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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

April 17, 2019

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

Dear Secretary Azar:

We write with serious concerns regarding the fiscal year (FY) 2019 Title X family planning services grants awarded on March 29, 2019.[1] For nearly 50 years, the Title X program has issued grant funding to providers that offer high-quality family planning and essential preventive health care services in their communities. The success of the program is due largely to the network of qualified family planning providers that have implemented the program's goals since its creation. The changes made to the Title X network and reports of external influence during the development of the funding opportunity announcement and application process appear to confirm concerns we have raised repeatedly as the Trump Administration continues to place political ideology over the well-being of women and families across the nation.[2]

The 2019 Title X grant awards pose significant changes to the program's family planning health center network. It is particularly alarming that five of the nine previously funded Title X grantees that did not receive funding include Planned Parenthood affiliates in five states: Hawaii, North Carolina, Ohio, Virginia, and Wisconsin. Collectively, these former grantees have decades of experience participating in the Title X program and a longstanding history providing high-quality sexual and reproductive health care in their communities for low-income individuals, adolescents, LGBTQ individuals, black women and other people of color.

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[1] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Population Affairs, *HHS Title X Family Planning Services Grants Award by State: Fiscal Year 2019 Grantees* (www.hhs.gov/opa/grants-and-funding/recent-grant-awards/index.html) (accessed Mar. 29, 2019).

[2] Letter to Alex Azar, Secretary, U.S. Department of Health and Human Services, from Democratic Members of the House Committee on Energy and Commerce (Apr. 3, 2018).

In contrast, one of the four new entities to receive funding includes the Obria Group, Inc. (Obria) of California, a chain of crisis pregnancy centers (CPC). [3] As reported last year, Obria clinics have an "unyielding stance on contraception" promoting "only natural family planning."[4] Additionally, while Obria affiliated clinics test for sexually transmitted infections (STIs), and some will treat STIs, "they don't distribute condoms to prevent them."[5] Despite being rejected for Title X funding in 2018,[6] under the new awards, Obria will receive $1.7 million this year and could receive as much as $5.1 million through 2022.[7] In its own statement announcing receipt of the award, Obria stated that it will "oversee the work of seven clinic partners, including three of its affiliates that don't provide contraceptives."[8] An Obria Group spokesperson further stated that, "none of the funds under this grant going to the subrecipients can be used for contraceptive drugs and devices." [9] Additionally, the continued funding of Beacon Christian Community Health Center (Beacon) of New York is similarly concerning given the absence of contraceptives or contraceptive counseling indicated as a women's health service they provide on their own website.[10] As a first-time Title X grantee last year with no reported sub-recipients, as of December 2018,[11] Beacon received $700,000 in FY 2018 and was awarded another $600,000 under the most recent announcement.[12]

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[3] *Trump administration awards $1.7 million family planning grant to anti-abortion group,* USA Today (Mar. 30, 2019).

[4] *Anti-abortion clinics tapping into federal funds under Trump,* Politico (Dec. 16, 2018).

[5] *Id.*

[6] *Id.*

[7] *Trump Administration Gives Family Planning Grant to Anti-Abortion Group,* New York Times (Mar. 29, 2019).

[8] Obria, *HHS Awards Obria Group $5.1 Million in Title X Family Planning Grants*, https://obriagroup.org/hhs-awards-title-x/ (accessed Apr. 1, 2019) (press release).

[9] *Trump administration awards $1.7 million family planning grant to anti-abortion clinics,* The Hill (Mar. 29, 2019).

[10] Beacon Christian Community Health Center, *Care We Provide*, www.beaconcchc.com/services (accessed Apr. 16, 2019).

[11] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Population Affairs, Title X Family Planning Directory (Dec. 2018) (www.hhs.gov/opa/sites/default/files/Title-X-Family-Planning-Directory-December2018.pdf).

