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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: Notice of proposed rulemaking.

SUMMARY: This document seeks comment on the proposed amendment of Title X regulations specifying the requirements Title X projects must meet to be eligible for awards. The amendment precludes project recipients from using criteria in their selection of subrecipients that are unrelated to the ability to deliver services to program beneficiaries in an effective manner.

DATES: To be considered, comments should be submitted by [**INSERT 30 DAYS FROM PUBLICATION IN THE FEDERAL REGISTER**]. Subject to consideration of the comments submitted, the Department will publish final regulations.

ADDRESSES: You may submit comments, identified by Regulatory Information Number (RIN) 937-AA04, by any of the following methods:

- *Federal eRulemaking Portal:* http://www.regulations.gov. Enter the above docket ID number in the ‘‘Enter Keyword or ID’’ field and click on ‘‘Search.’’ On the next Web page, click on ‘‘Submit a Comment’’ action and follow the instructions.
- *Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions] to:* Susan B. Moskosky, MS, WHNP-BC, Office of Population Affairs, Department of Health and Human Services, 200 Independence Avenue SW, Suite 716G, Washington, DC 20201. Comments received, including any personal information, will be posted without change to http://www.regulations.gov.

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; facsimile: 240-453-2801; email: OPA_Resource@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Title X Background

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 freely determine 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) and 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), and no federal funds in Title X or any federal program may be expended for abortions except in cases of rape, incest, or where the life of the mother would be endangered.[2] Additionally, Title X implementing

[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.

[2] Consolidated Appropriations Act, 2016, Division H, Title V, Pub. L. No. 114-113, secs. 506-07, 129 Stat. 2242, 2649 (2015).

regulations require that all pregnancy 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 mandates 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 to be served (and, in particular, low-income patients), 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 or by subawarding funds to qualified entities (subrecipients). HHS is

responsible for monitoring and evaluating the project recipient's performance and outcomes, and each project recipient that subawards to qualified 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, unrelated to the provider's ability to provide the services required under Title X. 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 unrelated to their ability to provide required services in an effective manner. When the state health department is a Title X recipient, these restrictions on subrecipient participation can apply. 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 and qualified 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 services, and accomplish Title X programmatic objectives more effectively.[3,4] 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.[5,6] 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

[3] 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. doi:10.1016/j.amepre.2016.02.013

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

[5] 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.

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

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.[7,8]

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, HHS 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.[9] 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.

[7] 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.
[8] Fowler, C. I., Gable, J., Wang, J., & Lasater, B. (2016, August). Family Planning Annual Report: 2015 National Summary. Research Triangle Park, NC: RTI International.
[9] 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.

None of these state restrictions are related to the subrecipients' ability to effectively deliver Title X services. The previously mentioned exclusions are based either on non-Title X health services offered or other activities the providers conduct with non-federal funds, or because they are a certain type of provider. The Title X program provides 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 that are unrelated to the ability of subrecipients to provide Title X services in an effective manner has been shown to have an adverse effect on access to Title X services and therefore the fundamental goals of the Title X program.

C. Litigation

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 in the cases. For example, in *Planned Parenthood of Kansas & Mid-Missouri v. Moser*, 747 F.3d 814, 824-25 (10th Cir. 2014), the U.S. Court of Appeals for the Tenth Circuit preliminarily upheld a state law that did not explicitly exclude a particular provider, but directed all Title X funding to be allocated to hospitals and community health centers. In finding that Title X did not provide a private cause of action for the plaintiffs, the Court reasoned: "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. . . . Absent private suits, HHS can maintain uniformity in administration with centralized control. . . . 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." Thus, while finding deference would be afforded any agency determination of Title X requirements, the court did not reach the merits of the plaintiff's Supremacy Clause claims.

