ETHICS AND PUBLIC POLICY CENTER

May 17, 2021

The Honorable Xavier Becerra
Attn: Title X Rulemaking
Office of Population Affairs
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Submitted via Federal eRulemaking Portal

Re: EPPC Scholar Comment Opposing Proposed Rule "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services," RIN 0937-AA11

Dear Secretary Becerra:

I am concerned scholar at the Ethics & Public Policy Center (EPPC) and write in strong opposition to the proposed rule "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services"[1] and to the repeal of the 2019 Title X Final Rule (2019 Rule).[2] I urge the U.S. Department of Health and Human Services (HHS or the Department) to withdraw the proposed rule from consideration for the reasons discussed below. The views expressed in this Comment are my own.

I. Title X, Its Abortion Prohibition, and the Proposed Rule.

Congress enacted Title X of the Public Health Service Act in 1970 to provide financial support for healthcare organizations offering voluntary family planning services.[3] Section 1001 of the Act establishes the general purpose of Title X grants and contracts, and provides certain criteria to be considered for making such grants and contracts, including that Title X projects "shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)."[4] Section 1008 explicitly excludes abortion from the scope of "family planning" for purposes of Title X, stating that "[n]one of the funds appropriated under this [title] shall be used in programs where abortion is a method of family planning."[5]

[1] 86 Fed. Reg. 19812.
[2] 84 Fed. Reg. 7714.
[3] 42 U.S.C § 300 et seq.
[4] 42 U.S.C. § 300(a).
[5] 42 U.S.C. § 300a-6.

HHS has issued a number of Title X regulations over the years, including most recently in 2019. The 2019 Rule remedied several problems with the prior regulations from 2000. Namely, the 2019 Rule promotes program integrity by ensuring that the Title X program is consistent with the underlying statute and statutory purposes, including that Title X funds are not used to subsidize abortion. Nevertheless, the Department proposes new regulations, which would largely be a readoption of the 2000 regulations with some additional requirements.[6] The Department claims that the 2019 Rule "undermined the public health of the population the program is meant to serve," without supporting this conclusion with adequate evidence and without analyzing each of the regulatory provisions and requirements it seeks to change and how they would serve legitimate public health goals.[7] As explained below, the proposed rule runs afoul of Title X's abortion prohibition and federal conscience protections, does not support Title X's purposes, undermines Title X project accountability and transparency, and provides a flawed analysis of the impact of the 2019 Rule and the projected impact of the proposed regulations. The proposed rule should be withdrawn.

II. The Proposed Rule Promotes Abortion as a Method of Family Planning in Violation of Section 1008 and Federal Conscience Protections.

Removal of abortion prohibition requirements. The Department proposes removing from § 59.7(a) a requirement that Title X grants will be awarded to the projects that "best promote the purposes of statutory provisions applicable to the Title X program, and ensure that no Title X funds are used where abortion is a method of family planning"[8] and replacing it with "best promote the purposes of Section 1001 of the Act."[9] Because no reason is given for this substitution it is per se arbitrary and capricious. It, at best, downplays and obscures Section 1008's prohibition against abortion as a method of family planning in grant and contract considerations and, at worst, encourages violation of Section 1008's statutory requirements because the removal of the language signals a lack of intent on the part of HHS to enforce it. At the very least the unexplained change in the proposed language would cause confusion. It should not be adopted and the language from the 2019 Rule should be retained.

Removal of assurance of compliance with abortion prohibition. The Department proposes deleting § 59.13 of the 2019 Rule, which requires that "[a] project may not receive funds under this subpart unless the grantee provides assurance satisfactory to the Secretary that the project does not provide abortion and does not include abortion as a method of family planning."[10] No reasoned explanation or evidence is given for why this specific assurance of compliance is "burdensome" or why it provides no "discernible compliance benefits."[11] Nor is there any explanation as to how such burden exceeds the benefits of inducing and assuring compliance with the law. Assurances of compliance are present in a multitude of other grant programs conducted by HHS and this assurance in particular is simple yet vital to ensure that Title X funds are not being used in ways that are contrary to Section 1008 and should be retained.

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[6] 86 Fed. Reg. at 19812.
[7] *Id*.
[8] 84 Fed. Reg. at 7788.
[9] 86 Fed. Reg. at 19832.
[10] 84 Fed. Reg. at 7788.
[11] 86 Fed. Reg. at 19817.

Requiring abortion counseling and referrals. Although the Department claims "individuals and grantees with conscience objections will not be required to follow the proposed rule's requirements regarding abortion counseling and referral,"[12] nothing in the text of the proposed regulations acknowledges or guarantees such a protection. It is arbitrary and capricious for HHS to acknowledge that conscience protections apply and to list several other regulatory and statutory provisions that govern the conduct of Title X grant recipients in the regulatory text but to exclude applicable conscience protections from the regulatory text. Despite acknowledging federal conscience rights, the preamble equates not receiving referrals, presumably including for abortion, as "inferior access,"[13] suggesting that HHS believes conscience rights can be outweighed by HHS's desire to require abortion referrals. This position is contrary to law.

Indeed, under the proposed rule § 59.5(a)(1), a Title X project would be required to provide pregnancy counseling services, which § 59.5(a)(5) states include abortion counseling and referrals.[14] This requirement is in direct violation of Section 1008 and should be removed.

The Department would also amend § 59.5(a)(1) to state:

> Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services, *must* be able to provide a referral to the client's method of choice and the referral *must* not unduly limit the client's access to their method of choice.[15]

Under this provision, individual subrecipients who provide only one family planning method or service as part of a broader Title X project will be required to refer clients to the contraceptive method of their choice, in possible violation of their conscience or organizational policy. For example, a subrecipient may oppose certain contraceptive methods on the grounds that they conflict with deeply held beliefs and would be forced to either violate their conscience or withdraw from providing professional services needed or wanted by clients in their service area. To the extent that referrals for contraception will be required, I suggest that grantees are allowed to provide referrals to the broad range of family planning methods and services and that conscience protection statutes be incorporated explicitly.

In § 59.5(a)(3), the proposed rule would require that projects "must . . . provide services in a manner that is *client-centered*," the proposed definition of which provides that "client values guide *all* clinical decisions."[16] Since a client may "value" abortion or contraception, this requirement will push out faith-based providers who cannot due to their conscience and faith refer for abortion or contraception. It may also violate the Hippocratic Oath if a "client value" would lead to self-harm that a provider declines to further or enable.

The Department's assertion in the preamble that conscience rights are protected is insufficient. There is no explicit conscience exemption acknowledged in the text of the legally-

[12] *Id.* at 19818.
[13] *Id.* at 19817.
[14] *Id.* at 19830.
[15] *Id.* (emphasis added).
[16] *Id.* at 19829–30 (emphasis added).

binding regulation. Further, there is no discussion in the proposed rule how Title X applicants or providers who have conscience objections will be evaluated or how they will be exempt from the regulation's stated requirements. Neither the regulation nor the preamble discusses the Religious Freedom Restoration Act (RFRA)[17] and how it would also apply to prohibited coercion contrary to religious beliefs. Without specific assurances and guarantees, HHS will limit the pool of potential applicants and providers by excluding those who have moral and religious objections to abortion. This is evidenced by the fact that between 2000 and 2018 there were very few new grant applicants submitted for Title X grant funding. With the advent of the 2019 Rule, the number of new applicants immediately soared, indicating that the explicit conscience protections were viewed favorably by many applicants. If the abortion counseling and referral requirements are added back as Title X project requirements, HHS will lose many, if not all, of these new grantees who will be forced to choose between the health of their patients and their own conscience.

As HHS acknowledged in 2008, the 2000 Rule's "current regulatory requirement that grantees must provide counseling and referrals for abortion upon request" (and what the Department is again proposing) violates Section 1008 and "is inconsistent with the health care provider conscience protection statutory provisions,"[18] including the Church, Coats-Snowe, and Weldon Amendments. The Church Amendments, enacted in the 1970s, protect the conscience rights of individuals and entities that object to performing or assisting in the performance of abortion procedures if doing so would be contrary to the provider's religious beliefs or moral convictions.[19] The Coats-Snowe Amendment, enacted in 1996, prohibits federal and state governments, including HHS, from discriminating against any health care entity, which includes Title X providers, on the basis that the entity, inter alia, refuses to provide referrals or make arrangements for abortions.[20] The Weldon Amendment, which has been part of every HHS appropriations act since 2005, provides that HHS funding may not be made available to a federal program, which includes Title X, if the program discriminates on the basis that the health care entity (from individuals to facilities) does not refer for abortions (inter alia).[21] Any attempt by HHS to return to the 2000's abortion counseling and referral requirements will likewise be "inconsistent" with federal conscience laws.