[12] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Population Affairs, *HHS Title X Family Planning Services Grants Award by State: Fiscal Year 2018 Grantees* (Aug. 3, 2018) (web.archive.org/web/20180803060926/www.hhs.gov/opa/grants-and-funding/recent-grant-awards/index.html) (accessed Apr. 15, 2019); U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Population Affairs, *HHS Title X Family*

In eliminating long-standing comprehensive sexual and reproductive health centers from the Title X network and directing funding to grantees that will not guarantee access to contraception or HIV and other STI prevention services, the funding decision contradicts the program's longstanding purpose of "providing individuals with comprehensive family planning and related preventive health services."[13] Annual program reporting shows that in 2017, 62 percent of Title X patients chose to rely on the most effective or moderately effective methods of contraception and fewer than 5.5 percent of patients selected natural family planning methods, such as withdrawal, the fertility awareness-based method, or abstinence.[14]

It is unclear how a grantee that does not provide contraceptives, nor allow their subrecipients to use Title X funds to provide contraceptives, will be able to provide a "broad range of acceptable and effective medically approved family planning methods," as required by statute, or meet the reproductive health care needs of those seeking services at a Title X health center.[15] We have consistently raised this concern and believe that funding grantees that do not provide contraceptives violates Congressional intent for the program. Our fears now appear to be coming to fruition.

The shift of funding toward CPCs that will not offer patients direct access to a broad range of contraceptive care and counseling is alarming. Further, reporting of Department of Health and Human Services (HHS) staff advising Obria on funding opportunities is cause for additional alarm.[16]

As has been raised before, such reporting is simply the latest examples of this Administration's opaque and ideologically driven decision-making process that presents serious concerns with the management of the program.[17]

Planning Services Grants Award by State: Fiscal Year 2019 Grantees (www.hhs.gov/opa/grants-and-funding/recent-grant-awards/index.html) (accessed Mar. 29, 2019).

[13] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Population Affairs, *About Title X Grants* (www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/index.html) (accessed Apr. 15, 2019).

[14] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Population Affairs, *Title X Family Planning Annual Report: 2017 National Summary* (Aug. 2018) (www.hhs.gov/opa/sites/default/files/title-x-fpar-2017-national-summary.pdf).

[15] Title X of the Public Health Service Act, 42 U.S.C. 300, et seq.

[16] *Trump Administration Gives Family Planning Grant to Anti-Abortion Group,* New York Times (Mar. 29, 2019).

[17] Letter to Alex Azar, Secretary, U.S. Department of Health and Human Services, from Democratic Members of the House Committee on Energy and Commerce (Feb. 28, 2019).

Since the Committee first raised concerns regarding delays to the Title X funding announcement in January 2018,[18] we communicated our concerns again in April 2018 and in February 2019 as the Administration has continued its efforts to dismantle the nation's sole dedicated family planning and related preventive health services program.[19]

Given these pressing and immediate concerns, and the questions that have gone unanswered, we request the following by April 24, 2019:

1. Responses to the outstanding 26 questions posed to HHS in the letters attached from the Committee dated January 29, 2018, April 3, 2018, and February 28, 2019.

2. All documents and communications among and/or between HHS and the Obria Group, Inc., including its Board of Directors, Medical Advisory Board, or National Advisory Board, and any other Obria affiliated clinics' staff or governing, medical, or advisory board members regarding Title X funding from March 1, 2017 through March 29, 2019.

3. All documents and communications among and/or between HHS and Beacon Christian Community Health Centers and its governing, medical, or advisory board members regarding Title X funding from March 1, 2017 through March 29, 2019

4. The Orbia Group, Inc. and Beacon Christian Community Health Center applications for Title X funding under both the FY 2018 and FY 2019 Title X Family Planning Services Funding Opportunity Announcements and the respective review materials, correspondence, and scores.

Finally, as previously requested on February 28, 2019, we request a briefing for Committee staff on a date to be determined no later than April 30, 2019.

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[18] Letter to Alex Azar, Secretary, U.S. Department of Health and Human Services, from Democratic Members of the House Committee on Energy and Commerce (Jan. 29, 2018).

[19] Letter to Alex Azar, Secretary, U.S. Department of Health and Human Services, from Democratic Members of the House Committee on Energy and Commerce (Apr. 3, 2018) and (Feb. 2, 2019) .

