(d) *Indirect or inadvertent residues.* [Reserved]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 59

RIN 937–AA04

Compliance With Title X Requirements by Project Recipients in Selecting Subrecipients

AGENCY: Office of Population Affairs, Office of the Secretary, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department is amending the regulations that apply to Title X Project Grants for Family Planning Services. The final rule amends eligibility requirements to require that no recipient making subawards for the provision of services as part of its Title X project may prohibit an entity from participating for reasons other than its ability to provide Title X services.

DATES: This Rule is effective on January 18, 2017.

FOR FURTHER INFORMATION CONTACT: Susan B. Moskosky, MS, WHNP–BC, Office of Population Affairs (OPA), 200 Independence Avenue SW., Suite 716G, Washington, DC 20201; telephone (240) 453–2800; email: *OPA_Resource@hhs.gov.*

SUPPLEMENTARY INFORMATION: On September 7, 2016, The Department issued a proposed rule seeking comment on amending eligibility criteria under the Title X family planning services program so that no recipient making subawards for the provision of services as part of its Title X project may prohibit an entity from participating for reasons unrelated to its ability to provide Title X services effectively. 81 FR 61639. As reiterated below, the proposed rule set forth the need for the amendment and sought public input.

I. Background

A. Title X Background

As discussed in the Notice of Proposed Rule Making (NPRM), the Title X Family Planning Program, Public Health Service Act (PHSA) secs. 1001 *et seq.* [42 U.S.C. 300], was enacted in 1970 as part of the Public Health Service Act. Administered by the Office of Population Affairs (OPA) within the Office of the Assistant Secretary for Health (OASH), Title X is the only federal program focused solely on providing family planning and related preventive services. In 2015, more than 4 million individuals received services through more than 3,900 Title X-funded health centers.[1]

Title X serves women, men, and adolescents to enable individuals to determine freely the number and spacing of children. By law, services are provided to low-income individuals at no or reduced cost. Services provided through Title X-funded health centers assist in preventing unintended pregnancies and achieving pregnancies that result in positive birth outcomes. These services include contraceptive services, pregnancy testing and counseling, preconception health services, screening and treatment for sexually transmitted diseases (STD), HIV testing and referral for treatment, services to aid with achieving pregnancy, basic infertility services, and screening for cervical and breast cancer. By statute, Title X funds are not available to programs where abortion is a method of family planning (PHSA sec. 1008). Additionally, Title X implementing regulations require that all pregnancy options counseling shall be neutral and nondirective. 42 CFR 59.5(a)(5)(ii).

The Title X statute authorizes the Secretary ''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).'' PHSA sec. 1001(a). In addition, in awarding Title X grants and contracts, the Secretary must ''take into account the number of patients to be served, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance.'' PHSA sec. 1001(b). The statute also requires that local and regional entities ''shall be assured the right to apply for direct grants and contracts.'' PHSA sec. 1001(b). The statute delegates rulemaking authority to the Secretary to set the terms and conditions of these grants and contracts. PHSA sec. 1006. These regulations were last revised in 2000. 65 FR 41270 (July 3, 2000).

Title X regulations delineating the criteria used to decide which family planning projects to fund and in what amount, include, among other factors, the extent to which family planning services are needed locally, the number of patients (and, in particular, low-income individuals) to be served, and the adequacy of the applicant's facilities and staff. 42 CFR 59.7. Project recipients receive funds directly from the federal government following a competitive process. The project recipients may elect to provide Title X services directly, subaward funds to subrecipients, or both. The Department is responsible for monitoring and evaluating the project recipient's performance and outcomes, and each project recipient that subawards to eligible subrecipients is responsible for monitoring the performance and outcomes of those subrecipients. The subrecipients must meet the same federal requirements as the project recipients, including being a public or private nonprofit entity, and adhering to all Title X and other applicable federal requirements. In the event of poor performance or noncompliance, a project recipient may take enforcement actions as described in the uniform grants rules at 45 CFR 75.371.

B. State Restrictions on Subrecipients

In the past several years, a number of states have taken actions to restrict participation by certain types of providers as subrecipients in the Title X program, for reasons other than the provider's ability to provide Title X services. In at least several instances, this has led to disruption of services or reduction of services. Since 2011, 13 states have placed restrictions on or eliminated subawards with specific types of providers based on reasons other than their ability to provide Title X services. In several instances, these restrictions have interfered with the ''capacity [of the applicant] to make rapid and effective use of [Title X federal] assistance.'' PHSA sec. 1001(b). Moreover, states that restrict eligibility of subrecipients have caused limitations in the geographic distribution of services and decreased access to services through trusted providers.

States have restricted subrecipients from participating in the Title X program in several ways. Some states have employed a tiered approach to compete or distribute Title X funds, whereby entities such as comprehensive primary care providers, state health departments, or community health centers receive a preference in the distribution of Title X funds. This approach effectively excludes providers focused on reproductive health from receiving funds, even though they have been shown to provide higher quality services, such as preconception

[1] Fowler, C.I., Gable, J., Wang, J., & Lasater, B. (2016, August). Family Planning Annual Report: 2015 National Summary. Research Triangle Park, NC: RTI International.

services, and accomplish Title X programmatic objectives more effectively.[2] [3] For example, in 2011, Texas reduced its contribution to family planning services, and also re-competed subawards of Title X funds using a tiered approach. The combination of these actions decreased the Title X provider network from 48 to 36 providers, and the number of Title X clients served was reduced dramatically. Although another entity became the statewide project recipient in 2013, the number of Title X clients served decreased from 259,606 in 2011 to 166,538 in 2015.[4] [5] In other cases, states have prohibited specific types of providers from being eligible to receive Title X subawards, which has had a direct impact on service availability, primarily for low-income women. In some cases, experienced providers that have historically served large numbers of patients in major cities or geographic areas have been eliminated from participation in the Title X program. In Kansas, for example, following the exclusion of specific family planning providers in 2011, the number of clients, 87 percent of whom were low income (at or below 200 percent of the Federal Poverty Level), declined from 38,461 in 2011 to 24,047 in 2015, a decrease of more than 37 percent. As with the declines in Texas, this is a far greater decrease than the national average of 20 percent.[6] [7]

In New Hampshire, in 2011, the New Hampshire Executive Council voted not to renew the state's contract with a specific provider that was contracted to provide Title X family planning services for more than half of the state. To restore services to clients in the unserved part of the state, the Department issued an emergency replacement grant, but there was significant disruption in the delivery of services, and for approximately three months, no Title X services were available to potential clients in a part of the state.