Requiring abortion counseling and referrals is also inconsistent with religious freedom protections in the First Amendment and RFRA. Supreme Court case law provides that funding conditions that burden religious exercise constitute cognizable burdens of religious exercise. Current or potential funding recipients under Title X that oppose abortion counseling and referrals for religious reasons would be substantially burdened in their religious exercise by the conditions in the proposed rule that they must counsel on and refer for abortions. There is no compelling government interest in requiring abortion counseling and referrals within the Title X program since Title X is focused on pre-conception and pre-pregnancy care and Section 1008 explicitly prohibits funding programs where abortion is a method of family planning. Such a requirement is also not the least restrictive means of advancing the any alleged government interest.

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[17] 42 U.S.C. § 2000bb et seq.
[18] 73 Fed. Reg. 78072, 78087.
[19] 42 U.S.C. § 300a-7 et seq.
[20] Public Health Service Act § 245, 42 U.S.C. § 238n.
[21] *See* HHS, *Conscience Protections for Health Care Providers* (last reviewed Mar. 22, 2018), https://www.hhs.gov/conscience/conscience-protections/index.html.

The 2019 Rule fixed the inconsistency with the 2000 regulations and brought HHS's Title X regulations into compliance with federal conscience laws, the First Amendment, and RFRA. As such, the 2019 regulations on abortion counseling and referrals should be retained: nondirective pregnancy counseling on abortion may be permitted, but not required, and abortion referrals should be prohibited, though providers may be permitted to give clients a health care provider referral list that includes some (but not all) providers who perform abortions. While medically necessary referrals, such as prenatal care for pregnant women and girls, should be required, elective abortion is *never* medically necessary. These requirements, which the Department seeks to rescind, are consistent with Section 1008 as upheld by the Supreme Court in *Rust v. Sullivan*[22] and necessary to protect the conscience rights of Title X providers who cannot counsel on or refer for abortion due to their moral or religious beliefs.

Abortion counseling and referrals should not be mandated at all within Title X projects, but to the extent they are allowed, I recommend that the text of the legally binding regulations explicitly acknowledge providers' conscience rights and explain how the application, evaluation, and compliance process with recognize and protect such rights. I also recommend that the Conscience and Religious Freedom Division in HHS's Office for Civil Rights be consulted in the formulation of any final rule and explicitly mentioned in the regulatory text and preamble as the unit within HHS that will ensure that any proposed regulations comply with all applicable federal conscience protection laws.

Removal of physical and financial separation between Title X projects and abortion services. The Department proposes deleting in whole cloth §§ 59.14 to 59.19 and removing the physical and financial separation requirements in the 2019 Rule that ensure separation between Title X services and the provision and promotion of abortion. The Department's proposal to offer Title X services in the same facilities where abortions are performed contradicts Title X's express prohibition in Section 1008 on using its funds "in programs *where* abortion is a method of family planning."[23] In this context, "where" means "at or in the place in which."[24] Thus, any Title X program hosted in a facility that also offers abortions as a method of family planning (such as at Planned Parenthood) is a Title X "program[] where"—in other words, a program "at or in the place in which"—"abortion is used as a method of family planning."

The 2019 separation regulations should be retained. They create a bright-line and are also necessary to ensure that Title X funds are not being used to create infrastructure that supports abortion. Without separation there is ambiguity and confusion between approved Title X activities and non-Title X activities, making it more difficult, if not impossible, for HHS to ensure compliance. This is especially true when physical space is shared. For example, the same staff could provide Title X services in the same location that they later provide non-Title X-funded abortions. The proposed rule would allow shared waiting rooms with signs advocating for abortion and Title X services right next to each other. It will lead Title X beneficiaries to believe abortion is an approved family planning method under the Title X program when it is not. Title X cannot legally fund the overhead of abortion activities and the proposed rule would allow exactly that. If HHS rejects this comment, at a minimum to avoid confusion, I recommend that HHS require that

[22] 500 US 173 (1991).
[23] 42 U.S.C. § 300a-6 (emphasis added).
[24] WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 2602 (2003).

abortion materials cannot be displayed in the same space during the provision of any Title X services and that provider signage and materials should clearly delineate between Title X services and services not permitted with Title X funds.

In the proposed rule, the Department concludes that there is "no diversion of grant funds that would justify the greatly increased compliance and oversight costs the 2019 rule required."[25] But Maine Family Planning (MPF), Maine's sole Title X provider prior to the 2019 Rule, has admitted in court that it uses Title X funds to directly support its abortion services. When MFP challenged the 2019 Rule in *Family Planning Association of Maine v. U.S. Department of Health and Human Services*, it claimed, in part, that it violates their patients' Fifth Amendment Due Process Clause right to choose an abortion.[26] In its brief, MPF acknowledged that its clinics providing abortion would close without Title X funding.[27] By refusing to comply with the Rule and voluntarily foregoing Title X funding, MFP clinics offering abortion services would not have to close *unless* MFP used Title X funds in some way to support their abortion services. Indeed, in a decision dismissing MFP's case, a Maine district court acknowledged as much: "The irony of [MFP's] argument, of course, is that it substantiates [the 2019 Rule]'s concern that the Title X program is subsidizing abortion."[28] MFP's admission supports the rationale behind the 2019 Rule's separation requirements and shows why the separation requirements are necessary and beneficial. The Department cites to the lack of evidence found by "legally required audits, regular site visits, and other oversight of grantees" as a reason for why the separation requirements are not necessary,[29] but the inability of the "legally required audits, regular site visits, and other oversight of grantees" to flag MFP's use of Title X to subsidize its abortion services demonstrates why the physical and financial separation requirements in the 2019 Rule are necessary to ensure compliance with Section 1008. It is arbitrary and capricious for HHS to not consider its grant recipients' *own admissions* concerning use of Title X funds to support abortion activities.

MFP was not the only court challenger to the 2019 Rule that was concerned about its impact on abortion, despite the fact that abortion is statutorily excluded from Title X projects. For example, California claimed the Rule "constitutes a significant impediment to low-income Title X patients' access to . . . abortion services."[30] Likewise, Oregon and other states claimed the Rule's separation requirements "will have consequences on all aspects of reproductive health for low-income clients, from access to contraception and abortion to screening and treatment for sexually transmitted infections."[31] Other plaintiffs in Oregon (including Planned Parenthood) stated the Rule's separation requirements "will deprive patients of information about abortion and access to abortion" and "imped[e] or delay[] [patients'] ability to obtain an abortion."[32] And according

[25] 86 Fed. Reg. at 19816.
[26] Pls.' Mem. in Supp. of Mot. for Prelim. Inj. 31–39, *Family Planning Ass'n of Me. v. U.S. Dep't of Health & Hum. Servs.*, No. 19-100 (D. Me. Mar. 25, 2019).
[27] *See id.* at 1–2 ("[I]f MFP is forced to leave the Title X program, it will have to close more than half of its clinics entirely, causing thousands of women in Maine to lose access to *both* family planning services and abortion services."); *id.* at 35 (indicating that if MFP does not implement the Rule, eleven to fifteen rural clinics offering abortion will close).
[28] *Family Planning Ass'n v. U.S. Dep't of Health & Human Servs.*, 466 F. Supp. 3d 259, 271 (D. Me. 2020).
[29] 86 Fed. Reg. at 19816.
[30] Cal.'s Notice of Mot. & Mot. for Prelim. Inj., with Mem. of Points & Auths. at 13, *California v. Azar*, No. 19-1184 (N.D. Cal. Mar. 21, 2019).
[31] Pl. States' Mot. for Prelim. Inj. at 29, *Oregon v. Azar*, No. 19-317 (D. Or. Mar. 21, 2019).
[32] Pls.' Mot. for Prelim. Inj. at 35, *Am. Med. Ass'n v. Azar*, No. 19-318 (D. Or. Mar. 21, 2019).

Washington State, the Rule's counseling, physical separation, and referral requirements "will impede patients' ability to obtain the [abortion] care they want and need."[33] Similarly, the dissent in the en banc Ninth Circuit decision upholding the 2019 Rule claimed the 2019 regulations will prevent some "from accessing abortion altogether."[34] But Title X physical and financial separation requirements should not impact abortion access unless Title X projects and funding were being used in some way to promote, encourage, or facilitate abortion services. This is not mere fungibility. It is the use of Title X funds to subsidize abortion in violation of Section 1008 and the Hyde Amendment, which prohibits taxpayer dollars from funding elective abortions. Again, it is arbitrary and capricious for HHS not to consider the admissions of its recipients on these matters when they contradict HHS's asserted views.

Setting aside whether the physical separation requirements are burdensome, the Department does not explain why the financial separation requirements in §§ 59.15 and 59.18 of the 2019 Rule are so onerous that they must also be rescinded. These provisions should be retained and are necessary to ensure program accountability, transparency, and integrity. To further these aims, I recommend that instructions to grantees include prohibited activities related to abortion, such as: offering any financial or material support, providing abortion supplies or equipment, making appointments for abortion, delivering drugs that initiate the abortion process, conducting or financing biomedical research on abortion methods, steering patients toward abortion during any counseling, or providing information or materials that are created for the purpose of driving business to abortion providers. I also recommend that all Title X staff (whether paid or volunteer) are required to be trained to fully understand the difference between permissible and impermissible Title X activities.

