

Office of the Secretary
US Department of Health and Human Services
Re: RIN 0937-AA11

May 10, 2021

Gentlepersons;

Thank you for this opportunity to comment on the above-captioned Notice of Proposed Rulemaking (NPRM) published by the U.S. Department of Health and Human Services (H.H.S.) and titled "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services," RIN 0937-AA11.

This proposed rule would rescind the existing rule governing the federal Family Planning Program (Title X of the Public Health Service Act), which the previous administration published in 2019 (84 Fed. Reg. 7714); furthermore, your agency's proposed rule would replace the current rule with a modified version of its predecessor rule, published in 2000 (65 Fed. Reg. 41270). For the reasons stated herein, the signers of this comment, who served as amici for the plaintiffs in cases challenging the legality of the 2019 regulation, strongly endorse the rescission of the 2019 rule and its replacement with the 2000 rule in modified form.

In addition, we urge the Department to immediately notify all recipients and sub-recipients of Title X funds that now are operating under the authority of the existing 2019 regulations that the agency will not enforce specific provisions, specifically:

- 45 C.F.R. §§ 59.14 and 59.16 to the extent that these regulations:
 - prohibit non-directive counseling regarding all lawful health care options on the part of clients who are pregnant and who require post-conception care, along with referral assistance in connection with obtaining follow-up care;
 - compel funding recipients to refer to prenatal care all clients who are medically verified as pregnant, regardless of their desires and wishes;
 - limit non-directive counseling to physicians and advance-practice providers, thereby barring such counseling when provided by trained family planning counselors;
 - bar funding recipients from providing clients with information regarding all qualified providers of pregnancy termination services in clients who choose pregnancy termination, not only certain community providers offering "comprehensive primary health care."
- 45 C.F.R. § 59.15 to the extent that this regulation:
 - requires physical and financial separation, as the term is used under the 2019 rule to lift all applicable restrictions related to referral for emergency care.

The signatories to these comments include 173 Deans, Chairs, and health policy scholars, representing some of the nation's leading experts in public health policy, reproductive and women's health policy, health law, and health care for medically underserved populations. Also commenting on this letter is the American Public Health Association, a diverse community of public health professionals that champions the health of all people and communities. Together, *Public Health Amici* seek to ensure the highest level of sexual and reproductive health care for all people by promoting evidence-based policies guided by science and principles of health equity and supported by the best research in the field.

As the Department notes, family planning is considered one of the most significant public health advances of the twentieth century. In setting policy for public health grant programs such as the Title X Family Planning Program (the nation's only public health grant program devoted exclusively to family planning), it is essential that evidence-based standards guide federal agencies, not only because of the importance of evidence-based health care practice generally, but also because of who depends on Title X. Title X is among several Public Health Service Act programs whose fundamental purpose is to improve access to necessary care within medically underserved communities and is aimed at populations facing deep poverty, elevated health risks, and the threat of deep inequality in health and health care. For this reason, amici applaud the proposed rule, which seeks to emphasize health equity and to restore the evidence-based foundation on which Congress intended Title X to rest. An earlier administration attempted to eliminate this program foundation in 1989 and was permitted to do so in *Rust v Sullivan*, 500 U.S. 173 (1991). This must not happen again, especially in the context of a type of health care whose knowledge base is strong and capable of implementing in a high-performing manner.

The 2019 rule undermined the ability to furnish high-quality care to devastating effect, as the Department cites in the evidence set forth as the basis for its proposed rule. Among the most disturbing aspects of the 2019 rule was its requirement that health care professionals withhold necessary and appropriate health information from their patients or force them to accept referrals for unnecessary care - something that, as we pointed out in our amicus brief,¹ raised major legal liability concerns while also potentially exposing patients to severe and long-lasting health consequences as a condition of federal funding. It is hardly surprising that participation rates declined dramatically and that large-scale access consequences ensued. Other deeply problematic aspects of the 2019 rule from an evidence-based practice perspective were:

- its rigid and unnecessary physical and financial separation requirements that had the effect of barring participation by many of the nation's highest-quality family planning service providers;
- its requirement that grantees force patients to accept compulsory referrals for pregnancy care even when they chose termination of pregnancy, likely elevating the risk of physical harm as a result of delays and mental and emotional anguish; and
- effectively barring trained counselors from counseling post-conception patients by preventing them from engaging in non-directive counseling.

In opposition to the 2019 rule, our amicus brief presented evidence regarding the likely negative consequences of the rule. Our brief further pointed out that the 1996 Appropriations Act, along with subsequent limits on agency rulemaking powers under the Patient Protection and Affordable Care Act (A.C.A.) barring regulations that interfere with the provider/patient relationship, create an unequivocal

¹ See, e.g., Brief for Public Health Deans, Scholars, and Chairs and the American Public Health Association in Support of Plaintiffs-Appellees, *Oregon v. Azar*, 950 F.3d 1067 (2020), No. 19- 35386."

agency duty to ensure that in implementing Title X, the H.H.S. Secretary ensure non-directive counseling by all Title X grantees and sub-recipients refrain from undermining providers' full and transparent communications with their patients.