Most recently, in 2016 Florida enacted a law that would have gone into effect on July 1, 2016, prohibiting the state from making Title X subawards to certain family planning providers.[8] In one county alone, 1,820 clients are served by the family planning provider that would have been excluded, and it is not clear how the needs of those clients would have been met.

None of these state restrictions have been related to the subrecipients' ability to deliver Title X services. Instead, these restrictions are based either on non-Title X funded health services offered or on other activities the providers may separately conduct using non-federal funds, or because of the provider's affiliation. The Title X program provides that the Secretary shall make awards for family planning services based on ''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 [Title X Federal] assistance.'' PHSA sec. 1001(b). Allowing 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.

C. Litigation

As discussed in the NPRM, litigation concerning these restrictions has led to inconsistency across states in how recipients may choose subrecipients. As the restrictions vary, so have the statutory and constitutional issues raised in the cases.

II. Final Rule and Responses to Public Comments

A. Overview of the Final Rule

The Department is finalizing the proposed rule with modifications. After reviewing the relevant comments, the Department is eliminating the qualifier ''effectively'' and changing ''unrelated to'' to ''other than'' in the regulatory language. The amendment now reads, ''No recipient making subawards for the provision of services as part of its Title X project may prohibit an entity from participating for reasons other than its ability to provide Title X services.'' The Department does not believe that including the term ''effectively'' is necessary for operation of this rule. Inclusion of ''effectively'' has the potential for inconsistent application and could create compliance burdens on recipients trying to apply a measure of ''effectiveness'' across a range of subrecipients. The revised language addresses the Department's concern that certain Title X recipients have imposed restrictions on subrecipients that are designed to further policy objectives other than the delivery of Title X services. Title X is the only federal program focused solely on providing family planning and related preventive services. Restrictions not directly related to that goal hinder the program's statutory mission and adversely affect the program's intended beneficiaries.

For example, as outlined in the NPRM, state restrictions on subrecipients for activities unrelated to Title X-funded services have kept eligible providers from serving priority populations.[9] Therefore, restricting participation by certain types of providers for such reasons will not be allowable under the rule. Similarly, while tiering Title X subawards may fulfill some state-based policy goals, tiering does not advance the specific Title X goals of providing ''a broad range of acceptable and effective family planning methods and services.'' PHSA sec. 1001(a). Prohibiting recipients from adding eligibility criteria for a reason other than the provision of Title X services ensures the broadest available pool of applicants for subawards and the use of federal resources in furtherance of statutory goals.

As is currently the case, applicants for new and continuing Title X grants that do not provide all services directly will describe the process and criteria by which they select subrecipients. Following implementation of this new rule, the Department will review this information to determine an applicant's eligibility to receive a new or continuing award. For new awards, the Department will assess whether any subrecipient restrictions are for reasons other than the subrecipient's ability to provide

[2] Robbins, C.L., Gavin, L., Zapata, L.B., Carter, M. W., Lachance, C., Mautone-Smith, N., & Moskosky, S.B. (2016). Preconception Care in Publicly Funded U.S. Clinics That Provide Family Planning Services. American Journal of Preventive Medicine.

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

[4] Fowler, CI, Lloyd, S, Gable, J, Wang, J, and McClure, E. (November 2012). Family Planning Annual Report: 2011 National Summary. Research Triangle Park, NC: RTI International.

[5] Fowler, C.I., Gable, J., Wang, J., & Lasater, B. (2016, August). Family Planning Annual Report: 2015 National Summary. Research Triangle Park, NC: RTI International.

[6] Fowler, CI, Lloyd, S, Gable, J, Wang, J, and McClure, E. (November 2012). Family Planning Annual Report: 2011 National Summary. Research Triangle Park, NC: RTI International.

[7] Fowler, C.I., Gable, J., Wang, J., & Lasater, B. (2016, August). Family Planning Annual Report: 2015 National Summary. Research Triangle Park, NC: RTI International.

[8] H.B. 1411, 2016 Leg., Reg. Sess. (Fla. 2016). The law was preliminarily enjoined on June 30, 2016. *Planned Parenthood of Southwest and Central Florida* v. *Philip, et al.,* No. 4:16cv321–RH/CAS, 2016 U.S. Lexis 86251 (N.D. Fla. June 30, 2016)(''the defunding provision does not survive the unconstitutional conditions doctrine.''). The law was permanently enjoined on August 18, 2016, in an unpublished order.

[9] Stevenson AJ, Flores-Vazquez IM, Allgeyer RL, Schenkkan P, Potter JE. Effect of Removal of Planned Parenthood from the Texas Women's Health Program. N Engl J Med. 2016 Mar 3;374(9):853–60.

Title X services. For continuing awards, the Department will work with recipients to help entities come into compliance prior to an award being made. If, despite the Department's assistance, compliance is not achieved, the Department will discontinue funding in accordance with all applicable rules and regulations. If available and as appropriate, this will include administrative appeals and a recoupment and re-awarding of funds. Further, if a current recipient amends the scope of its approved project by changing its process for selecting subrecipients, that request requires prior approval and the Department will apply the same review criteria. 45 CFR 75.308.

B. Responses to Public Comments

Overall, 145,303 comments were received. Approximately 91 percent (132,032) of the total comments received were in favor of the proposed rule. The vast majority of comments both favoring and opposing the rule were duplicate comments. Comments came from a wide variety of individuals and organizations, including private citizens, health care providers, religious organizations, patient advocacy groups, professional organizations, research institutions, consumer organizations, and state and federal agencies and representatives. Many of the comments dealt with a range of issues beyond the scope of this rulemaking including, but not limited to, the separation of church and state, additional confidentiality protections, provider fraud, and general opposition to Title X funding. A summary of the applicable comments, and the Department's responses, follows below.

Comment: One commenter stated the comment period was too short for the rule and did not allow enough time for response on its significant economic and federalism impacts.

