FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

GREG WALDEN, OREGON
RANKING MEMBER

ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

February 28, 2019

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

We write to express our dismay that the U.S. Department of Health and Human Services (HHS or the Department) has published a rule revising the regulations for the Title X family planning program that undermines the integrity of this critical program and the health of the patients it serves. [1] As published on the website of the Office of Population Affairs (OPA) on Friday, February 22, 2019, this rule will significantly harm the Title X program by dismantling the network of qualified family planning providers and threatening access to care—namely for those who already face barriers to high quality sexual and reproductive health care including individuals with low incomes, adolescents, LGBTQ individuals, African-American women, and other people of color.

We have serious concerns regarding the final rule's compliance with the Title X statute, the public health implications of this action, and the Administration's rationale for these changes. Additionally, we have questions about the Department's expansive claim of authority under this rule, HHS's failure to account for the significant costs created as a result of the final rule, and the internal regulatory process used by the Department to review and finalize this rule.

On June 1, 2018, HHS proposed substantial changes to the regulations that govern the Title X family planning program—the nation's only federal program dedicated solely to affordable family planning and related sexual and reproductive health services. Following the release of this proposed rule, Members of Congress, public health advocates, health care

---

[1] *Compliance with Statutory Program Integrity Requirements,* HHS-OS-2018-008, RIN 0937-ZA00 (https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-03461.pdf?utm_campaign=pi%20subscription%20mailing%20list&utm_source=federalregister.gov&utm_medium=email).

providers, and hundreds of other stakeholders voiced significant concerns with the proposal and emphasized that the proposed rule would undermine Congressional intent for the program,[2] would reduce access to care,[3] and would interfere with the provider-patient relationship by forcing providers to violate their medical ethics if they stay in the program.[4]

However, despite these well-founded concerns, the Administration has moved forward with the proposed rule's regulatory changes, which prohibit Title X providers from referring their patients for abortion services, even when requested by a client, and requires Title X projects to have strict financial and physical separation from "activities that fall outside the program's scope."[5] The final rule also eliminates references in regulations to "medically approved" family planning methods, as well as the requirement that pregnant patients receive nondirective pregnancy options counseling.[6]

It is clear to us that these changes are designed to ensure family planning providers that offer abortion services—even though this care is not funded through the Title X program—are ineligible from receiving Title X funds, and that patients who seek this care face additional significant hurdles to obtaining an abortion. The Department also appears to be encouraging the participation of non-traditional applicants, such as those who promote abstinence-only-until marriage or natural family planning but who do not or will not offer a broad range of effective contraceptive methods and services, despite the statutory requirement to do so.[7]

Furthermore, the final rule requires additional documentation of efforts, if any, made to encourage family participation in family planning decisions. This challenges the trust of patient confidentiality, particularly for minors, that has long been the underpinning of care offered within a Title X health center. While the Department states that this rule is "sensitive to confidentiality issues," it does not clarify how and only references "serious risk to the minor" as a reason for a health care professional to practice appropriate discretion related to family engagement.[8]

---

[2] *See* Letter to Alex Azar, Secretary, U.S. Dep't Health and Human Services, from Frank Pallone, Jr. Ranking Member, House Committee on Energy and Commerce, July 31, 2018 (energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Pallone%20Letter%20re%20Title%20X%20Proposed%20Rule.pdf).

[3] *See* Letter to Alex Azar, Secretary, U.S. Dep't Health and Human Services, et al, from American Public Health Association, July 30, 2018.

[4] *See* Letter to Alex Azar, Secretary, U.S. Dep't Health and Human Services, from American Medical Association, July 31, 2018 (www.ama-assn.org/press-center/press-releases/ama-opposes-proposed-rule-title-x-family-planning-program).

[5] *Supra* n.1, at 6.

[6] *Id.* at 95.

[7] *See* 42 U.S.C. § 300 (a).

[8] *Supra* n. 1 at 15, 139.

Additionally, HHS has failed to adequately consider the true economic significance of this final action by only taking into account the costs borne by Title X grantees—in itself nearly $50 million in the first year alone—instead of more holistically considering the substantial associated public health costs that will result from the final rule. In fact, the Department states in the final rule that "it is difficult to forecast all of [the rule's] effects, and acknowledges the uncertainty regarding the estimates."[9] Given the impact of this rule on the four million patients that rely on Title X each year, moving forward with this rule while lacking more specific economic estimates is unacceptable.

Finally, we believe that this Administration has continually engaged in an opaque and abnormal decision-making process that has limited the ability of Congress to adequately oversee the Department's actions. Since Democratic Members first raised concerns about delays to the Title X funding announcement in January 2018,[10] as well as political leadership changes within OPA, we have had serious concerns with this Administration's management of the program.[11] These concerns are only heightened given recent claims by multiple stakeholder organizations that they were forced to schedule meetings with the Office of Information and Regulatory Affairs (OIRA) pursuant to Executive Order 12866 prior to the publication of the final rule in a very short timeframe or did not receive responses at all.