Thank you for your attention to these concerns and related requests. To discuss compliance, schedule the briefing, or with any questions, please contact Jesseca Boyer or Jacquelyn Bolen of the 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

GREG WALDEN, OREGON
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January 29, 2018

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 you today with serious concerns about the status of the Title X family planning program. In particular, we are greatly alarmed by the Health and Human Services (HHS) Office of Population Affairs' (OPA) unexplained multi-month delay in posting a Title X funding announcement, and by the apparent serious instability at OPA, which administers the program. The Title X program provides critical funds to organizations which ensure that all women in need have access to affordable contraceptive care.[1] The ongoing delay in posting the funding announcement creates a very serious risk that grantees will face a funding gap that will impede their ability to provide these essential services and may adversely affect the health and well-being of women and families across the nation.

According to an HHS grant opportunity posting, OPA expected to post the grant application for Title X funds by November 1, 2017, with an application due date of January 3, 2018 and an award date of April 1, 2018.[2] As of today, OPA still has not posted the grant application. In the past, OPA has given organizations 60 to 90 days to submit applications, and HHS will also need time to review those applications once they are received.[3]

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[1] Department of Health and Human Services, *About Title X Grants* (www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/statutes-and-regulations/index.html) (accessed Jan. 22, 2018).

[2] Department of Health and Human Services, Grants.gov, *Availability of funds for Title X Family Planning Grants* (Oct. 11, 2017) (PA-FPH-18-001).

[3] *Trump admin delays spark fear for family planning groups over funding*, The Hill (Jan. 18, 2018).

In light of these timelines, it seems highly unlikely that OPA will be able to award grant funds by April 1, 2018. Additionally, as a result of a decision by HHS last July, all current grantees' funding ends in either March or June of this year. The grantees that rely on this funding to provide family planning and reproductive health services are therefore at risk of a funding lapse, which in turn is likely to disrupt delivery of care to adolescents and women who can least afford it.

The apparent instability at OPA and potential funding lapse is particularly troubling because repeated studies have shown that the Title X program is hugely successful. Title X was enacted in 1970 with broad bipartisan support in order to provide family planning information and services to "all those who want them but cannot afford them."[4]

In 2016, the program served four million people nationwide,[5] and it has played a key role in the substantial decline in unintended pregnancies.[6] For example, one study demonstrated that "services provided by clinics that received Title X funding helped women avert 822,300 unintended pregnancies in 2015, thus preventing 387,200 unplanned births and 277,800 abortions."[7] The study further pointed out that "without the services provided by Title X–funded clinics, the U.S. unintended pregnancy rate would have been 31 percent higher and the rate among teens would have been 44 percent higher."[8]

Title X grants also save taxpayers money in the long term. For every public dollar spent on family planning services and preventive care, taxpayers save $7.09, for a net savings of $13.6 billion in 2010 on treatment for sexual transmitted infections, pregnancy, and related services that would have otherwise been paid for by Medicaid.[9]

Given the effectiveness of the Title X program, and its benefits to the American people, I am deeply disturbed by what appears to be inexcusable delays in the Title X grant application process.

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[4] Richard Nixon, *Statement on Signing the Family Planning Services and Population Research Act of 1970* (Dec. 26, 1970).

[5] Department of Health and Human Services, Office of Population Affairs, *Title X Family Planning Annual Report 2016 Summary* (August 2017)).

[6] Lawrence B. Finer, Ph. D. and Mia R. Zolna, M.P.H., *Declines in Unintended Pregnancy in the United States, 2008 – 2011*, New England Journal of Medicine (March 3, 2016).

[7] Jennifer Frost et al., *Publicly Funded Contraceptive Services at U.S. Clinics, 2015*, Guttmacher Institute (April 2017).

[8] *Id.*

[9] Jennifer J. Frost, Adam Sonfield,, Mia Zolna and Lawrence B. Finer, *Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program,* The Milbank Quarterly, Vol. 92, No. 4 (2014).