Encouraging abortion through lobbying, education, and legal action. The Department proposes deleting the 2019 Rule's prohibition in § 59.16, restricting Title X project funds from being used for lobbying, education, and legal action that encourages the use of abortion as a method of family planning.[35] Because no reason is given for this change it is arbitrary and capricious. Removing these restrictions indicates that Title X funds could be used in such a way to promote abortion. As such, the lobbying, education, and legal action restrictions on Title X funds in § 59.16 should be retained.

Seeking ways to force states to fund abortion providers. In the proposed rule, HHS is critical of state restrictions on the eligibility of "otherwise qualified providers" to partner with the state as subrecipients in its Title X program "based either on the non-Title X activities of the providers or because they are a certain type of provider."[36] This is a thinly veiled reference to state policies that prohibit Title X and other state family planning funding from going to Planned Parenthood or other abortion providers. HHS invited comments on ways it can "ensure that Title X projects do not undermine the program's mission by excluding otherwise qualified providers as subrecipients."[37] I urge HHS *not* to limit states' ability to choose its Title X subrecipients, even if that means states may choose not to partner with abortion providers. No state should be forced to

[33] State of Wash.'s Mot. for Prelim. Inj. at 44, *Washington v. Azar*, No. 19-3040 (E.D. Wash. Mar. 22, 2019).
[34] *California v. Azar*, 950 F.3d 1067, 1109 (9th Cir. 2020) (Paez, J., dissenting).
[35] 84 Fed. Reg. at 7789–90.
[36] 86 Fed. Reg. at 19817.
[37] *Id.*

funnel taxpayer dollars to abortion providers. The chilling restriction suggested by the Department is especially problematic because of Section 1008's abortion prohibition and because it raises federalism concerns.

Attempts to restrict Title X grantees' ability to select subrecipients of their own choosing will undermine the ability of grantees to construct a seamless plan for implementation of their specific proposal. States and regions of the United States have differing family planning needs and unique obstacles for meeting those needs. A successful Title X project takes into account the cultural realities of the targeted area of service when building the Title X proposal and implementation plan. An important aspect of this cultural sensitivity is met by allowing grantees the freedom to select subrecipients that are responsive to these unique needs. Adopting exclusionary requirements for the selection of subrecipients that stray beyond the statutory requirements of the program will interfere with the sensitive balance needed for successful implantation of the Title X program and can jeopardize the ability of a Title X grantee to meet targets for care. I strongly urge HHS to permit states and other grantees the freedom to select qualified subrecipients of their choosing so as not to undermine the program's mission nor unnecessarily interfere with clients' access to family planning services.

In 2016, HHS already attempted imposing a Title X regulation that limited the ability of States and other Title X grantees to exercise flexibility in choosing their subrecipients. This regulation, however, was rendered void by a joint resolution of disapproval passed by Congress under the Congressional Review Act and signed by the President.[38] Any attempt by HHS to similarly limit states' ability to choose its subrecipients will be unlawful under the Congressional Review Act.[39] Further, any attempt to do so in a final rule without first proposing regulatory text for public inspection would fail the "logical outgrowth" test under the Administrative Procedure Act.[40]

III. The Proposed Rule's Definitions and Additions Do Not Support Title X's Purposes.

A. Proposed Definitions

Advanced practice provider. The Department proposes removing the requirement that nondirective pregnancy counseling be provided by physicians or advanced practice providers.[41] No rationale is given for this deletion. Ensuring counseling is done by physicians or advanced practice providers helps preserve the patient/health care provider relationship and promotes optimal health for every Title X client. This requirement should be retained.

Client-centered care. The Department proposes adding a definition of "client-centered care," which provides "client values guide all clinical decisions."[42] The proposed definition of "quality healthcare" states that such care is "client-centered," and in § 59.5(a)(3), the proposed

[38] Joint Resolution Providing for Congressional Disapproval Under Chapter 8 of Title 5, United States Code, of the Final Rule Submitted by Secretary of Health and Human Services Relating to Compliance with Title X Requirements by Project Recipients in Selecting Subrecipients, Pub. L. 115-23, 131 Stat. 89 (Apr. 13, 2017).
[39] *See* 5 U.S.C. § 801(b)(2).
[40] 5 U.S.C. § 551 et seq.
[41] 84 Fed. Reg. at 7787, 7789.
[42] 86 Fed. Reg. at 19829.

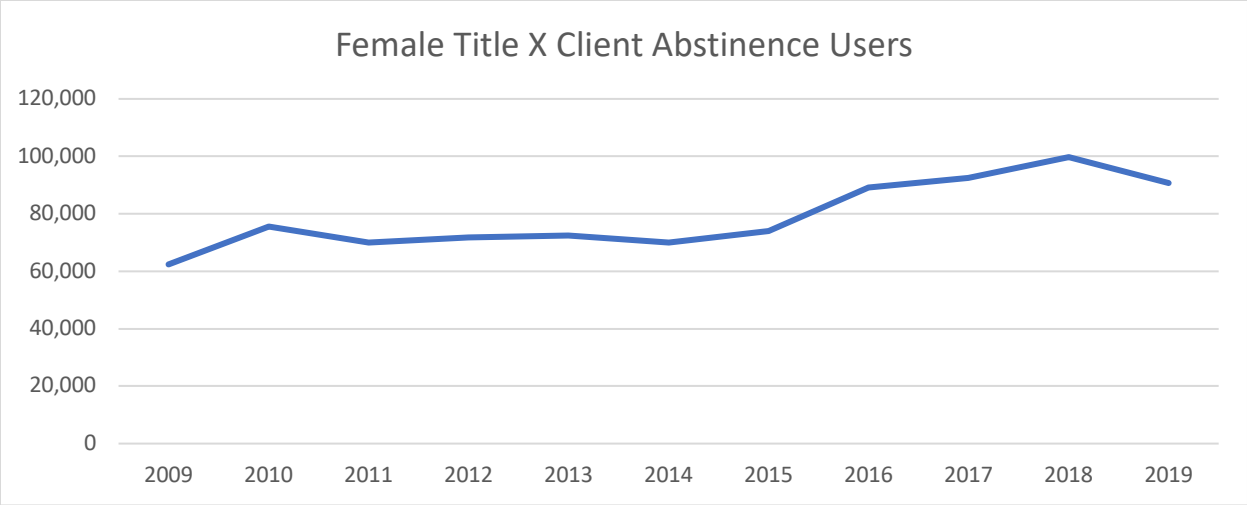
rule would require that projects "must . . . provide services in a manner that is client-centered . . . ."[43] The requirement that "client values guide *all* clinical decisions" leaves no room for Title X providers who have conscience objections to abortion counseling and referrals when their client "values" abortion. It violates conscience protection statutes. It also does not leave room for the professional medical judgment of Title X providers when the health care professional's medical judgment conflicts with their client's values. The requirement that "client values guide all clinical decisions" should be dropped from definition of "client-centered care."

Family planning services. The Department proposes several changes to the definition of "family planning services."

Abortion counseling. First, the Department proposes including "pregnancy testing and counseling" within the definition of "family planning services."[44] The proposed regulations later state in § 59.5(i) that projects *must* offer pregnancy counseling on: "(A) Prenatal care and delivery; (B) Infant care, foster care, or adoption; and (C) Pregnancy termination."[45] This redefinition of family planning services to including counseling on "pregnancy termination," a.k.a. abortion, is blatantly inconsistent with Section 1008's prohibition against abortion as a method of family planning and violates conscience protection statutes. If a Title X program refers a client for abortion, it is, in fact, a program where abortion is considered a method of "family planning." HHS can correct this error by not including abortion counseling under the definition of "family planning services" in Title X.

Abstinence. The proposed definition of "family planning services" deletes, without explanation (and thus arbitrarily and capriciously), the reference to the family planning method of "choosing not to have sex."[46] Abstinence is an important family planning method and an effective way to not have an unplanned pregnancy or get an STI, both of which Title X seeks to prevent. In fact, HHS's *Family Planning Annual Report* identified that over 90,000 females used abstinence as their primary contraceptive method in 2019.[47] Despite decrease in overall Title X clients over the last decade, the number of female clients using abstinence has generally increased.[48] See figure below.

