X provide distinct services for adolescents. *See* PHS Act sec. 1001(a), 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)”). Congress also amended Title X in 1981 to require that, “[t]o the extent practicable, entities which receive grants or contracts under this subsection shall encourage family [sic] participation in projects under this subsection.” Omnibus Budget Reconciliation Act of 1981, Pub. L. 97-35, sec. 931(b)(1), 95 Stat. 357, 570 (1981); PHS Act sec. 1001(a), 42 U.S.C. 300(a). Since 1997,⁴ Congress has included a rider in HHS’s annual appropriations act that provides that “[n]one of the funds appropriated in this Act may be made available to any entity under title X of the PHS Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services.” Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, sec. 207, 132 Stat. 348, 736 (2018). The same appropriations rider also requires that such an applicant certify to the Secretary that it “provides counseling to minors on how to resist attempts to

³ *See* Omnibus Consolidated Rescissions and Appropriations Act, 1996, Pub. L. 104-134, Title II, 110 Stat. 1321, 1321-221 (1996).

⁴ *See* Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1998, Pub. L. 105-78, sec. 212, 111 Stat. 1467, 1495 (1997).

coerce minors into engaging in sexual activities.” *Id.* By means of another rider, Congress requires 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.” Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, sec. 208, 132 Stat. 348, 736 (2018).

B. Title X Regulations

Since 1971, the Department has repeatedly exercised rulemaking authority with respect to the Title X program. Section 1006(a) of the Act, 42 U.S.C. 300a-4, grants rulemaking power to the Department: It provides that “[g]rants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate.” The Department began to exercise that authority by issuing regulations implementing section 1008 in 1971. *See* 36 FR 18465 (Sept. 15, 1971). Although those regulations, and revised regulations issued in 1980 (45 FR 37436 (June 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 provide further guidance on the application of that prohibition. In 1982, the Department’s Office of Inspector General (OIG) audited 32 Title X clinics and found that the Department’s failure to provide such guidance had created confusion about precisely what activities were proscribed by the section and resulted in variations in practice among grantees.⁵ The General Accounting Office (GAO, now the Government Accountability Office) recommended that “the Secretary establish

⁵ HHS OIG, Review of PHS Title X Family Planning Grantees, Audit Control No. 12-33177 (Nov. 18, 1982).

clear operational guidance by incorporating into the Title X program regulations and guidelines, HHS’ position on the scope of the abortion restriction in section 1008.”⁶

1. 1988 Regulations and *Rust v. Sullivan*

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. The Department noted “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.” 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, Final Rule, 53 FR 2922, 2923 (Feb. 2, 1988). The Department sought to address this deficiency.

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 any abortion activities; and implemented compliance standards for family planning projects under Title X to specifically prohibit certain actions that promote or encourage, or advocate abortion as a method of family planning, such as the use of project funds for lobbying for abortion, developing and disseminating

⁶ GAO, No. HRD-82-106, Restrictions on Abortion and Lobbying Activities in Family Planning Programs Need Clarification, at 22 (Sept. 24, 1982), <https://www.gao.gov/assets/140/138760.pdf>.

materials advocating abortion, or taking legal action to make abortion available as a method of family planning. 53 FR 2922 (Feb. 2, 1988).

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). The Court first rejected the claim that the regulations violated the Administrative Procedure Act. Under *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), the Supreme Court reasoned that “substantial deference” was owed “to the interpretation of the authorizing statute by the agency authorized with administering it.” *Rust*, 500 U.S. at 184. Applying that framework, the Court concluded that—although the language of section 1008 did not speak directly to the issues of counseling, referral, advocacy, or program integrity—because the “broad language of Title X plainly allows the Secretary’s construction of the statute, . . . we are unable to say that the Secretary’s construction of the prohibition in § 1008 to require a ban on counseling, referral, and advocacy within the Title X project is impermissible.” *Id.* The Court similarly declined to view the regulations skeptically because they represented a change in policy; instead, it 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.* at 186-87. 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.’” *Id.* (internal citations omitted). Finally, the Supreme 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. 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 § 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 Supreme 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 § 1008 is constitutional” because Congress “may ‘make a value judgment favoring childbirth over abortion and . . . implement that judgment by the allocation of public funds.’” *Rust*, 500 U.S. at 192 (internal citations omitted; ellipsis in original). The Court explained that the counseling and referral provisions were consistent with the First Amendment as follows:

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.

Rust, 500 U.S. at 193-94. The Court also explained that the requirement of physical and financial program separation was consistent with the First Amendment as follows:

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 the public fisc, and the Secretary has simply required a certain degree of separation from the Title X project in order to ensure the integrity of the federally funded program.

Rust, 500 U.S. at 198. Finally, 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.

2. Suspension of 1988 Regulations and Finalization of 2000 Regulations

The 1988 Regulations continued to govern the Title X program until February 5, 1993, when a new Administration suspended them pursuant to a Presidential Memorandum and issued a proposed regulation, 58 FR 7464, that it finalized seven years

later, *see* 65 FR 41270 (July 3, 2000) (the “2000 Regulations”). The 2000 Regulations essentially returned to the 1981 Regulations (with one revision), which eliminated provisions (a) prohibiting Title X projects from counseling or referring project clients for abortion as a method of family planning; (b) requiring grantees to separate their Title X project physically and financially from any abortion activities; and (c) implementing 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 were necessary to separate Title X project activities from non-Title X abortion activities, it 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 affirmatively required that Title X providers counsel on, and refer for, abortion at the request of a Title X client.

Finally, the 2000 Regulations “incorporated in the regulatory text the policies relating to nondirective counseling and referral of the 1981 Program Guidelines for Project Grants for Family Planning Services [1981 Guidelines].” 65 FR at 41271. Those 1981 Guidelines, for the first time, required nondirective counseling about pregnancy options, including abortion, and did so in a way that “creat[ed] the appearance of treating each option identically,” despite the statutory prohibition on funding programs where

abortion is a method of family planning. *See* 53 FR at 2923 (discussing requirements imposed by 1981 guidelines).

3. 2016 Regulation

On December 19, 2016, the Department finalized a rule that amended Title X eligibility requirements, requiring that no grantee/recipient 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 (Dec. 19, 2016) (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. To that end, the Department asserted that “[a]llowing project recipients, including states and other entities, to impose restrictions on subrecipients for reasons other than their ability to provide Title X services has been shown to have an adverse effect on the number of people receiving Title X services and the fundamental goals of the Title X program.”

Yet the 2016 Regulation, if implemented, would have entailed certain adverse consequences. As an initial matter, it would have denied States and other grantees the freedom to choose subrecipients as they saw fit, within the Title X statutory parameters. Moreover, it could have resulted in the discontinuation of funding for entire States. A comment from the chief legal officers and/or governors from nine States explained their opposition to the rule as follows: “[The purpose of Title X is] to promote and assist in the establishment of voluntary family planning projects that offer a broad range of acceptable and effective family planning methods and services. The program is also targeted toward

services for adolescents. This rule does not further that goal; but rather it is intended to protect funding for certain providers even at the expense of the entire program.”

The 2016 Regulation took effect on January 18, 2017, but was nullified under the Congressional Review Act less than three months later. The President signed Pub. L. 115-23, “Providing for congressional disapproval under chapter 8 of title 5, United States Code, of the final rule submitted by Secretary of Health and Human Services relating to compliance with Title X requirements by project recipients in selecting subrecipients” on April 13, 2017. As a result, the 2016 Regulation must be “treated as though such rule had never taken effect.” 5 U.S.C. 801(f). Because of the joint resolution of disapproval, the Department is prohibited from reissuing the nullified 2016 Regulation in “substantially the same form” or issuing a “new rule that is substantially the same” as the nullified 2016 Regulation. 5 U.S.C. 801(b).

II. Need for Change

The Department must consider the effectiveness of its policies enforcing statutory mandates on a continuing basis. As the Supreme Court noted in *Rust v. Sullivan*, an 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. 173, 186-87 (1991). “Agencies are free to change their existing policies as long as they provide a reasoned explanation for the change.” *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). This “reasoned analysis” requirement does not demand that an agency “demonstrate to a court’s satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that

the agency believes it to be better, which the conscious change of course adequately indicates.” *U.S. Aid Funds, Inc. v. King*, 200 F. Supp. 3d 163, 169–70 (D.D.C. 2016) (citing *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)); *see also New Edge Network, Inc. v. FCC*, 461 F.3d 1105, 1112–13 (9th Cir. 2006) (rejecting an argument that “an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance”).

The Department now believes the policies outlined in this proposed rule are based on the best interpretation of, and provide appropriate guidance for compliance with, Title X. In particular, the Department believes that the policies outlined in this proposed rule provide for the best interpretation of section 1008 of Title X and of associated provisions, including the appropriations provisos and riders governing the Title X program. The standards proposed here are 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 pregnant women must be referred for appropriate prenatal care services, rather than receiving them within a Title X project, because those services are not part of family planning services within the Title X program. *See* H.R. Rep. No. 91-1472 (1970), as reprinted in 3 U.S. Code Cong. & Adm. News 5068 (discussing the scope of the program).

A. Statutory Compliance

As discussed in section II.B. below, the Department interprets section 1008 to establish a broad prohibition on funding, directly or indirectly, activities related to

abortion as a method of family planning. Thus, the Department believes that section 1008's mandate is most clearly met where there is a clear separation between Title X programs and programs in which abortion is presented or provided as a method of family planning. The 2000 regulations are inconsistent with that interpretation insofar as they require referral for abortion, allow the use of funds for infrastructure building that could be used for abortion services, and do not require clear physical and financial separation between Title X activities and abortion-related services. In addition, the regulations do not ensure transparency and accountability in the use of taxpayer funds insofar as they fail to provide the Department information about subrecipients, to ensure monitoring for potential misuse of funds, and to address expressly federal laws (including a Title X specific appropriations proviso) that prohibit the use of taxpayer funds for political activity or lobbying. Finally, the regulations prescribe inadequate grant criteria for selecting recipients of Title X funds who will comply with all of these requirements. If finalized and implemented as proposed, the new regulations would 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.

B. Ensuring That Title X Funds Are Not Used in Projects Where Abortion Is a Method of Family Planning

As part of its ongoing obligation to ensure compliance with federal law, the Department has determined that the existing regulations do not ensure compliance with the prohibition in section 1008 that “none of the funds appropriated” for Title X “be used in programs where abortion is a method of family planning.” In the view of the Department, that prohibition includes any action that directly or indirectly facilitates,

encourages, or supports in any way the use of abortion as a method of family planning. That interpretation follows from the text and purpose of the statute.

To begin, section 1008 “broad[ly]” “prohibits the use of Title X funds ‘in programs where abortion is a method of family planning.’” *Rust*, 500 U.S. at 184. Although Title X does not define “method of family planning,” the ordinary meaning of that phrase, coupled with the statutory examples of “natural family planning methods” and “infertility services,” 42 U.S.C. 300(a), suggests decisions about the number and spacing of one’s children. This interpretation is consistent with the Title X regulation’s description of the purpose of the program. *See* 42 CFR 59.1 (Title X voluntary family planning “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.”). And the exclusion of funding for abortion as a method for such decisions “embodies a view that abortion is inappropriate as a method of family planning.” 53 FR 2922, 2922 (Feb. 2, 1988). Congress, thus, chose to fund Title X programs/projects that offer only preconception methods of family planning and “create[d] a wall of separation between” those programs and others where abortion is “a method of family planning.” 53 FR at 2922. The text of Title X’s prohibition is also notably broad in prohibiting funding not only for providing and promoting abortion itself as a method of family planning, but in prohibiting funding for any program “where abortion is a method of family planning”—even if funds spent on such a program could be insulated from the provision or promotion of abortion.

The legislative history confirms this meaning. The Conference Report stated that “[i]t is, and has been, the intent of both Houses that the funds authorized under this

legislation be used only to support preventive family planning services, population research, infertility services, and other related medical, information and education activities.” H.R. Conf. Rep. No. 91–1667 at 8 (1970). Congressman John D. Dingell, Jr., the principal sponsor of section 1008, further explained on the floor of the House:

I set forth in my extended remarks the reasons why I offered to the amendment [sic], which prohibited abortion as a method of family planning. . . . With the “prohibition of abortion”, the committee members clearly intended that abortion is not to be encouraged or promoted in any way through this legislation. Programs that include abortion as a method of family planning are not eligible for funds allocated through this Act.

116 Cong. Rec. 37375 (1970).

To give effect to Section 1008, the Department now considers it important and appropriate to draw a wall of separation between Title X programs and prohibited activities. Title X programs may not directly or indirectly facilitate, promote, or encourage abortion in any way. For example, referral is an integral part of the provision of any method of family planning. When provided for abortion, a referral necessarily treats abortion as a method of family planning and runs afoul of the statute. Similarly, Title X programs that subsidize other programs where abortion is a method of family planning, through infrastructure building, cost sharing, or otherwise, run afoul of the statute. Congress made clear that “none” of the Title X funds should go to support such programs.

The Department previously took the position, in a notice published concurrently with the 2000 Regulations, that section 1008 precluded only funding of activities that

“directly facilitate the use of abortion as a method of family planning, such as providing transportation for an abortion, explaining and obtaining signed abortion consent forms from clients interested in abortions, negotiating a reduction in fees for an abortion, and scheduling or arranging for the performance of an abortion, promoting or advocating abortion within Title X program activities, or failing to preserve sufficient separation between Title X program activities and abortion-related activities.” Provision of Abortion-Related Services in Family Planning Services Projects, 65 FR 41281 (July 3, 2000) (“Notice”). The Department mandated that providers provide counseling on and referral for abortion, if requested by the client.

But the Department no longer considers that position appropriate in light of restrictions set forth in the statute. Section 1008 does not merely prohibit “direct” funding for abortion. It prohibits *all* funding for programs “where abortion is a method of family planning.” That broad language captures not just the activities of the program itself, but also any activities facilitated, encouraged, or promoted by the program. Limiting section 1008’s prohibition to only “direct” facilitation of abortion creates confusion about which activities are proscribed by the section, and, in the Department’s view, fails to ensure that Title X funds are not being used in “programs where abortion is a method of family planning.” The Department’s previous view was erroneous in requiring counseling and referral for abortion, allowing the sharing of physical space, and permitting infrastructure building when physical space could be shared. In these proposed regulations, the Department proposes to correct all three errors.

