

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

Docket No.: HHS-OS-2018-0008 for “Compliance with Statutory Program Integrity Requirements”

July 31, 2018

The Association of State and Territorial Health Officials (ASTHO) is pleased to provide comments regarding “Compliance with Statutory Program Integrity Requirements for Title X” (Docket No: HHS-OS-2018-0008). ASTHO is the national nonprofit organization representing the public health agencies of the 50 States, the U.S. territories and freely associated states, and the District of Columbia. ASTHO members, the chief health officials of these jurisdictions, are dedicated to formulating and influencing sound public health policy and ensuring excellence in public health practice. That is the point of view we take in providing our comments.

ASTHO affirms that reproductive health services (1) improve birth outcomes for both mothers and infants through preconception, prenatal, and inter-conception care, (2) increase access to education and contraception for males and females to enable responsible and respectful sexual activity, and (3) safeguard and promote the public’s health. ASTHO also strongly supports access to medically accurate, science-based information and services that are age appropriate and culturally competent.

ASTHO supports cost-effective, fiscally responsible healthcare. In 2010, every dollar spent on services provided by publicly funded family planning clinics saved an estimated \$7.09 in Medicaid and other public expenditures. These savings can be attributed to preventing unintended pregnancies and reducing the incidence and impact of preterm and low birth weight births, sexually transmitted infections (STIs), infertility, and cervical cancer secondary to public investment in family planning programs. In this same time period, publicly funded clinics saved federal and state governments an estimated \$13.6 billion. Services provided at Title X-supported clinics accounted for \$7 billion of that total. Access to education and contraception yields an economic benefit to states and the country as a whole.<sup>1</sup> Restricting or limiting access to contraception will have predictable negative economic impacts by shifting costs to state Medicaid and other safety net programs.

Below, please find ASTHO comments on specific provisions included in the proposed rule.

Proposed:

**§ 59.2 Definitions** *Family Planning*

**§ 59.5 What requirements must be met by a family planning project?**

The proposed regulations redefines “Family Planning” from a “broad range of methods” to a “broad range of acceptable and effective choices” (59.2 Definitions) and removes “language specifying that the family planning methods and services offered by a Title X project be ‘medically approved’” and “does not require a project to provide every acceptable and effective family planning method or service” (D. Section 59.5 What requirements must be met by a family planning project?). This would allow organizations to provide a single method or limited methods of family planning “as long as the Title X project as a whole offers a broad range of family planning methods and services.”

**ASTHO Comments:** ASTHO supports access to medically accurate, science-based information, as well as access to medically appropriate and effective reproductive health services.<sup>2</sup> Further, ASTHO believes in promoting consumer access to services regardless of age, geography, disability, race, ethnicity, religion, sex, gender, gender identity, sexual orientation, education, income, country of origin, marital status, or language.<sup>3</sup> The proposed rule allows for two-tiers of providers and individual clinics—those that offer the full range of contraceptive options and those that may only offer one “choice.” ASTHO opposes this change, as it undermines quality and trust with providers, who may not counsel on or provide the full range of contraceptive options. This has the potential to exacerbate contraceptive health deserts, particularly in rural areas and sites that primarily serve adolescents or other vulnerable populations, driving up unintended pregnancy rates.

Proposed:

**§ 59.5 What requirements must be met by a family planning project?**

The proposed rule would require that Title X service providers “should offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site.”

**ASTHO Comments:** ASTHO supports maximizing funding and health insurance to enable and support integrating reproductive health services in primary care settings, including those that do not have Title X funds.<sup>4</sup> ASTHO is concerned this new rule could inadvertently disqualify local and state health department sites from Title X funding. While the language stipulates that a provider “should offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity,” it is within the section on “what requirements *must* (emphasis added) be met by a family planning project?” This implies that state and local health agencies could be excluded as (a) most state and local health agencies do not provide direct primary care, and (b) there is no definition regarding what “physical proximity to Title X site” means, nor what robust referral linkages entail. This is especially concerning in areas that are federally designated as primary care health professional shortage areas. Additionally, these referral primary health providers would be required to provide the same level of reporting as Title X subrecipients, which would create an additional regulatory burden on primary care practices and individual physicians who are not receiving funding.