[43] *Id.* 19829–30.
[44] *Id.* at 19829.
[45] *Id.* at 19830.
[46] 84 Fed. Reg. at 7787.
[47] OFFICE OF POPULATION AFFAIRS, U.S. DEP'T HEALTH & HUM. SERVS., Title X: FAMILY PLANNING ANNUAL REPORT: 2019 NATIONAL SUMMARY A-20 (2020), https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf.
[48] *See id.*



The removal of abstinence or "choosing not to have sex" as a family planning method undermines the purpose of Tile X to offer a broad range of effective family planning methods, and its exclusion is contrary to evidence. The phrase "choosing not to have sex" should be retained in the definition of "family planning services."

Preconception services. The Department also proposes deleting the "family planning services" definition's inclusion of "preconception counseling, education, and general reproductive and fertility health care."[49] Because no explanation is given for this deletion it is arbitrary and capricious. Preconception counseling, education, and health care helps improve maternal and infant outcomes, as well as the health of those who seek family planning services, and can help prevent diseases and future complications. The definition of "family planning services" should explicitly include a reference to preconception counseling, education, and health care. I also recommend that preconception counseling include adoption as well, as those who are not currently pregnant may also be interested in adoption as a way to grow their families.

Health equity. The Department proposes adding a definition of "health equity," which it defines as "when every person has the opportunity to attain their full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances."[50] Under the proposed rule, Title X applicants and recipients will be required to "ensure[] equitable . . . service" and will be ranked in selection for an award according to their ability "to advance health equity."[51] Applicants and recipients would thus be at risk of losing an award, or not being granted one, for failure to meet this unlawfully vague requirement. It is unclear what "full health potential" means or when it is achieved. There is no discussion in the proposed rule as to how existing Title X projects prohibit anyone from attaining, or disadvantaging them from achieving, "their full health potential" or why such a requirement is consisted with or needed to fulfill Title X's purposes. Nevertheless, under proposed § 59.5(a)(3), Title X projects would be required to provide services in a manner that "ensures equitable and

[49] 84 Fed. Reg. at 7787.
[50] 86 Fed. Reg. at 19829.
[51] *Id.* at 19830, 19832.

quality service delivery."[52] No explanation is given for how a Title X project can, in fact, ensure equity in general and specifically in a way that does not lead to actual discrimination based on a protected basis. Indeed, to the extent the requirement for equity is to be read in conjunction with a requirement for "inclusivity" (discussed below), it will violate Title VI and Section 1557 of the Patient Protection and Affordable Care Act,[53] among other civil rights laws and the Constitution, by giving certain classes of people preferential treatment. Finally, there is no discussion of the increased burden on applicants and providers to ensure equity within their programs. Moreover, the requirement that "every person ha[ve] the opportunity" conflicts with Section 1006 of Title X,[54] § 59.5(a)(6),[55] and proposed § 59.7(a)(1),[56] all of which prioritize persons from "low-income families" within the Title X program.

The definition of and requirement for "equity" should not be included in Title X regulations.

Inclusivity. The Department proposes that "[i]nclusivity ensures that all people are fully included and can actively participate in and benefit from family planning, including, but not limited to, individuals who belong to underserved communities . . . ."[57] The proposed definition then provides a list of those whom it deems are part of "underserved communities."[58] HHS, however, provides no evidence that all the communities on the list are in fact underserved and does not specify whether the communities are unserved with regards to Title X services or elsewise. In fact, according to HHS's 2019 annual report, "Title X providers serve a racially and ethnically diverse population," with 32% of Title X clients identified with a nonwhite race category, 33% self-identified as Hispanic or Latino, and 15% identified as limited English proficiency.[59]

Proposed § 59.5(a)(3) would requires that Title X projects provide services in a manner that is "inclusive."[60] But ensuring "all people" are included, can participate in, and benefit from family planning contradicts Section 1006, which states priority of services is given to "persons from low-income families,"[61] § 59.5(a)(6) requiring that clients from low-income family be given priority,[62] and proposed § 59.7(a)(1) taking into consideration the number of low-income clients to be served for Title X funding.[63] As stated above, segregation or prioritization of Title X services by protected classes such as race violates the Constitution and several civil rights laws. This definition and requirement are should not be included.

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[52] *Id.* at 19830.
[53] 42 U.S.C. § 18116.
[54] *See* 42 U.S.C. § 300a-4(c)(1).
[55] 86 Fed. Reg. at 19830.
[56] *Id.* at 19831–32.
[57] *Id.*at 19829.
[58] *Id.*
[59] OFFICE OF POPULATION AFFAIRS, U.S. DEP'T HEALTH & HUM. SERVS., Title X: FAMILY PLANNING ANNUAL REPORT: 2019 NATIONAL SUMMARY ES-3 (2020), https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf.
[60] 86 Fed. Reg. at 19830.
[61] 42 U.S.C. § 300a-4(c)(1).
[62] 86 Fed. Reg. at 19830.
[63] *Id.* at 19831–32.

The proposed rule also incorporates the list of allegedly "underserved communities" into the composition of the advisory committee in § 59.6(b)(2).[64] It should be enough for the committee to include individuals that are broadly representative in terms of demographic factors of the population or community for which the materials are intended, without including a list of assumed underserved communities. The list itself is not necessary, is not inclusive by nature of excluding certain communities, and may not be representative of the population or community to be served in terms of demographics or which communities are underserved. To the extent it results in segregation or prioritization of Title X services or committee membership by protected classes such as race, it violates the Constitution and several civil rights laws. The description of the committee composition should not be changed from the 2019 Rule and the list of allegedly underserved communities should not be included in the description.

The Department states that "to use inclusive language," it will use the word "client" in § 59.5(a)(5) to replace the word "women" and in § 59.5(a)(6) and (7) to replace the word "persons."[65] It is unclear how these changes are "inclusive" (or scientifically based). Only biological women can get pregnant, a fact HHS's regulatory impact analysis recognizes by discussing statistics involving "women served" and "women served using contraceptives."[66] The word "clients" cannot be more inclusive than "persons" as all clients are persons, but not all persons are clients.

Because HHS is concerned with issue of equity and impacts on minority communities, it would be arbitrary and capricious for HHS not to consider the impact of its proposed rule change on the number of abortions that would increase in minority populations due to the change. If HHS rejects the recommendations and retains provisions related to "equity," "inclusivity," and "underserved communities," it must analyze the impact of the proposed rule's elimination of physical and financial separation requirements on minority communities. Specifically, HHS knows that many abortion providers dropped out of the Title X program because they would not abide by the separation requirements and that abortion providers have admitted that Title X funds enabled their abortion activities. Accordingly, if HHS proceeds with the rule, it must consider the "equity" and Title VI disparate impacts of a rule that would actually result in increased abortion and concomitant reduction in the population of minority communities compared to white communities. It is incumbent upon HHS to calculate how many African-American and Hispanic babies will be aborted that otherwise would have lived to become thriving members of their communities but for the proposed rule changes. This is a real and foreseeable cost to society that must be calculated before finalizing of the rule.

Low-income family. The proposed rule's definition of "low-income family" deletes the reference in the 2019 Rule's definition to providing (only) contraceptive services to women who have "insurance coverage through an employer that does not provide the contraceptive services sought by the woman because the employer has a sincerely held religious or moral objection to providing such coverage."[67] No explanation was given for this deletion and it is thus arbitrary and capricious. Consistent with the U.S. Supreme Court decision in *Burwell v. Hobby Lobby Stores,*

[64] *Id.* at 19831.
[65] *Id.* at 19820.
[66] *Id.* at 19824.
[67] 84 Fed. Reg. at 7787.

Inc.,[68] this provision is one of the lesser restrictive means for the government to provide contraception to women directly instead of requiring employers to violate their sincerely held religious beliefs. This is a win-win solution to the government's asserted compelling interest in giving women access to contraceptives while still protecting the conscience rights of employers. It is unclear why HHS would remove this provision, unless providing contraceptives is not a compelling government interest. This provision should be retained in the definition of "low-income family."

Trauma-informed. The Department proposes adding a definition of "trauma-informed," explaining:

> a program, organization, or system that is trauma-informed realizes the widespread impact of trauma and understands potential paths for recovery; recognizes the signs and symptoms of trauma in clients, families, staff, and others involved with the system; and responds by fully integrating knowledge about trauma into policies, procedures, and practices, and seeks to actively resist re-traumatization.[69]

Proposed § 59.5(a)(3) would require Title X projects to provide services in a manner that is "trauma-informed."[70] The definition of "trauma-informed" is vague and does not specify what type of trauma Title X providers must be prepared to respond to. There was no analysis of whether existing Title X providers are trauma-informed, the increased burden on providers to become trauma-informed, or whether it will lead to providers dropping out. No evidence was provided for why such a requirement is even necessary for Title X projects and how it supports Title X's purposes. This definition and requirement should not be included.

Quality healthcare. The Department proposes adding a definition of "quality healthcare," which it defines as "safe, effective, client-centered, timely, efficient, and equitable."[71] For the reasons discussed above this definition should not include "client-centered" or "equitable."