At least two other U.S. Courts of Appeal have specifically held that Title X prohibits state laws that have restrictive subrecipient eligibility criteria. *See Planned Parenthood of Houston & Se. Tex. v. Sanchez,* 403 F.3d 324, 337 (5th Cir. 2005) ("[A] state eligibility standard that altogether excludes entities that might otherwise be eligible for federal funds is invalid under the Supremacy Clause."); *Planned Parenthood Fed'n of Am. v. Heckler,* 712 F.2d 650, 663 (D.C.Cir.1983) ("Although Congress is free to permit the states to establish eligibility requirements for recipients of Title X funds, Congress has not delegated that power to the states. Title X does not provide, or suggest, that states are permitted to determine eligibility criteria for participants in Title X programs." (internal quotation marks and citation omitted)); *see also Planned Parenthood of Cent. N. Carolina v. Cansler,* 877 F. Supp. 2d 310, 331-32 (M.D.N.C. 2012) ("Therefore, the Court concludes once again that the fact that Plaintiff may, at some point in the future, be able to apply directly for Title X funding does not mean that the state may now or in the future impose additional eligibility criteria or exclusions with respect to the Title X

funding administered by the state."); *Planned Parenthood of Billings, Inc. v. State of Mont.*, 648 F. Supp. 47, 50 (D. Mont. 1986) ("Based on the foregoing, the Court concludes the co-location proviso contained in the Montana General Appropriations Act of 1985 adds an impermissible condition of eligibility for federal funding under the Public Health Service Act, in violation of the Supremacy clause.").

These and other appellate courts have also considered First Amendment issues in adjudicating state restrictions, though not all cases have involved Title X funds. Some courts have concluded certain state restrictions do not violate the Constitution. *See, e.g.*, *Planned Parenthood of Indiana, Inc. v. Comm'r of Indiana State Dep't of Health,* 699 F 3d 962, 988 (7th Cir. 2012); *see also Planned Parenthood Ass'n of Hidalgo Cty. Texas, Inc. v. Suehs,* 692 F.3d 343, 350 (5th Cir. 2012). Other courts have found the restrictions violate the Constitution by conditioning funding on First Amendment rights. *See Planned Parenthood Association of Utah v. Herbert, No. 2:15-CV-00693-CW,* 2016 U.S. App. LEXIS 12788, *36-38, (10th Cir. July 12, 2016)); *Planned Parenthood of Southwest and Central Florida v. Philip et al.,* No. 4:16cv321-RH/CAS, 2016 U.S. Dist. LEXIS 86251, *15-16 (N.D. Fl. June 30, 2016); *Planned Parenthood of Greater Ohio v. Hodges*, No 1:116cv539, 2016 U.S. Dist. Lexis 106985, *22 (S.D. Oh. August 12, 2016).

II. Proposed Rule

The Department is proposing to amend the regulations at 42 CFR 59.3 to require that project recipients that do not provide services directly may not prohibit subrecipients from participating on bases unrelated to their ability to provide Title X services

effectively. The proposed rule will maintain uniformity in administration, ensure consistency of subrecipient participation across grant awards, improve the provision of services to populations in appropriate geographic areas, and guarantee Title X resources are allocated on the basis of fulfilling Title X family planning goals. The deleterious effects already caused by restrictions in several states as outlined above justify a rule in order to fulfill the purpose of Title X. The proposed rule helps fulfill the declared purpose of providing a broad range of family planning methods and services to populations most in need. Nothing in the statute supports giving discretion to project recipients to make eligibility restrictions that may adversely affect accessibility of Title X services.

The proposed rule will further Title X's purpose by protecting access of intended beneficiaries to Title X service providers that offer a broad range of acceptable and effective family planning methods and services. Title X regulations at 42 CFR 59.7 lay out the criteria for how the Department decides which family planning projects to fund and in what amount, based on the Department's judgment as to which projects best promote the purposes of the statute. Among these criteria are: the number of patients to be served (in particular, low-income patients), as well as the adequacy of the applicant's facilities and staff.

Data show that specific provider types with a reproductive health focus provide a broader range of contraceptive methods on-site, and are more likely to have protocols that assist

clients with initiating and continuing to use methods without barriers.[10] In addition, these providers have been shown to serve disproportionately more clients in need of publicly funded family planning services than do public health departments and federally qualified health centers (FQHCs). One reproductive-focused provider constitutes ten percent of all publicly supported family planning centers, yet serves more than one-third of the clients who obtain publicly supported contraceptive services. In comparison, one-third of all publicly funded clinics are administered by public health departments, and they serve only about one-third of clients that receive publicly-funded family planning services. On average, an individual FQHC serves 330 contraceptive clients per year and a health department serves 750, as compared to specific family planning providers that on average serve 3,000 contraceptive clients per year.[11] To exclude providers that serve large numbers of clients in need of publicly funded services limits access for patients who need these services. Furthermore, in 2011, 71 percent of family planning organizations in Texas widely offered long-acting reversible contraception; in 2012-2013 following enactment of legislation in Texas that reduced funding and restricted provider participation in the state's family planning program, only 46 percent of family planning agencies did so.[12]

[10] Frost JJ et al., Variation in Service Delivery Practices Among Clinics Providing Publicly Funded Family Planning Services in 2010, New York: Guttmacher Institute, 2012, <www.guttmacher.org/pubs/clinic-survey-2010.pdf>.