Impact of the 2019 Rule

As we argued in our amicus brief, and as the Department sets forth in the proposed rule, the 2019 rule undermined the mission of the Title X program. Provider participation dropped dramatically, and as a result, the rule significantly reduced the number of clients served and the level of care furnished. Following the rule's implementation, the program experienced a dramatic decline in the number of family planning grantees and service sites: approximately 25 percent of Title X clinics (over 1,000 services sites)² withdrew from the program, jeopardizing reproductive health care for over 1.6 million people.³ Eight states lost over half of their family planning networks, and six states were left with no Title X-funded care at all.⁴

Similarly, the public health impact of the 2019 rule has been immense. First, the rule severely compromised access to essential health care services such as contraception counseling and provision, sexually transmitted disease diagnosis and treatment, cervical and breast cancer screenings, prenatal care, and more. Within the first five months of the 2019 rule being in effect, the number of clients served fell by 840,000 – a 21 percent decrease.⁵ Service reductions caused by the 2019 rule may have led to over 180,000 unintended pregnancies.⁶ Loss of access to services such as treatment for sexually transmitted diseases has had incalculable consequences, as has the impact of the loss of Title X capacity for early pregnancy detection and rapid access into care for women who choose to continue with their pregnancy. The results of these delays will be measured through changes in infant mortality, childhood disability, and maternal mortality, with the consequences falling the hardest on people and communities in the least position to offset the damage – impoverished populations disproportionately consisting of members of racial and ethnic minority groups.

Additionally, the rule meant that any provider remaining within the Title X network, including community health centers, had to abandon adherence to professional practice guidelines, end the use of experienced counselors for non-directive counseling, and direct remaining clinical staff to withhold material information from their patients contrary to the standard of care as embodied in government guidelines.

The 2019 rule barred qualified providers from the program outright and drove away other highly qualified family planning providers. Despite official predictions that other providers would come forward to compensate for these losses, this type of compensation never materialized. Predictive judgment is only as sound as the evidence base on which the exercise of judgment rests. In the case of the 2019 rule, not only was the assertion of the need for the rule not based on evidence, but the prediction regarding a rapid influx of new, qualified providers lacked any factual grounding regarding either the existence of such

² Frederiksen et al (2020). Current Status of the Title X Network and the Path Forward. Kaiser Family Foundation. <https://www.kff.org/womens-health-policy/issue-brief/current-status-of-the-title-x-network-and-the-path-forward/>

³ Dawon, R. (2020). Trump Administration's Domestic Gag Rule Has Slashed the Title X Network's Capacity by Half. The Guttmacher Institute. <https://www.guttmacher.org/article/2020/02/trump-administrations-domestic-gag-rule-has-slashed-title-x-networks-capacity-half>

⁴ Frederiksen et al (2020). Current Status of the Title X Network and the Path Forward. Kaiser Family Foundation. <https://www.kff.org/womens-health-policy/issue-brief/current-status-of-the-title-x-network-and-the-path-forward/>

⁵ Fowler, C. I., Gable, J., Lasater, B., & Asman, K. (2020, September). Family Planning Annual Report: 2019 National Summary. Washington, DC: Office of Population Affairs, Office of the Assistant Secretary for Health, Department of Health and Human Services.

⁶ Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services, 86 Fed. Reg. 19812, 19833 (proposed April 15, 2021) (to be codified at 42 C.F.R. pt. 59).

providers or their willingness to participate in a federal grant program serving at-risk populations. The Office of Population Affairs has been unable to find new grantees and service providers to offset the enormous care gaps created by the 2019 rule. The 2019 rule was allowed to take effect despite the risks to access it posed, and policymakers now have measurable evidence of the extent of the injury caused by such a short-sighted policy choice. We have clear evidence regarding the destructive impact of a rule that bars participation by effective providers while driving away others. As was evident at the time, the 2019 rule amounted to nothing more than a baseless prediction, and its implementation has carried significant consequences for access and health.

