Assistant Secretary for Health, Office of Population Affairs

Attention: Family Planning, United States Department of Health and Human Services

Re: HHS-OS-2018-0008

RIN 0937-ZA00

July 26, 2018

Gentlepersons;

These comments on the above-captioned proposed rule are submitted by faculty and researchers at the Milken Institute School of Public Health, George Washington University. The only school of public health in the nation's capital, the School is known both nationally and internationally for the breadth and quality of its research and scholarship on critical issues of public health law and policy.

Numerous members of the School's faculty and research staff are widely recognized for their expertise in women's health, reproductive health and health care, access to health care for medically underserved and vulnerable populations, and the role of publicly funded health care providers in ensuring appropriate care for people with public and private health insurance who nonetheless experience significant access barriers.

In the area of family planning and related primary and preventive services, the School is particularly well known for its research into the role of community health centers in ensuring access to high quality, comprehensive family planning services for communities and populations experiencing medical underservice as a result of elevated poverty, higher health risks, and a shortage of high-quality primary care. Our research[1] has documented health centers' importance to women of childbearing age; in 2016, health centers served nearly 6.2 million low-income women of reproductive age. Our work also has focused on the impact of health center participation in the Title X family planning program. Our research has consistently shown[2] that despite the fact that family planning is a required service of all health centers under § 330 of the Public Health Service Act, Title X participation by health centers – nearly one

[1] Susan F. Wood, Community Health Centers and Family Planning in an Era of Policy Uncertainty (Kaiser Family Foundation, March 2018), available at https://www.kff.org/womens-health-policy/report/community-health-centers-and-family-planning-in-an-era-of-policy-uncertainty/

[2] Susan F. Wood et al., Health Centers and Family Planning: Results of a Nationwide Study (George Washington University, 2013), available at https://hsrc.himmelfarb.gwu.edu/cgi/viewcontent.cgi?article=1059&context=sphhs_policy_facpubs

in four do so – is associated with significantly strengthened health center performance, as measured by the scope of effective family planning methods available onsite, the availability of more comprehensive counseling and patient support services, and adherence to HHS' strong evidence-based practice guidelines[3] that are an explicit condition of participation under current Title X policies but not a condition of § 330 grant funding.

For this reason, we are deeply concerned about any proposed changes to Title X policies that could adversely impact health center participation, given Title X's major role in strengthening and enhancing health centers' family planning performance. We also are concerned generally about any proposed policy shifts that could lead to a weakening of access by medically underserved populations and individuals to the most effective forms of family planning and note HHS' striking failure to consider the impact of its proposed access restrictions on the unintended pregnancy rate, as well as the consequences of such an increase for health outcomes and health care costs.

The proposed rules would impose practice restrictions at direct odds with federal requirements applicable to community health centers, thereby fundamentally threatening their continued participation in Title X

Given the critical role played by health centers in the provision of health care to medically underserved women of reproductive health age, the impact of the proposed rule on their participation in Title X emerges as a major issue in analyzing both its policy and cost implications. Indeed, how the rule might affect health centers becomes an even more urgent consideration given the deleterious impact that the proposed rule is expected to have on program participation by certain other providers who face likely exclusion simply because they furnish both family planning and access to safe abortion services for community residents. Because the proposed rules would stack the deck against medically underserved communities by driving away vital sources of health care, full Title X participation by health centers becomes a matter of urgency.

There is abundant evidence to suggest what happens when community health centers are called on to help mitigate the impact of policies that undermine, rather than promote, access to care by excluding other safety net providers. Indeed, Texas was a proving ground for such a policy when it adopted a similar exclusionary policy under its state-funded family planning program, the Texas Women's Health Program (WHP). The change in Texas's law effectively stripped Planned Parenthood clinics of their ability to participate in WHP; to prevent the adverse fallout from this exclusion, health centers were expected to expand their reach.[4] In some Texas counties, estimates were that non-Planned Parenthood providers, including health centers, would experience over a 500 percent increase in the demand for family

[3] These guidelines can be found at https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html