Response: Given the limited scope of this rulemaking, the Department believes that notice was sufficient because ''interested parties [had] a reasonable opportunity to participate in the rulemaking process'' and were not ''deprived of the opportunity to present relevant information by lack of notice that the issue was there.'' *Am. Radio Relay League* v. *FCC*, 524 F.3d 227, 236 (D.C. Cir. 2008) (citations omitted). In fact, the Department received over 145,000 responses to the notice of proposed rulemaking, many with detailed suggestions on different aspects of the proposed rule. Therefore, the Department does not believe that extending the comment period was necessary or warranted.

Comment: Several commenters suggested the Department lacks legal authority to issue a rule in this area.

Response: The Department disagrees. The Title X statute explicitly provides rulemaking authority for the making of conditions for grants. 42 U.S.C. 300a–4(a). The Department has engaged in rulemaking for this program on multiple occasions. See, *e.g.,* 65 FR 41270 (July 3, 2000); 65 FR 49057 (Aug. 10, 2000); 53 FR 2922 (Feb. 2, 1988). In addition, courts, including the Supreme Court, have consistently upheld this authority. *Rust* v. *Sullivan,* 500 U.S. 173 (1991). On the very issue of state legislation affecting Title X, the U.S. Court of Appeals for the Tenth Circuit stated: ''HHS has deep experience and expertise in administering Title X, and the great breadth of the statutory language suggests a congressional intent to leave the details to the agency . . . . Of course, administrative actions taken by HHS will often be reviewable under the Administrative Procedure Act, but only after the federal agency has examined the matter and had the opportunity to explain its analysis to a court that must show substantial deference.'' *Planned Parenthood of Kansas & Mid-Missouri* v. *Moser,* 747 F.3d 814, 824–25 (10th Cir. 2014). The Department is choosing to exercise that authority to promulgate a rule that it believes, as discussed above, is ''reasonably related to the purposes of the enabling legislation'' (the standard to which the Supreme Court has held previous exercises of this authority). *Mourning* v. *Family Publication Service,* 411 U.S. 356, 369 (1973).

Comment: Commenters stated the rule was not clear in how it applied to recipients who provide some services directly and contract out some services.

Response: The rule applies to all project recipients whenever they make subawards for the provision of Title X services. It is not intended to require those who directly provide all Title X services to start providing subawards. However, if a project recipient makes subawards for any Title X services, it may not prohibit an entity from participating in the program as a subrecipient for reasons other than that entity's ability to provide Title X services.

Comment: Commenters stated clarification is needed about how the proposed rule will affect services at the state level and speculated that the proposed rule will cause a disruption in services.

Response: The primary goals of the rule change are to ensure consistency of subrecipient participation, improve provision of services, and guarantee Title X resources are used to fulfill Title X goals. The final rule will be applied in a prospective manner, meaning with the submission of new competitive applications or, for recipients applying for non-competing funds, with the initiation of a new budget period. As a result, it is unlikely that the rule will cause disruption during a budget period, as each renewed budget period requires approval prior to an award. In the instance when a recipient makes a change to its process for selecting subrecipients in the middle of a budget period, if found to be out of compliance it may cause an interruption in the provision of services, but such mid-cycle changes are expected to be very rare. As previously stated, the Department will make every effort to help entities come into compliance, and will award replacement grants to other providers when necessary to minimize any disruption of services.

The final regulation will not invalidate conflicting state laws. Instead, the regulation informs states with conflicting laws that if they intend to apply for new or continuing Title X funds, they would need to comply with federal law under which a recipient may not exclude an entity from participating for reasons other than its ability to provide Title X services. The rule will not interfere with statutory requirements in those states where recipients directly provide all Title X services, or where recipients select subrecipients based solely on their ability to provide Title X services.

Comment: Commenters stated the proposed rule would allow Title X service providers that also provide abortion services to redirect their non-Title X funds toward abortion services or use Title X funding to fund abortion.

Response: Title X funds cannot be used for abortions. The Title X statute prohibits any of the funds appropriated under Title X to be used in programs where abortion is a method of family planning. PHSA sec.1008. Title X provides family planning and related reproductive health services such as: testing and counseling for sexually transmitted diseases (STDs), including HIV; contraceptive methods including method-specific counseling; breast and cervical cancer screening; pregnancy tests and counseling, and other related services to over four million low-income women, men, and adolescents each year.

Additionally, beyond cost-sharing and program income requirements, federal grant programs do not generally have the authority to stipulate what recipients do with non-federal funds. *See Planned Parenthood of C. and N.*

Ariz. v. *State of Ariz.,* 718 F.2d 938, 945 (9th Cir. 1983), in which the court stated: ''we hold that as a matter of law, the freeing up theory cannot justify withdrawing all state funds from otherwise eligible entities merely because they engage in abortion-related activities disfavored by the state.'' The commenters also assume, without substantiation, that federal funding will supplant private funding for family planning, allowing the private funding to be used to fund abortions instead of additional family planning services and programs. According to the uniform grant rules, grants funds and any program-generated income must be used to further the objectives of the Title X program and would not be allowed to be diverted for non-allowable activities. 45 CFR 75.307 (e). Speculation about the indirect effects of Title X funding is not a sufficient basis to justify making subawards based on reasons other than the ability to provide Title X services.

Comment: Commenters stated that Title X should fund sites that provide comprehensive primary care rather than sites providing primarily reproductive health care.

Response: The Department appreciates the value of providers, such as federally qualified health centers (FQHCs), which deliver comprehensive primary care services in communities. The Department also respects states' rights to spend their own (non-Federal) funds. However, the Title X program was specifically enacted to offer a broad range of family planning services, and not comprehensive primary care. While Title X has neither the authority nor purpose of providing comprehensive primary care, to the extent FQHCs may be the best providers of family planning services in a particular area, there is no prohibition on FQHCs being selected by project recipients as subrecipients.