1. Abortion Counseling and Referral Requirement.

As discussed above, the Department has concluded the requirement under 42 CFR 59.5(a)(5) that a project must provide abortion counseling and referrals to pregnant women upon request is inconsistent with section 1008.⁷ That requirement appears to be premised on the notion that the statute is neutral on the question whether Title X funds may be used to encourage or promote abortion. But the Department rejects that notion: “Family planning,” as clearly manifested by the text of Title X and bolstered by its legislative history, refers to activities with the purpose of facilitating the initiation of, or preventing, pregnancy, not terminating it.⁸ Understood in context, referral activities are integral parts of the provision of any method of family planning. Thus, Section 1008 prohibits a Title X grantee, within the scope of the Title X project, from referring for abortion as a method of family planning. In the 2000 regulation, the Department took the position that the statute’s requirement that pregnancy counseling be nondirective justified imposing a regulatory requirement of abortion referral upon request. The Department now believes this view was erroneous. Referrals for abortion are, by definition, directive. Therefore, such referral activity is inconsistent with the prohibition on abortion as a method of family planning in Section 1008.

In addition, the requirement that Title X projects offer pregnant women the opportunity to be provided information and counseling regarding, and referrals for,

⁷As 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 activity that did not have the immediate effect of promoting abortion, or which did not have the principal purpose or effect of promoting abortion, was permitted. *Id.*

⁸ Put differently, the family planning services covered by Title X are almost exclusively preconception services, while abortion is not.

abortion is inconsistent with the conscience protections embodied in the Church, Coats-Snowe, and Weldon Amendments. *See* 42 U.S.C. 300a-7; PHS Act sec. 245, 42 U.S.C. 238n; Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, sec. 507(d), 132 Stat. 348, 764 (2018); Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. 507(d), 131 Stat. 135, 562 (2017). The Department acknowledged this problem in the preamble to 2008 regulations implementing these conscience protections. Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law; Final Rule, 73 FR 78072 (Dec. 19, 2008). Responding to commenters who suggested that enforcing the conscience statutes would be inconsistent with the abortion referral requirements for family planning clinics in the Title X regulations, the Department observed, “[w]ith regards 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.” 73 FR at 78087.⁹ Although those 2008 conscience statute regulations were partially repealed in 2011, 76 FR 9968 (February 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. The abortion referral and counseling requirements in the

⁹ In January 2018, the Department issued a notice of proposed rulemaking to revise and expand these regulations. *See* Protecting Statutory Conscience Rights in Health Care; Delegation of Authority, 83 FR 3880 (Jan. 26, 2018).

current Title X regulations, thus, cannot be enforced against objecting grantees or applicants, and such requirements cannot be used to deny participation in the Title X program or a Title X project of objecting family planning providers.¹⁰

For these reasons, the Department proposes to change the Title X regulations to eliminate the requirement that Title X projects provide abortion referral and counseling. In addition, consistent with the purpose of the program, the proposed rule would prohibit recipients from using Title X funds to perform, promote, refer for, or support abortion as a method of family planning. This rule would better align with both the best reading of section 1008 and with the Federal conscience statutes. Recognizing, however, the duty of a physician to promote patient safety, a doctor would be permitted to provide nondirective counseling on abortion.¹¹ Such nondirective counseling would not be considered encouragement, promotion, or advocacy of abortion as a method of family planning, as prohibited under section 59.16 of this proposed rule. Moreover, as permitted by the 1988 Regulations, a doctor would be permitted to provide a list of licensed, qualified, comprehensive health service providers, some (but not all) of which provide abortion in addition to comprehensive prenatal care. Providing such a list would be permitted only if a woman who is currently pregnant clearly states that she has already

¹⁰ We note that the Department has recently received a letter from the Attorney General of the State of Texas alleging discrimination against the State of Texas with respect to Title X, contending that the Department had improperly removed Texas from the list of eligible Title X grant recipients and referencing the protections embodied in the Church, Hyde/Weldon, and Coats/Snowe Amendments. Attorney General of Texas, Letter on Discrimination Against Texas Regarding Title X Grants (March 22, 2018), https://www.texasattorneygeneral.gov/files/epress/Texas_AG_letter_to_HHS_regarding_Title_X.pdf?cachebuster:96.

¹¹ That counseling on abortion be nondirective is required by the appropriations law applicable to Title X. *See Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, Title II, 132 Stat. at 716-17* (“all pregnancy counseling shall be nondirective”).

decided to have an abortion. This is discussed in more detail below, and the Department seeks public comment on this issue.

2. Possible Co-Mingling of Funds Between Title X Projects and the Abortion Activities of the Title X Grantee/Subrecipient

A second statutory problem is raised by the fact that the 2000 Regulations required financial, but not physical, separation between Title X Projects and the abortion activities of the Title X grantee/subrecipient. Organizations that actively include abortion as a method of family planning have consistently received Title X funding. The 2000 regulations permit shared facilities, common staff, and single file systems between Title X supported activities and non-Title X abortion-related activities in the following ways:

- (a) A common waiting room is permissible, as long as the costs [are] properly pro-rated;
- (b) common staff is permissible, so long as salaries are properly allocated and all abortion related activities of the staff members are performed in a program which is entirely separate from the Title X project;
- (c) a hospital offering abortions for family planning purposes and also housing a Title X project is permissible, as long as the abortion activities are sufficiently separate from the Title X project;
- and (d) maintenance of a single file system for abortion and family planning patients is permissible, so long as costs are properly allocated. 65 FR 41281, 41282 (July 3, 2000).

These 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, and the appearance and perception that Title X funds being used in a given program may also be supporting that program's abortion activities. 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 themselves be recipients of Title X funds. The Guttmacher Institute’s recent report, *Abortion Incidence and Service Availability in the United States, 2014*, provides detail about the various types of facilities at which abortions are performed. 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. 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.” It defines “abortion clinics” as “nonhospital facilities in which half or more of patient visits are for abortion services, regardless of annual abortion caseload.” According to the Guttmacher Institute, nonspecialized clinics accounted for 24% of all abortions in 2008;¹² 31% in 2011;¹³ and 36% in 2014.¹⁴ In addition, nonspecialized clinics represented 26% of abortion providers in 2008; 30% in 2011; and 31% in 2014. Further, despite a 3% drop in the total number of abortion facilities between 2011 and 2014, the number of abortion

¹² Jones, R.K., Kooistra, K., Abortion incidence and access to services in the United States, 2008, *Guttmacher Institute Perspectives on Sexual and Reproductive Health* (Jan. 10, 2011), https://www.guttmacher.org/sites/default/files/article_files/4304111.pdf.

¹³ Jones, R.K., Jerman, J., Abortion incidence and service availability in the United States, 2011, *Guttmacher Institute Perspectives on Sexual and Reproductive Health* (Feb. 3, 2014), https://www.guttmacher.org/sites/default/files/article_files/abortion_incidence_in_the_united_states_2011.pdf.

¹⁴ Jones, R.K., Jerman, J., Abortion incidence and service availability in the United States, 2014, *Guttmacher Institute Perspectives on Sexual and Reproductive Health* (Jan. 17, 2017), https://www.guttmacher.org/sites/default/files/article_files/abortion-incidence-us.pdf.

clinics dropped by 17%, while the number of nonspecialized clinics performing abortions remained stable. 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, whether Title X projects provide abortion services, and whether the Federal government (and, ultimately, Federal taxpayers), is funding abortion services provided by organizations that are recipients (or subrecipients) of Title X grants/funds. The Department believes that such potential co-mingling and confusion is evidence that the 2000 Regulations neither adequately reflect nor further the text and purpose of section 1008. As discussed above, the Department interprets section 1008 to require Title X project activities to be separate and distinct from non-Title X abortion activities. Thus, when a grantee 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 proposed regulation would reduce, and potentially eliminate, any confusion—actual or potential—as to the scope of services supported by Title X funds by requiring Title X projects to maintain clear physical and financial program separation from programs that use abortion as a method of family planning. This bright-line rule would create a clearer, more transparent system of separation and accountability, similar to that established by the 1988 Regulations and affirmed by the Supreme Court in *Rust*. It would also assure fidelity to the text and purpose of section 1008, and facilitate auditing

and enforcement of program requirements. The proposed rule would not, however, restrict the use of non-Title X funds outside the Title X program, nor would it impose restrictions on funds provided by other Federal programs. And it would not prevent a woman from seeking and obtaining an abortion. It would only draw a bright line between permissible services provided with Title X funds and services that cannot be so provided.

3. Infrastructure Building that Creates Fungibility Concerns Related to Abortion Services.

The current flexibility in the use of Title X funds raises additional concerns about the fungibility of assets that could be used—sometimes with an attendant increase in marginal cost—to build infrastructure for abortion services. By law, Title X providers must secure other sources of revenue to leverage Title X grants. *See* 42 CFR 59.7(c) (“No grant may be made for an amount equal to 100 percent for the project’s estimated costs.”). Medicaid is the primary source of additional revenue. But unlike Title X, which is a grant program, Medicaid is a reimbursement program. 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 recipients 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.¹⁵

In another 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 Medicaid reimbursement for the clients they serve.¹⁶

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 from Guttmacher in the report *Stronger Together: Medicaid, Title X Bring Different Strengths to Family Planning Effort* 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

¹⁵ Sonfield, A., Hasstedt, K., Gold, R. B., Moving forward. Family planning in the era of health reform, *Guttmacher Institute* (March 2014), <https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform>.

¹⁶ Gold, R. B., Stronger Together: Medicaid, Title X Bring Different Strengths to Family Planning Effort, *Guttmacher Institute* (May 17, 2007), <https://www.guttmacher.org/gpr/2007/05/stronger-together-medicare-title-x-bring-different-strengths-family-planning-effort>.

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 service has as well.

The proposed physical and financial separation of Title X projects from all activities that could not be funded by those programs, as well as the separate provision addressing the use of Title X funds for infrastructure purposes, would address this concern. 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.

C. Ensuring Responsible Use of Taxpayer Funds.

In addition to ensuring compliance with section 1008, the Department seeks to address three additional concerns posed by the 2000 regulations with respect to the responsible use of taxpayer funds.

1. Ensuring Transparency of Subrecipients of Funds to Assist Oversight and Enforcement Efforts.

Transparency in the use of governmental funds is an important principle for responsible government. This transparency helps to ensure accountability for, and wise use of, taxpayers' money. Current Title X regulations, however, do not require grantees to submit information to the government about their subrecipients, referral agencies, or other partners to whom Title X funds may flow. This lack of information is a barrier to OPA's oversight of the activities of its program and project subrecipients and, ultimately, to governmental accountability for those funds.

Therefore, under the new regulations, Title X grant applicants would be required to share the following within their applications and, if funded, in required reports and responses to performance measures, wherever practicable:

- Names and locations of subrecipients, referral individuals and agencies, as well as services provided and to be provided by those entities;
- Detailed descriptions of any partnerships, including the extent of collaboration, with subrecipients, referral individuals and agencies, as well as less formal

partners within the community, in order to demonstrate a seamless continuum of care for clients;

- A clear explanation of how the grantee will ensure adequate oversight and accountability for quality and effectiveness outcomes among subrecipients and those who serve as referrals for ancillary or core services.

2. Expanding Monitoring of the Use of Title X funds.

The Department has additional concerns about the potential for misuse of Title X funds and misbilling or overbilling of other Federal or state programs by Title X grantees under the current regulatory scheme. Although Title X is the only discrete domestic family planning grant program, other programs also fund family planning. In fact, 75% of all family planning services are funded through Medicaid; only 10% are funded through Title X.¹⁷ Not infrequently, Title X grant recipients also claim Medicaid reimbursement for services they provide to clients. In fact, according to the National Family Planning & Reproductive Health Association, “Medicaid is by far the largest revenue stream for the Title X provider network, comprising 40% of an average funding mix [and] is also the fastest growing revenue stream.”¹⁸ It is not inconsequential, then, to note cases of misuse/overbilling with respect to reimbursement for family planning services.

Numerous studies have documented misuse/overbilling for family planning services. The HHS Office of Inspector General (OIG) conducted a Federal audit of Medicaid-reimbursed claims for family planning services in New York State and found

¹⁷ Hasstedt, K., Sonfield, A., Gold, R.B. Public funding for family planning and abortion services, FY 1980-2015, *Guttmacher Institute* (April 2017), <https://www.guttmacher.org/report/public-funding-family-planning-abortion-services-fy-1980-2015>.

¹⁸ Hays B., Title X in Context, *National Family Planning & Reproductive Health Association* (July 2016), <https://www.nationalfamilyplanning.org/file/documents---policy-briefs/Title-X-in-Context.pdf>.

that about 25% of a sample of such claims were not eligible for Family Planning Benefit Program (FPBP) reimbursements.¹⁹ Overall, 61 Federal audits conducted by the Department's OIG found overbilling among Medicaid providers. On average, at least 14% of the Federal share of funding was overbilled by providers, with one provider overbilling at least 54% of the Federal share.²⁰ Although misuse among Medicaid recipients does not necessarily predict or imply misuse of grant funds among Title X grantees, the Department is aware of specific examples of misuse/overbilling by such grantees. For example:

- In New York State, one Medicaid provider was found to have received significant overpayments for family planning services.²¹ The same provider, also a Title X grantee,²² was found by the Health Resources and Services Administration (HRSA) to be in billing violation during a program integrity audit.²³
- A Medicaid provider, under threat of being terminated from the Illinois Medicaid program, was charged with overbilling for birth control.²⁴ This same provider is a current Title X grant recipient.²⁵

¹⁹ HHS OIG, Review of Federal Medicaid Claims Made for Beneficiaries in the Family Planning Benefit Program in New York State, Report No. A-02-07-01001 (May 22, 2008), <https://oig.hhs.gov/oas/reports/region2/20701001.htm>.

²⁰ Foster, C.G., 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>.

²¹ Letter, State of New York Office of the Medicaid Inspector General, "Letter on Family Planning Chargeback to Managed Care Network Providers, Final Report, Audit # 09-1415, Provider # ---," --- (June 10, 2009).

²² Philipson, D., Letter to the editor: Title X initiative threatens to affect the well-being of our communities, *The Rivertowns Enterprise* (Apr. 1, 2011), <https://www.plannedparenthood.org/planned-parenthood-hudson-peconic/newsroom/letter-editor-title-x-initiative-threatens-affect-well-being-our-communities-rivertowns-enterpr>.