[11] 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>.

[12] White, K., Hopkins, K., Aiken, A., Stevenson, A., Lopez, C. H., Grossman, D., & Potter, J. (2013). The impact of reproductive health legislation on family planning clinic services in Texas. Contraception, 88(3), 445. doi:10.1016/j.contraception.2013.05.059

In April 2014, CDC and the Office of Population Affairs released clinical recommendations, "*Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*,"[13] (QFP) which identify core components of quality family planning services. Preconception care (PCC) was identified as one of the most important services to be provided as part of high quality family planning. As explained in QFP, preconception care services "promote the health of women of reproductive age before conception, and help to reduce pregnancy-related adverse outcomes, such as low birth weight, premature birth, and infant mortality." A nationally representative study was performed prior to release of these recommendations to assess the prevalence of PCC services being delivered. Study results were tabulated according to the type of publicly funded site where the services were provided (Community Health Center, Health Department, Planned Parenthood, Outpatient Hospitals, and other clinics). Study results indicated that all provider types lagged behind the focused reproductive health providers in providing these PCC services, an indication of higher quality services.[14]

Another study, using nationally representative survey data, examined four aspects of the scope and quality of family planning service delivery before release of the QFP: the scope of family planning services provided, contraceptive methods provided onsite, written contraceptive counseling protocols, and youth-friendly services. In assessing the

[13] 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. doi:10.15585/mmwr.mm6509a3

[14] 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. doi:10.1016/j.amepre.2016.02.013

scope of family planning services provided, providers were asked about the provision of the following services in the past three months: pregnancy diagnosis and counseling, contraceptive services, basic infertility services, STD screening, and preconception health care. To assess contraceptive methods provided onsite, questions were asked regarding the provision of a range of reversible methods on site, as well as the presence of contraceptive counseling protocols. Again, as described in the previous study, results were tabulated according to the type of publicly funded site where services were provided. Across all four aspects, the focused reproductive health providers provided services that were broader in scope and of higher quality across all four aspects of family planning service delivery.[15]

Data show that restricting specific providers of Title X services has harmful effects on access to family planning services and is linked with increased pregnancy rates that are not in line with population-wide trends. In addition, studies have shown that state actions to exclude specific family planning providers from publicly funded programs has contributed to a host of barriers to care and poor health outcomes, including reduced use of highly effective methods of contraception and corresponding increases in rates of childbirth among populations that rely on Federally supported care;[16] decreased utilization rates of other preventive services, including cancer screenings, particularly for

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

[16] Frost, J.J., Frowirth, L., & Zolna, M.R. Contraceptive Needs and Services, 2013 Update, Guttmacher Institute, July 2015.

women with low educational attainment;[17] and an increase in reported barriers to reproductive health care services, particularly for young, low-income, Spanish-speaking, and immigrant women.[18] Specifically, in Texas, when certain Title X providers were barred from participation in the program, in counties where those providers provided services, uptake of the most effective forms of contraception decreased by up to 35.5 percent, and the rate of childbirth covered by Medicaid increased by 1.9 percentage points, while pregnancy rates decreased in the rest of the state. Specifically, the study assessed rates of contraceptive method provision, method continuation, and childbirth covered by Medicaid between 2011 and 2014, corresponding to two years before and two years after the providers' exclusion.[19]

Denying participation by family planning providers that can provide effective services has also resulted in populations in certain geographic areas being left without a Title X provider for an extended period of time, such as in New Hampshire in 2011 (detailed previously). In some cases, excluded providers do not have the administrative capacity to directly apply for and manage a Title X grant, as was the case in Kansas when specific family planning providers were excluded by the state from participation in the Title X Program. The data show that restrictions hurt the priority population for publicly funded family planning services, and that providers that are focused specifically on family