OPA's efforts to ensure widespread access to quality family planning services is consistent with efforts to provide comprehensive care. Family planning is a subset of comprehensive care services, which are particularly important for women and men of reproductive age. Given the fact that family planning services are often not provided, or are provided with poor quality in some primary care settings,[10] OPA efforts are focused on ensuring that quality family planning services are included within the broader set of comprehensive preventive care needs of all Americans.[11]

In addition, women of reproductive age often report that their family planning provider is also their usual source of health care.[12] Providers of family planning services serve as entry points for their clients to other essential health care services. Preconception care (PCC), which includes screening for obesity, smoking, and mental health, is a key service provided as part of high quality family planning care. PCC improves women and men's health and can increase a person's ability to conceive and to have a healthy birth outcome. In a nationally representative sample of publicly funded clinical administrators, conducted in 2013–2014, written protocols for preconception care screening, which serve as instructions for clinicians providing these services, were more common in dedicated reproductive health centers compared with primary care centers and health departments.[13]

Comment: Commenters stated that the proposed rule would be discriminatory against men and adolescents because the ''notice shows HHS intends to impose a preference for prioritizing funding to 'specific providers with a reproductive health focus.'''

Response: Title X regulations require projects to provide services without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status. 42 CFR 59.5(a)(4). The Title X statute specifically mentions adolescents as a priority population for receiving Title X services. In fact, in 2015 approximately 44 percent of the Title X clients served were between the ages of 15 and 24 years. Moreover, OPA funds projects to improve outreach and male-centered services in an effort to increase the number of men who use Title X services. Between 2003 and 2014, Title X providers served a total of 3.8 million males, nearly doubling the percentage of male family planning users from 4.5 percent in 2003 to 8.8 percent in 2014.[14] In addition, the 2014 report *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs* [15] (QFP) identifies a specific set of family planning and related services that should be provided to men and adolescents.

Comment: Commenters stated that use of the word ''effectively'' in the proposed rule is vague. The commenters asserted that it would be difficult to determine which policies were allowable under the rule without a clear definition of ''effectively.''

Response: As noted previously, after reviewing the relevant comments, the Department recognizes the challenge of measuring effectiveness across all grant recipients and subrecipients as a condition of participation, and is eliminating the qualifier ''effectively'' from the regulatory language. The amendment now reads, ''No recipient making subawards for the provision of services as part of its Title X project may prohibit an entity from participating for reasons other than its ability to provide Title X services.'' The Department believes that the revised language addresses the Department's concern that certain Title X recipients have imposed restrictions on subrecipients that are designed to further policy objectives other than the ability to provide Title X services. A recipient imposing a ban on particular types of providers or imposing a tiering structure is prohibiting subrecipients from participating on factors other than the ability to provide Title X services. Only qualifications of recipients tied to Title X objectives, such as the ability to make rapid and effective use of federal funds and compliance with Title X regulations, are relevant factors. The revised language is clear and does not depend on the meaning of ''effectively.''

Comment: Commenters stated that the Title X program lacks a clear evidence-based process for establishing program guidelines.

Response: The Department has adopted an evidence-based approach for defining program guidelines, such as what constitutes ''quality'' family planning services. Quality family planning services were defined in the 2014 clinical recommendations, *Providing Quality Family Planning*

[10] Wood, S., et al., Scope of family planning services available in Federally Qualified Health Centers. Contraception, 2014. 89(2): p. 85–90.

[11] CDC, Providing Quality Family *Planning Services: Recommendations of the CDC and the U.S. Office of Population Affairs.* MMWR Recommendations and Reports, 2014. 63(4): p. 1–54.

[12] Frost J. U.S. women's use of sexual and reproductive health services: Trends, sources of care and factors associated with use, 1995–2010. New York, NY: Guttmacher Institute; 2013.

[13] Robbins CL, Gavin L, Zapata LB, Carter MW, Lachance C, Mautone-Smith N, Moskosky SB. Preconception Care in Publicly Funded U.S. Clinics That Provide Family Planning Services. Am J Prev Med. 2016 Sep;51(3):336–43.

[14] Besera, G, Moskosky, S., Et. Al. (2016), Male Attendance at Title X Family Planning Clinics—United States 2003–2014. Morbidity and Mortality Weekly Report, 65(23), 602–605.

[15] Gavin, L., & Pazol, K. (2016). Update: Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2015. MMWR. Morbidity and Mortality Weekly Report MMWR Morb. Mortal. Wkly. Rep., 65(9), 231–234.

Services (QFP).[16] These recommendations were developed using an evidence-based approach, and adopted the Institute of Medicine's (IOM) definition of health care ''quality,'' which is:

''The degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.'' [17]

The process of developing QFP recommendations was rigorous and aligned with current national and international standards for guidelines development; a priority was placed on clinical services for which there was evidence of effectiveness as defined by the presence of research demonstrating a protective impact on a behavioral or health outcome.[18] [19]

For this reason, the provision of *quality* care is very likely to result in a change in health outcomes. This emphasis on improving the quality of care is consistent with global and national efforts that have highlighted its importance to achieving key outcomes. For example, quality care has been identified by the Institute of Medicine (IOM) and other leaders in health care delivery as the driving factor that will achieve the goals of improved health, client experience and cost savings.[20] [21]

OPA's development and implementation of the QFP recommendations in the Title X program also demonstrates that steps have been taken to address comments from another IOM report published in 2009.[22] The 2009 report urged OPA to ensure that its recipients follow ''current evidence-based professional clinical recommendations,'' and consider ''making the Title X guidelines the standard used by all federal health programs.''

Comment: Commenters questioned the legitimacy of the findings of the study by Robbins et al.[23] related to Title X service providers cited by the Department including challenging the assumption that the existence of written clinical protocols indicated higher quality care.

Response: Regarding the findings of the study by Robbins et al.,[24] the Department clarifies that written clinical protocols are not printed worksheets given to clients. Rather, they are explicit guidance that clinicians use to provide services in accordance with nationally recognized standards of care. Furthermore, written clinical protocols are associated with higher quality care.[25]

Comment: Commenters requested information about how OPA will ensure that compliance with and enforcement of the proposed rule are integrated into the final rule and Title X award process.