²³ HRSA, Program Integrity: FY13 audit results (2017), <https://www.hrsa.gov/opa/programintegrity/auditresults/fy13results.html>.

²⁴ Wang, A., Planned Parenthood Settles with Illinois on Medicaid Payments, *Modern Healthcare* (Sept. 6, 2012), <http://www.modernhealthcare.com/article/20120906/INFO/309069993>; Wang, A., Medicaid Probes

- Another Title X recipient and Medicaid provider in Pennsylvania was found out of compliance by HRSA for overbilling.²⁶
- A Medicaid provider (and Title X grantee) in Washington State was audited following charges that it engaged in improper billing practices. The Washington Medicaid Fraud Control Unit investigated; as a result of the investigation, the grantee reimbursed the Medicaid program.²⁷
- The state of Nebraska found that significant abortion-related expenses were charged against the Title X grant by a subrecipient.²⁸ The same subrecipient, also a Medicaid provider, was also charged with “false, fraudulent, and/or ineligible claims for reimbursement” to Medicaid.²⁹ In addition, a sample of 10 payments to subrecipients was reviewed by the state of Nebraska; nine of the ten lacked documentation to support Title X reimbursement. The report stated: “The Agency

Planned Parenthood Fees, *Crain’s Chicago Business* (July 9, 2012), <http://www.chicagobusiness.com/article/20120707/ISSUE01/307079977/medicaid-probes-planned-parenthood-of-illinois>.

²⁵ Wang, A.L., Planned Parenthood settles with Illinois on Medicaid payments, *Modern Healthcare* (Sept. 6, 2012) <http://www.modernhealthcare.com/article/20120906/INFO/309069993>; HHS Office of Population Affairs, Title X family planning directory of grantees (2017), <https://www.hhs.gov/opa/title-x-family-planning/title-x-grantees/index.html>.

²⁶ HRSA, Program Integrity: FY2012 audit results (2017), <https://www.hrsa.gov/opa/programintegrity/auditresults/fy12results.html>.

²⁷ Stucke, J., Planned Parenthood undergoes leadership changes, audit, *The Spokesman-Review* (May 21, 2009), <http://www.spokesman.com/stories/2009/may/21/planned-parenthood-undergoes-leadership-changes/>. Referenced Audit # 09-04-08 of Yakima County, Washington.

²⁸ Nebraska Auditor of Public Accounts, State of Nebraska Statewide single audit: Year ended June 20, 2015 (2016), http://www.auditors.nebraska.gov/APA_Reports/2016/SA200-03242016-July_1_2014_through_June_30_2015_Statewide_Single_Report.pdf.

²⁹ Second Amended Complaint, *Thayer v. Planned Parenthood of the Heartland*, No. 4:11-cv-00129 (S.D. Iowa, filed July 26, 2012).

did not have adequate monitoring procedures to ensure payments to subrecipients were for allowable activities and costs.”³⁰

- In Wisconsin, an audit of a Title X grantee found Medicaid overbilling problems, including no proof of prescription, excessive reimbursements beyond what is allowable, and other irregularities.³¹
- In Massachusetts, a Title X grantee was subject to an OIG investigation, where the grantee admitted to comingling Title X expenses with all other family planning expenses, a clear violation of Federal requirements.³²

These examples raise concerns about the integrity of the Title X program. While only a few of these cases involve documented misuse of Title X funds or violation of Title X’s financial requirements, the Department is concerned these instances suggest that at least some recipients or subrecipients of Title X funds may not understand, and/or may not be in compliance with, requirements regarding the receipt or use of Federal funds, including Title X funds.

More broadly, grantees from a variety of federal programs commonly fail to verify personnel costs with the actual time spent on the grant-supported activities compared to time spent on non-grant functions by fully documenting time with personnel activity reports. In addition, it is not uncommon for project costs in federal reports to be inconsistent with time and status reports or bookkeeping ledgers, or for grantees to lack

³⁰ Nebraska Auditor of Public Accounts, State of Nebraska Statewide single audit: Year ended June 20, 2015 (Mar. 24, 2016), http://www.auditors.nebraska.gov/APA_Reports/2016/SA200-03242016-July_1_2014_through_June_30_2015_Statewide_Single_Report.pdf.

³¹ Wisconsin Department of Health Services, Audit Reveals Significant Overpayments to Family Planning Clinics (Aug. 3, 2016), <https://www.dhs.wisconsin.gov/news/releases/fp-summary-results.pdf>.

³² HHS OIG, Audit of Tapestry Health Systems, Inc. Title X Financial Management Systems, Report No. A-01-99-01504 (May 2000), <https://oig.hhs.gov/oas/reports/region1/19901504.pdf>.

adequate documentation for the amount allocated to the grant for indirect costs. Yet infrastructure costs can benefit the organization generally, rather than only as it pertains to activities permitted under the grant project.³³

The Department believes it necessary to address this issue with expanded monitoring, reporting, transparency, and accountability requirements. Because of the specific statutory prohibitions and requirements imposed on Title X projects, and the regulatory requirement—both currently and as proposed—for financial separation, the Department does not believe that the general grants management requirements are sufficient to address the issue. Rather, the Department proposes specific requirements to ensure legal and ethical usage of taxpayer dollars. These requirements are discussed in greater detail below, but they include requiring programs to: ensure compliance with statutory requirements; have a plan in place to demonstrate that grantees and subrecipients are aware of certain reporting requirements that apply in their state; provide adequate training with respect to those requirements; maintain records about clients for whom state reporting requirements apply; receive approval for any change in the usage of grant funds; and fully account for and justify charges against the Title X grant.

3. Enforcing Other Statutory Requirements on the Use of Title X Funds.

The current regulations also raise concerns about compliance with other federal laws that govern expenditures of taxpayer funds.

In addition to the Anti-Lobby Act, 18 U.S.C. 1913, the Department's annual appropriations act establishes a comprehensive framework prohibiting the use of Federal

³³ National Historical Publications and Records Commission, An introduction to financial management for grant recipients, National Archives (June 17, 2015) <https://www.archives.gov/files/nhprc/pdfs/grant-financial-management.pdf>.

funding, including Title X funds, for publicity and propaganda. One set of prohibitions applies across the Executive Branch: “No part of any funds appropriated in this or any other Act shall be used by an agency of the executive branch, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, and for the preparation, distribution or use of any kit, pamphlet, booklet, publication, radio, television, or film presentation designed to support or defeat legislation pending before the Congress, except in presentation to the Congress itself.”³⁴ Another provision applies to federal contractors: “No part of any appropriation...shall be used directly or indirectly, including by private contractor, for publicity or propaganda purposes within the United States not heretofore authorized by Congress.”³⁵

Yet another provision, which expressly applies to the Departments of Labor, Health and Human Services, and Education, adds “electronic communication” and substitutes “video” for “film” in the list of prohibited media, sweeps into its ambit “any State or local legislature or legislative body,” and adds “any proposed or pending legislation, administrative action, or order issued by the executive branch of any State or local government” to the prohibited targets.³⁶ This prohibition is coupled with the directive that no part of the Labor, HHS, and Education appropriation “shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient” who engages in a similar list of lobbying activities.³⁷ The Appropriations Act also contains an explicit prohibition against the use of Title X funds “for any activity

³⁴ Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. E, sec. 715, 132 Stat. 348, 590 (2018).

³⁵ Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. E, sec. 718, 132 Stat. 348, 591 (2018).

³⁶ Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, sec. 503(a), 132 Stat. 348, 762 (2018).

³⁷ Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, sec. 503(b), 132 Stat. 348, 763 (2018).

(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.³⁸

Finally, the Byrd Amendment applies to the recipients of Federal contracts, grants, or loans, as well as the funded parties to cooperative agreements. It prohibits them from using such funds to lobby in connection with the award, extension, continuation, renewal, amendment, or modification of the funding mechanism under which monetary assistance was received.³⁹

The current regulations offer no guidance on the application of these restrictions to the Title X program. Yet these restrictions on the use of appropriated funds clearly 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. Without guidance from the Department, it is possible that Title X grantees could intentionally, or unintentionally and unknowingly, use Title X funds for prohibited lobbying or political activities, or use such funds to support or pay dues/association fees to organizations where a majority of funds are used for such purposes. Indeed, issues surrounding family planning and abortion are highly controversial and routinely the subject of debate and policy consideration in the political and legislative processes at the national, state and local levels. As a consequence, and even without consideration of violations of these requirements, it is important that recipients of Title X funds fully understand the statutory prohibition on the use of Federal funds for lobbying and political activity.

³⁸ Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, Title II, 132 Stat. 348, 716-717 (2018); Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Title II, 131 Stat. 135, 521 (2017).

³⁹ 31 U.S.C. 1352(a).

The proposed rule would provide more explicit direction, in requiring Title X grantees to provide a written assurance that they both understand and agree to the prohibitions related to lobbying and political activity with the use of grant funds. Because of the specific statutory prohibitions applicable to Title X, and the regulatory requirement—both currently and as proposed—of financial separation, the Department does not believe that the general grants management requirements would be sufficient to address the issue.

D. Inadequate Grant Review Criteria.

The current Title X regulations set forth application review criteria that give HHS significant flexibility in determining awards, but need to be updated to more fully ensure 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. The statute sets forth several factors that HHS shall take into account in making grants and contracts,⁴⁰ but these factors are nonexclusive: The statute does not prohibit HHS from taking other factors into account and does not specify how much weight to attribute to each factor. The current regulations similarly contain a non-exclusive list of application review criteria—which include, but go beyond the statutory criteria—and do not specify how much weight to attach to each factor, giving HHS discretion to vary the weighting of the criteria in its competitions.

As a result, while the statute and current regulations give HHS discretion in considering and weighting factors, the application review criteria in the regulation could

⁴⁰ Title X provides that, “[i]n making grants and contracts under this section the Secretary shall take into account the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant and its capacity to make rapid and effective use of such assistance.” PHS Act Sec. 1001(b); 42 U.S.C. 300(b).

be more comprehensive and rigorous, so that the strongest prospective grantees are more likely to be selected, and less qualified applicants would be less likely to garner high scores. The Department is focused on ensuring compliance with the statutory Title X requirements (*see* 42 U.S.C. 300-300a-6; Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, Title II, secs. 207-08, 132 Stat. 348, 716-17, 736), including the program integrity provisions referenced elsewhere herein; expanding the type and nature of the Title X providers and ensuring the diversity of such providers, so as to fill gaps in 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. These goals, which are consistent with the statute and permissible under the existing regulations, would be best achieved by amending the regulations to more fully specify the application criteria, while still adhering to the statutory requirement that certain factors be considered and maintaining the Department's flexibility to consider other factors in making awards.

Therefore, through the proposed rule, the Department seeks to achieve a two-fold goal:

1. Update application review criteria to better achieve the statutory requirements and goals of Title X.
2. Increase competition and rigor among applicants, encouraging broader and more diverse applicants and better ensuring the selection of quality applicants.

The Department and OPA desire to award grants for the establishment and operation of those Title X projects that would best promote the purposes of Title X and meet the statutory requirements.

The Department proposes revising the current application review criteria at 45 CFR 59.7 through this rulemaking process to establish the following criteria for selection of Title X grantees. Under this proposed regulation, any grant applications that do not clearly address how the proposal will satisfy the requirements of the regulation would not proceed to the competitive review process, but would be deemed ineligible for funding. The Department would explicitly summarize each provision of the regulation (or include the entire regulation) within the Funding Announcement, and would require applicants to describe their affirmative compliance with each provision. If a proposal is deemed compliant with the regulation, then applicants would be rated based on at least the following criteria for selection within the competitive grant review process:

(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)" (PHS Act Sec. 1001(a), 42 U.S.C. 300(a)), which meet all of the statutory and regulatory requirements and restrictions, and where "none of the funds...shall be used in programs where abortion is a method of family planning." (PHS Act Sec. 1008, 42 U.S.C. 300a-6).

(2) The degree to which "the relative need of the applicant" (PHS Act Sec. 1001(b), 42 U.S.C. 300(b)) is demonstrated in the proposal, and the applicant shows capacity to "make rapid and effective use" (PHS Act Sec. 1001(b), 42 U.S.C. 300(b)), of grant funds, including and especially among a broad range of partners and diverse

subrecipients and referral individuals and organizations, and among non-traditional Title X partnering organizations.

(3) The degree to which the applicant takes into account “the number of patients to be served” (PHS Act Sec. 1001(b), 42 U.S.C. 300(b)), 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” (PHS Act Sec.1001(b), 42 U.S.C. 300(b)) and the applicant proposes innovative ways to provide services to unserved or underserved patients.

The Department seeks public comment as to whether additional regulatory application review criteria may be necessary or advisable to implement the Department’s interpretation of the statutory provisions applicable to Title X, in particular section 1008; to protect the rights of individuals and entities who decline to participate in abortion-related activities; or to ensure that all services funded through Title X offer optimal health benefits to clients of all ages. The Department also seeks public comment as to whether the protections and services funded through Title X are adequately implemented and clearly understood throughout the Title X program, in order to alleviate the current confusion, and avoid future confusion, among clients and the general public.

III. Statutory Authorities

The Department has legal authority to amend Title X regulations on the requirements applicable to projects for family planning services under section 1006 of the Public Health Service Act, 42 U.S.C. 300a-4. 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.” The Department has repeatedly exercised that authority to issue regulations to guide Title X grantees in carrying out the program.

The proposed regulations described below in the section-by-section discussion of the proposed rule would clarify, require compliance with, and provide for the enforcement of, statutory limitations and requirements placed on Title X projects and grantees. These include section 1008 of the Act, which prohibits “funds appropriated under this subchapter” from being “used in programs where abortion is a method of family planning” and has been reiterated through annual appropriations provisos that “amounts provided to said [voluntary family planning] projects, under such title shall not be expended for abortions.” *See, e.g.*, Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, Title II, 132 Stat. 348, 716 (2018); Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Title II, 131 Stat. 135, 521 (2017); Consolidated Appropriations Act, 2016, Pub. L. 114-113, Div. H, Title II, 129 Stat. 2242, 2602 (2015). They also include annual appropriations provisions directing that “all pregnancy counseling shall be nondirective”⁴¹ and 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

⁴¹ Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, Title II, 132 Stat. 348, 716 (2018). Nondirective counseling has been described in Congressional proceedings and debates throughout the years. For example, “nondirective counseling is the provision of information on all available options without promoting, advocating, or encouraging one option over another.” Congressional Record (1992, April 30). Family Planning Amendments Act of 1991, House of Representatives. 138 Cong. Rec. H2822-02, 1992 WL 86830. Non-directive counseling does not mean the Title X provider or counselor is uninvolved in the process, nor does it mean that counseling and education offer no direction, but that clients take an active role in processing their experiences and identifying the direction of the interaction. The Title X provider/counselor promotes the client’s self-awareness and empowers the client to change and develop agency over personal circumstances, offering a range of options, consistent with the client’s expressed need and with the statutory and regulatory requirements governing the Title X program.

office.”⁴² *See, e.g.*, Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, Title II, 132 Stat. 348, 716-717 (2018).