[17] Lu, Y. and Slusky, D.J.G., "The Impact of Family Planning Cuts on Preventive Care," Princeton Center for Health and Wellbeing Working Paper, (May 20, 2014), available at http://ssrn.com/abstract=2442148.
[18] Texas Policy Evaluation Project, *Research Brief: Barriers to Family Planning Access in Texas* (May 2015), available at http://www.utexas.edu/cola/orgs/txpep/_files/pdf/TxPEP-ResearchBrief_Barriers-to-Family-Planning-Access-in-Texas_May 2015.pdf.
[19] Effect of Removal of Planned Parenthood from the Texas Women's Health Program. (2016). New England Journal of Medicine N Engl J Med, 374(13), 1298-1298. doi:10.1056/nejmx160006

planning service provision generally provide better access and higher quality family planning services, which is the purpose of the program[20]

Under the proposed rule, all project recipients that do not provide the services directly must only choose subrecipients on the basis of their ability to effectively deliver Title X required services.[21] Non-profit project recipients that do not provide all services directly must also allow any qualified providers that can effectively provide 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 programmatic objectives of Title X. Project recipients that directly provide services will not be required to start awarding to subrecipients. For instance, some recipients provide services directly, meaning they directly operate the service sites, the business operations are controlled by the recipient, and the recipient directly controls the clinics (e.g., clinic hours, staffing, etc.) and the delivery of services (e.g., consistent clinical protocols throughout the system). This is the case for some public recipients, such as state health departments, as well as non-profits. For example, some state departments of health provide all services directly – the local and county health departments are considered part of the state, and the staff in the health departments are state health department staff. In comparison, some health departments make subawards

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

[21] Grant recipients would also continue to be subject to uniform grant rule requirements, 45 CFR 75.352.

to county health departments and/or non-profit agencies within their services network for the delivery of family planning services.

Under the proposed rule, a tiering structure—described above—would not be allowable unless it could be shown that the top tier provider (e.g., community health center or other provider type) more effectively delivered Title X services than a lower tier provider. In addition, a preference for particular subspecialty providers would have to be justified by showing that they more effectively deliver Title X services. Furthermore, actions that favor 'comprehensive providers' would require justification that those providers are at least as effective as other subrecipients applying for funds. The proposed rule does not limit all types of providers from competing for subrecipient funds, but delimits the criteria by which a project recipient can allocate those funds based on the objectives in Title X.

The Department seeks comments on several issues. The Department is cognizant of administrative burdens on both itself and project recipients that could result from the proposed changes, as discussed further below in the Regulatory Impact Analysis, and seeks comment on how to minimize them. Additionally, the Department seeks input on whether other portions of the Title X rules might need to be amended to conform to this rule regarding the selection of subrecipients. We invite comments on the utility of requiring compliance reports or other records demonstrating a project recipient's criteria for selecting providers, or whether a complaint-driven process would promote the same goals more efficiently. Project recipients found out of compliance would have all the

same rights to appeal adverse determinations under the proposed rule as they do any other agency decision. For example, after voluntary compliance avenues have failed and the Department determines to terminate the grant, grantees could appeal wrongful termination claims through the Departmental Appeals Board process. 42 CFR 59.10.

While the Department is also aware of the scope of the proposed rule, it does not believe it will interfere with other generally applicable state laws. If, for example, a state law requires certain wage rates, or addresses family leave or non-discrimination, this rule will not interfere with that law, since all subrecipients will be similarly situated as to that state law. Only those laws which directly distinguish among Title X providers for reasons unrelated to their ability to deliver services would be implicated, and then, only if the state chooses to continue to apply for funding. The Department seeks comment on the regulatory language and ways it may be seen as interacting with other state law provisions.

While specifically seeking comment on the issues outlined above, the Department invites comments on any other issues raised by the proposed regulation.

III. Regulatory Impact Analysis

A. Introduction

HHS has examined the impact of this proposed 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. No. 96-354, September 19, 1980), the Unfunded Mandates Reform Act of 1995 (Pub. L. No. 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. HHS expects that this proposed rule will not have an annual effect on the economy of $100 million or more in at least 1 year. Therefore, this rule will not be an economically significant regulatory action as defined by Executive Order 12866.

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, 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 anticipates that the proposed 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 proposed rule would not trigger the Unfunded Mandate Reform Act because it will not result in any expenditure by states or other government entities.