B. Proposed Requirements

Additional project requirements. HHS complains that the 2019 Rule created burdensome requirements.[72] But the proposed rule proposes adding a number of new requirements in § 59.5(a)(3), namely that Title X services provided be "client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed" and "ensure[] equitable and quality service delivery consistent with nationally recognized standards of care."[73] Under § 59.4, grant applicants would be required to describe how the proposed project will satisfy the regulatory requirements of Title X.[74] There is no discussion in the proposed rule about the benefit of these additional requirements, how these additional requirements will impact the reporting and compliance burden estimate, how they support Title X's purposes, or whether they will lead to Title X providers dropping out of the

[68] 573 U.S. 682 (2014).
[69] 86 Fed. Reg. at 19830.
[70] *Id.*
[71] *Id.* at 19829.
[72] *See id.* at 19817, 19820.
[73] *Id.* at 19830.
[74] *Id.*

program. None of these requirements are mandated by Congress and do not support the Title X's purposes. They should be rejected.

Information and educational materials. Under addition § 59.6(b)(3)(ii) [sic] of the proposed rule, the Advisory Committee shall review the content of Title X informational and educational materials, both print and electronic, to ensure, among other requirements, that it is "inclusive and trauma informed."[75] The Department provided no analysis whether these additional broad requirements will disqualify existing Title X providers or disincentivize potential applicants and providers. The Department also does not take into account the additional resources and time an applicant or provider, much less the Advisory Committee, must undergo to certify that all Title X materials "ensure[] that all people are fully included and can actively participate in and benefit from family planning" and "fully integrat[e] knowledge about trauma into policies, procedures, and practices, and seek[] to actively resist re-traumatization."[76] This proposed requirement should be rejected.

Requiring provision of all or most family planning methods or services. The Department proposes removing the requirement in § 59.5(a)(1) that each project is "not required to provide every acceptable and effective family planning method or service."[77] The existing provision helps facilitate participation by organizations that have a conscience objection to certain Title X services, but provide excellent service in other Title X areas. No reason is given why every grantee or subrecipient should be required to provide *all* Title X services, so long as the overall Title X project offers a broad range of services. The proposed change, if adopted, will limit the diversity of partnering service providers who can increase the breadth of affiliated services for clients. It also disincentivizes the government from choosing the best qualified applicants for specific services and instead settling for a single sub-par applicant who happens to provide more services. The existing qualification provision should be retained.

IV. The Proposed Rule's Removal of Compliance Requirements Undermines Project Transparency and Accountability.

Removal of applicant and grantee compliance requirements. The Department proposes deleting multiple requirements in the 2019 Rule related to applicants' and providers' compliance:

- § 59.7(b), requiring "each applicant to describe its plans for affirmative compliance with each requirement" [78];
- § 59.11, clarifying that "concern with respect to the confidentiality of information, however, may not be used as a rationale for noncompliance with laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws" [79];

[75] *Id.* at 19831.
[76] *See id.* at 19829–30.
[77] 84 Fed. Reg. at 7787.
[78] *Id.* at 7788.
[79] *Id.*

- § 59.13, relating to assurance of compliance with prohibition on abortion as a method of family planning[80]; and
- § 59.17(b)(2), relating to maintaining records to demonstrate compliance state notification laws, including the reporting of a minor clints' age.[81]

No reason is given for deleting these requirements that applicants and providers comply with various aspects of the regulations, and it is thus arbitrary and capricious. These deletions undermine the transparency and accountability of Title X projects and limits HHS' ability to ensure oversight. The reporting requirements related to minors are especially important to protect children who are victims of sexual abuse and assault. No entity should be able to hide behind confidentiality to justify not complying with mandatory child abuse reporting requirements. I am concerned about reports of Planned Parenthood clinics not reporting multiple pregnancies and abortions in children under the age of consent. Pregnancy in any child under the age of consent for that state represents a criminal violation and harm to these children, and lack of reporting of these crimes should result in immediate loss of Title X funds. These compliance requirements should be retained.

Removal of subrecipient compliance requirements. The Department proposes deleting the 2019 Rule's § 59.1 requirement that the regulations apply to subrecipients and that grantees shall require and ensure subrecipients comply with the regulations.[82] No rationale is given for removing this requirement, rendering it arbitrary and capricious. The reporting of subrecipients, partnerships, and oversight plans is necessary to prohibit Title X recipients from ignoring the misuse of those funds by those with whom they work or funneling money to subrecipients who would otherwise be ineligible to receive Title X funds. Further, unlike the 2019 Rule, HHS's proposed addition of § 59.5(a)(13) does not specify that the regulations apply to subrecipients.[83] The removal of an explicit compliance requirement, without at minimum an explanation that subrecipients are assumed to have to comply with all Title X regulations, suggests that such compliance is no longer required. Not having such a requirement opens up the Title X program for abuse and an inability of HHS to ensure proper oversight. The subrecipient compliance requirement should be retained.

The Department also proposes removing certain requirements to report information about each subrecipient and agency or individual providing referral services, specifically the name, location, expertise, and services actually provided.[84] The rationale given is that it will "reduce" the reporting burden.[85] But the Department in § 59.5(a)(13) proposes to retain the following reporting requirements: subrecipients and agencies or individuals providing referral services and the services to be provided, the extent of the collaboration, and an explanation "of how the recipient will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients."[86] Requiring the name, location, and specific expertise of a subrecipients or referral agency or individual, and the services *actually* provided in addition to the above reporting requirements is necessary to ensure transparency, compliance, and accountability. HHS does not explain why those specifics were burdensome to report; the extent to which no longer requiring

[80] *Id.*
[81] *Id.* at 7790.
[82] *Id.* at 7786.
[83] 86 Fed. Reg. at 19831.
[84] 84 Fed. Reg. at 7788.
[85] 86 Fed. Reg. at 19820.
[86] *Id.* at 19831.

reporting on such basic information as name, location, and specific expertise, as well as the service provided, would significantly reduce the alleged burden; and why such a burden overcomes the benefits of transparency, compliance, and accountability. These reporting requirements should be retained.

Removal of family participation requirements. Section 1001 of Title X provides: "To the extent practicable, entities which receive grants or contracts under this subsection shall encourage family participation in projects under this subsection."[87] As the preamble explains,

> since FY 1998, Congress has included a rider in HHS's annual appropriations act that provides that "[n]one of the funds appropriated in this Act may be made available to any entity under Title X of the PHS Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services. . . . The same appropriations rider also requires that such an applicant certify to the Secretary that it "provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities."[88]

Yet, the Department proposes deleting the 2019 Rule requirement in § 59.5(a)(14) that Title X projects: "Encourage family participation in the decision to seek family planning services; and, with respect to each minor patient, ensure that the records maintained document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged)."[89] The proposed definition of "low-income family" likewise deletes the requirement that Title X providers document "specific actions taken by the provider to encourage the minor to involve her/his family (including her/his parents or guardian) in her/his decision to seek family planning services," except in cases of abuse or incest.[90] No reasons are given for these deletions. This is particularly concerning considering almost 1 in 5 Title X clients are adolescents, and HHS studies confirm the benefits of parent-adolescent communication in the family planning context.[91] Documentation is necessary to confirm compliance and monitor whether the needs of vulnerable minors are met. America's minors deserve no less. Since these provisions ensure a statutory requirement, have a scientific basis, and benefit minors, they should be retained. The notes of 5 U.S.C. § 601 require agencies to assess how regulatory actions impact the families, including stability, marital commitment, and parental supervision of their children, among other family impacts. The proposed rule has clear impacts on families, children, and parental rights but HHS has not conducted the required analysis.

Changes to the list of applicable regulations. The proposed rule deletes "45 CFR Part 92—Uniform administrative requirements for grants and cooperative agreements to state and local

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[87] 42 U.S.C. § 300(a).
[88] 86 Fed. Reg. at 19813 (first alteration in original).
[89] 84 Fed. Reg. at 7788.
[90] *Id.* at 7787.
[91] *See, e.g.*, Tanya M. Coakley et al., *Parent-Youth Communication to Reduce At-Risk Sexual Behavior: A Systemic Literature Review*, 27 J. HUM. BEHAV. SOC. ENVIRON. 609 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6726439/; Aletha Y. Akers et al., *Family Discussion About Contraception & Family Planning: A Qualitative Exploration of Black Parent 7 Adolescent Perspectives*, 41 PERSPECT. SEX REPROD. HEALTH 160 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2951274/.

governments" from its list of regulations that apply to Title X grants in §§ 59.9 and 59.10 of the 2019 Rule (carried over from the 2000 regulations).[92] No explanation is given for this omission or why it is not included in the proposed § 59.12, which includes a table of the appliable regulations.

The Department proposes adding 45 CFR 87 ("Equal Treatment of Faith-based Organizations") to the list of regulations that apply to Title X family planning services programs.[93] I agree with this addition. The Department, however, should also include reference to 45 CFR 88 ("Protecting Statutory Conscience Rights in Health Care; Delegations of Authority"), the conscience protection rule, which will apply to the Title X program once litigation over it is resolved favorably.