The proposed regulations also would require compliance with, and provide for the enforcement of, statutory provisions applicable to the provision of family planning services to minors and other vulnerable populations. Title X itself requires that, “[t]o the extent practicable, entities which receive grants or contracts under this subsection shall encourage family [sic] participation in projects under this subsection.” Omnibus Budget Reconciliation Act of 1981, Pub. L. 97-35, sec. 931(b)(1), 95 Stat. 375, 570 (1981); 42 U.S.C. 300(a). A rider in HHS’s annual appropriations act adds 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.” Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, sec. 207, 132 Stat. 348, 736 (2018). It also requires an applicant to certify that it “provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.” *Id.* And another provision in the annual HHS appropriations act states 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.” Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, sec. 208, 132 Stat. 348, 736 (2018).

Finally, the proposed regulations would require compliance with, and provide for the enforcement of, several additional laws that protect the conscience rights of

⁴² Pub. L. 107-116, Title II, 115 Stat. 2177, 2186 (2002).

individuals and entities who decline to perform, participate in, or refer for abortions, including the Church Amendments (42 U.S.C. 300a-7), the Coats-Snowe Amendment (section 245 of the Public Health Service Act, 42 U.S.C. 238n), and the Weldon Amendment, *see, e.g.*, Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, sec. 507(d), 132 Stat. 348, 764 (2018); Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, sec. 507(d), 131 Stat. 135, 521 (2017) (collectively, the “conscience statutes”). The Church Amendments, for example, prohibit grantees from discriminating in the employment of, or the extension of staff privileges to, any health care professional because she refused, because of her religious beliefs or moral convictions, to perform or assist in the performance of any lawful sterilization or abortion procedures. They 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 her religious beliefs or moral convictions.⁴³ The

⁴³ In addition, section 300a-7(c)(1) provides that “[n]o entity which receives a grant, contract, loan, or loan guarantee under the [Act] . . . may (A) discriminate in the employment, promotion, or termination of employment of any physician or other health care personnel, or (B) . . . in the extension of staff or other privileges to any physician or other health care personnel . . . because he refused to perform or assist in the performance of . . . [an] abortion” on the grounds that doing so “would be contrary to his religious beliefs or moral convictions. . . .” 42 U.S.C. 300a-7(c)(1). Section 300a-7(c)(2) provides that “[n]o entity which receives . . . a grant or contract for biomedical or behavioral research under any program administered by [HHS]” may discriminate in the employment of or the extension of staff privileges to any health care professional “because he refused to perform or assist in the performance of” “any lawful health service” based on religious belief or moral conviction. 42 U.S.C. 300a-7(c)(2). Section 300a-7(d) provides that “[n]o individual [may] be required to perform or assist in the performance of any part of a health service program . . . funded in whole or in part under a program administered by the Secretary of Health and Human Services” if doing so “would be contrary to his religious beliefs or moral convictions.” 42 U.S.C. 300a-7(d). Section 300a-7(e) prohibits any entity that receives funding under the PHS Act from denying admission to, or otherwise discriminating against, “any applicant (including for internships and residencies) for training or study because of the applicant’s reluctance . . . to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions . . . contrary to or consistent with the applicant’s religious beliefs or moral convictions.” 42 U.S.C. 300a-7(e). In addition, section 300a-7(b) provides in part that “[t]he receipt of any grant, contract, loan, or loan guarantee under the [PHS Act] . . . by any individual or entity does not authorize any court or any public official or other public authority to require” (1) the individual to perform or assist in an abortion if it would be contrary to his/her religious beliefs or moral convictions; or (2) the entity to make its facilities available for abortions, if the performance of abortions in

Coats-Snowe Amendment prohibits the Federal government and any State or local government that receives Federal financial assistance from discriminating against any health care entity (including individual providers) on the basis that the entity refuses to, among other things, (1) receive training in induced abortion; (2) require or provide abortion training; (3) perform abortions; (4) provide referral for such abortions or abortion training; or (5) make arrangements for any such activities. *See* 42 U.S.C. 238n(a). And the Weldon Amendment prohibits funds made available in HHS’s annual appropriations act from being “made available to a Federal agency or program, 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 provide, pay for, provide coverage of, or refer for abortions.” It provides that “health care entity” includes an individual physician or other health care professional” *See, e.g.,* Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, sec. 507(d), 132 Stat. 348, 764 (2018).

IV. Provisions of the Proposed Rule

A. Section 59.1 To what programs do these regulations apply?

Under federal law, including Title X, subrecipients of federal funds who agree to assist a primary grantee in implementing the grant project are required to comply with the same requirements that are imposed on the grantee. In order to ensure clarity and full implementation of the requirements of Title X and its implementing regulations, the Secretary proposes to amend § 59.1 to make it clear that these regulatory requirements

the facilities is prohibited by the entity on the basis of religious beliefs or moral convictions, or provide personnel for the performance of abortions if it would be contrary to the religious beliefs or moral convictions of such personnel. 42 U.S.C. 300a-7(b).

apply equally to subrecipients and to grantees, that grantees are responsible for requiring that their subrecipients (and the subrecipients of such subrecipients) agree to comply with such requirements, and that grantees are responsible for ensuring that their subrecipients so comply.

Title X authorizes the Secretary to not only award grants but also enter into contracts to establish and operate voluntary family planning projects. 42 U.S.C. 300(a). Although contracts are used for Title X training, the Department is not aware of a history of establishing or operating Title X family planning projects by use of contracts instead of grants. Nevertheless, because the use of contracts to establish and operate family planning projects is explicitly authorized in the statute, the Department believes that the regulations should state that the substantive requirements for Title X family planning projects apply to projects whether they are established by grants or contracts. Therefore these rules propose to specify in § 59.1 that, except for §§ 59.3, 59.4, 59.8, and 59.10, the regulations of this subpart would also be applicable to the execution of contracts under Title X to assist in the establishment and operation of voluntary family planning projects. Applicable regulations would be applied in accordance with the statutes, procedures, and regulations that apply to the execution of a Federal contract, as distinct from a grant. Section 59.1 would specify that the use of the terms “grant,” “award,” “grantee,” and “subrecipient” in applicable regulations of this subpart would apply similarly to contracts, contractors and subcontractors, and the use of the term “project” or “program” would also apply to a project or program established by use of a contract. The Departments would specify that §§ 59.3, 59.4, 59.8, and 59.10 would not apply to contracts, because those sections generally describe processes specifically applicable to grants and grant

applications, as distinct from the substantive requirements of the other sections of this subpart. Because of the lack of a history of using contracts to establish or operate Title X projects, and because Title X funds used for a contract would offset funds used for a grant, the Department does not believe that specifying that these regulations also generally apply to Title X contracts would affect the regulatory or economic impact of these proposed rules. The Department invites comment on the applicability of these regulations to contracts for the provision of family planning services under Title X.

B. Section 59.2 Definitions.

The current Title X regulations include a limited number of definitions that are very general in scope including “Act,” “family,” “low-income family,” “nonprofit,” “Secretary,” and “state.” Important terms, such as “family planning,” “grantee,” and “subrecipient,” are not defined. The Department believes that, as a result of these omissions, the Title X regulations fail to provide sufficient clarity for prospective grantees and subrecipients, current grantees and subrecipients, and the general public. To ensure greater clarity and accountability in the use of Title X funds, the Secretary proposes the addition of four new definitions to the Title X regulations, 42 CFR 59.2:

- Family Planning
- Grantee
- Program or Project
- Subrecipient

Under the proposed regulations, “family planning” would be defined 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. These means include 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 include preconceptional 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.

Family planning and family planning services are never coercive and are strictly voluntary. Family planning does not include post-conception 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 Department believes that this proposed definition, which largely tracks the definition of “family planning” in the 1988 Regulations, would provide greater clarity to grantees and subrecipients as to the type of activities that can be provided by projects funded under Title X. It is clear that Congress intended the term “family planning” to be broader in scope than simply contraception; natural family planning and infertility services are included as mandatory services explicitly enumerated in section 1001(a). Physical examinations, breast and cervical cancer screenings, sexually transmitted disease (STD) and human immunodeficiency virus (HIV) testing, and pregnancy testing and counseling would continue to be authorized by this definition under the rubric of “general reproductive and fertility health care.” The proposed definition includes concepts from the 1988 rule identifying family planning as a process of establishing objectives for the number and spacing of children and the means of achieving those

objectives. The proposed definition elaborates on “objectives” by specifying they involve both goals and plans, as inherent in the term family “planning.” The definition specifies that the process is “voluntary,” “strictly voluntary,” and “never coercive,” consistent with the statutory requirement that Title X apply only to “voluntary” family planning. The definition specifies that family planning includes management of infertility (including adoption). Both this definition and the 1988 definition include general reproductive health care.⁴⁴ The 1988 definition elaborated that it included diagnosis and treatment of infections which threaten reproductive capability. This proposed definition would include that aspect of reproductive health care, as well as the goal of improving maternal and infant outcomes and the health of those who seek family planning services.

The other newly proposed definitions are designed to provide greater clarity concerning which entities are subject to the provisions of Title X.

The Department proposes that “project” or “program” be defined as 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, 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. These proposed definitions are consistent with current Title X program practices.⁴⁵

⁴⁴ The Department is aware that, in the international context, the term “reproductive health care” is often used to encompass abortion and related services. Given the long-standing prohibition on the use of Title X funds for programs/projects where abortion is a method of family planning and the focus of the Title X program on pre-conception care, the Department does not use the term in such a manner; in the Title X context, “reproductive health” or “reproductive health care” does not encompass abortion or abortion-related services.

⁴⁵ See, e.g., “Definitions” section of the “Program Requirements for Title X Funded Family Planning Projects,” Version 1.0 (April 2014), <https://www.hhs.gov/opa/sites/default/files/ogc-cleared-final-april.pdf>.

The Department proposes definitions of “grantee” and “subrecipient” because confusion surrounds their meanings. In this proposed rule, “grantee” would mean the entity that receives Federal financial assistance through a grant and assumes legal and financial responsibility and accountability for the awarded funds and for the performance of the activities approved for funding and for making the required reports to OPA.

A clear definition of “subrecipient” is necessary to ensure program integrity related to both financial and programmatic requirements. Title X service sites (*i.e.*, clinics) that provide Title X services directly to individuals may receive Title X grant monies from the grantee (or another subrecipient) as a secondarily named provider or as an agency that provides services, but may not be specifically named within the grant application. There is a need for transparency that currently does not exist. The Department does not have an accurate understanding of any grantee’s subrecipients, of what role each subrecipient plays in the overall function of the Title X project, or of the extent to which Title X funding supports the efforts of the subrecipient. Additional transparency would help to ensure accountability for, and wise use of, taxpayers’ money. Current Title X regulations, however, do not require grantees to submit information to the government about their subrecipients, referral agencies, or other partners to whom Title X funds may flow. This lack of information is a barrier to OPA’s oversight of the activities of its program and project subrecipients and, ultimately, to governmental accountability for those funds.

Therefore, the Department proposes 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. This proposed definition would help clarify the entities that receive Title X monies, how they use these funds, and how their services comply with the purpose of the Title X program. In addition, the definition would elucidate the relationship between the grantees and their subrecipients, and would convey, along with the proposed changes to § 59.1, that grantees are responsible for ensuring that their subrecipients (and the subrecipients of such subrecipients) comply with all statutory and regulatory requirements.

To the extent an entity receives Title X funds from a grantee or a subrecipient, it receives funds to provide Title X services, and is thus a subrecipient subject to the Title X statute and regulations. By contrast, some referral agencies do not receive funds from the Title X grant program, but may nevertheless provide information, counseling, or services to a Title X client. A referral agency or individual is a person or entity which is a specialist in a certain field of service and to whom the Title X project refers patients for additional services not available at the Title X clinic site, or not adequately available at the site, to serve the immediate needs of the patient. For example, an individual may visit the Title X clinic for contraceptive services, but in the course of conversation, it may be revealed that the individual wants to end a current intimate and unhealthy relationship. In this case, a referral could then be made to an entity that has expertise in relationship counseling beyond what is available in this Title X clinic. In this and similar cases, the referral agencies would not be considered subrecipients, since they do not receive Title X

funds. But because such services are an extension of the overall Title X service provision, in certain cases referral agencies participate in, and receive intrinsic non-monetary benefits as a result of, a formal or informal partnership with a Title X project.

Accordingly, we seek comment on whether such a referral agency should be subject to the same reporting requirements as a grantee or subrecipient—by means of requiring grantees and subrecipients to use referral agencies only if they require the referral agencies to submit the required information. This could apply if the referral agency:

- has a written agreement with the grantee or another subrecipient;
- specifically uses its inclusion in the Title X project to expand its influence in the community; or
- conducts its services, activities, or communications in such a way that its participation in the Title X project is central, or very important, to its existence.

Finally, this proposed rule would amend 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 employers’ religious beliefs or moral convictions. This would preserve conscience protections for entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act, while providing free or low-cost family planning services for such women at risk of unintended pregnancy or who otherwise desire comprehensive, holistic, family planning services.

The proposed definition of “low income family” would maintain the ability of a Title X project to determine whether unemancipated minors who desire confidential

services are low income based on their own resources. However, to ensure compliance with the statutory requirement that Title X projects encourage family participation in the decision of minors to seek family planning services, Title X clinics would be required to document in the minor's medical records the specific actions taken with respect to each minor to encourage such family participation. Documentation of such encouragement would not be required if the Title X clinic documents in the medical record that (1) the minor is suspected to be the victim of child abuse or incest and (2) it has, consistent with and if permitted or required by applicable State or local law, reported the situation to the relevant authorities.