B. Summary of the Proposed 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 factors unrelated to the providers' ability to provide the services required under Title X effectively. In at least several instances, this has led to disruption of services or reduction of services where a public entity, such as a state health department, holds a Title X grant and makes

subawards to subrecipients for the provision of services. In response to these actions, this proposed rule requires that any Title X recipient subawarding funds for the provision of Title X services not prohibit a potential subrecipient from participating for reasons unrelated to its ability to provide services effectively.

C. Need for the Proposed Rule

Certain states have policies in place which limit access to high quality family planning services by restricting specific types of providers from participating in the Title X program. These policies, and varying court decisions on their legality, has led to uncertainty among grantees, inconsistency in program administration, and diminished access to services for Title X target populations. These restrictive state policies exclude certain providers for reasons unrelated to their ability to provide Title X services effectively. As a result of these state policies, providers previously determined by Title X grantees to be effective providers of family planning services have been excluded from participation in the Title X program. In turn, the exclusion of these high quality providers is associated with a reduction in the quality of family planning services, the number of Title X service sites, reduced geographic availability of Title X services, and fewer Title X clients served.[22,23] This proposed regulation seeks to ensure that state policies regarding Title X do not direct funding to subrecipients for reasons other than their ability to meet the objectives of the Title X program.

[22] 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.
[23] Fowler, C. I., Gable, J., Wang, J., & Lasater, B. (2015, August). Family Planning Annual Report: 2014 national summary. Research Triangle Park, NC: RTI International.

Reducing access to Title X services has many adverse effects. Title X services have a dramatic effect on the number of unintended pregnancies and births in the United States. For example, services provided by Title X-funded sites helped prevent an estimated 1 million unintended pregnancies in 2010 which would have resulted in an estimated 501,000 unplanned births.[24] The Title X program also helps prevent the spread of STDs by providing screening and treatment.[25] The program helps reduce maternal morbidity and mortality, as well as low birth weight, premature birth, and infant mortality.[26,27] Title X as it exists today is also very cost effective: every grant dollar spent on family planning saves an average of $7.09 in Medicaid-related costs.[28]

In addition to reducing access to the Title X program, these policies 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. 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

[24] 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>.
[25] Fowler, CI, Gable, J, Wang, J, and McClure, E. (November 2013). Family Planning Annual Report: 2012 National Summary. Research Triangle Park, NC: RTI International.
[26] 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>.
[27] 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/
[28] 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. doi:10.1111/1468-0009.12080

without barriers, disproportionately serve more clients in need of family planning services, and provide higher quality services as stipulated in national recommendations, "*Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs."*

Policies that eliminate specific reproductive health providers for reasons unrelated to their ability to provide the quality family planning services in an effective manner may shift funding from relatively high quality family planning service providers to providers of lower quality. This, in turn, can reduce access to high quality family planning services for the populations that need these services the most. This regulation takes the simplest approach to reverse the adverse effects of these policies that exclude certain reproductive health care providers for reasons unrelated to their ability to provide services effectively.

D. Analysis of Benefits and Costs

1. Benefits to potential Title X clients and reduced federal expenditures

This proposed rule directly prohibits Title X recipients that subaward funds for the provision of Title X services from excluding an entity from participating for reasons unrelated to its ability to provide services effectively. Following the implementation of policies this regulation proposes to reverse, states shifted funding away from family planning service providers previously determined to be most effective. We believe that this proposed rule is likely to undo these effects, resulting in a shift toward service providers previously determined to be the most effective. To the extent that a state may come into compliance with this regulation by relinquishing its Title X grant or not

applying for 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, we expect that this will reverse the associated reduction in access to Title X services and deterioration of outcomes for affected populations.

Research has shown that every grant dollar spent on family planning saves an average of $7.09 in Medicaid-related expenditures.[29] In addition to reducing spending, these services improve health and quality of life for affected individuals, suggesting 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 birth weight births. [30] 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 federally qualified health centers (FQHCs).[31] Therefore, eliminating discrimination against certain providers is expected to result in an increased number of patients served and services delivered by the Title X program. We expect that the return on investment among higher quality, more efficient providers is even higher than the average return on investment discussed above, and that shifting funding away from these providers has reduced the return on

[29] 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. doi:10.1111/1468-0009.12080

[30] 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. doi:10.1111/1468-0009.12080

[31] 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>.

investment to family planning services. We estimate that the changes proposed here will reduce unintended pregnancies, increase savings to Medicaid, and improve the health and wellbeing of many individuals across the country.