Response: The Department believes that relying on our existing enforcement mechanisms rather than developing new reporting requirements or new certification requirements will be the most efficient means of ensuring compliance. The primary goals of the rule change are to ensure consistency of subrecipient participation, improve provision of services, and guarantee Title X resources are used to fulfill Title X goals. As part of the funding opportunity announcement (FOA) for each grant cycle, applicants are required to describe how their projects will address Title X requirements. This includes, but is not limited to, fully describing if they will not provide all services directly, the process and selection criteria used, or to be used, to select subrecipients, service sites and providers, including a description of eligible entities for funding as subrecipients.[26] Recipients applying for non-competing continuation funds (those with part of their project period remaining after their current budget period, for example, in year one or two of a three-year project period) will also be required to describe, if they will not provide all services directly, the process and selection criteria used or to be used for selection of service sites and providers, including a description of eligible entities for funding as subrecipients. For recipients applying for non-competing continuation funds, the Department will work with them to help entities come into compliance prior to an award being made. If, despite the Department's assistance, compliance is not achieved, the Department will discontinue funding in accordance with all applicable rules and regulations. If available and as appropriate, this will include administrative appeals and a recoupment and re-awarding of funds. Further, if a current recipient amends the scope of its approved project by changing its process for selecting subrecipients, that request requires prior approval and the Department will apply the same review criteria. 45 CFR 75. Additionally, recipients are subject to uniform grant rule requirements related to subawards, 45 CFR 75.352, and all other applicable rules.

Comment: Commenters stated concern that the Department did not consider the alternative of modifying the grant process to make it easier for providers restricted from being eligible as a subrecipient in specific states to receive grants directly from Title X.

Response: The grants process is established by the Department to ensure integrity and accountability in the award and administration of grants, and to protect federal resources across all Departmental programs. As a result, the Department does not consider suggestions to change the grants process for specific applicants under Title X a viable alternative to this rule.

Applicants who meet the eligibility criteria in the funding opportunity announcement (FOA) may submit, directly, an application for consideration as a Title X recipient, independent of the size of the entity. Applicants should also have the option to be considered eligible as a subrecipient. The rule addresses recipients or applicants that propose excluding potential subrecipient entities

[16] CDC, Providing Quality Family Planning Services: Recommendations of the CDC and the U.S. Office of Population Affairs. MMWR Recommendations and Reports, 2014. 63(4): p. 1–54.

[17] Institute of Medicine, Crossing the quality chasm: A new health system for the 21st century, ed. Committee on Quality of Health Care in America. 2001, Washington, DC: National Academies of Science.

[18] CDC, Providing Quality Family Planning Services: Recommendations of the CDC and the U.S. Office of Population Affairs. MMWR Recommendations and Reports, 2014. 63(4): p. 1–54.

[19] Gavin, L., S.B. Moskosky, and W. Barfield, Developing U.S. Recommendations for Providing Quality Family Planning Services. American Journal of Preventive Medicine, 2015. 49((2) Supplement 1).

[20] Institute of Medicine, Crossing the quality chasm: A new health system for the 21st century, ed. Committee on Quality of Health Care in America. 2001, Washington, DC: National Academies of Science.

[21] Berwick, D., T. Nolan, and J. Whittington, The Triple Aim: Care, Health, and Cost. Health Affairs, 2008. 27(3): p. 759–769.

[22] Institute of Medicine, A Review of the HHS Family Planning Program: Mission, Management, and Measurement of Results, ed. A. Stith Butler and E. Clayton. 2009, Washington, DC: National Academies Press.

[23] Robbins, C.L., Gavin, L., Zapata, L.B., Carter, M.W., Lachance, C., Mautone-Smith, N., & Moskosky, S.B. (2016). Preconception Care in Publicly Funded U.S. Clinics That Provide Family Planning Services. American Journal of Preventive Medicine.

[24] Robbins, C.L., Gavin, L., Zapata, L.B., Carter, M.W., Lachance, C., Mautone-Smith, N., & Moskosky, S.B. (2016). Preconception Care in Publicly Funded U.S. Clinics That Provide Family Planning Services. American Journal of Preventive Medicine.

[25] Committee on Patient Safety and Quality Improvement. Committee Opinion No. 629: Clinical guidelines and standardization of practice to improve outcomes. Obstet Gynecol. 2015 Apr;125(4):1027–9.

[26] United States of America. Office of the Assistant Secretary for Health. Office of Population Affairs. Announcement of Anticipated Availability of Funds for Family Planning Services Grants. 5 Oct. 2016. Accessed on 2 Dec. 2016 at *http://www.hhs.gov/opa/sites/default/files/FY-17-Title-X-FOA-New-Competitions.pdf.*

based on criteria other than the entity's ability to provide Title X services.

Comment: Commenters stated that states should not have to fund Planned Parenthood because these commenters claim the organization has perpetuated Medicaid fraud. Commenters also stated that the proposed rule would allow for preferential treatment of Planned Parenthood and that by allowing Title X funds to be awarded to Planned Parenthood it could create a monopoly in family planning service providers.

Response: No comment provided evidence to support allegations that any Title X provider has engaged in Medicaid fraud. Entities that are suspended, excluded or debarred from participation in federal health care programs are not eligible to receive awards under the Title X program. Furthermore, the Uniform Administrative Requirements, Cost Principles and Audit Requirements for HHS Awards stipulate requirements for making financial assistance awards to applicants and existing recipients that include the need to take into consideration the ability of the applicant to use federal funds properly in the manner intended. 45 CFR 75.205. These rules also require an assessment of the applicant's ability to meet legal, financial, and administrative obligations prior to receiving federal funds, as well as during the entire duration of the project period in which the federal funds are expended. This is accomplished by several methods, including, but not limited to, the awarding program office and grants management office conducting a risk assessment, which directly assesses the applicant for financial stability, quality of management systems, history of performance, audit reports and findings, and ability to implement effectively statutory, regulatory, and other requirements. The awarding program office and the grants management office also evaluate the applicant using the Federal Awardee Performance and Integrity Information System (FAPIIS). These steps must be completed prior to the initial award and are assessed throughout the entire project period. Additionally, Government-wide suspension and debarment activities are used to safeguard federal funds by disallowing awards to organizations and their principals based on a lack of business honesty or integrity. Federal agencies only do business with those organizations, and only provide funding for those principals, that have a satisfactory record of business ethics and integrity. 2 CFR part 180, subpart D.

The rule will not provide any preferential treatment, nor disadvantage any applicant, from receiving Title X family planning service grants. In contrast to the assertion made by the commenter, this final rule encourages providers to compete based on their ability to provide Title X services. The rule will ensure consistent opportunity of subrecipient participation across geographic areas, and guarantee Title X resources are allocated on the basis of fulfilling Title X goals.