V. The Proposed Rule's Analysis of the Impact of the 2019 Rule and the Projected Impact of the Proposed Rule Is Flawed.

HHS requested public comments "that might facilitate refinement of the [financial] analysis prior to regulatory finalization."[94] I provide the following response.

Federal law requires agencies (subject to the Paperwork Reduction Act), such as HHS, to issue guidelines for "ensuring and maximizing the quality, objectivity, utility, and integrity of information" (including statistical information) disseminated in rulemaking.[95] Such standards of information quality are necessary to strengthen the accuracy and credibility of public policy. Office of Management and Budget (OMB) guidelines explain: "'Objectivity' focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased."[96] The term "utility" refers to "the usefulness of the information for the intended audience's anticipated purposes."[97] And "integrity" refers to "security—the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification."[98] The proposed rule fails to meet OMB's basic standards of objectivity, utility and integrity for the reasons detailed below (among others).

According to HHS, implementation of the 2019 Title X Final Rule prompted 18 providers (representing 19 grants and 231 subrecipients) to discontinue participation in the program, eliminating 945 Title X-funded service sites.[99] The Department contends that readoption of the 2000 regulations (with some modifications) would "strengthen the program and ensure access to equitable, affordable, client-centered, quality family planning services for all clients, especially for low-income clients."[100] In turn, the expansion of the patient base would—presumably—prevent

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[92] 65 Fed. Reg. 41280.
[93] 86 Fed. Reg. at 19820, 19832.
[94] *Id.* at 19826.
[95] *See* 44 U.S.C. § 3516; 67 Fed. Reg. 8451.
[96] 67 Fed. Reg. at 8453.
[97] *Id.*
[98] *Id.*
[99] OFFICE OF POPULATION AFFAIRS, U.S. DEP'T HEALTH & HUM. SERVS., Title X: FAMILY PLANNING ANNUAL REPORT: 2019 NATIONAL SUMMARY ES-2 (2020), https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf. Eight other agencies (representing nine grants) reached the end of their funding period.
[100] 86 Fed. Reg. at 19812.

a host of costly reproductive health conditions, thereby eliminating negative consequences and their costs to society.[101] The data upon which these and other policy conclusions are based is empirically flawed and unreliable. This undermines the Department's rationale for the proposed rule.

1. ***Ignoring benefits and assuming harms of 2019 Rule***. The proposed rule summarily states: "The 2019 Final Rule increased compliance and oversight costs, with no discernible benefit."[102] But the Department fails to explain how ensuring program integrity and statutory compliance creates "no discernible benefit." Similarly, there is no particularized analysis of the exact increase of compliance and oversight costs or what requirements in the 2019 Rule specifically created such an allegedly burdensome increase.

   To the extent there was a gap in services from Planned Parenthood and other providers dropping out mid-year, they were not forced out by HHS or the proposed Rule. They chose their abortion services over Title X services, presumably because referring clients for abortion is vital to their bottom line. HHS should not reward Planned Parenthood and other abortion providers for holding their Title X clients hostage to benefit their own financial interests.

2. ***Missing calculations.*** The Department fails to replicate the calculations used to derive its forecast of the reduced costs to taxpayers that would result from the proposed rule. In the absence of such calculations, the public is unable to judge the credibility of the policy rationale—which is the primary function of public notice and comment. HHS must "show its work."

3. ***Ignoring alternate sources of family planning services.*** The Department assumes, without sufficient evidence, that the lack of formal Title X providers and projects means that family planning services are not available to those who seek it, and as such, there will be a host of negative consequences, such as unintended pregnancies. Specifically, the Department fails to account for patients who may have received services from alternate service providers after Title X grantees (subrecipients and service sites) left the Title X program. Indeed, the proposed rule itself acknowledges that Planned Parenthood continued to provide family planning services—though not officially under the Title X project or funding—and that "a comparison of Planned Parenthood's two most recent annual financial reports [(2018–2019 and 2019–2020)] indicates no subsequent decrease in the number of patients served and an increase, from 9.8 million to 10.4 million, in the number of services provided per annum (pre-pandemic)."[103] The Department mentions that six states lost all Tile X providers when a number dropped out of the program, but there is no analysis of whether individuals in these states are able to attain family planning services outside of the Title X program, such as the case with Planned Parenthood clients.[104] Indeed, if Title X providers that refused to

[101] According to the Department, "Services of the type provided under Title X likely result in reduced costs to taxpayers as a result of a reduction in unintended pregnancies, pre-term and low-birthweight births, sexually transmitted infections, infertility, and cervical cancer. This report 49 estimates that each dollar spent on these services results in a net Government saving of $7.09." *Id.* at 19825.
[102] *Id.* at 19816.
[103] *Id.* at 19826.
[104] *Id.* at 19815.

comply with the 2019 Rule continued to provide family planning services in similar volume, despite lack of Title X funds, the end goal of the program is being met at lower cost.

4. ***Ignoring the unprecedented impact of COVID.*** The Department's analysis of the 2019 Rule brushes over the unprecedented impact of COVID-19, its attendant lockdowns and quarantine orders across the country, and the decline in "non-essential" health care services across the board. The Department merely states that the preliminary figures for FY2020 "likely represents an underestimate for a typical year of the program under the current regulations since services were likely disrupted by the ongoing public health emergency."[105] Nevertheless, the Department uses an estimate of 2,512,066 clients served as the baseline annual impact of the 2019 Title X rule "corresponds to the number of clients served in 2019 among remaining grantees as of March 2021."[106] This figure fails to account for the dramatic effects of COVID on the number of service providers as of March 2021.

   The Department used the 2020 figure as the low-bound estimate for Title X services under the 2019 Rule. At the same time the RIA plans for a "two-year phase-in" for the proposed Rule to achieve the estimated numbers and reach "long-run equilibrium estimates," it limits the 2019 Rule's impact to the partial year in which it went into effect and numerous providers dropped out mid-grant cycle and a year characterized by the COVID pandemic.[107] There is less than two years of data for the 2019 Rule and not even a year's worth of data unaffected by COVID.

   According to research by The Commonwealth Fund, "The COVID-19 pandemic has dramatically changed how outpatient care is delivered in health care practices."[108] The report states that service providers have been deferring elective and preventive visits to decrease the risk of virus transmission among patients and health care workers.[109] The researchers also documented that many patients have been avoiding clinic visits because they do not want to risk exposure.[110] "The number of visits to ambulatory practices declined nearly 60 percent by early April" 2020, according to the study.[111] Although a partial rebound has occurred, the Department's data does not account for the changes.

   Similarly, research published in the Journal of the American Medical Association documented that COVID-19 had a negative effect on 97% of 724 medical practices surveyed by the Medical Group Management Association.[112] The Texas Medical

[105] *Id.* at 19822.
[106] *Id.*
[107] *Id.* at 19822–23.
[108] Ateev Mehrotra et al., *The Impact of the COVID-19 Pandemic on Outpatient Visits: Practices Are Adapting to the New Normal*, THE COMMONWEALTH FUND (June 25, 2020), Impact COVID-19 Pandemic Outpatient Visits: Adapting New Normal | Commonwealth Fund.
[109] *Id.*
[110] Ateev Mehrotra et al., *The Impact of the COVID-19 Pandemic on Outpatient Visits: A Rebound Emerges*, THE COMMONWEALTH FUND (May 19, 2020), https://www.commonwealthfund.org/publications/2020/apr/impact-covid-19-outpatient-visits.
[111] *Id.*
[112] Rita Rubin, COVID-19's CRUSHING EFFECTS ON MEDICAL PRACTICES, SOME OF WHICH MIGHT NOT SURVIVE, J. AM. MED.ASS'N (June 18, 2020), https://jamanetwork.com/journals/jama/fullarticle/2767633.