2. Costs to the Federal government associated with disseminating information about the rule and evaluating grant applications for conformance with policy

Following publication of a final rule that builds upon this proposal and public comments, OPA will work to educate Title X program recipients and applicants about the requirement to not prohibit a potential subrecipient from participating for reasons unrelated to its ability to provide services effectively. OPA will send a letter summarizing the change to current recipients of Title X funds and post the letter to its website. OPA will also add conforming language to its related forthcoming funding opportunity announcements (FOAs). OPA has 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. We double this salary cost to account for overhead and benefits. As a result, we estimate a cost of approximately $1,800 - $5,300 to disseminate information following publication of the final rule.

3. Grant recipient costs to evaluate and implement the policy change

We expect that, if this proposed rule is finalized, stakeholders including grant applicants and recipients potentially affected by this proposed 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 in behavior is required. For the states that currently hold Title X grants and have laws or policies restricting Title X subrecipients, the final rule would implicate state law or policy. State agencies that currently restrict subawards would need to carefully revise their current practices in order to comply with these changes.

We estimate that current and potential recipients will spend an average of one to two hours processing the information and deciding what action to take. We note 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 we believe 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, we estimate 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, we estimate that dissemination will result in a total cost of approximately $9,700-$19,300.

4. Summary of impacts

Public funding for family planning services is likely 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 will lead to fewer unintended pregnancies, improved health outcomes, reduced Medicaid costs, and increased quality of life for many individuals and families. The proposed 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 provide Title X funding to subrecipients for reasons other than their ability to best meet the objectives of the Title X program.

We estimate costs of $11,400-$24,600 in the first year following publication of the final rule, and suggest that this rule is beneficial to society in increasing access to and quality of care. We note that the estimates provided here are uncertain.

E. Analysis of Regulatory Alternatives

We carefully considered the option of not pursuing regulatory action. However, as discussed previously, not pursuing regulatory action means allowing the continued

provision of Title X funds to subrecipients for reasons other than their ability to provide high quality family planning services. This, in turn, means accepting reductions in access to and quality of services to populations who rely on Title X. As a result, we chose to pursue regulatory action.

F. Executive Order 13132 Federalism Review

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. The Department particularly invites comments from states and local governments, and will consult with them as needed in promulgating the final rule. While we do not believe this rule will cause substantial economic impact on the states, it will implicate some state laws if states wish to apply for federal Title X funds. Therefore, the following federalism impact statement is provided.

EO 13132 establishes the need for Federal agency deference and restraint in taking action that would curtail the policy-making discretion of the states or otherwise have a substantial impact on the expenditure of state funds. The proposed rule simply sets the conditions to be eligible for federal funding for both public and private entities. The proposed rule will not have a significant impact on state funds as, by law, project grants must be funded with at least 90 percent federal funds. 42 U.S.C. 300a-4(a). Furthermore, states that are the project recipients of Title X grants are not required to issue subawards

at all. However, those that choose to do so would be required to do so in a manner that considers only the ability of the subrecipients to meet the statutory objectives.

States remain entirely free to set their policies and funding preferences as to family planning services paid for with state funds. While this proposed rule will eliminate the ability of states to restrict subawards with Title X funds for reasons unrelated to the statutory objectives of Title X, they remain free to set their own preferences in providing state-funded family planning services. The rule does not impose any additional requirements on states in their performance under the Title X grant, other than to avoid discrimination in making subawards, should they choose to make such subawards. And states remain free to apply for federal program funds, subject to the eligibility conditions. For the reasons outlined above, the proposed rule is designed to achieve the objectives of Title X related to providing effective family planning services to program beneficiaries with the minimal intrusion on the ability of project recipients to select their subrecipients.

G. Paperwork Reduction Act of 1995

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

List of Subjects in 42 CFR Part 59

Birth control, Family planning, Grant programs.

Dated: August 31, 2016

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Sylvia M. Burwell

Secretary

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 proposes to amend 42 CFR part 59 as follows:

PART 59—GRANTS FOR FAMILY PLANNING SERVICES

Subpart A—Project Grants for Family Planning Services

1. The authority citation for subpart A 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 unrelated to its ability to provide services effectively.

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