[4] Sara Rosenbaum, Planned Parenthood Community Health Centers, and Women's Health: Getting the Facts Right (Health Affairs Blog, 2015), available at https://www.healthaffairs.org/do/10.1377/hblog20150902.050150/full/

planning services;[5] it is likely that the exclusion of safety net clinics nationally simply because they also offer safe abortion services will lead to similar results across the country.[6] Even with supplemental family planning funding, health centers simply cannot ramp up sufficiently to meet this rising level of need given their simultaneous obligations to serve all community residents, from birth through old age. Certainly, they cannot expand their reach without a major infusion of new funding. As a result, women, their children, their families, and the Medicaid program will pay an enormous price;[7] indeed, Texas itself reported that the WHP experienced a 41 percent drop in the number of clients with contraceptive claims or prescriptions filled from FY2011 to FY2015.[8]

Given the experience in Texas, as well as the Administration's obvious intention to drive out of Title X those clinics serving medically underserved populations and communities that also provide access to safe abortions, the imperative is to avoid further diminution of the Title X provider network. But as one of us has written elsewhere,[9] the proposed rules threaten to produce precisely this result, elevating the likelihood that health centers will leave the program rather than engage in practices that directly contravene the conditions of their § 330 grant funding or that raise serious problems in connection with their medical liability coverage under the Federal Tort Claims Act.

Continued participation in Title X becomes an existential problem for health centers under the proposed rules. First, under proposed 45 C.F.R. § 59.14, neither trained counselors nor mid-level health professionals such as certified nurse practitioners and physicians' assistants – the mainstay of high-quality health center care – could provide counseling services covering the full range of health care options. Only "medical doctors" would be permitted to provide abortion-related information. Second, under the proposed rule, the speech of "medical doctors" would be so circumscribed as to place their conduct below any reasonable professional standard of care. This is because the proposed rule would

[5] Leighton Ku, et al., Deteriorating Access to Women's Health Services in Texas: Potential Effects of the Women's Health Program Affiliate Rule. Geiger Gibson/RCHN Community Health Foundation Research Collaborative, George Washington University. Policy Research Brief No. 31. (2012). http://www.rchnfoundation.org/?p=913

[6] Kinsey Hasstedt, Federally Qualified Health Centers: Vital Sources of Care, No Substitute for the Family Planning Safety Net. The Guttmacher Institute. https://www.guttmacher.org/gpr/2017/05/federally-qualified-health-centers-vital-sources-care-no-substitute-family-planning

[7] Amanda Stevenson et al., Effect of Removal of Planned Parenthood from the Texas Women's Health Program N. Eng. J. Med. 374:853-860 (March 3, 2016)

[8] Final report of the Former Texas Women's Health Program: Fiscal Year 2015 Savings and Performance, available at https://hhs.texas.gov/reports/2017/03/former-texas-womens-health-program-fiscal-year-2015-savings-performance

[9] Sara Rosenbaum, The Title X Family Planning Proposed Rule: What's At Stake for Community Health Centers? (Health Affairs Blog, June 25, 2018), available at https://www.healthaffairs.org/do/10.1377/hblog20180621.675764/full/

force health center physicians, as a condition of Title X participation, to furnish their patients with incomplete and inaccurate information. Physicians would be forced to withhold information until patients have reached a specific point in their health status. They would be barred from identifying specific sources of safe and effective abortions; they also would be barred from referring their patients to sources of care. Furthermore, they would be barred from thoughtfully counseling their patients about which of the various treatment options might best meet their health needs and those of their families. Thus, the patient-centered approach to care – a hallmark of health center practice and HRSA performance expectations – would be directly undermined.

In short, health center clinical and patient support staff would be gagged from properly advising and counseling their patients in accordance with the professional standard of care. They would instead be forced to withhold medically appropriate information and, indeed, to affirmatively mislead their patients about their options.

The proposed rule thus poses two types of legal risks for health centers: failure to follow the professional standard of care, in violation of the Federal Tort Claims Act (FTCA);[10] and violation of conditions associated with federal grant funding under § 330.

FTCA violations: The Federally Supported Health Centers Assistance Act (FSCAA) of 1992 placed health centers under the Federal Tort Claims Act (FTCA) of 1946. This liability protection umbrella essentially treats the health centers program as a federal agency similar to the Department of Veterans Affairs and the Indian Health Service. It provides the means by which health centers are insured against medical liability claims raised by their patients, a fundamental prerequisite to their ability to operate. Although it limits the size of recovery, the FTCA does not immunize providers against medical liability claims; as is entirely appropriate, health centers remain liable for practices that fall below the professional standard of care.