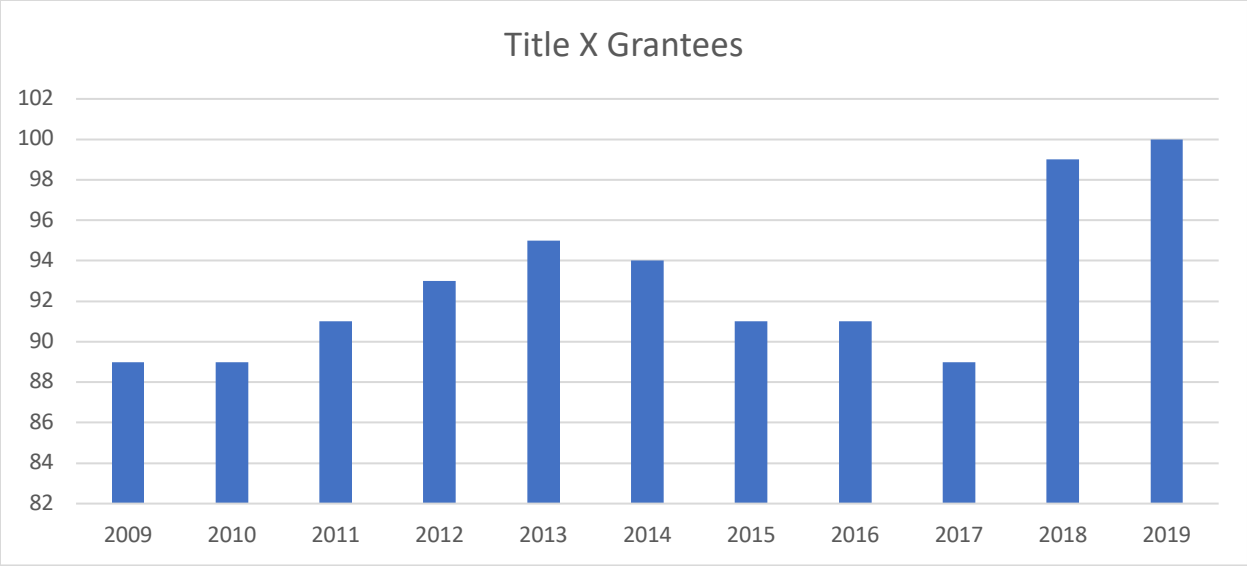
Association reported that 68% of practicing physicians in that state had cut their work hours, and state medical associations in Indiana and New York reported similar effects of the pandemic on medical practices.[113]

The Department's lack of analysis of the significant impact of COVID on health care services is glaring in light of HHS's own recognition of COVID risks and concerns. For example, on HHS's "find a family planning clinic" website, an alert bar at the top states "please call to ensure your clinic is open" with a link to COVID-19 updates.[114] Additionally, only a few days before the proposed rule was issued, on April 12, 2021, the FDA—over a year after the pandemic started—lifted the requirement that Mifepristone (the abortion pill) be dispensed in-person during the COVID-19 pandemic because it "may present additional COVID-related risks to patients and healthcare personnel."[115] If such a time-sensitive service poses such risks to patients and healthcare personnel such that it cannot be done in-person, it stands that Title X services, which are less time-sensitive (though important), are not being conducted in-person to the same extent they otherwise would be due to COVID-related risks and concerns. I urge HHS to consider the unprecedented and ongoing impact of COVID-19 on the availability of new Title X applicants and providers and the provision of Title X services in 2020 and in the future, and not attribute to the 2019 Rule that which is plainly due to COVID.

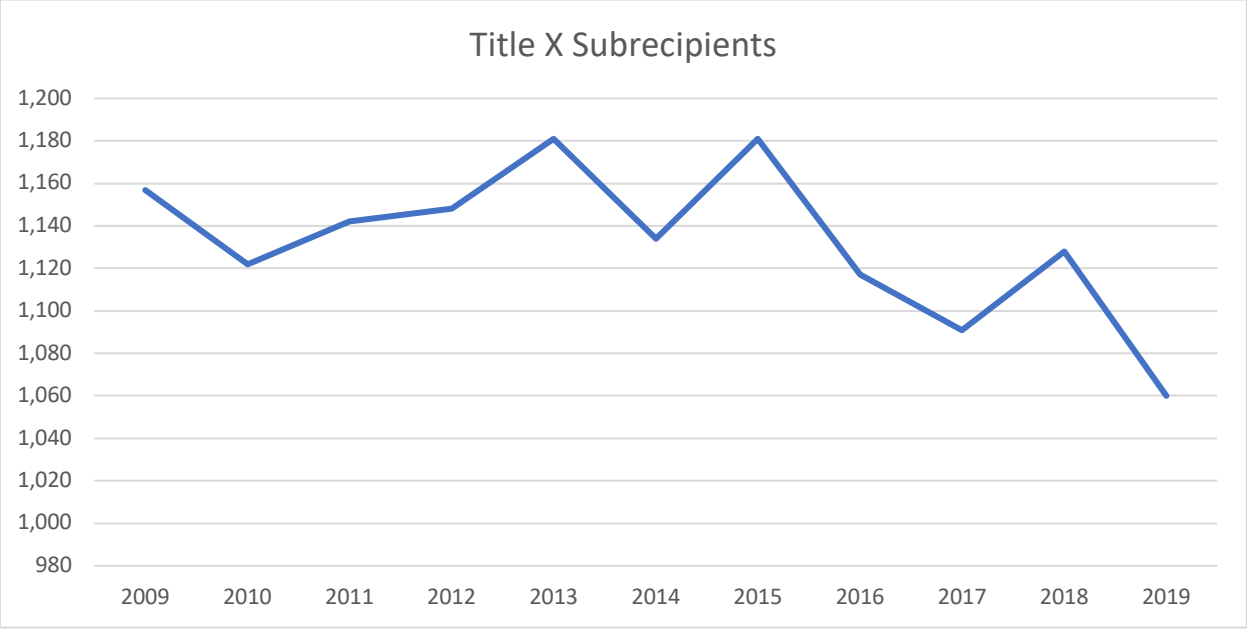
5. ***Using erroneous baseline.*** Compounding these errors, the Department adopts as its baseline (to calculate the effects of the proposed rule) various data on service provision that fails to account for either service substitutions or the pandemic. For these reasons, the Department's benefit-cost analysis is erroneous.

6. ***Ignoring long-term trends.*** The Department fails to account for long-term trends in the declining number of Title X subrecipients and service sites. Based on data from the OPA's Title X Family Planning Annual Report, the number of grantees increased by 12% between 2009 and 2019 (89 to 100).[116] See figure below.

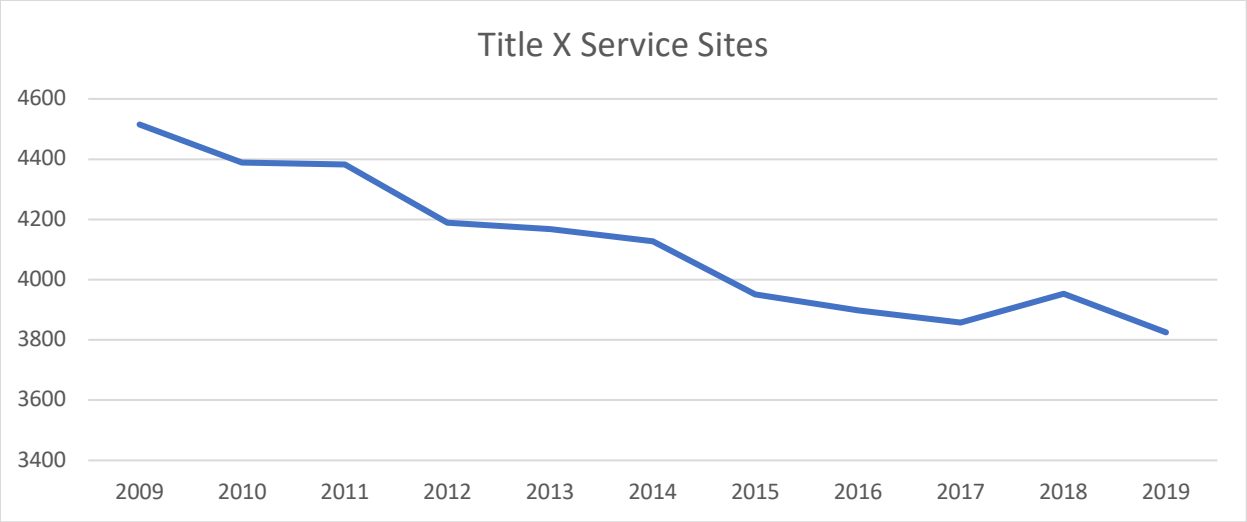
[113] *Id.*
[114] *See Clinic Locator*, HHS OFFICE OF POPULATION AFFAIRS, https://opa-fpclinicdb.hhs.gov (last visited May 17, 2020).
[115] Letter from Janet Woodcock, Acting Comm'r of Food & Drugs, U.S. Food & Drug Admin., to Maureen G. Phipps, Am. Coll. of Obstetricians & Gynecologists, and William Grobman, Society for Maternal-Fetal Med., re In-Person Dispensing Requirement in the Mifepristone REMS Program During the COVID-19 Pandemic at 2 (Apr. 12, 2021), *available at* https://www.aclu.org/sites/default/files/field_document/fda_acting_commissioner_letter_to_acog_april_12_2021.pdf.
[116] OFFICE OF POPULATION AFFAIRS, U.S. DEP'T HEALTH & HUM. SERVS., Title X: FAMILY PLANNING ANNUAL REPORT: 2019 NATIONAL SUMMARY A-2 (2020), https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf.