The irony is that policymakers did not need the 2019 rule to understand the consequences of policies that exclude qualified providers for reasons unrelated to their ability to provide covered services in a highly effective fashion. The post-implementation experience of the 2019 rule closely mirrors the outcomes observed in connection with a 2011 Texas policy barring participation in its women's health program by full-spectrum reproductive health care providers. This policy led to a steep decline in access to care, which other health care providers could not reverse. Between 2011 and 2016, enrollment in the Texas program fell by 24%, and the percentage of enrollees receiving care fell by 39%.⁷ The Texas policy triggered multiple adverse health effects: a 35% reduction in the use of the most effective forms of contraception, escalating unintended pregnancy rates, and rising teen birth rates.⁸

Similarly, the public health impact of the 2019 rule has been vast. In addition to severely compromising access for over 1.6 million individuals to essential health care services such as contraception counseling and provision, sexually transmitted disease diagnosis and treatment, cervical and breast cancer screenings, prenatal care, experts estimate that the decline in service provision may lead to over 180,000 unintended pregnancies.^{9,10} These consequences do not take into account the uncalculated toll of untreated sexually transmitted diseases^{11,12} and the loss of early prenatal care and pregnancy support, which has been associated with a rise in infant mortality and maternal mortality.^{13,14} Reduction in service access was mainly concentrated among the lowest-income clients and racial and ethnic minorities, attributing to increases in health inequities.

In Support of the Proposed Rule: "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services"

We support H.H.S.'s assertion that the 2019 rules created unambiguously negative consequences, admitting the ambiguity in the statutory text as established in *Rust v. Sullivan*. Additionally, we support H.H.S.'s determination that the 2019 physical and financial separation requirements increased costs

⁷ Excluding Planned Parenthood has been Terrible for Texas Women, Center for Public Policy Priorities (Aug 2017).

⁸ Lawrence B. Finer & Mia R. Zolna, Declines in Unintended Pregnancy in the United States, 2008-2011, 374 *New England J. Med.* 843 (2016).

⁹ Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services, 86 *Fed. Reg.* 19812, 19833 (proposed April 15, 2021) (to be codified at 42 C.F.R. pt. 59).

¹⁰ Dawon, R. (2020). Trump Administration's Domestic Gag Rule Has Slashed the Title X Network's Capacity by Half. The Guttmacher Institute. <https://www.guttmacher.org/article/2020/02/trump-administrations-domestic-gag-rule-has-slashed-title-x-networks-capacity-half>

¹¹ Turner CF, Rogers SM, Miller HG, et al. Untreated Gonococcal and Chlamydial Infection in a Probability Sample of Adults. *JAMA.* 2002;287(6):726-733. doi:10.1001/jama.287.6.726

¹² Owusu-Eduesei, Kwame Jr PhD, PMP⁺; Chesson, Harrell W. PhD⁺; Gift, Thomas L. PhD⁺; Tao, Guoyu PhD⁺; Mahajan, Reena MD, MHS⁺; Ocfemia, Marie Cheryl Bañez MPH⁺; Kent, Charlotte K. PhD⁺ The Estimated Direct Medical Cost of Selected Sexually Transmitted Infections in the United States, 2008, Sexually Transmitted Diseases: March 2013 - Volume 40 - Issue 3 - p 197-201 doi: 10.1097/OLQ.0b013e318285c6d2

¹³ Partridge S, Balayla J, Holcroft CA, Abenheim HA. Inadequate prenatal care utilization and risks of infant mortality and poor birth outcome: a retrospective analysis of 28,729,765 U.S. deliveries over 8 years. *Am J Perinatol.* 2012 Nov;29(10):787-93. doi: 10.1055/s-0032-1316439. Epub 2012 Jul 26. PMID: 22836820.

¹⁴ Alexander, Greg R., and Milton Kotelchuck. "Assessing the role and effectiveness of prenatal care: history, challenges, and directions for future research." *Public health reports* 116.4 (2001): 306.

without providing any discernable benefits. We support H.H.S.'s proposal to rescind – rather than amend - the 2019 rules and readopt the 2000 regulations in revised form for public health and health equity reasons.¹⁵

In addition, we applaud the proposed addition of several revisions that will strengthen the 2000 rule, specifically: the rule's emphasis on health equity; services that are client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; selection criteria that include the ability to advance health equity; the requirement that participating providers lacking a broad range of family planning methods and services have referral arrangements with providers that can address a client's method of choice; billing confidentiality; and maintaining the 2019 rule insofar as it requires reporting of abuse and trafficking. In our view, moreover, the proposed rule strikes a better balance between the conscience rights of providers and the central goal of Title X - to provide access to a broad range of contraceptive options. The 2019 rule allowed concerns over conscience to eclipse the right to unbiased medical care and reproductive self-determination. As drafted, the proposed rule preserves institutional and individual conscience rights while ensuring that clients will be referred to providers that can meet their needs.

Finally, recognizing that this goal can be accomplished only by statute, we support the proposed 19 percent increase from the program's current funding levels. Increased funding will be required to address the immensely negative impact the 2019 regulations had on Title X networks, service provision, and women's health.

Title X is an indispensable part of the nation's public health infrastructure. The 2019 rule was designed to undermine access and had its intended effect. This rule positions the program once again as the indispensable source of reproductive health care Americans have come to rely on.

Sincerely,

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¹⁵ Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services, 86 Fed. Reg. 19812, 19833 (proposed April 15, 2021) (to be codified at 42 C.F.R. pt. 59).

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