As with any medical liability insurer, the FTCA requires health centers and other providers to maintain rigorous risk-management practices. These practices include avoiding the types of negligent conduct that can elevate the risk of medical injury. Incomplete, heavily-censored patient counseling, a prohibition on medically appropriate referral practices, and the intentional provision of false and misleading information is grounds for medical liability. The fact that a payer so orders such practices is no defense, a fundamental principle of law established in *Wickline v State of California*. [11] In other words, it is no defense in a medical liability case to argue that physicians simply have followed a payer's instructions, as would be the case under these proposed Title X funding rules. By forcing community health centers to mislead their patients about their health care options and to offer incomplete information regarding referrals for care and where patients can seek care, Title X would create exactly this type of liability risk. Community health centers that accept Title X funding effectively would be

[10] See Health Resources and Services Administration website About the Federal Tort Claims Act (FTCA), available at https://bphc.hrsa.gov/ftca/about/index.html

[11] 192 Cal. App. 3d (1986)

instructed to withhold crucial information from their patients and to engage in counseling designed to mislead regarding the full complement of health care options and where and how to obtain care. Indeed, the proposed rule would compel grantees to actively engage in dishonest speech – to not merely withhold accurate information, but to affirmatively steer patients to providers that in fact may not even offer the desired treatment.

Paradoxically, the proposed rule is characterized by HHS as a strategy for leaving undisturbed "the duty of a physician to promote patient safety." The irony of this justification – given the lengths to which the proposed rule appears to go in forcing grantees to withhold counseling services and to affirmatively mislead their own patients – knows no limits. We assume that lawyers advising health centers across the country will begin to advise their clients to avoid Title X funding entirely, not only because of the intrusiveness of the funding terms – down to the very content of physicians' speech – but because the rules actually may elevate liability risk by forcing clinicians to affirmatively misrepresent treatment options and steer them away from important health care.

Violating § 330: Section 330 of the Public Health Service Act[12] is unequivocal. To receive funding, federal grantees – who depend on Section 330 grants for 19 percent of their annual operating funds – must provide a defined range of "required primary health services." These required services are in turn defined as certain "basic health services," of which voluntary family planning is one. Required services also include "referrals to providers of medical services (including specialty referral when medically indicated) . . ." Health centers themselves do not furnish abortion services. But abortion is a medical service that patients might need or want; as such, health centers are expected to refer for care. Any attempt to withhold information about appropriate sources of referral health care would amount to a direct violation of health centers' most basic referral obligations. In other words, to force health centers to provide information only about prenatal care and to bar health centers from freely providing their patients with information about where and how to obtain a legal abortion in the safest and most appropriate setting is at direct odds with health centers' federal duty of care under § 330 itself.

Given the implications of the rules for health center liability concerns as well as their ability to satisfy § 330 requirements, should these proposed rules become law, many community health centers that participate in Title X can be expected to forgo continued participation; hundreds of other health centers may refuse to accept Title X funding at all rather than expose themselves to significant legal risk. Nothing in the proposed rule suggests that HHS has even remotely considered this possibility or taken such a result into account in estimating the impact of the proposed policy on access to Title X-funded care, the quality of care, and ultimately, the cost of care.

The agency's cost estimates are fundamentally flawed, incomplete, and misleading

The Regulatory Impact Statement accompanying the proposed rules is fundamentally deficient in numerous respects.

[12] 42 U.S.C. § 254b(b)(1)

First, as noted, the estimates fail to gauge the adverse impact of the proposed rules on health center participation, even as the administration touts the priority placed on increasing participation by clinics that, like community health centers, offer comprehensive onsite primary care in addition to family planning. By failing to consider the adverse effects of the proposed rules on health center participation, HHS undercuts one of its most fundamental stated aims and produces absurd results – the adoption of policies whose effect may be to drive away the very clinics the agency hopes to attract to the program.

Any credible impact estimate would have been sure to focus on the potential spillover effects on the largest primary care safety net system for underserved communities and populations and its ability to continue to accept Title X funding given the radical changes in policy being proposed. No such estimates have been prepared. Yet the proposed rules can be expected to deter, not improve, health center participation, leading to the departure of potentially hundreds of health centers, which today account nationally for care for one in 12 Americans[13] and 3 in 10 low-income women of childbearing age.[14] Indeed, the agency's fundamental failure in this regard directly undercuts its statement in the Preamble to the proposed rule[15] that the rule, as proposed, will "increase the number of entities interested in participating in Title X as grantees or subrecipient service providers and, thereby . . . increase patient access to family planning services focused on optimal health outcomes. . ." Such an assertion directly flies in the face of even a cursory review of the relationship between health center duties and the new standards, which points instead to the potential for the new rule to drive health centers away from the Title X program, not promote their participation.