This final rule does not favor particular providers, and does not deter competition between providers; it requires recipients to evaluate potential subrecipients based on their ability to provide Title X services. As a result, new and existing providers will be able to receive Title X funding based on their ability to provide Title X services.

III. Regulatory Impact Analysis

A. Comments Received in Response to Executive Order 13132 Federalism Review

Comment: Several commenters were critical of the Federalism analysis performed under Executive Order 13132. These commenters stated the rule was targeted at states and their traditional authority over health care. Additionally, many commenters suggested the proposed program requirement violated the Tenth Amendment, the Spending Clause, and preemption principles. Several commenters additionally asserted that Title X federal funding conditions should not interfere with state priorities, even when using federal funds.

Response: Title X was enacted in order for family planning projects to offer a broad range of family planning methods and services. It was not enacted as a federal-state cooperative statute, as is evidenced by the eligibility of nonprofit, private entities to apply for grants directly. Currently, 40 nonprofit entities receive Title X funding directly from the Department. Further, every state has at least one Title X recipient, and 13 states and the District of Columbia, have only nonprofit, private recipients.

The Supreme Court has long been clear that the Tenth Amendment limitation on the Congressional regulation of state affairs does not limit the range of conditions legitimately placed on federal grants. *Oklahoma* v. *Civil Serv, Comm'n,* 330 U.S. 127 (1947). The Department may attach conditions to the awarding of funds to carry out best its statutory goals. *South Dakota* v. *Dole,* 483 U.S. 203 (1987); *Rust* v. *Sullivan,* 500 U.S. 173, 191 (1991) (''We have recognized that Congress' power to allocate funds for public purposes includes an ancillary power to ensure that those funds are properly applied to the prescribed use.'') The possible loss of future Title X grants does not amount to coercing the states (or nonprofit private entities) to capitulate to program requirements. Similarly, as the rule only attaches requirements to the receipt of federal funds, it would not invalidate any state laws with which it conflicts. States often opt not to apply for federal grant funds where the federal program requirement conflicts with state law priorities. Therefore, there is no preemption of state laws caused by this rule.

It must also be emphasized that this rule applies to all Title X project recipients, not only to project recipients that represent state health departments. As the NPRM explained, ''All project recipients that do not provide services directly must only choose subrecipients on the basis of their ability to deliver Title X required services. Nonprofit recipients that do not provide all services directly must also allow any eligible providers that can provide Title X services in a given area to apply to provide those services, and they may not continue or begin contracting (or subawarding) with providers simply because they are affiliated in some way that is unrelated to the programmatic objectives of Title X.'' 81 FR at 61643.

Comment: One commenter also suggested that the proposed rule violated spending clause principles. Specifically, the commenter argued, given the vagueness of ''effectively,'' grant recipients would not be on clear notice of what would be expected of them.

Response: As noted above, the Department eliminated the qualifier ''effectively'' from the regulatory language. The amendment now reads, ''No recipient making subawards for the provision of services as part of its Title X project may prohibit an entity from participating for reasons other than its ability to provide Title X services.'' As explained previously in this preamble, restrictions placed on organizations unrelated to the delivery of Title X services and tiering approaches would not be allowed. As this requirement will only be applied in future FOAs and continuation funding applications, there will be additional opportunities for the Department to provide guidance consistent with this final rule and entities may seek further guidance from the Department as to what other practices may be problematic before applying before applying for funds. Thus, applicants will have the option to

apply for funds knowing the relevant conditions, or to decline to do so.

As stated in the NPRM, Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This rule will not cause substantial economic impact on states or nonprofit private entities. It may implicate state laws only if those states with contrary laws wish to apply for federal Title X funds. States that choose to do so and also choose to subaward Title X funds will be required to do so in a manner that considers only the ability of the subrecipients to meet the statutory objectives of Title X.

B. Comments Received in Response to Economic Impact Analysis Under E.O. 12866

Comment: Commenters stated concern that the Department did not consider regulatory alternatives.

Response: This regulation is the simplest way to achieve the goal of ensuring that Title X recipients determine subrecipients based on their ability to provide Title X services. As a result, more complex regulatory alternatives in the impact analysis were not discussed. The Department did consider the no action alternative, but concluded that it would not further the statutory goals served by the regulation. These commenters and others described various regulatory alternatives, and these alternatives, such as direct grants, are discussed in the final rule.

Comment: Commenters stated concern that the impact analysis did not address impacts to states and service providers affected by the rule.

Response: Contrary to the assertions made by the commenters, the impact analysis did estimate costs borne by recipients, including recipients that represented state health departments, associated with evaluating the rule and modifying policies to ensure compliance with the rule, and the impact analysis noted that the rule may result in some shifts in funding from some family planning services providers to other family planning services providers.

Comment: Commenters stated concern that the impact analysis did not address the consequences of states electing not to participate in Title X.

Response: The primary goal of the impact analysis was to determine the societal impact of the rule. If a potential recipient decides not to participate in Title X as a result of the rule, this may result in a reallocation of resources, and under certain circumstances this could result in a reduction in the utilization of services in some areas. If Title X funding and the associated services declined in a specific area, this would correspond with a commensurate increase in services in other areas due to the reallocation of funding. Although the Department does not anticipate this to occur widely, this shift would represent an indirect transfer of federal funding for health care services from individuals in some areas to individuals in other areas, which the Department estimates would have no net effect on total Title X expenditures by the United States.

1. Introduction

The Department has examined the impact of this final rule under 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 of 1980 (Pub. L. 96–354, September 19, 1980), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Order 12866 directs 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). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. The Department expects that this final rule will not have an annual effect on the economy of $100 million or more in any one year. Therefore, this rule is not an economically significant regulatory action as defined by Executive Order 12866 or a major rule under either the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501, or the Congressional Review Act, 5 U.S.C. 801.

The Regulatory Flexibility Act (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses 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; (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''). For similar rules, the Department considers a rule to have a significant economic impact on a substantial number of small entities if at least five percent of small entities experience an impact of more than three percent of revenue. The Department anticipates that the final rule will not have a significant economic impact on a substantial number of small entities.