C. Section 59.3 Who is eligible to apply for a family planning services grant or to participate as a subrecipient as part of a family planning project?

Consistent with the requirements of the Joint Resolution of Disapproval, signed by the President on April 13, 2017 (referenced above), the Department proposes to revise the heading and remove paragraph (b) of § 59.3. Because of the joint resolution of disapproval, the Department is prohibited from reissuing the nullified 2016 Regulation in “substantially the same form” or issuing a “new rule that is substantially the same” as the nullified 2016 Regulation. 5 U.S.C. 801(b). This proposed rule does not seek to re-issue the nullified provision at all, much less in substantially the same form, nor does the Department seek to issue, in this rulemaking, a new rule that is substantially the same as the nullified provision.

D. Section 59.5 What Requirements Must be Met by a Family Planning Project?

Section 1001(a) of the Title X statute requires Title X projects to “offer a broad range of acceptable and effective family planning methods and services (including

natural family planning methods...).” The current regulations state, somewhat differently, that projects must “[p]rovide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents),” and note that “[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.” 42 CFR 59.5(a)(1).

The current regulation, while worded differently than the statute, does not override the statutory requirement that projects offer “a broad range of acceptable and effective family planning methods and services (including natural family planning methods...).” 42 U.S.C. 300(a). Although the current regulations require that projects provide, at a minimum, a broad range of “medically approved” family planning methods, they do not preclude the Department from requiring more, namely, as the statute provides, “a broad range of acceptable and effective family planning methods and services (including natural family planning methods . . .).” Moreover, the current regulations do not define “medically approved,” and have not required that a family planning method be regulated, approved, or certified by any particular agency or accreditation body. If a family planning method is, as required by the statute, “acceptable and effective,” it is likely to be approved by at least some medical sources. For example, 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.⁴⁶ 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)).⁴⁷ On this basis, fertility awareness-based methods of family planning could be said to be “medically approved.” Medical doctors and professional organizations can differ on which methods of health care they approve, including different methods of family planning. Such differences may be based on differing areas of expertise, or differing views of the health care method.

Similarly, certain family planning methods or services may not fall under the regulatory jurisdiction or expertise of some government agencies. The Food and Drug Administration has regulatory jurisdiction over drugs, biologics, and medical devices. As such, while it has regulatory authority over and approves or clears contraceptive drugs and devices, FDA would not necessarily have regulatory jurisdiction over, or an approval process for, other family planning methods. Some fertility awareness-based methods of family planning might be a drug or device, such as certain fertility awareness kits that are or contain a medical device.⁴⁸ Other fertility awareness-based methods of family planning might not be drugs or devices, use drugs or devices, or be sold in conjunction with drugs

⁴⁶ See Women’s Preventive Services Initiative, Clinical Recommendations, *American College of Obstetricians and Gynecologists*, <https://www.womenspreventivehealth.org/recommendations/contraception>.

⁴⁷ See HRSA, Women’s Preventive Services Guidelines, <https://www.hrsa.gov/womens-guidelines-2016/index.html>.

⁴⁸ See FDA Enforcement History, <https://www.fda.gov/iceci/enforcementactions/enforcementstory/enforcementstoryarchive/ucm106947.htm> (“Warning Letter Issued for “Fertility Awareness Kit”).

or devices. Some methods might be merely instructional, or might include the recommendation that certain kinds of drugs or devices be used, without the “method” itself being a drug or device. When HRSA added fertility awareness-based methods of family planning and counseling to its women’s preventive services guidelines, it did so even though the guidelines already included all FDA-approved contraceptive and sterilization methods, because the birth control methods FDA has approved or cleared are all drugs and devices.⁴⁹ The fact that non-drug and non-device fertility awareness-based methods of family planning are not on FDA’s list of approved birth control methods does not mean that such fertility awareness-based methods are not “medically approved,” but rather means that they are not drugs or medical devices, and, thus, not under FDA’s jurisdiction and not subject to FDA’s approval or clearance.

The Department proposes to revert to the statutory language that Title X projects “offer a broad range of acceptable and effective family planning methods and services.” In so doing, the proposed rule would remove the language specifying that the family planning methods and services offered by a Title X project be “medically approved.” That language does not appear in the statute and may cause confusion about the type of family planning methods or services that a project may or should provide, and the type of approvals (if any) necessary before a Title X project can provide such method or service. The statutory language of “acceptable and effective family methods or services” provides better guidance for the types of methods and services that Congress sought to fund.

The proposed rule would also make it more explicit that the requirement to provide a “broad range” of acceptable and effective family planning methods and

⁴⁹ See FDA, <https://www.fda.gov/ForConsumers/ByAudience/ForWomen/FreePublications/ucm313215.htm>.

services does not require a project to provide every acceptable and effective family planning method or service. The meaning of “broad range” has been the subject of inquiries from grantees and lawmakers at all levels of government, as well as from members of the public, and has resulted in potentially inconsistent interpretations of the “broad range” mandate. Some have interpreted the “broad range” requirement of section 1001(a), as well as of 42 CFR 59.5(a)(1), to require that a project provide all forms of family planning approved or cleared by the Food and Drug Administration (FDA). The plain language of the statutory (and regulatory) requirements, however, does not require projects to provide every acceptable and effective family planning method or service (or, under the current regulation, acceptable and effective medically approved family planning methods and services), but rather a broad range of such methods and services.

Not every grantee or subrecipient can provide—or should be required to provide—all services. The proposed rule would also make it more explicit that the requirement to provide a “broad range” of acceptable and effective family planning methods and services does not require a project to provide every acceptable and effective family planning method or service. This proposed change reflects the fact that, as the range of available family planning methods has significantly increased over the last few decades, it has become increasingly difficult and expensive for a Title X project to offer all acceptable and effective forms of family planning. Indeed, family planning projects are confronted with a variety of pharmacological, technological, or medical device options to consider in service delivery, with widely varying costs. Staffing limitations, technological capacity, economics (including costs and demand), and conscience concerns may be taken into account when grantees or subrecipients determine which

methods they will offer within their scope of services. For example, natural family planning (NFP) services (and other fertility-awareness based methods) are a recognized form of family planning services under the statute, but many couples or families seeking these services may prefer specialized, single-method NFP service sites. Other sites serving men may offer only family planning methods relevant to that population. Another site may be a hospital satellite location which is primarily diagnostic in function, although it also offers some on-site family planning services. Such sites are permissible as components of a Title X family planning project, as long as the overall project provides a broad range of acceptable and effective family planning methods and services. In these examples, some participants in the Title X project offer specialized services, but not a broad range of family planning methods and services. However, such limited family planning service offering is permissible as long as the overall Title X project offers a broad range of family planning services, including contraceptives.⁵⁰

Thus, under the proposed rule, no Title X project would be required to provide every acceptable and effective family planning method or service, but all Title X projects would be required to provide a broad range of family planning methods. Family planning methods which are permitted with Title X funds include (but are not limited to): male condom, spermicide, cervical cap, fertility awareness based methods, female condom, diaphragm, vaginal contraceptive ring, IUD, oral contraceptives, shot/injection, implantable rod, vasectomy, and sexual risk avoidance (or avoiding sex). Under the proposed rule, any organization that desires to provide only a single method, or limited number of methods of family planning, may participate, as long as the Title X project as a

⁵⁰ The Department notes that the Title X statute would not permit a Title X project to provide only one (or a limited number of) family planning methods and services.

whole offers a broad range of family planning methods and services. Title X specifically identifies natural family planning, infertility services, and services for adolescents, as voluntary family planning services that Title X projects “shall offer,” 42 U.S.C. 300(a), making these family planning methods and services mandatory for each Title X project (although, as discussed elsewhere herein, it is not required that each provider within a project offer each method). That is, included in the broad range of acceptable and effective family planning methods and services that each Title X project must offer are natural family planning methods, infertility services, and services for adolescents.

The proposed rule would also remove the requirement that past grantees be consulted for new services or projects in their locale as set forth in paragraph (a)(10)(i) of the current regulation. We believe that removing this requirement would encourage a broader range of applicants and permit innovative approaches that may not have been envisioned or supported by past grantees. While communication and coordination is often beneficial and encouraged, removing the requirement for consultation is intended to have the effect of loosening the status quo for service provision in a community in favor of a broader reach in order to previously underserved populations.

The proposed rule would make it clear that, as contemplated by the statute, family planning is not limited to, or synonymous with, access to various methods of contraception, but includes a broader understanding of family planning methods and services. Family planning services should fit the family planning needs of the individual, and/or couple (if applicable). And in order to promote a holistic approach to family planning and reproductive health, the proposed rule would inform Title X service providers that they should offer either comprehensive primary health services onsite or

have a robust referral linkage with primary health providers who are in physical proximity to the Title X site. This provision decreases the overall cost and transportation challenges related to access for vital health care services that may be discovered as a result of routine family planning screening and consultation. Title X service providers should ensure that they have a broad range of partners and diverse subrecipients in order to make it easier for all clients, particularly low income clients, to access necessary medical services and related educational and counseling services, as stipulated by the statute and as necessary to ensure that screening, diagnosis, and treatment can be provided within close proximity of the clinic, and to ensure that the most needy have access to care.⁵¹

To expand transparency surrounding Title X services, the proposed rule would require applicants to provide the following within their applications (to the extent secured at the time of application) and, if funded, in required reports, and in response to performance measures, wherever practicable:

⁵¹ 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. The report also found that women who receive care at Title X clinics generally have worse health 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. Since Title X family planning services are generally limited to preconception services, it is important that Title X sites assist clients to achieve optimal preconception health. A large number of women experience unintended pregnancies, making the inclusion of preconception health screenings in the continuum of family planning care all the more important for all clients (male and female), not only those seeking pregnancy. Preconception health care is important because pregnancy may stress and affect extant health conditions; linkages to comprehensive primary health care may be critical to ensuring 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.

- Names and locations of subrecipients, referral individuals and agencies, as well as services provided and to be provided by those entities;
- Detailed descriptions of all partnerships with such entities, including the extent of any collaboration with subrecipients, referral individuals and agencies—as well as with less formal partners within the community—in order to demonstrate a seamless continuum of care for clients;
- A clear explanation of how the grantee will ensure adequate oversight and accountability for quality and effectiveness outcomes among subrecipients and those who serve as referrals for ancillary or core services.

In addition, in order to promote compliance with a requirement present in both Title X itself and the Title X appropriations provisions,⁵² the proposed rule would require Title X service providers to encourage family participation in the decision of minors to seek family planning services and to document, in the records maintained with respect to each minor, the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).⁵³

E. Section 59.7 Criteria for Selection of Grantees.

As discussed above, the Department is focused on achieving better integration of primary and preventive care among a diverse group of applicants, using review criteria as a meaningful instrument to assess the quality of the applicant and the application. The current regulations give HHS flexibility in selecting grantees and determining awards, but

⁵² See 42 U.S.C. 300(a); Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, sec. 207, 132 Stat. at 736.

⁵³ Of course, as noted above, the fact that child abuse, child molestation, incest, or the like is suspected and has been reported to the appropriate authorities, consistent with State or local reporting or notification laws, would constitute such reason.

could better ensure that review criteria are geared to achieving the selection of grantees that can best achieve the goals and purposes of the Title X program. Therefore, through the proposed rule, we would seek to achieve a two-fold goal:

- Update application review criteria to better achieve the statutory requirements and goals of Title X.
- Increase competition and rigor among applicants, encouraging broader and more diverse applicants, and better ensuring quality applicants will be selected.

The Department desires to award grants for the establishment and operation of those Title X projects that would best promote the purposes of Title X and meet the statutory requirements imposed on Title X projects.

We propose revising the current application review criteria at § 59.7 through this rulemaking process to update and expand criteria for selection of Title X grantees as follows. Any grant applications that do not clearly address how the proposal will satisfy the requirements of this regulation would not proceed to the competitive review process, but would be deemed ineligible for funding. The Department would explicitly summarize each provision of the regulation (or include the entire regulation) within the Funding Announcement, and would require each applicant to describe their affirmative compliance with each provision. If the proposal is deemed compliant with the regulation, then applicants would 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,” (PHS Act Sec. 1001(a), 42 U.S.C. 300(a)), which meet all of the statutory and regulatory requirements and restrictions, and where “none of the funds...shall be used in programs where abortion is a method of family planning.” (PHS Act Sec. 1008, 42 U.S.C. 300a-6.)

(2) The degree to which “the relative need of the applicant” (PHS Act Sec 1001(b), 42 U.S.C. 300(b)) is demonstrated in the proposal and the applicant shows capacity to “make rapid and effective use” (PHS Act Sec. 1001(b), 42 U.S.C. 300(b)) of grant funds, including and especially among a broad range of partners and diverse subrecipients and referral individual and organizations, and among non-traditional Title X partnering organizations.

(3) The degree to which the applicant takes into account “the number of patients to be served” (PHS Act Sec. 1001(b), 42 U.S.C. 300(b)), 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” (PHS Act Sec.1001(b), 42 U.S.C. 300(b)) and the applicant proposes innovative ways to provide services to unserved or underserved patients.

These proposed criteria would advance compliance with the text and purpose of Title X by seeking grantees to better serve the targeted population with services that are needed, focused on family planning in the context of holistic health in both the short and long term.

The Department seeks public comment as to whether additional regulatory application review criteria may be necessary or advisable to reflect the text and purpose of the statutory provisions applicable to Title X, in particular section 1008; to protect the

rights of individuals and entities who decline to participate in abortion-related activities; or to ensure that all services funded through Title X offer optimal health benefits to clients of all ages. The Department also seeks public comment as to whether the protections and services funded through Title X are adequately implemented and clearly understood throughout the Title X program, in order to alleviate the current confusion, and avoid future confusion, among clients and the general public.

F. Section 59.11 Confidentiality.

As discussed above, Title X grantees and subrecipients are required to comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, and the like. Section 59.11 currently 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.” To ensure that Title X grantees and subrecipients comply with applicable reporting requirements, the proposed rule would clarify that concerns about confidentiality of information may not be used as a rationale for noncompliance with such reporting laws.