For the reasons we have set forth, it is a fundamental error to assume that community health centers will expand Title X participation as hundreds of other clinics find themselves barred from the program. In fact, the opposite may be true: If these proposed rules are finalized, community health centers that now fully and actively participate in Title X and offer strong and vibrant family planning programs may be forced to be the first to head for the doors. As the health centers themselves stated in their initial public statement regarding the proposed rule, "Should this proposed rule be adopted, health centers would have to choose between allowing federal regulations to dictate what they can and must discuss with their patients, and losing a critical source of revenue to support patient care. Either way, patients would not be well-served."[16] Ultimately, many health centers may decide that accepting Title X funding would

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[13] Julia Paradise et al, Community Health Centers: Recent Growth and the Role of the ACA (Kaiser Family Foundation, 2017) available at https://www.kff.org/report-section/community-health-centers-recent-growth-and-the-role-of-the-aca-issue-brief/

[14] Susan F. Wood, Community Health Centers and Family Planning in an Era of Policy Uncertainty (Kaiser Family Foundation, March 2018), available at https://www.kff.org/womens-health-policy/report/community-health-centers-and-family-planning-in-an-era-of-policy-uncertainty/

[15] 83 Fed. Reg. 25502, 25525

[16] See, NACHC Statement Regarding the Proposed Rule for Title X Funding, available at http://www.nachc.org/news/new-nachc-statement-regarding-the-proposed-rule-for-title-x-funding/

be far too great a compromise in terms of quality of care for the patients they serve and would pose far too great a legal risk. The estimates never consider this potential outcome.

The agency's impact estimates suffer from other fatal flaws as well. The agency never explains the basis for its assertion that the new standards will encourage participation by more providers, and as we have shown, the opposite result likely will transpire. Furthermore, to the extent that it bars certain safety net providers simply because they also offer separately funded abortion services, the proposed rule never acknowledges its potential impact on access to care. As a result, the impact estimate never considers the well-documented impact of such a policy – as evidenced most clearly by the recent Texas example – on unintended child-bearing among low-income women. Because the impact estimate fails to take into account the adverse access consequences of the proposed policies, it never considers the effect of increasing unintended pregnancy rates or the extensively documented[17] health and social consequences of a rise in unintended pregnancy, such as infant mortality, maternal mortality, lifelong childhood disability, and family impoverishment and its related effects.

Furthermore, the economic effects of unintended pregnancy are enormous. One such cost not taken into account is the impact of these proposed policies on nationwide Medicaid spending. Medicaid now pays for nearly half of all U.S. births;[18] as a result, the cost impact on Medicaid flowing from a spike in unintended pregnancy and childbearing is a principal concern. In Texas, for example, that state's shift in policy, which presaged the current proposed rule, led to a significant increase in Medicaid-covered childbirths;[19] ultimately, costs in connection with the greater need for advanced medical care for high-risk infants and special-needs children can be expected to rise as well. Yet the proposed rule contemplates none of these costs despite the Texas experience, which establishes an absolute precedent for this rule's effects because of its virtually identical nature.

Because the agency's cost and access impact estimates are so fundamentally flawed, we recommend that the rule be set aside in its entirety. Even a cursory review underscores the extent to which this rule will undermine, rather than advance, the core mission and purpose of Title X.

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[17] See, e.g., Institute of Medicine, The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families (National Academy Press, 1995); Guttmacher Institute, Unintended Pregnancy in the United States (2016), available at https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states

[18] Anne Rossier Markus et al., Medicaid Covered Births, 2008 Through 2010, in the Context of the Implementation of Health Reform, *Women's Health Issues* 23:5 pp. e273-e280, available at https://www.whijournal.com/article/S1049-3867(13)00055-8/fulltext

[19] Amanda Stevenson et al., Effect of Removal of Planned Parenthood from the Texas Women's Health Program N. Eng. J. Med. 374:853-860 (March 3, 2016)

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