Proposed:

**§ 59.2 Definitions.** *Low Income Family (a) Unemancipated Minors*

**§ 59.5 What requirements must be met by a family planning project?**

The proposed rule would “require Title X service providers to encourage family participation in the decision of minors to seek family planning services and ensure that the records maintained with respect to each minor document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).” The rule clarifies that “unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources, provided that the Title X provider has documented in the minor’s medical records the specific actions taken by the provider to encourage the minor to involve her/his family (including her/his parents or guardian) in her/his decision to seek family planning services, except that documentation of such encouragement is not be required if the Title X provider has documented in the medical record, (1) that it suspects the minor to be the victim of child abuse or incest and (2) that it has, consistent with and if permitted or required by applicable State or local law, reported the situation to the relevant authorities.” Further, projects “may not receive funds under this subpart unless it... conduct[s] a preliminary screening of any teen who presents with a sexually transmitted disease (STD), pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor. Such screening would be required with respect to any individual who is under the age of consent in the state of the proposed service area.”

**ASTHO Comments:** Privacy and confidentiality are central components of healthcare, with federal and state laws and regulations providing formal protections around personal health information, medical records, and other aspects of health privacy. Conversations between a provider and minor patient discussing the engagement of a trusted adult family member as further support for that minor fall within appropriate discussions for healthcare visits. The requirement to “document the specific actions taken to encourage family participation” implies that action must be taken beyond encouraging the minor to seek family participation and a directive to ensure family participation. Additionally, unless there is reasonable suspicion of abuse, ASTHO opposes the requirement of further screening minors who are pregnant or test positive for STIs because the proposed changes will erode adolescent-provider relationships through requiring further screening. The ability to confidentially access contraception or other reproductive health services may determine whether an individual decides to access services at all, particularly for adolescents. Exceptions to this are child abuse and incest or for additional state and local laws for on reporting or screening for suspicions of abuse. This new rule would erode confidentiality within the patient-provider relationship for minors. Further, it could cause confusion within Title X and for providers. Medicaid allows family planning services to be provided confidentially to “individuals of childbearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who desire such services and supplies.”<sup>5</sup> This either creates a two-tier system of care for individuals receiving family planning under Medicaid at Title X clinics or imposes requirements onto Medicaid in which individuals of childbearing age should receive contraception confidentially.

ASTHO recommends that state and territorial health agencies help lead efforts to educate regarding laws and regulations to inform providers, clients, and educators about state and federal laws on reproductive health, such as access to confidential services, requirements for medically accurate reproductive health information, and adolescent access to reproductive health services and mandatory

reporting.<sup>6</sup> Adolescents continue to see barriers to accessing reproductive services, particularly when it comes to confidentiality.<sup>7</sup> On a nationwide survey, approximately 70 percent of youths who had not told a parent about clinic visits said that they would not seek family planning services. Approximately 25 percent reported that they would have unsafe sex if they could not have confidential services.<sup>8</sup>

Proposed:

**§ 59.2 Definitions.** *Program, project or subrecipient*

**§ 59.5 What requirements must be met by a family planning project?**

The proposed rule requests comment on “whether such a referral agency should be subject to the same reporting requirements as a grantee or subrecipient—by means of requiring grantees and subrecipients to use referral agencies only if they require the referral agencies to submit the required information.” It further explains that it would require “reporting the following information in grant applications and all required reports:

- (i) Subrecipients and referral agencies and individuals by name, location, expertise and services provided or to be provided;
- (ii) Detailed description of the extent of the collaboration with subrecipients, referral agencies and individuals, as well as less formal partners within the community, in order to demonstrate a seamless continuum of care for clients; and
- (iii) Clear explanation of how the grantee will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients and those who serve as referrals for ancillary or core services.”

**ASTHO Comments:** ASTHO does not support including any provisions that would increase administrative burdens, such as requiring a referral agency or individual to adhere to the same reporting requirements as a grantee or subrecipient. Strong partnerships are essential to successfully implementing family planning programs, particularly considering the budget limitations that many state and territorial health departments must work within. ASTHO recognizes the family planning visit as an opportunity to link individuals to additional service providers, including family practitioners, pediatricians, obstetrician-gynecologists, social workers, mental health providers, lactation consultants, nutritionists, home visitors, and public health workers.<sup>9</sup> As a state health agency plans a family planning project, it needs to retain current partners and recruit new partners to align programs, connect with provider champions, and share their expertise. Agencies may partner or collaborate with hundreds of individuals and organizations from informal referral networks to subgrantees. However, requiring referral networks to the same reporting requirements and rendering them unfunded would be burdensome to state and local health departments.

Proposed:

**§ 59.2 Definitions.** *Low Income*

The proposed rule redefines that “low-income family” includes a woman with “health insurance coverage through an employer which does not provide the contraceptive services sought by the woman because it has a sincerely held religious or moral objection to providing such coverage.”