G. Section 59.13 Standards of Compliance with Prohibition on Abortion.

Current Title X regulations at 42 CFR 59.5(a)(5) state that “[e]ach project supported under this part must ... not provide abortion as a method of family planning.” However, the Department has determined that such regulations do not provide sufficient guidance to ensure that Title X projects comply with section 1008 and do not encourage or promote abortion as a method of family planning. Proposed § 59.13 would accordingly require that programs seeking Title X funding provide assurance satisfactory to the

Secretary that, as Title X grantees, they do not provide abortions and do not include abortion as a method of family planning. The proposed rule would also require assurance that grantees are in compliance with the prohibition on promoting abortion as a method of family planning; the maintenance of separation of the Title X project from prohibited activities; and the prohibition on activities that encourage, promote, or advocate for abortion. These specific requirements are designed to enable the Secretary to obtain, at the application stage, information relevant to determining whether a program or project will, in fact, comply with the statutory prohibition. Therefore, under the proposed rule, an applicant for Title X funds would be ineligible for those funds if it is unable to demonstrate to the satisfaction of the Secretary that it (and its subrecipients, if applicable) would comply with the regulations implementing section 1008.

H. Section 59.14 Prohibition on Referral for Abortion.

Proposed § 59.14 would expressly prohibit Title X projects from performing, promoting, referring for, or supporting, abortion as a method of family planning.⁵⁴ As discussed above, the Department believes that the current requirement under 42 CFR 59.5(a)(5)(ii) that a project provide abortion referrals to pregnant women upon request is inconsistent with section 1008, premised on an erroneous notion that the statute is neutral on the question whether Title X funds may be used to encourage or promote abortion as a method of family planning, and violative of Federal health care conscience statutes. The proposed provision would better implement section 1008 and better align

⁵⁴ In the case of rape and/or incest, it would not be considered a violation of the proposed 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, provided that the Title X provider has complied with all 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.

the regulations implementing Title X with those Federal health care conscience statutes. It would also promote grantee diversity by expanding the number of qualified entities that would be willing and able to apply to provide Title X services, since potential grantees and subrecipients that refuse to provide abortion referrals may have been ineligible or discouraged from applying for Title X grants or seeking to provide family planning services under a Title X project by the requirements of the current regulations.

Proposed § 59.14 would prohibit referral for abortion as a method of family planning or any other affirmative action to secure such an abortion in a Title X project. Under the proposed provision, referrals could not be used as an indirect means to encourage or promote abortion. In addition, Title X projects do not themselves provide post-conception care. Thus, proposed § 59.14 would require that pregnant women be referred outside of the Title X project for prenatal care and other related medical and social services, as well as for other services relating to pregnancy after pregnancy is confirmed. In no case would the proposed provision permit a Title X-funded family planning program to make a referral for, or determine the appropriateness of, abortion as a method of family planning. As discussed above, a doctor, though not required to do so, would be permitted to provide nondirective counseling on abortion.⁵⁵ Such nondirective counseling would not be considered encouragement, promotion, or advocacy of abortion as a method of family planning, as prohibited under section 59.16 of this proposed rule. Moreover, a doctor would also be permitted to provide a list of licensed, qualified, comprehensive health service providers, some (but not all) of which provide abortion in

⁵⁵ That counseling on abortion be nondirective is required by the appropriations law applicable to Title X. *See Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, Title II, 132 Stat. at 716-17* (“all pregnancy counseling shall be nondirective”).

addition to comprehensive prenatal care. Providing such a list would be permitted only in cases where a program client who is currently pregnant clearly states that she has already decided to have an abortion.⁵⁶ No participant in the Title X program may promote or support abortion as an acceptable mechanism of family planning through that Title X program. Thus, all other patients would be provided a list of licensed, qualified, comprehensive health service providers (including providers of prenatal care) who do not provide abortion as a part of their services, along with referrals for prenatal care and social services.

It is important to recognize that proposed § 59.14 would not 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. Neither would proposed § 59.5, or § 59.14 preclude a health care professional from disclosing to a woman any physical findings the professional has made regarding the woman's condition; communicating an assessment of the urgency of the need for treatment; or ensuring that the woman is referred to the appropriate specialist for treatment of the condition, including emergent conditions, with adequate follow-up provided. Further, the proposed provision does not propose to alter the current requirement that Title X grantees and subrecipients provide for "necessary referral to other medical facilities when medically indicated," 42 CFR 59.5(b)(1); *see also* 42 CFR 59.5(b)(8); rather, to further emphasize this requirement, we are proposing to include consistent language in § 59.14. Under this current provision of the Title X regulation, Title X projects must refer patients directly to a provider of emergency medical services (*i.e.*, hospital emergency room),

⁵⁶ The list may not identify in any way the providers that perform abortions in addition to comprehensive prenatal care.

when such services are medically indicated. To ensure that such provisions are not abused in order to provide referral for abortion as a method of family planning, we propose conforming amendments to § 59.5(b)(1) and (8), which make such referrals subject to the requirements and prohibitions contained in proposed § 59.14(a).

Further, it is not the intent of the proposed regulatory provision at § 59.14 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 a condition that might make her extant pregnancy high risk. Nor would the provision preclude a health professional from disclosing to the woman any physical findings he or she has made regarding her condition and communicating his or her assessment of the urgency of her need for treatment or action, consistent with the exercise of his or her professional judgment, although the treatment or action might fall outside the parameters of the Title X program. Read together, proposed § 59.14 and current § 59.5(b)(1) would require that, if a woman who comes to a Title X-funded family planning program is confirmed to be pregnant, she must be referred externally for services related to her pregnancy. The program would be permitted to provide her with a listing of licensed health care providers of appropriate prenatal medical care and delivery services, from which she may choose. But Title X projects would not directly or indirectly encourage or promote abortion as a method of family planning through the manner in which referrals are made, or the manner in which such list is constructed. As noted above, we propose conforming changes to § 59.5(a)(5).

I. Section 59.15 Maintenance of Physical and Financial Separation.

Proposed § 59.15 would create a requirement of both physical and financial separation between Title X services and any abortion services provided by the Title X grantee or subrecipient. As noted above, the current Title X program only requires financial (or bookkeeping) separation between Title X services and any abortion services provided by the Title X grantee or subrecipient. In accordance with section 1008, the Department wishes to ensure, among other things, that there is a clear separation between Title X services and any abortion services provided by a Title X grantee or subrecipients and that Title X funds are not being used to build infrastructure that supports, or may be used to support, the separate abortion business of a Title X grantee or subrecipient.

Proposed § 59.15 would require that Title X projects be physically and financially separate from programs in which abortion is provided or presented as a method of family planning, including programs that refer for abortions and programs that encourage, promote or advocate abortion as a method of family planning. It would describe relevant criteria that the Secretary proposes to use in determining whether a project has demonstrated sufficient separation from prohibited activities. Thus, proposed § 59.15 would prohibit locating a Title X supported family planning program in a fashion which would not be physically and financially separate. This proposed standard would take into account the degree of separation of, among other things, waiting, consultation, examination, and treatment areas—as well as telephone numbers, email addresses, any official communication devices, including social media, or websites. Thus, under the proposed provision, an impermissible use of Title X funds might occur when the physical facility of a grantee or subrecipient organization’s Title X-funded family planning program shares space with any abortion-related operations.

By requiring that Title X projects be physically and financially separate from abortion-related activities conducted by the grantee or subrecipient, proposed § 59.15 would help facilitate compliance with Section 1008's prohibition on abortion as a method of family planning. It would also facilitate the Department's enforcement against grantees or subrecipients that do not comply with the statutory requirement that abortion not be a method of family planning in a Title X project. In particular, proposed § 59.15 would allow the Department (and grantees) to make better case-by-case determinations about whether particular Title X projects or clinic locations have sufficient physical and financial separation from prohibited activities. To determine whether sufficient separation exists in a particular case, the Department would weigh all relevant factors, including:

- The existence of separate, accurate accounting records;
- 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;
- The existence of separate personnel, electronic or paper-based health care records, and workstations;
- The extent to which signs and other forms of identification of the Title X project are present, and signs and materials referencing or promoting abortion are absent.

Because circumstances or site-specific factors are complex and organizational realities are varied, the Department would consider individual circumstances unique to a grantee or Title X provider. We intend to take a case-by-case approach in order to ensure

program integrity, with sensitivity to individual projects and providers, and without imposing unnecessary requirements. We seek comment on whether additional factors should be considered, or whether any of the proposed factors should be omitted.

The Department also seeks public comment as to whether additional regulatory provisions are necessary to reflect the text and purpose of section 1008. Even with a bright line rule of actual physical separation, confusion could still arise if the separate facilities – one facility providing Title X services and one providing abortion as a method of family planning – are operated under the same name. Similarly, the lack of a requirement of organizational separation could continue to blur the line between permitted and prohibited Title X services and activities, making enforcement more difficult. For example, individuals seeking Title X services may mistakenly visit non-Title X sites engaged in activities such as abortion which are actually prohibited by Title X, but that have the same names and are part of the same organization as the Title X site. The Department, therefore, seeks public comment as to whether additional regulatory provisions, such as a requirement for a Title X clinic to operate under a distinct name from a facility that provides abortion as a method of family planning, or for organizational separation, are necessary to ensure compliance with section 1008.

J. Section 59.16 Prohibition on Activities that Encourage, Promote or Advocate for Abortion.

Consistent with the statutory provisions discussed above, and the prohibition in section 1008 on the use of Title X funds in programs where abortion is a method of family planning, proposed § 59.16 sets out a number of restrictions designed to ensure that Title X grantees and subrecipients do not promote or encourage abortion as a method

of family planning using Title X funds. The proposed rule would prohibit the following actions when undertaken with Title X funds: lobbying, providing speakers that promote abortion in the project or by the use of project funds, attending events or conferences during which such lobbying takes place, paying dues to organizations that advocate for the availability of abortion services, taking legal action to make abortion available as a method of family planning, and developing or disseminating materials advocating abortion as a method of family planning or otherwise promoting a favorable attitude toward abortion. Thus, consistent with proposed § 59.15, any grantee or subrecipient engaging in these activities with non-Title X funds, would be required to give evidence that such use of funds is physically and financially separate from the use of Title X funds.

K. Section 59.17 Compliance with Reporting Requirements.

New provision § 59.17 would address explicitly 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. The Consolidated Appropriations Act, 2018 included the following provision: “Notwithstanding any other provision of law, no provider of services under Title X of the Public Health Service Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.” *See* Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, sec. 208, 132 Stat. 348, 736 (2018); Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, sec. 208, 131 Stat. 135, 539 (2017); Consolidated Appropriations Act, 2016, Pub. L. 114-113, Div. H, sec. 208, 129 Stat. 2242, 2620 (2015). This provision is consistent with language that has been included in

appropriations acts for HHS since fiscal year 1999. *See, e.g.*, Department of Health and Human Services Appropriations Act, 1999, Pub. L. 105-277, Title II, sec. 219, 112 Stat. 2681, 2681-363 (1998). The Department interprets this statutory notification/reporting requirement as encompassing not only any State or local law requiring reporting or notification dealing with child abuse, child molestation, sexual abuse, rape, or incest, but also those State or local laws respecting intimate partner violence and human trafficking because such criminal activities would be encompassed within the categories of crime enumerated in the Appropriations Act (“child abuse, child molestation, sexual abuse, rape, or incest”). In addition, the Department interprets this reporting/notification requirement as applicable to all victims of such crimes, regardless of age, because the victims of sexual abuse, rape, or incest can be any age. Current Title X regulations permit the use of confidential information obtained by project staff to comply with State and local reporting requirements,⁵⁷ but do not expressly address the requirement to report child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or other sexual exploitation, nor affirmatively impose an obligation on Title X grantees and subrecipients to comply with State reporting or notification requirements.

Title X grantees and subrecipients have an affirmative obligation to comply with notification or reporting requirements; merely being aware of such requirements is insufficient to comply with the law. As Representative Ernest Istook said during the debate regarding the provision:

⁵⁷ *See* 42 CFR 59.11.

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 (1997). Some practitioners have proposed that providers avoid soliciting or determining the age of the adolescent or the age of their sexual partner as a means of assuring the adolescent of confidential services and, thus, avoiding the potential responsibility of reporting. But Title X exempts neither Title X clinics nor Title X healthcare providers from their responsibility to comply with State and local reporting laws. Sexual exploitation, abuse, or assault (including statutory rape) are crimes that affect individuals, families, and communities. Title X projects should lead the Nation in 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 coercion⁵⁸; and in assuring appropriate support and management of teens (and women) who have been exploited, abused or coerced into unequal sexual partnerships.

The Department believes that existing efforts to ensure compliance with State and local reporting laws protecting minors and other vulnerable populations should be strengthened. While a 2005 report from the Department's Office of Inspector General (OIG) revealed that OPA informs and periodically reminds Title X grantees and subrecipients of their responsibilities regarding State child-abuse and sexual-abuse

⁵⁸ As noted above, 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 Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. H, sec. 207, 132 Stat. 348, 736 (2018); Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, sec. 207, 131 Stat. 135, 538 (2017); Consolidated Appropriations Act, 2016, Pub. L. 114-113, Div. H, sec. 207, 129 Stat. 2242, 2620 (2015).

reporting requirements, it could not determine the extent to which grantees actually comply with these requirements.⁵⁹ Through the proposed rule, the Department would require, as a condition of receiving Title X funding, that a project provide assurance that it has a plan in place to comply with State and local laws requiring notification or reporting and maintains appropriate documentation of compliance with these reporting requirements.

Proposed § 59.17 would clarify the affirmative 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. It would require that Title X grantees and subrecipients have in place a plan that demonstrates 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. As part of prevention, protection, and risk assessment efforts, grantees and subrecipients should include in such plan 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. In addition, Title X projects would be 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 would be required with respect to any individual who is under the age of

⁵⁹ HHS OIG, Letter on Federal Efforts to Address Applicable Child Abuse and Sexual Abuse Reporting Requirements for Title X Grantees (OEI-02-03-00530) (April 25, 2005), <https://www.hhs.gov/opa/sites/default/files/child-abuse-reporting-requirements.pdf>.

consent in the jurisdiction in which the individual receives Title X services. If positively diagnosed, projects are permitted to also treat STDs.

Additionally, proposed § 59.17 would require 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 law, and what reports or notifications were made to appropriate State agencies. The Department would use this documentation to ensure appropriate compliance with State and local reporting requirements.