We therefore ask that you to respond to the following questions as soon as possible, and no later than February 12, 2018:

1. What is the status of the Title X grant application process?

    a. When does OPA expect to make the grant applications publicly available?

    b. How long will applicants have to complete applications?

    c. Will OPA process applications on an expedited basis?

    d. Does OPA expect to award grants by April 1?

    e. If OPA will not be making grant funding available by April 1, does OPA intend to make available cost extensions for current grantees until fiscal year 2018 funding awards are distributed to ensure there is no lapse in service? Similarly, if the grant award process is delayed beyond June 30, 2018, does OPA have a contingency plan to ensure there is no lapse in service in those service areas?

    f. How many existing Title X grantees will be affected if extensions are not provided beyond March 31, 2018? Please outline which states and territories, and the number of patients as per the most recent Family Planning Annual Report.

2. What is the reason for the substantial delay in release of the Title X grant application?

    a. How many employees does OPA currently have assigned to the grant application process? How many employees were assigned to this process for the grants that were awarded in fiscal years 2016 and 2017?

    b. Has OPA, or any employee of the office of OPA, consulted with outside organizations regarding the Title X grant application process?

3. On January 12, the Deputy Assistant Secretary for the Office of Population Affairs, Teresa Manning, left her post nine months after her appointment. Ms. Manning was reportedly escorted from the HHS building by security.[10]

    a. What were the circumstances behind Ms. Manning's departure as director of OPA?

    b. If Ms. Manning left voluntarily, was her departure planned? When did she give notice of her intent to resign?

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[10] *Anti-birth control official who led Title X departs HHS*, Politico (Jan. 12, 2018).

c. Was Ms. Manning's departure in any way related to the delay in the Title X grant application process?

d. Has OPA assessed the way in which a change of leadership at OPA at this critical time will impact the timing of the Title X grant awards?

Thank you in advance for your attention to this critical matter. If you have any questions, or would like to further discuss compliance with this request, please contact Christina Calce or Jacquelyn Bolen of the Democratic Committee staff at (202) 225-3641.

Sincerely,

Frank Pallone, Jr.
Ranking Member

Gene Green
Ranking Member
Subcommittee on Health

Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

GREG WALDEN, OREGON
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Minority (202) 225–3641

April 3, 2018

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

Dear Secretary Azar:

We write to you with serious concerns regarding the 2018 Funding Opportunity Announcement (FOA) for Title X Family Planning Service Grants that the U.S. Department of Health and Human Services (HHS or the Department) released on February 23, 2018, which differs significantly from Title X FOAs from previous years.[1] The Title X program provides critical funds to organizations that deliver these essential services in their communities, and the revisions to this year's FOA strongly suggest that, once again, the Trump Administration is prioritizing political ideology over the well-being of women and families across the nation.

The 2018 Title X FOA – a 60-page document that outlines the federal family planning program's priorities, eligibility, and requirements for participation – deviates from Title X FOAs from previous years. It de-emphasizes U.S. Food and Drug Administration (FDA)-approved contraceptive care in favor of "natural family planning methods," appearing to encourage the participation of abstinence-only providers and crisis pregnancy centers (CPCs) while discouraging the participation of comprehensive reproductive health centers in the program.[2] For example, the 2018 FOA does not include a single explicit reference to "contraceptives" or "contraceptive services," but refers to natural family planning methods six times.[3]

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[1] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Population Affairs, *Announcement of Anticipated Availability of Funds for Family Planning Services Grants* (Feb. 23, 2018) (www.hhs.gov/opa/sites/default/files/FY18%20Title%20X%20Services%20FOA_Final_Signed.pdf).

[2] *Id.*

[3] *Id.*

By failing to reference longstanding guidance on the standard of care for providing comprehensive medical services related to family planning and contraceptive services, the 2018 FOA shifts Title X's focus from "required" services to "core" services, which do not include contraceptives. For example, the 2018 FOA neither references nor mentions the nationally recognized clinical standards developed jointly by the Centers for Disease Control and Prevention (CDC) and the Office of Population Affairs (OPA) in 2014 that define quality for family planning care.[4] Instead, the 2018 FOA references "core family planning services" on four occasions without referring to any existing program guidelines, regulations, or statutory language.[5] It is worth noting that contraceptive services are notably missing from the list of "core" services in the 2018 FOA, and the document does not explicitly require grant applicants to list all contraceptive methods and services offered through their Title X projects. Instead, applicants are required to list only the "family planning methods" they intend to offer. Unlike in previous years, providers are not asked to justify any failure to offer the full range of FDA-approved contraceptives.[6]

We have significant concerns with the 2018 FOA for the reasons described above and strongly believe that the individuals who seek care through the Title X program should have access to the full range of contraceptive options. This Administration should be working to ensure that Title X patients receive comprehensive family planning and related preventive health services instead of pursuing ideological priorities that will not best serve all patients.