For nearly 50 years, Title X has enabled millions of people to more effectively plan for their future, while also providing access to critical preventive health care services that many would have otherwise gone without. The success of Title X is largely due to the network of qualified family planning providers that have implemented the program's goals since its creation. It is disturbing that the Administration has chosen to undermine the ongoing success of this program by finalizing this rule.

For the reasons described above, we ask that you respond in writing to each of the following questions, as well as provide a briefing to Committee staff by March 14, 2019:

1. The final rule eliminates the requirement that Title X projects offer "medically approved" family planning methods. How does HHS currently interpret this term? Why has HHS removed this term from the regulations? If the term "medically approved" is unclear, as HHS has argued, please explain why this term cannot be redefined.

2. Under the final rule, is it possible that a Title X applicant could be awarded a grant if the project only offers "natural family planning" and one additional contraceptive method, such as condoms—instead of a broad range of Food and Drug Administration (FDA)-

---

[9] *Id.* at 228.

[10] Letter to Alex Azar, Secretary, U.S. Dep't Health and Human Services, from Democratic Members of the House Committee on Energy and Commerce (Jan. 29, 2018).

[11] *See* Letter to Alex Azar, Secretary, U.S. Dep't Health and Human Services, from Democratic Members of the House Committee on Energy and Commerce (Apr. 3, 2018).

approved contraceptive methods? If so, please provide the rationale for narrowing the contraceptive offerings that would be made available to patients.

3. The Department notes that science and family planning methods, including contraceptives, have "advanced significantly since Congress enacted Title X in 1970,"[12] in explaining why fertility awareness-based methods are specified as a form of natural family planning in the rule and additional methods of contraception are not. Given the Administration's own admission of scientific advancements of contraceptives, will HHS clarify that a broad range of contraception must be covered?

4. HHS contends that the financial and physical separation requirements are intended to "eliminate the risk of co-mingling or misuse of Title X funds."[13] While the Department argues the potential co-mingling and confusion provides sufficient supporting evidence for this change, the final rule fails to provide any specific examples that necessitate this change. Does HHS have evidence to justify the separation requirements? If so, please provide detailed information regarding such evidence.

5. The Department asserts in the final rule that there is "insufficient compliance"[14] with Section 1008, the abortion prohibition provision in the Title X statute. What is the evidence to support this assertion?

6. The final rule updates and expands the review and selection criteria for grant applicants to "ensure the criteria serve as a meaningful instrument to assess the quality of the applicant and the application."[15] On what basis does HHS believe that expanded selection criteria will result in higher quality applications? How does HHS intend to measure the quality of an applicant and the application based on the expanded selection criteria?

7. The final rule states that the current selection criteria lack rigor and allow "less qualified applicants to garner high scores… affording the Department little help in selecting strong Title X grantees."[16] What evidence does the Department rely upon to support this assertion? How will the expanded selection criteria address this deficiency?

8. The Department contends that the new selection criteria will assist HHS in ensuring that "providers are free to explore and test new ways to better provide service to patients."[17]

---

[12] *Supra* n. 1 at 60.

[13] *Id.* at 7.

[14] *Id.* at 235.

[15] *Id.* at 15.

[16] *Id.* at 15-16.

[17] *Id.* at 149.

Is HHS maintaining that this is not currently permitted and/or that current grantees are not engaged in this type of innovation? Please elaborate on how this rule will ensure greater innovation.

9. Though the HHS proposed rule emphasized that family planning "does not include postconception care,"[18] the final rule would both require prenatal referrals and allow adoption referrals for pregnant patients. What evidence did the Department rely on in making an exception to include adoption as a postconception care Title X service but not the other options previously covered under the statute? Please provide detailed information regarding such evidence. Does the Department view referrals for adoption and prenatal care as nondirective?

10. Adhering to the Quality Family Planning (QFP) guidelines, the federal clinical standards created by the Centers for Disease Control and Prevention (CDC) and OPA, is a Title X program requirement in which pregnancy counseling is required. Given that the final rule makes pregnancy counseling optional, does the Department intend to remove the requirement that Title X providers adhere to the QFP?

11. Why did the Department not take into account the economic impact on Title X patients, such as the lack of access to previously available health care services, which public health experts have said could result from the final rule? Were the economic impacts on state and local health care systems taken into consideration?

12. Given that this rule clearly adversely affects public health, why did the Administration not choose to consider this final rule to be "economically significant," as defined by Executive Order 12866?

13. Why did HHS move forward with finalizing this action and publishing the final rule despite requests from impacted stakeholders, as recently as February 20, 2019, to meet with OIRA pursuant to Executive Order 12866?

14. Did HHS consult with any external organizations, advocacy groups, or non-governmental entities in the drafting or finalization of this rule? If so, please provide the names of the organizations and the dates of each correspondence, as well as the dates of any meetings held with such organizations.

---

[18] *Id.* at 51.

Thank you for your prompt attention to this important matter. Should you have any questions or would like to discuss compliance with this request, please contact Jacquelyn Bolen or Jesseca Boyer on the Energy and Commerce Committee staff at (202) 225-3641.

Sincerely,

Frank Pallone, Jr.
Chairman

Anna G. Eshoo
Chairwoman
Subcommittee on Health

Diana DeGette
Chair
Subcommittee on Oversight
and Investigations