L. Section 59.18 Appropriate Use of Funds.

Consistent with section 1008, proposed § 59.18 would prohibit the use of Title X funds to build infrastructure of a Title X grantee or subrecipient for purposes outside of those permitted under the Title X regulations and authorized within section 1001 of the Public Health Service Act and not barred by section 1008—that is, to offer family planning methods and services, which do not include abortion as a method of family planning. It would clarify that grantees should use the majority of grant funds to provide direct services to clients and give a detailed accounting for usage related to grant dollars, both in applications for funding and in any annually required reporting. Under proposed § 59.18, any change in the usage of grant funds within the grant cycle would require the approval of the Department. In addition, § 59.18 would require each project to fully account for, and justify, charges against the Title X grant.

As detailed previously, the current flexibility in the usage of Title X funds permits an interchangeability of assets that grantees may have used to build infrastructure for non-Title X purposes, including abortion services. This danger is exacerbated because

Title X providers must secure other sources of revenue to leverage Title X grants. *See* 42 CFR 59.7(c). Infrastructure building may include physical space, health information technology systems, including electronic health records, bulk purchasing of contraceptive and other clinic supplies, clinical training for staff, and community outreach and recruitment. Title X is the only discrete, domestic, Federal grant program solely focused on the provision of cost-effective family planning services, and 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 become only more important. The Department accordingly proposes (1) to prohibit use of Title X funds for infrastructure building for purposes outside of the Title X program, (2) to require a detailed accounting for usage related to grant dollars, and (3) to prohibit any change in the use of grant funds without the approval of the Department. In this way, the proposed section would ensure that Title X funds are used for the purposes expressly mandated by Congress—that is, to offer family planning methods and services.

M. Section 59.19 Transition Provisions

The Department proposes two different periods of transition to these requirements. Most of the proposed changes to the Title X regulations are merely clarifications of existing statutory requirements or impose requirements that would not seem to require a lengthy period of time for compliance. The Department recognizes, however, that it might take a longer period of time for grantees and subrecipients to comply with the proposed requirement to establish and maintain physical separation of the Title X project from the provision of abortion. Accordingly, the following compliance dates are proposed to provide a transition period:

- Section 59.15: Requirement for physical separation: One year after the date of publication of the final rule.
- All other proposed requirements, including the requirement for financial separation: 60 days following publication of the final rule.

V. Regulatory Impact Statement

A. Introduction and Summary

We have examined the impacts of this proposed 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 (RFA), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 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, Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

1. Executive Orders 12866 and 13563 and the Congressional Review Act

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). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting 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) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this rulemaking is not “economically significant” as measured by the \$100 million threshold. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of the rulemaking and are including it here in order to provide further evidence of the value of this proposed rule. This proposed rule has been submitted to the Office of Management and Budget for review.

2. Regulatory Flexibility Act (RFA)

The RFA requires agencies that issue a regulation to analyze options for regulatory relief of small entities, businesses, and 501(c)(3) and 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.”) HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least

5 percent of small entities experience an impact of more than 3 percent of revenue. HHS proposed to certify that the proposed rule would not 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.” The current threshold after adjustment for inflation is \$150 million. HHS does not expect this proposed rule to result in expenditures that would exceed this amount.

4. Executive Order 13132

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. HHS has determined that the proposed rule, if finalized, would not contain policies that would 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 proposed changes in the rule represent the Federal Government regulating its own program. Accordingly, HHS concludes that the proposed 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 Proposed Rule

This rule proposes to amend the regulations governing the Title X program to ensure programmatic compliance and integrity. Specifically, the proposed 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.

(4) We evaluate the effects of this rule over 2019-2023. Costs are estimated to be \$45.5 million in 2019 and \$14.6 million in subsequent years. Present value costs of \$88.6 million and annualized costs of \$21.1 million are estimated using a 3 percent discount rate; present value costs of \$72.4 million and annualized costs of \$21.6 million are estimated using a 7 percent 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 removal of abortion counseling and referral requirements that potentially violate federal health care conscience protections. Enhanced patient service and care.				
COSTS	3 Percent	7 Percent	3 Percent	7 Percent
Quantified Costs	88.6	72.4	21.1	21.6
Non-quantified Costs				
None				

We invite comment on all aspects of this regulatory impact analysis, including the assumptions and conclusions contained in the analysis.

B. Analysis of Economic Impacts

1. Need for the Proposed Rule

This proposed rule seeks to address two categories of problems:

(1) Insufficient compliance with the statutory program integrity requirements and 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 discussed supra in Part II (Need for Change) fall into one or more of these categories.

While the current 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 not used to encourage or promote abortion in any way. For example, the current 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 build infrastructure for abortion services, including physical space, health information technology systems, including electronic health records, bulk purchasing of contraceptives and other clinic supplies, clinical training for staff, and community recruitment.

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 funded services and abortion-related services for which Title X funds cannot be used.

The current 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 expressly address the obligation of Title X grantees and subrecipients to comply with State 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 current regulations do not require Title X providers to 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 current regulations fail to require grantees to provide the Department sufficient information about the subrecipients with which they (or their subrecipients) contract and any referral agencies or other partners to whom Title X funds may flow, thus precluding OPA from exercising appropriate oversight of the activities of its program and project subrecipients.

This proposed rule addresses each of the foregoing problems. First, to assist the Department in ensuring compliance with, and enforcement of, the section 1008 prohibition, the proposed rule would prohibit family planning projects from using Title X funds to provide or present abortion as a method of family planning; require assurances of compliance; eliminate the requirement that Title X projects provide abortion counseling and referral; prohibit Title X projects from performing, promoting, referring for, or supporting, abortion as a method of family planning; require physical and financial separation of Title X activities from those which are prohibited under section 1008;

prohibit certain activities that encourage, promote, or advocate for abortion; 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 proposed rule would reiterate the voluntary, non-coercive nature of Title X services; require Title X facilities to encourage family participation in a minor's decision to seek family planning services; explicitly prohibit 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; incorporate the encouragement of family participation into the regulations; clarify the affirmative duty of projects to comply with State and local laws requiring notification and reporting of criminal sexual exploitation; clarify that confidentiality of information may not be used as a rationale for noncompliance with such notification or reporting laws; and require assurances of compliance and maintenance of records.

To assist the Department in ensuring compliance with, and enforcement of, conscience protections embodied in the Church, Coats-Snowe, and Weldon Amendments, the proposed rule would eliminate the requirement that Title X projects provide abortion counseling and referral; prohibit Title X projects from performing, promoting, referring for, or supporting, abortion as a method of family planning; and clarify that single-method service sites are permissible as components of a Title X family planning project, as long as the overall project provides a broad range of acceptable and effective family planning methods and services.

The Department believes that these proposed changes would ensure fidelity to the statutory requirements and purposes of the Title X program, the appropriations provisos

and riders addressing the Title X program, and obligations and requirements established under other Federal law. They would do so by aligning the current regulations with these statutory provisions and providing the Department with the oversight tools necessary to ensure compliance.

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 proposed rule would clarify the definition of family planning; require the referral of pregnant patients for appropriate prenatal and/or social services; require the provision of comprehensive primary health services onsite or through a robust referral linkage; and update the application review criteria.

The Department expects that these proposed changes would ensure that the Title X program takes a holistic approach to family planning through the inclusion of referral to prenatal care and social services for pregnant clients and requiring either comprehensive primary health services onsite or through a robust referral linkage.

Third, to improve transparency regarding the provision of services, the proposed rule would require additional information from applicants and grantees regarding subrecipients, referral agencies, and community partners; require a clear explanation of how grantees would ensure adequate oversight and accountability for compliance and quality outcomes among subrecipients and those who serve as referrals for ancillary or core services; and require each project supported under Title X to fully account for, and justify, charges against the Title X grant. The Department anticipates that these proposed changes will provide the information necessary to ensure, and determine compliance with

the statutory provisions on, program integrity, and the legal and ethical usage of taxpayer dollars.

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 would have the authority to initiate compliance reviews and take appropriate action to assure compliance with the provisions in this proposed rule.

2. Affected Entities

This proposed rule would affect the operations of entities who may receive Title X grants or be 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. These entities operated at 3,898 service sites, and provided services to 4,007,552 people. For purposes of this analysis, we assume that these numbers will remain the same across time. Title X services were delivered by 3,550 clinical services provider 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). 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. 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. 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. To estimate the number of FTEs in these categories, we assume that there are 1,403 encounters per FTE for individuals in these

categories, which implies approximately 1,219 FTEs in this category in 2016. To convert FTEs reported in Family Planning Annual Report (FPAR) to the number of individuals in these categories, we assume that each individual works an average of between 0.5 FTEs and 1.0 FTEs delivering Title X services, with 0.75 FTEs as our central estimate, uniformly 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-funded family planning services. We use these estimates as our estimate of service providers affected by this rule.

We estimate 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 Statistics⁶⁰ and salaries from the U.S. Office of Personal Management.⁶¹ We use 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, we use the average wage across this group when discussing impacts affecting the group. We use 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 recipients, we take the average wage across all occupations in the U.S. We assume that the 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

⁶⁰ Bureau of Labor Statistics, Occupational Employment and Wage Statistics (May 2016), https://www.bls.gov/oes/2016/may/oes_nat.htm.

⁶¹ 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>.

Virginia. We divide annual salaries by 2,087 hours to derive hourly wages. We assume that the total dollar value of labor, which includes wages, benefits, and overhead, is equal to 200 percent 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, we estimate impacts over five years starting in 2019.

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

In order to comply with the regulatory changes proposed in this proposed rule, affected entities would first need to 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, we estimate that potential grantees and subrecipients range between 100% and 300% of their 2016 values, with a central estimate of 200%. This implies 182 potential grantees and 2,234 potential subrecipients. We estimate that learning the 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 a final rule in this rulemaking.

b. Training

Individuals involved with delivering family planning services would also need to receive training on the requirements of the proposed rule. To convert FTEs reported in FPAR to the number of individuals that would receive training, we assume that each individual works an average of between 0.5 FTEs and 1.0 FTEs delivering Title X services, with 0.75 FTEs as our central estimate. This implies that there are approximately 4,733 clinical service providers and 1,625 other service providers who would need training in order to ensure compliance with these regulations when finalized. We estimate that these individuals would require an average of 4 hours of training in the

first year following publication of this rule. In subsequent years, we assume 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. We estimate 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. We estimate that this would require half of an FTE at the GS-13 level and half of an FTE at the GS-14 level. We estimate that all of these costs would be incurred in the first year following publication of the final rule. As a result, using wage information provided in Table 2, this would imply costs of \$0.43 million in the first year following publication of a final rule in this rulemaking.

c. Assurance Submissions

Title X grantees and subrecipients would face new assurance requirements because of this proposed rule. We estimate that these new requirements would require a lawyer to spend an average of 3 hours reviewing the assurances, 3 hours reviewing organizational policies and procedures, or to take other actions to assess compliance, and a medical and health services manager to spend 2 hours total for the same tasks the first year following publication of the final rule at each grantee and subrecipient. In subsequent years, we estimate 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 to take 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. As a result, using wage information provided in Table 2, this would imply costs of \$1.2 million in the first year and \$0.9 million in subsequent years following publication of a final rule in this rulemaking.

d. Documentation of Compliance

Title X grantees and subrecipients would need to document their compliance with new requirements because of this proposed 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. We estimate 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. We estimate 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 in Table 2, this would imply costs of \$2.0 million in the each year following publication of a final rule in this rulemaking.

Second, grantees must generate reports with information related to subrecipients, referral agencies and individuals involved in the grantee's Title X project. We estimate 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. As a result, using wage information provided in Table 2, this would imply costs of \$0.3 million in each years following publication of a final rule in this rulemaking.

e. Monitoring and Enforcement

This proposed rule would result in additional monitoring of Title X grantees and subrecipients in order to ensure compliance with new regulatory and existing statutory requirements. We estimate 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 spent by Federal staff. We estimate 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 a final rule in this rulemaking.

f. Physical Separation

As a result of this proposed rule, Title X providers would be required to provide Title X services at facilities that physically separate from locations at which abortion as a method of family planning is provided. A Congressional Research Service⁶² report estimates that 10% of clinics that receive Title X funding offer abortion as a method of family planning separately from 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, we estimate that between 10% and 30% of service sites,

⁶² Napili, A., *Title X (Public Health Service Act) Family Planning Program*, Congressional Research Service Report RL33644 (Aug. 31, 2017).

with a central estimate of 20%, would need to be evaluated to determine whether they comply with the proposed physical separation requirements. We estimate that this evaluation 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 a final rule. Similarly, we estimate that this evaluation would affect between 10% and 30% of grantees, with a central estimate of 20%. We estimate that this would require an average of an additional forty hours, divided evenly between lawyers and management staff, at each affected grantee, in the first year following publication of a final rule. We estimate 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, we estimate that an average of between \$10,000 and \$30,000, with a central estimate of \$20,000, would be incurred to come into compliance with physical separation requirements in the first year following publication of a final rule in this rulemaking. As a result, using wage information provided in Table 2, this would imply costs of \$24.38 million in the first year following publication of a final rule.

g. Encouraging Parental Involvement in Family Planning Services

Title X providers are already required by the statute to encourage minors to involve their parents in family planning services. However, it is currently unclear whether this requirement is being satisfied by Title X providers. As a result, this proposed rule would require that actions be taken to satisfy this requirement and that such actions be documented in a minor's medical record. We believe that this will result in improved compliance with the statutory requirement that minors be encouraged to involve their parents in family planning services. As noted previously, we estimate that complying

with the requirement to document the encouragement of family participation will result in 600,000 adolescent patients' medical records requiring documentation as a result of these requirements each year. We estimate that an additional 0-50% of these adolescents, with a central estimate of 25%, would receive additional encouragement to involve parents as a result of a final rule in this rulemaking proceeding each year. We estimate 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 in each year following publication of a final rule in this rulemaking. As a result, using wage information provided in Table 2, this would imply costs of \$2.93 million in each year following publication of a final rule.

4. Estimated Benefits:

This proposed 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 proposed rule, we also expect the quality of service to improve. Finally, the proposed 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 in the preamble, 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, and has been reiterated through annual appropriations provisions. This proposed 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 would ensure greater accountability for the use of Federal funds, mitigate confusion about what services the Federal government supports and funds, and increase the amount of Title X funds that are used to deliver family planning services.

b. Patient/Provider Benefits and Protections

The Department expects that the proposed rule would have additional benefits for patients and providers. Benefits for patients are at least twofold. First, as noted above, the new regulation would require 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 would promote seamless care and services for patients while expanding the breadth of services available within the states, territories and throughout the regions.