In addition, the 2018 FOA shifts final Title X grant decision-making authority in a way that may prevent adequate oversight of these decisions. In previous years, regional health officials, the HHS Assistant Secretary for Health, and the HHS Deputy Assistant Secretary for Population Affairs shared this authority.[7] Under the 2018 FOA, Valerie Huber, the Acting Deputy Assistant Secretary for Population Affairs, has exclusive authority to make the final decision on which entities will receive Title X funding.[8]

Huber, the former President and CEO of Ascend – a national organization that promotes youth abstinence education – is a longtime advocate of abstinence over FDA-approved contraceptive methods. During her tenure at Ascend, Huber publicly stated: "[W]e must normalize sexual delay more than we normalize teen sex, even with contraception."[9] Additionally, given recent reports that Ms. Huber and other HHS political appointees appear to have disregarded the concerns raised by career agency employees on HHS's efforts to end the

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[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] *Abstinence Advocate Gets Final Say on Family Planning Dollars*, Politico (Mar. 7, 2018).

[8] *See* note 1.

[9] *See* note 7.

Teen Pregnancy Prevention Program.[10] We question whether Ms. Huber can independently select grantees without political or ideological bias. Granting the final decision-making authority over Title X awards to someone who prioritizes ideology over the well-documented public health gains associated with expanded contraceptive access raises major questions about the Trump Administration's commitment to health of the millions of women and families across America who rely on the Title X program.

In light of the concerns described above, we ask that you provide a response to the following questions, as well as a briefing to Committee staff, by no later than April 7, 2018:

1. Please provide a timeline detailing the sequence of events related to the drafting, revision, and release of the 2018 FOA.

2. Please provide any communications between HHS and/or employees of HHS and outside advocacy organizations that pertain to the drafting of the 2018 FOA.

3. Please provide an explanation for the substantial delay that occurred in releasing the Title X grant application.

4. Who within the Department was responsible for final sign-off on the 2018 FOA?

5. At any point in the drafting process for the 2018 FOA, were HHS employees instructed not to reference or to remove references to "contraceptives" and "contraceptive services?" If so, who gave this instruction?

6. At any point in the drafting process for the 2018 FOA, did any HHS employees express concern that the document neglected to reference "contraceptives" and "contraceptive services?

7. Does the Department intend to enforce existing program guidelines, regulations, and/or statutes pertaining to services that are required to be offered by Title X grant recipients?

8. Who within the Department was responsible for the decision to grant sole, final decision-making authority regarding Title X grant recipients to the Deputy Assistant Secretary for Population Affairs? Please provide a written explanation detailing why this decision was made, as well as an overview of any analysis conducted regarding how this policy change will impact the distribution of Title X grant awards.

9. On January 12, 2018, the former Deputy Assistant Secretary for Population Affairs, Teresa Manning, left her post nine months after her appointment and was reportedly

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[10] *Notes, emails reveal Trump appointees' war to end HHS teen pregnancy program,* NBC News (Mar. 20, 2018).

escorted from the HHS building by security.[11] What were the circumstances behind Manning's departure, and was her departure in any way related to the delay of or revisions to the Title X grant application process?

Thank you for your prompt attention to this critical matter. Should you have any questions or would like to further discuss compliance with this request, place contact Christina Calce, Jacquelyn Bolen, or Miles Lichtman of the Democratic Committee staff at (202) 225-3641.

Sincerely,

Frank Pallone, Jr.
Ranking Member

Gene Green
Ranking Member
Subcommittee on Health

Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

[11] *Anti-Birth Control Official Who Led Title X Departs HHS*, Politico (Jan. 12, 2018).

FRANK PALLONE, JR., NEW JERSEY
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2125 RAYBURN HOUSE OFFICE BUILDING
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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

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[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]

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[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)-

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[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]

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[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.

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[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