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 $146 million, using the most current (2015) implicit price deflator for the gross domestic product. This final rule would not trigger the Unfunded Mandate Reform Act because it will not result in any expenditure by states or other government entities.

2. Summary of the Final Rule

Since 2011, 13 states have taken actions to restrict participation by certain types of providers as subrecipients in the Title X program based on reasons other than the providers' ability to provide Title X services. In at least several instances, this has led to disruption of services or reduction of services in instances where a public entity, such as a state health department, is a Title X recipient and makes subawards to subrecipients for the provision of services. In response to these actions, this final rule requires that any Title X recipient subawarding funds for the provision of Title X services not prohibit an entity from participating as a subrecipient for reasons other than its ability to provide Title X services.

3. Need for the Final Rule

Certain states have policies in place that limit access to family planning services by restricting specific types of providers from participating as subrecipients in the Title X program. These policies, and varying court decisions on their legality, have led to uncertainty among recipients, inconsistency in program administration, and reduced access to services for Title X priority populations. These restrictive state policies exclude certain entities for reasons other than their ability to provide Title X services.

As a result of these state policies, providers previously determined by Title X recipients to be eligible providers of family planning services have been excluded from participation in the Title X program. In turn, the exclusion of these providers is associated with a reduction in the number of Title X service sites, reduced geographic availability of Title X services, and fewer Title X clients served between 2011 and 2014.[27] [28] This final regulation seeks to ensure that state and nonprofit private entity policies regarding Title X do not direct or restrict funding to subrecipients for reasons other than their ability to provide Title X services.

Reducing access to Title X services has many adverse effects. Title X services have a large effect on reducing the number of unintended pregnancies and unplanned births in the United States. For example, the Guttmacher Institute estimates that in 2014 publicly funded contraceptive care at Title X-funded clinics has helped women to prevent approximately 50 percent of an estimated total 1.9 million unintended pregnancies prevented by publically supported services nationally, and 70 percent (904,000) of the 1.3 million unintended pregnancies prevented by women with the help of publicly funded providers. The 904,000 unintended pregnancies would have resulted in an estimated 439,000 unplanned births, 326,000 abortions, and 139,000 miscarriages.[29] The Title X program also helps prevent the spread of STDs by providing screening and treatment.[30] The program helps reduce maternal morbidity and mortality, as well as low birth weight, preterm birth, and infant mortality.[31] [32] Title X, as it exists today, is also very cost beneficial: every grant dollar spent on family planning saves an average of $7.09 in Medicaid-related costs.[33]

In addition to reducing access to the Title X program, these policies that restrict specific types of providers from being eligible to participate in the Title X project may reduce the quality of Title X services, as described previously. Research has shown that providers with a reproductive health focus provide services that more closely align with the statutory and regulatory goals and purposes of the Title X program.[34] In particular, these entities provide a broader range of contraceptive methods on-site, are more likely to have written protocols that assist clients with initiating and continuing contraceptive use without barriers, disproportionately serve more clients in need of family planning services, and may provide higher quality services.[35]

The Department is concerned that policies that restrict certain types of entities from becoming subrecipients for reasons other than their ability to provide Title X services could limit the set of available providers for reasons unrelated to the quality of family planning services they provide. This, in turn, could reduce access to care and may reduce the availability of high quality family planning services. This regulation takes the simplest approach to reverse the adverse effects of policies that have excluded certain entities for reasons other than their ability to provide Title X services.

4. Analysis of Benefits and Costs

a. Benefits to Potential Title X Clients and Reduced Federal Expenditures

This final rule directly prohibits Title X recipients that subaward funds for the provision of Title X services from excluding an entity from participating for reasons other than its ability to provide Title X services. Following the implementation of policies this regulation would address, states shifted funding away from family planning service providers previously determined to be eligible. The Department believes that this final rule is likely to undo these effects. To the extent that a state may come into compliance with this regulation by relinquishing its Title X grant or not applying to continue a Title X grant, other organizations could compete for Title X funding to deliver services in areas where a state entity previously subawarded funds for the delivery of Title X services. In turn, the Department expects that this has the potential to reverse the associated reduction in access to Title X services and deterioration of outcomes for affected populations.

As previously stated, research has shown that every grant dollar spent on family planning saves an average of $7.09 in Medicaid-related expenditures.[36] In addition to reducing spending, these services improve the health and quality of life for affected individuals, suggesting that the return on investment to these family planning services is even higher. For example, these services reduce the incidence of invasive cervical cancer and sexually transmitted infections in addition to improving birth outcomes through reductions in preterm and low birthweight births.[37] Data show that specific provider types with a reproductive health focus have been shown to serve disproportionately more clients in need of publicly funded family planning services than do public health departments and FQHCs.[38] Therefore, eliminating restrictions against certain providers has the potential to result in an increased number of clients served and services delivered by the Title X program.

b. Costs to the Federal Government Associated With Disseminating Information About the Rule and Evaluating Grant Applications for Conformance With Policy

Following publication of the final rule, OPA will educate Title X program recipients and applicants about the requirement not to prohibit an entity from participating for reasons other than

[27] Fowler, CI, Lloyd, S, Gable, J, Wang, J, and McClure, E. (November 2012). Family Planning Annual Report: 2011 National Summary. Research Triangle Park, NC: RTI International.

[28] Fowler, C. I., Gable, J., Wang, J., & Lasater, B. (2015, August). Family Planning Annual Report: 2014 National Summary. Research Triangle Park, NC: RTI International.

[29] Frost JJ, Frohwirth L, and Zolna MR. Contraceptive Needs and Services, 2014. New York: Guttmacher Institute, 2015, <*https://www.guttmacher.org/report/contraceptive-needs-and-services-2014-update*>.

[30] Fowler, CI, Gable, J, Wang, J, and McClure, E. (November 2013). Family Planning Annual Report: 2012 National Summary. Research Triangle Park, NC: RTI International.

[31] Kavanaugh ML and Anderson RM, Contraception and Beyond: The Health Benefits of Services Provided at Family Planning Centers, New York: Guttmacher Institute, 2013 <*https://www.guttmacher.org/sites/default/files/report_pdf/health-benefits.pdf*>.