Second, the proposed regulation would protect certain patients from further victimization. It would do so by requiring Title X grantees and subgrantees 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 and children.

For providers, the proposed regulation is expected to create benefits through respect for conscience. It would 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 and referrals. Potential grantees, and subrecipients that refuse to provide abortion counseling and referrals may now be eligible and interested in applying to provide family planning services under the current Title X regulations. 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 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.”⁶³ Facilitating open communication between providers and their patients helps to eliminate barriers to care, particularly for minorities. 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.”⁶⁴ 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 or moral convictions feel they are being treated fairly and that their religious or moral convictions are respected.⁶⁵

C. Analysis of Regulatory Alternatives

The Department carefully considered the alternatives to this proposed rule, but concluded that none 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 law; and (2) lack of transparency regarding the provision of services.

⁶³ 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>.

⁶⁴ 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>.

⁶⁵ *Id.*

First, the Department considered maintaining the status quo and utilizing programmatic guidance and funding opportunity announcements (FOAs, also known as notices of funding opportunities) to address the problems described above. Such actions, however, would be incompatible with part 59 as it currently exists. Specifically, Title X providers would still be required to provide counseling on, and referral for, abortion upon request, a requirement inconsistent with section 1008 that could be discouraging to, and disqualify, potential grantees and subrecipients that refuse to counsel on, or provide referrals for, abortion. The maintenance of this requirement, as noted above, potentially violates the Coats-Snowe Amendment and the Weldon Amendment. Moreover, there would be 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 using 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 in the preamble, application review criteria must serve as a meaningful instrument to assess the quality of the applicant and the application. The current application review criteria 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. While the Department has discretion under the current criteria to issue FOAs that add to criteria in the regulation, as past FOAs have done, and the Department could thus seek to strengthen the selection criteria through FOA requirements, such an approach is inadequate to ensure that appropriate criteria are fully set forth, required by regulation, and give the public notice of the long term commitment of the program.

HHS 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, we considered:

(1) *Maintaining the status quo*, where only line-item financial separation from activities that treat abortion as a method of family planning is required. Currently Title X costs must be pro-rated from abortion-related activities. There is a need for greater financial oversight and accountability than is possible under the current regulations, in order to ensure that Title X funds are used only for permissible Title X services. And the current 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.

(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 to some extent, the current confusion between Title X and abortion-related services. The Department determined that this less restrictive option might serve the same goal in erasing 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 it would be likely that the segregation of staff/staff responsibilities within the same reception area 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 partially mitigate, but not eliminate, the public perception and confusion. Different examination rooms would likely have little impact because patients would likely 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.

Thus, for these reasons and the reasons for our decision to propose both physical and financial separation, we preliminary determine that both of these options would be insufficient to ensure statutory compliance and clarity regarding such compliance. The Department seeks public comment on these alternatives.

The Department seeks comment on whether additional policies or requirements, beyond those proposed herein, should be imposed to ensure compliance. These include expanding the requirement that referral agencies that do not receive Title X funds but nevertheless provide information, counseling, or services to Title X clients be subject to the same reporting and compliance requirements as do grantees and subrecipients; and requiring organizational separation in addition to physical and financial separation.

The Department invites comment on both its proposed approach and other approaches to assure compliance with the statutory requirements, along with the provision of holistic family planning services, age appropriate education and services for adolescents, and other services that promote healthy outcomes and provide transparency regarding the provision of services.

D. Executive Order 13771

Executive Order 13771 (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 proposed rule, if finalized as proposed, is expected to be an Executive Order 13771 regulatory action. The Department estimates that this rule generates \$13.6 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 proposed rule has a significant impact on a substantial number of small entities. HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least 5 percent of small entities experience an impact of more than 3 percent of revenue.

We calculate the costs of the proposed changes per service site over 2019-2023. The estimated average annualized cost of the rule per service site is approximately \$5,423 using a 3 percent discount rate. We note 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 proposed 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 the proposed rule would 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, Pub. L. 105-277, sec. 654, 112 Stat. 2681 (1998), requires Federal departments and agencies to determine whether a proposed policy or regulation could affect family well-being.⁶⁶

Agencies must assess whether the proposed 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.⁶⁷ If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law.

The Department believes the action taken in this proposed 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.

The Secretary proposes to certify that this proposed rule has been assessed in accordance with Section 654 of the Treasury and General Government Appropriations

⁶⁶ 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>.

⁶⁷ Treasury and General Government Appropriations Act, 1999, Pub. L. 105-277, sec. 654, 112 Stat. 2681, 2681-528- 2681-530 (1998).

Act of 1999, Pub. L. 105-277, sec. 654, 112 Stat. 2681 (1998), and would not negatively affect family well-being.

G. Paperwork Reduction Act

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

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

We are soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA. The collections of information required by the proposed rule relate to § 59.2 (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).

Proposed § 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 proposed § 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.

Proposed § 59.5 would require Title X providers to report, in grant applications and in all required reports, information regarding subrecipients and referral agencies and individuals, including a detailed description of the extent of collaboration and a clear explanation of how the grantee would 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).

Proposed § 59.7 would require Title X grant applicants to describe, within their applications, their affirmative compliance with each provision of the regulations governing the Title X program.

Proposed § 59.13 would require 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 would 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.

Proposed § 59.17 would require Title X grantees to provide appropriate documentation or other assurance satisfactory to the Secretary that it has in place and has implemented a plan to comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking. It would also require Title X grantees to maintain records to demonstrate compliance with the requirements of § 59.17, and make continuation of funding for Title X services contingent upon demonstrating to the Secretary that the criteria have been met.

Lastly, proposed § 59.18 would require 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 recipients to sign. We anticipate two separate burdens of response: (1) assurance of compliance; and (2) documentation of compliance. The burden for the assurance of compliance is the cost of grantee and/or subrecipient staff time to (a) review the assurance language as well as the underlying language related to stated requirements; (b) to review grantee and/or subrecipient policies and procedures or to take other actions to assess grantee and/or subrecipient compliance with the requirements to which the grantee and/or subrecipient is required to assure compliance.

The labor cost would include a lawyer spending an average of 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. We estimate 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 ($(\$67.25 \times 3 + \$52.58 \times 1) \times 1,208$ grantees and subrecipients). We estimate 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 ($(\$67.25 \times 1 + \$52.58 \times 1) \times 1,208$ grantees and subrecipients).

The Department estimates that all recipients and subrecipients will review their organizational policies and procedures or take other actions to self-assess compliance with applicable Title X requirements each year, spending an average of 4 hours doing so. The labor cost is a function of a lawyer spending an average of 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 ($(\$67.25 \times 3 + \$52.58 \times 1) \times 1,208$ 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. We assume 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. We estimate 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 x 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, 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 x 1,208 grantees and subrecipients).

Table #3 - Proposed Annual Recordkeeping and Reporting Requirements or Burden of Response in Year One/Subsequent Years following Publication of the Final Rule						
Regulation Burden	OMB control No.	Respondents Responses	Hourly rate (\$)	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting (\$)
Assurance of Compliance		1,208/1,208	63.58/62.36	8/6	9,664/7,248	614,000/452,000
Documentation of Compliance		1,208/1,208	52.58/52.58	2/2	2,416/2,416	254,000/254,000
Documentation on Minor’s Medical Records		600,000/600,000	49.08/49.08	.03/.03	100,000/100,000	982,000/982,000
Total Cost						5,813,000/5,424,000

The Department asks for public comment on the proposed information collection including what additional benefits may be cited as a result of this proposed rule.

Comments regarding the collection of information proposed in this proposed rule must refer to the proposed rule by name and docket number, and must be submitted to both OMB and the Docket Management Facility where indicated under ADDRESSES by the date specified under DATES.

When it issues a final rule, the Department plans to publish in the Federal Register the control numbers assigned by the Office of Management and Budget (OMB). Publication of the control numbers notifies the public that OMB has approved the final rule's information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 42 CFR Part 59

Abortion, Birth control, Family planning, Grant programs.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 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, grantees shall require subrecipients (and the subrecipients of subrecipients) to comply with the requirements contained in such regulations pursuant to their written contracts with such subrecipients, and shall be required to ensure that their subrecipients (and the subrecipients of subrecipients) comply with such requirements.

(b) Except for §§ 59.3, 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, new definitions of “Family Planning” and “Grantee”;
- b. Revising the definition of “Low income family”; and

c. Adding, in alphabetical order, new definitions of “Program and project”, and “Subrecipient”.

The revisions and additions read as follows:

§ 59.2 Definitions.

* * * * *

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 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 include preconceptional 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 never coercive and are 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 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). “Low-income family” also includes members of families whose annual 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 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) With respect to contraceptive services, a woman can be considered from a “low-income family” if she has health insurance coverage through an employer which does not provide the contraceptive services sought by the woman because it has a sincerely held religious or moral objection to providing such coverage.

* * * * *

Program and *project* are used interchangeably and 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.

* * * * *

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?

Any public or nonprofit private entity in a State may apply for a grant 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 and other fertility-awareness based

methods) and services (including infertility services, including 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, support, or present abortion as a method of family planning.

* * * * *

(12) 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.

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

(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.

(14) Encourage 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).

(b) * * *

(1) Provide for medical services related to family planning (including physician's consultation, examination prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, 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. Revise § 59.7 to 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 amounts?

(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.

(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 provision of the regulation (or include the entire regulation) within the Funding Announcement, and shall require each applicant to describe their plans for affirmative compliance with each provision.

(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), which meet all of the statutory and regulatory requirements and restrictions, and where 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 is demonstrated in the proposal and the applicant shows capacity to make rapid and effective use of grant funds, including and especially among a broad range of partners and diverse subrecipients and referral individuals and organizations, and among non-traditional Title X partnering organizations.

(3) The degree to which the applicant takes into account the number of 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 patients.

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 Prohibition on referral for abortion.

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.

§ 59.13 Standards of compliance with prohibition on abortion.

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.

§ 59.14 Prohibition on referral for abortion.

(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. If asked, a medical doctor may provide a list of licensed, qualified, comprehensive health service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care), but only if a woman who is currently pregnant clearly states that she has already decided to have an abortion. This list is only to be provided to a woman who, of her own accord, makes such a request. The list shall not identify the providers who perform abortion as such. All other patients will be provided, upon request, a list of licensed, qualified, comprehensive health service providers (including providers of prenatal care) who do not provide abortion as a part of their services.

(b) *Referral for prenatal services.* 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 must be referred for appropriate prenatal and/or social services (such as prenatal care and delivery, infant care, foster care, or adoption), and shall be given assistance with setting up a referral appointment to optimize the health of the mother and unborn child. She must also be provided with information necessary to protect her health and the health of the unborn child until such a time as the referral appointment is kept. 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 emergency medical services.

(c) *Use of permitted referrals to encourage abortion.* 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. Recognizing, however, the duty of a physician to promote patient safety, a doctor may, if asked, provide a list of licensed, qualified, comprehensive health service providers (some of which also provide abortion, in addition to comprehensive prenatal care). Such information related to abortion is permitted only if a woman who is currently pregnant clearly states that she has already decided to have an 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 otherwise promote abortion as a method of family planning.

(e) *Examples.* (1) A pregnant client of a Title X project requests prenatal care services, which project personnel are qualified to provide. Because the provision of such services is outside the scope of family planning supported by Title X, the client must be referred to appropriate providers of prenatal care. Provision of prenatal services within the Title X project is inconsistent with this part.

(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 comprehensive care 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 her a list of licensed, qualified health care professionals in the area (some of whom provide abortion as part of their primary health care services). The list includes, among other licensed, qualified, comprehensive health care providers, a local health care professional who provides abortions in addition to comprehensive prenatal care. Inclusion of this provider/clinic on the list is consistent with paragraph (a) 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 that provide prenatal care and abortions. None of the entries on the list are providers that principally provide abortions. Although there are several appropriate licensed, qualified providers of

prenatal care in the area that do not provide or refer for abortions, none of these providers are 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 project counselor tells her that the project does not consider abortion a method of family planning and therefore does not refer for abortion. The counselor further tells the client that the project can help her to obtain prenatal care and necessary social services, and provides her with a list of such providers from which the client may choose. Such actions are consistent with paragraph (a) 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 does not constitute 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 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.* 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. Prohibited actions include the use of Title X project funds for the following:

(1) Lobbying for the passage of legislation to increase in any way the availability of abortion as a method of family planning;

(2) Providing speakers or educators who, in the Title X project or the use of Title X project funds, promote the use of abortion as a method of family planning;

(3) Attending events or conferences during which the grantee or subrecipient engages in lobbying;

(4) 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;

(5) Using legal action to make abortion available in any way as a method of family planning; and

(6) Developing or disseminating in any way materials (including printed matter, audiovisual materials and web-based materials) advocating abortion as a method of family planning or otherwise promoting a favorable attitude toward abortion.

(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)(6) of this section.

(2) A Title X project makes an appointment for a pregnant client with an abortion clinic. The Title X project has violated paragraph (a) 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. Payment of dues to the association violates paragraph (a)(4) 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)(4) 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)(1) 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)(1) 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) 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) 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 implemented a plan to comply with State laws Such plan shall include, at a minimum, policies and procedures with respect to such notification and reporting 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 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; 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 teen who presents with a sexually transmitted disease (STD), pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor. Such screening would be required with respect to any

individual who is under the age of consent in the state of the proposed service area.

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 where required by law,

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 sole purpose of ensuring compliance with the requirements of this section.

§ 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 with 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 give a detailed accounting for the use of grant dollars, both in their applications for funding, and within any annually required reporting. Further, any

significant change in the usage 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 any possible misuse of Title X funds through misbilling or overbilling, or any other unallowable expense.

§ 59.19 Transition provisions.

(a) In accordance with § 59.15, with respect to the requirement for physical separation that is effective after [DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER], covered entities must comply with the applicable new requirements [DATE 1 year after the publication of the final rule].

(b) In accordance with § 59.15, with respect to the requirement for financial separation is effective after [DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER], covered entities must comply with the applicable new requirements no later than [DATE 60 days AFTER PUBLICATION OF THE FINAL RULE].

(c) In regards to all other requirements are effective after [DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER], covered entities must comply no later than 60 days following publication of the final rule.

Dated: May 24, 2018.

Alex M. Azar II

Secretary

Department of Health and Human Services.

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