**ASTHO Comments:** ASTHO does not support this change unless it is coupled with robust resources and additional guidance. Title X was never intended to be an insurance program, and this change would burden an already underfunded program. Operationally, the proposed changes do not specify how this

expansion would work. The proposed rule does not specify whether women without access in their insurance could receive contraception free of charge or at a low cost based on their income. It also does not specify whether they would only receive family planning from Title X funding or other services would also apply, even if insurance may cover those portions. Further, how would Title X agencies confirm that the women's insurance does not provide contraception? We strongly encourage further clarification in the final rule.

Proposed:

**§ 59.18 Appropriate Use of Funds**

**§ 59.15 Maintenance of physical and financial separation**

The proposed rule states that “infrastructure building may not include physical space, health information technology systems, including electronic health records, bulk purchasing of contraceptive and other clinic supplies, clinical training for staff, and community outreach and recruitment.”

**ASTHO Comments:** ASTHO opposes this restriction and recommends that the federal government help lead and implement adequate funding to support quality, accessible, and effective reproductive health services, including funding for infrastructure and workforce needs.<sup>10</sup> Title X requires that “grantees are responsible for the training of all project staff”<sup>11</sup> and must “provide for orientation and in-service training for all project personnel.”<sup>12</sup> To not fund this is counterintuitive and creates a very high risk for poor quality services. In addition, it creates an unfunded mandate for programs.

The restriction on bulk purchasing of contraceptives is counterintuitive, as it drives up costs and reduces the purchasing power of public dollars. Further, the economic impact of changes to infrastructure funds is dramatically underestimated. Additional reporting requirements will necessitate changes to electronic health record templates by all grantees, including state and territorial health agencies. Approximately 70 percent of service sites report that they are using an electronic health record system, seven percent are in the process of adopting a system, and 14 percent are planning to adopt a system between May 2015 and May 2017.<sup>13</sup> For Title X grantee and subrecipient agencies to comply with the proposed rule changes they would need to make changes within electronic health record systems, including: (1) documenting in a minor's medical records the specific actions taken to encourage family participation in the minor's decisions to seek family planning services, (2) documenting screening to rule out victimization of minors, and (3) maintaining records that would identify the age of any minor clients served, the age of their sexual partner(s) where required by law, and what reports or notifications were made to appropriate state agencies. Not allowing for infrastructure payments for electronic health records changes is omitted in both V. Regulatory Impact Statement sections B. Analysis of Economic Impacts and G. Paperwork Reduction Act. Infrastructure changes in electronic health records are costly, especially when changes happen after a system has been designed. By modifying or adding templates to an existing system, the vendor may adjust the price because of terms brought up after development.<sup>14</sup> Title X centers would need to pay for modifying the electronic health record templates and staffing time for the proposed requirements, an additional estimated infrastructure burden on top of the cost for provider training and time to input the information as reflected in those sections. Further, the department requires changes in the use of grant funds without specifying the amount or percentage of the change, a major burden among grantees.

Proposed:

**§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amounts?**

The proposed rule states, “Any grant applications that do not clearly address how the proposal will satisfy the requirements of the regulation would not proceed to the competitive review process, but would be deemed ineligible for funding.” It further explains that the “Department would explicitly summarize each provision of the regulation (or include the entire regulation) within the funding announcement, and would require applicants to describe their affirmative compliance with each provision.”

**ASTHO Comments:** ASTHO is gravely concerned this proposed change would impact traditional Title X awardees, including governmental public health agencies. This section changes the seven points of criteria<sup>15</sup> that each family planning application will be scored to determine the extent to which the applicant will best serve individuals in need throughout the anticipated service areas. Completely removed are the current criteria concerning the adequacy of the applicant’s facilities and staff and the relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project.<sup>16</sup> Moreover, the proposed change indicates, “Any grant applications that do not clearly address how the proposal will satisfy the requirements of the regulation would not proceed to the competitive review process, but would be deemed ineligible for funding.” Yet it does not list any proposed criteria that applications would need to follow. ASTHO disagrees with bypassing the comment process for new criteria, as it may explicitly rule out state health agencies through the application process alone or include a subjective standard without oversight. In essence, this provision could remove applications based on subjective criteria and could add an additional layer of political review prior to the current peer-review process—long-held gold standard—within the grant application cycle.

