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July 27, 2018

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.

Submitted via www.regulations.gov

RE: Title X: Comments on Notice of Proposed Rulemaking re: Compliance with Statutory Program Integrity Requirements – HHS-OS-2018-0008

Thank you for the opportunity to provide comment on the recently released Notice of Proposed Rulemaking (NPRM) on Compliance with Statutory Program Integrity Requirements (HHS-OS-2018-0008).

Bi-State Primary Care Association is a nonpartisan, nonprofit 501(c)(3) charitable organization that promotes access to effective and affordable primary care and preventive services for all, with special emphasis on underserved populations in Vermont and New Hampshire. Bi-State's combined Vermont and New Hampshire membership includes 29 Community Health Centers (CHCs) delivering primary care at 126 sites and serving over 315,000 patients.

Many of Bi-State's members are federally-qualified health centers and as such are required to offer voluntary family planning services to their patients. This is part of a broad range of services provided that treat the whole person. Additionally, some of Bi-State's members currently participate in the Title X program. To-date, this program has been highly successful in ensuring access to critical services for vulnerable Vermonters and New Hampshireites.

Federal Title X funding helps ensure that every person - regardless of income or health care coverage - has access to basic, preventative reproductive health care. We have several concerns with the proposed rule:

- The proposed rule prevents patients from obtaining full and accurate information about their reproductive health care from their providers.
- Clarifications are needed in the rule regarding life-threatening conditions.
- The proposed rule would have a significant impact on patient-provider relationship.
- The referral agency requirements, including reporting, are unclear and potentially cause unnecessary reporting burdens.

More information about each of these is below:

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Patient education and access to care

Community Health Centers (CHCs) provide care through a unique whole person model. As a key part of the primary care safety-net, they provide high-quality, affordable, coordinated care to medically underserved persons. They focus on low-income individuals and those who face significant geographic, transportation, and socioeconomic barriers to care. CHCs treat all patients regardless of ability to pay or insurance status offering a financial assistance to all patients with incomes below 200%FPL.

Whole person care meets the patient where they are: addressing social and environmental factors that impact their health and ability to access care. Serving as Patient Centered Medical Homes and coordinating care outside the primary care practice enables our CHC staff to foster trusting relationships and improve the health outcomes of their patients. A critical aspect of this care model is the belief that everyone – regardless of race, ethnicity, income, or geography – deserves the best medical care and comprehensive, medically-informed, and accurate information available. We are concerned that the proposed rule would interfere with the patient-provider relationship by limiting a provider’s ability to give their patients comprehensive information according to evidence-based clinical guidelines, even when the patient asks for the information. The proposed rule would be inconsistent with the model of care that everyone deserves the most comprehensive, medically- informed, and accurate health care information from their providers.

Should this proposed rule be adopted, our members would have to choose between allowing federal regulations to dictate what they can and must discuss with their patients (as required under § 59.14 of the proposed rule), and losing a critical source of revenue to support patient care.

Additionally, we are concerned about the impact on patients of the proposed requirements around lists of outside providers. We are concerned that if these patients receive a general list of providers that does not indicate which ones offer the specific service they are seeking, they may not be able to identify an appropriate provider on their own, or determine how to contact one. This would make it significantly more difficult for the patient to access care. We request that the final promulgated rule indicate that this list contain full contact information: phone numbers, street address, website, and which services are offered.

Life-threatening conditions

The proposed rule includes language regarding ectopic and other life-threatening conditions related to pregnancy. We request clarification regarding these conditions and that Title X providers be supported in providing accurate information to their patients. We are concerned that some aspects of the proposed rule, ie. § 59.14(b): “in cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of emergency medical services”, could be misinterpreted to mean that

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the patient could be referred only to an emergency department and not to other types of providers who are qualified to treat these types of urgent or emergent conditions.

Patient-provider relationship

We are also concerned about the impact this proposed rule would have on the patient-provider relationship. High-quality, comprehensive medical care relies on the ability of providers to have honest, trust-filled conversations with their patients. Any restriction of the ability of providers to engage in these conversations, limiting the information provided to a patient, compromises that relationship. Providers of all types comply medical ethics and these ethics include ensuring their patients have access to all the information necessary to make meaningful decisions about their own health care. As currently proposed, this rule would limit conversation and interfere with professional codes of ethics. Providers at CHCs are committed to their patients and maintaining this critical relationship. Any erosion of the patient-provider relationship will have deleterious effects on both the providers delivering the care and the patients receiving the care.

Referral Agency Requirements

We have some questions and concerns regarding the potential requirements on “referral agencies” (providers to whom Title X grantees and subrecipients could refer patients but who do not receive Title X funds themselves), as laid out in the preamble discussion of §59.2. It is unclear how broadly these requirements would apply and which reporting requirements would apply to these referral agencies. It appears that these requirements would apply to the many entities who collaborate informally with Title X providers. Additionally, the breadth of reporting requirements do not appear to coordinate with information currently reported by providers.

CHCs are required¹ to have referral agreements with a range of providers in their communities to ensure continuity of care and optimal delivery of services. CHCs are concerned that if the Title X requirements on referral agencies are too burdensome, these external partners may be disincentivized from continuing these collaborations. The proposed rule could be interpreted that the Title X recipient has an affirmative duty to “ensure adequate oversight and accountability for quality and effectiveness of outcomes”² for all of its external partners. The external partner would be required to report performance data on all Title X-related services and possibly permit the Title X recipient to intervene in the operations of another entity to ensure quality. An external partner could decide that it is preferable to terminate the collaborative relationship rather than comply with the new reporting requirements. The result of this would be to potentially place the Title X recipient out of compliance with a key federal requirement. Additionally, it could also reduce

¹ Federally-Qualified Health Centers are obligated to comply with referral requirements found in the Health Center Compliance Manual. More information about this is available here:

<https://bphc.hrsa.gov/programrequirements/compliancemanual/>.

² Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. 25502 (June 1, 2018) (to be codified at 42 CFR Part 59).

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access to and coordination of care for patients.

We request that any new reporting requirements be coordinated with existing requirements to avoid duplicative or unnecessary reporting burdens. We also request that the requirement regarding “ensuring adequate oversight and accountability for quality and effectiveness of outcomes” be clarified so that it is not so burdensome as to discourage providers from collaborating with those providers who participate in the Title X program.

Title X is a successful, bipartisan program that has enabled access to care for vulnerable patients for decades. On behalf of the patients served by CHCs in New Hampshire and Vermont, we urge the Administration to withdraw this proposed rule and reconsider changes to this program.

Sincerely,



Tess Stack Kuenning, CNS, MS, RN
President and Chief Executive Officer