[32] Preconception Health and Reproductive Life Plan. (n.d.). Retrieved May 18, 2016, from *http://www.hhs.gov/opa/title-x-family-planning/initiatives-and-resources/preconception-reproductive-life-plan/*.

[33] Frost, J.J., Sonfield, A., Zolna, M.R., & Finer, L.B. (2014). Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program. Milbank Quarterly, 92(4), 696–749.

[34] Robbins, C.L., Gavin, L., Zapata, L.B., Carter, M.W., Lachance, C., Mautone-Smith, N., & Moskosky, S.B. (2016). Preconception Care in Publicly Funded U.S. Clinics That Provide Family Planning Services. American Journal of Preventive Medicine.

[35] Robbins, C.L., Gavin, L., Zapata, L.B., Carter, M.W., Lachance, C., Mautone-Smith, N., & Moskosky, S.B. (2016). Preconception Care in Publicly Funded U.S. Clinics That Provide Family Planning Services. American Journal of Preventive Medicine.

[36] Frost, J.J., Sonfield, A., Zolna, M.R., & Finer, L.B. (2014). Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program. Milbank Quarterly, 92(4), 696–749.

[37] Frost, J.J., Sonfield, A., Zolna, M.R., & Finer, L.B. (2014). Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program. Milbank Quarterly, 92(4), 696–749.

[38] Frost JJ, Zolna MR and Frohwirth L, Contraceptive Needs and Services, 2010, New York: Guttmacher Institute, 2013, <*http://www.guttmacher.org/pubs/win/contraceptive-needs-2010.pdf.*>

its ability to provide Title X services. OPA will send a letter summarizing the change to current recipients of Title X funds and post the letter to its Web site. Language conforming to this final rule will be included in forthcoming FOAs and continuation application guidance. OPA also has other existing channels for disseminating information to stakeholders. Therefore, based on previous experience, the Department estimates that preparing and disseminating these materials will require approximately one to three percent of a full-time equivalent OPA employee at the GS–12 step 5 level. Based on federal wage schedule for 2016 in the Washington, DC area, GS–12 step 5 level corresponds to an annual salary of $87,821. The salary cost is doubled to account for overhead and benefits. As a result, the Department estimates a cost of approximately $1,800–$5,300 to disseminate information following publication of the final rule.

c. Grant Recipient Costs To Evaluate and Implement the Policy Change

The Department expects that stakeholders, including grant applicants and recipients potentially affected by this final policy change, will process the information and decide how to respond. This change will not affect the majority of current recipients and, as a result, the majority of current recipients will spend very little time reviewing these changes before deciding that no change on their part is required. For the states that currently hold Title X grants and have laws or policies restricting eligibility of Title X subrecipients based on reasons other than their ability to deliver Title X services, the final rule may implicate the state's law or policy. State agencies that currently restrict subrecipients would need to consider their current practices carefully in order to comply with this final rule if they wish to continue obtaining Title X grants and engaging subrecipients.

The Department estimates that current and potential recipients will spend an average of one to two hours processing the information and deciding what action to take. The Department notes that individual responses are likely to vary, as many parties unaffected by these changes will spend a negligible amount of time in response to these changes. According to the U.S. Bureau of Labor Statistics,[1] the average hourly wage for a chief executive in state government is $54.26, which the Department believes is a good proxy for the individuals who will spend time on these activities. After adjusting upward by 100 percent to account for overhead and benefits, it is estimated that the per-hour cost of a state government executive's time is $108.52. Thus, the average cost per current or potential grant recipient to process this information and decide upon a course of action is estimated to be $108.52–$217.04. OPA will disseminate information to an estimated 89 Title X grant recipients. As a result, it is estimated that dissemination will result in a total cost of approximately $9,700–$19,300.

d. Summary of Impacts

Public funding for family planning services has the potential to shift to providers that see a higher number of patients and provide higher quality services. Increases in the quantity and quality of Title X service utilization could lead to fewer unintended pregnancies, improved health outcomes, reduced Medicaid costs, and increased quality of life for many individuals and families. The final rule's impacts will take place over a long period of time, as it will allow for the continued flow of funding to provide family planning services for those most in need, and it will prevent future attempts to prohibit Title X funding to current and potential subrecipients for reasons other than their ability to meet the objectives of the Title X program.

The Department estimates approximate costs in the range of $11,400–$24,600 in the first year following publication of the final rule. This rule is beneficial to society in increasing access to and quality of care.

e. Analysis of Regulatory Alternatives

The Department carefully considered the option of not pursuing regulatory action. However, as discussed previously, not pursuing regulatory action would allow the continued denial of Title X funds to entities for reasons other than their ability to provide Title X services. This, in turn, means accepting reductions in access to and quality of services to populations who rely on Title X. As a result, the Department chose to pursue regulatory action.

C. Paperwork Reduction Act of 1995

The amendments in this rule will not impose any additional data collection requirements beyond those already imposed under the current information collection requirements that have been approved by the Office of Management and Budget.

Date: December 12, 2016.

Sylvia M. Burwell,

Secretary.

List of Subjects in 42 CFR part 59

Birth control, Family planning, Grant programs.

Therefore, under the authority of section 1006 of the Public Health Service Act as amended, and for the reasons stated in the preamble, the Department amends 42 CFR part 59 as follows:

PART 59—GRANTS FOR FAMILY PLANNING SERVICES

■ 1. The authority citation for Part 59 continues to read as follows:

Authority: 42 U.S.C. 300a–4.

■ 2. Section 59.3 is revised to read as follows:

§ 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?

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

(b) No recipient making subawards for the provision of services as part of its Title X project may prohibit an entity from participating for reasons other than its ability to provide Title X services.

[FR Doc. 2016–30276 Filed 12–14–16; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 191 and 192

[Docket No. PHMSA–2016–0016; Amdt. Nos. 191–24; 192–122]

RIN 2137–AF22

Pipeline Safety: Safety of Underground Natural Gas Storage Facilities

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Interim final rule.

SUMMARY: This interim final rule (IFR) revises the Federal pipeline safety regulations to address critical safety issues related to downhole facilities, including wells, wellbore tubing, and casing, at underground natural gas storage facilities. This IFR responds to Section 12 of the Protecting our Infrastructure of Pipelines and Enhancing Safety Act of 2016, which was enacted following the serious