Proposed:

**§ 59.1 To what programs do these regulations apply?**

The proposed rule does not adequately discuss the regulatory or economic impact of applying the same requirements of contracts as family planning grants to entities stating, “substantive requirements for Title X family planning projects apply to projects whether they are established by grants or contracts.” Further, the proposed rule states that “because of the lack of history of using contracts to establish or operate Title X projects, and because Title X funds used for a contract would offset funds used for a grant, the Department does not believe that specifying that these regulations also generally apply to Title X contracts would affect the regulatory or economic impact of these proposed rules.”

**ASTHO Comments:** Grants and contracts have different functions and purposes. Generally, contracts are used “to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the United State Governments.”<sup>17</sup> Grants, however, are used as a legal relationship between the United States government and a state or local government to “to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring (by purchase, lease, or barter) property or services for the direct benefit or use of the United States Government.”<sup>18</sup> The regulations of contracts and grants are different, as well. Contracts are usually not renewable, while grants usually are renewable. Payment is made in accordance with the terms and conditions of the contract and may allow for advance, progress, or performance-based payments in contracts. Grants use advance payments with



some exceptions. The proposed rule does not specify how contracts would be used for family planning projects when the purpose of the Title X program is to carry out a public purpose instead of acquiring property or services for the direct benefit of the United States government. Additionally, the proposed rule contends there is no regulatory or economic impact because of lack of prescient and that “contract[s] would offset funds used for a grant.” The proposed rule does not address whether Title X funds used for contracts would offset funds used for grants. Would this lower the dollar amount available for grant-funded projects to state and local health departments?

Proposed:

**§ 59.17 Compliance with reporting requirements.**

The proposed rule requires Title X project to “comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking (collectively, ‘State notification laws’).” Title X projects may not “receive funds under this subpart unless it provides appropriate documentation or other assurance satisfactory to the Secretary that it:

- (1) Has in place and implemented a plan to comply with State laws. Such plan shall include, at a minimum, policies and procedures with respect to such notification and reporting....
- (2) Maintains records to demonstrate compliance with each of the requirements set forth in paragraph (b)(1) of this section....:
- (3) Continuation of grantee or subrecipient funding for Title X services is contingent upon demonstrating to the satisfaction of the Secretary that the criteria have been met.
- (4) The Secretary may review records maintained by a grantee or subrecipient for the sole purpose of ensuring compliance with the requirements of this section.”

**ASTHO Comments:** ASTHO opposes this change, as Title X agencies already comply with state and local laws around child abuse, molestation, sexual abuse, and incest. Mandatory detailing in record of intimate partner violence and rape, as well as requiring additional screening of these clients, revictimizes them and erodes patient-provider trust.

Proposed:

**§ 59.14 Prohibition on Referral for Abortion**

The proposed rule states only “a doctor may, if asked, provide a list of licensed, qualified, comprehensive health service providers (some of which also provide abortion, in addition to comprehensive prenatal care). Such information related to abortion is permitted only if a woman who is currently pregnant clearly states that she has already decided to have an abortion.” It further clarifies that the list, provided by a physician, must include comprehensive service providers (including prenatal care providers) and may include abortion providers, however “list shall not identify the providers who perform abortion as such.”

**ASTHO Comments:** Many state public health agencies regulate healthcare professions and their scope of practice. ASTHO believes that any healthcare provider permitted to provide this counseling should not be restricted, in any manner or form, from providing their scope of services. In addition, many state-based clinics are staffed by a wide range of providers. It is burdensome and costly to only authorize doctors when other clinic staff are qualified and routinely council patients on all other aspects of reproductive health. Additionally, withholding information erodes the provider-patient relationship.

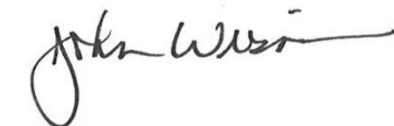
Only providing a list and barring providers from discussing the list prohibits providing full information to patients who are asking for specific information. ASTHO supports individuals having access to science-based, medically-accurate, and effective reproductive health services. ASTHO also supports comprehensive reproductive, sexual, and healthy relationship education that is evidence-based, scientifically and medically accurate, and culturally and linguistically appropriate.<sup>19</sup> The proposed rule offers a confusing definition of “nondirective counseling.” This creates a system of different standards of quality based on the provider and encourages withholding medically accurate information.

Thank you for the opportunity to comment on the proposed rule. If you have any questions or would like additional information, please contact Ellen Pliska ([epliska@astho.org](mailto:epliska@astho.org)), ASTHO’s senior director of family and child health.

Sincerely,



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John Wiesman, DrPH, MPH  
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<sup>1</sup> Frost JJ, Gold RB, Frohwirth L and Blades N. “Variation in Service Delivery Practices Providing Publicly Funded Family Planning in 2010.” New York: Guttmacher Institute, 2012. Available at: <http://www.guttmacher.org/pubs/clinic-survey-2010.pdf>.

<sup>2</sup> ASTHO. “Access to Reproductive Health Services Position Statement.” Available at <http://www.astho.org/Policy-and-Position-Statements/Position-Statement-on-Reproductive-Health/>.

<sup>3</sup> ASTHO. “Access to Reproductive Health Services Position Statement.” Available at <http://www.astho.org/Policy-and-Position-Statements/Position-Statement-on-Reproductive-Health/>.

<sup>4</sup> ASTHO. “Access to Reproductive Health Services Position Statement.” Available at <http://www.astho.org/Policy-and-Position-Statements/Position-Statement-on-Reproductive-Health/>.

<sup>5</sup> Section 1905(a)(4)(C) of the Social Security Act. Available at: [https://www.ssa.gov/OP\\_Home/ssact/title19/1905.htm](https://www.ssa.gov/OP_Home/ssact/title19/1905.htm)

<sup>6</sup> ASTHO. “Access to Reproductive Health Services Position Statement.” Available at <http://www.astho.org/Policy-and-Position-Statements/Position-Statement-on-Reproductive-Health/>.

<sup>7</sup> National Institute for Health Care Management Foundation. “Protecting Confidential Health Services for Adolescents and Young Adults: Strategies and Considerations for Health Plans, May 2011.” Available at: <http://www.nihcm.org/images/stories/NIHCM-Confidentiality-Final.pdf>.



<sup>8</sup> Benson Gold R. “Unintended Consequences: How Insurance Processes Inadvertently Abrogate Patient Confidentiality.” *Guttmacher Policy Review*. 2009. 12(4):12-16. Available at: <http://www.guttmacher.org/pubs/gpr/12/4/gpr120412.pdf>.

<sup>9</sup> ASTHO. “Access to Reproductive Health Services Position Statement.” Available at <http://www.astho.org/Policy-and-Position-Statements/Position-Statement-on-Reproductive-Health/>.

<sup>10</sup> ASTHO. “Access to Reproductive Health Services Position Statement.” Available at <http://www.astho.org/Policy-and-Position-Statements/Position-Statement-on-Reproductive-Health/>.

<sup>11</sup> Office of Population Affairs. “Program Requirements for Title X Funded Family Planning Projects.” Version 1.0 April 2014. Available at: <https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf>.

<sup>12</sup> 42 CFR 59.5 (b)(3) Available at: <https://www.gpo.gov/fdsys/pkg/CFR-2017-title42-vol1/xml/CFR-2017-title42-vol1-sec59-5.xml>.

<sup>13</sup> Office of Population Affairs. “Service Delivery Infrastructure: Title X Sustainability Assessment.” Available at: <https://www.hhs.gov/opa/title-x-family-planning/title-x-service-delivery-improvement/infrastructure/index.html>.

<sup>14</sup> The National Learning Consortium. “Contracting Guidelines and Checklist for Electronic Health Record (EHR) Vendor Selection.” 2012. Available at: <https://www.healthit.gov/sites/default/files/contracting-guidelines-and-checklist-for-ehr-vendor-selection.docx>.

<sup>15</sup> Office of Population Affairs. “Program Requirements for Title X Funded Family Planning Projects.” Version 1.0 April 2014. Available at: <https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf>.

<sup>16</sup> NFPRHA. <https://www.nationalfamilyplanning.org/file/documents---policy--communication-tools/NFPRHA-Title-X-NPRM-Analysis-FINAL.pdf?erid=1900044&trid=41d2b967-4233-4fec-a5e0-65c6255da>.

<sup>17</sup> 31 USC 6303 – Chapter 63-Using Procurement Contracts and Grants and Cooperative Agreements. Available at: <http://uscode.house.gov/view.xhtml?path=/prelim@title31/subtitle5/chapter63&edition=prelim>.

<sup>18</sup> 31 USC 6303 – Chapter 63-Using Procurement Contracts and Grants and Cooperative Agreements. Available at: <http://uscode.house.gov/view.xhtml?path=/prelim@title31/subtitle5/chapter63&edition=prelim>.

<sup>19</sup> ASTHO. “Access to Reproductive Health Services Position Statement.” Available at: <http://www.astho.org/Policy-and-Position-Statements/Position-Statement-on-Reproductive-Health/>.