Despite a 12% increase in grantees during this time period (2009–2019), the number of subrecipients decreased by 8% and the number of service sites decreased by 15%.[117] See figures below.



[117] *See id.*



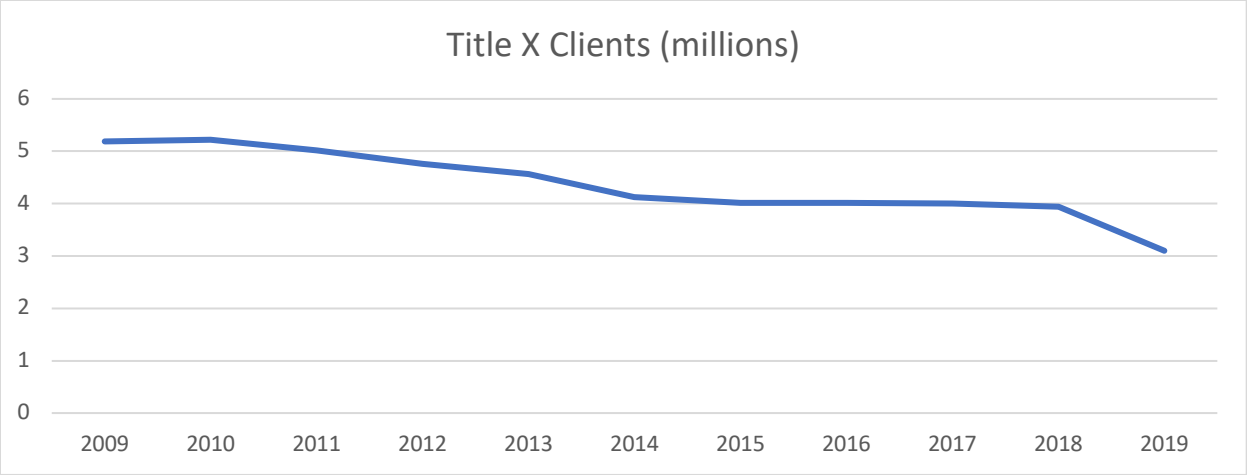
7. ***Ignoring long-term decline in Title X clients.*** The proposed rule states:

> We predict that the main effect of the proposed rule would be to return to Title X program impact levels observed prior to the 2019 Final Rule. Our estimates of the long-run equilibrium of grantees, subrecipients, service sites, and total client [sic] served are informed by the data from fiscal years 2016–2018 the last three years of data that are unaffected by the drops experienced following the 2019 Final Rule. Specifically, we adopt the average across these three years as our long-run estimates.[118]

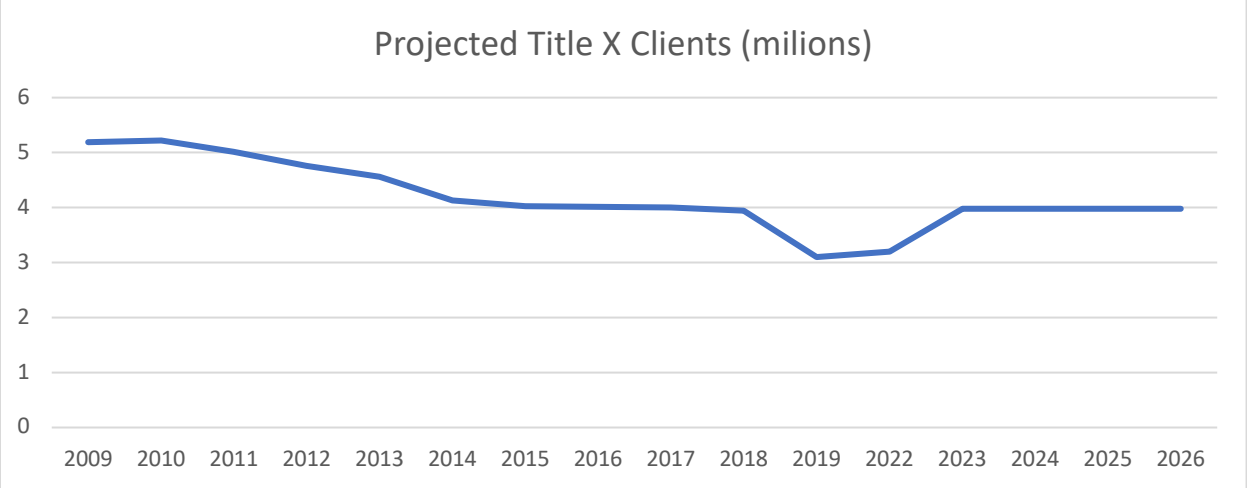
The Department assumes that an increased number of grantees and service sites will lead to increased Title X clients served and that the number of clients served from 2022 on will remain constant. But this estimate does not reflect the actual long-term trend in clients served over time, which—despite any increase in grantees or service sites—has undergone a larger decline than the three years (2016–2018) identified in the proposed rule.[119] See figure below.

[118] 86 Fed. Reg. at 19823.

[119] OFFICE OF POPULATION AFFAIRS, U.S. DEP'T HEALTH & HUM. SERVS., Title X: FAMILY PLANNING ANNUAL REPORT: 2019 NATIONAL SUMMARY A-6 (2020), https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf.



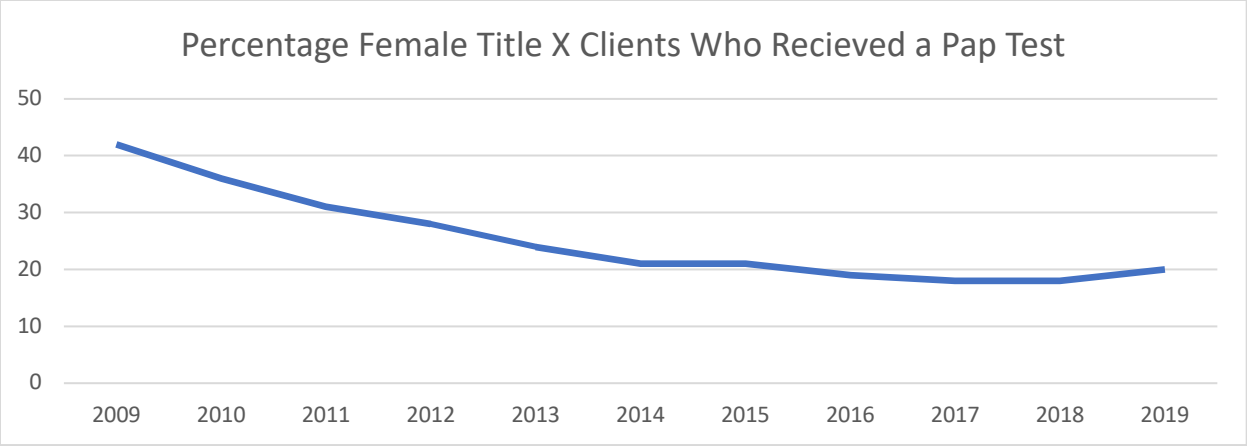
The vast majority of the decline in clients over the last decade was under the 2000 regulations that HHS wants to return to. Yet the Department provides no explanation for why the number of projected clients in years 2023–2026 will now remain at 3,983,849, and not continue the consistent downward trend of the last decade. The figure below includes the Department's projections for 2022–2026,[120] which assumes no change in the number of clients for four years running—despite the longer trend line downward of the program.



8. ***Ignoring trends in contraceptive usage and screening guidelines.*** The Department fails to account for trends in the increased use of long-acting contraceptive methods, as well as changes in cervical cancer screening guidelines that reduce the number of clinic visits. See figure below.[121]

[120] *Id.*; 86 Fed. Reg. at 19823.

[121] OFFICE OF POPULATION AFFAIRS, U.S. DEP'T HEALTH & HUM. SERVS., Title X: FAMILY PLANNING ANNUAL REPORT: 2019 NATIONAL SUMMARY A-23 (2020), https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf.



9. ***Using non-methodically valid source.*** The Department asserts that the proposed rule "would also enhance the equity and dignity associated with access to family planning services provided by Title X."[122] In support of that broad claim, the Department cites "a recent research brief . . . providing suggestive evidence that birth control has an important positive impact on women's lives."[123] The "research brief" lacks methodological validity. It simply summarizes nonrandom telephone interviews with 30 women by the Urban Institute.[124] Participants were selected based on indications that they had faced insurance- or cost-related barriers to accessing birth control and/or were concerned about their ability to pay for birth control in the coming year.[125] This source should not be relied upon by HHS.

10. ***Using outdated source based on hypothetical assumptions.*** HHS asserts that the 2019 Final Rule "may have led to up to 181,477 unintended pregnancies" as a result of the decrease in clients receiving Title X services.[126] The calculation was based on "a hypothetical scenario" devised by the Guttmacher Institute—a pro-choice research organization with ties to Planned Parenthood—that rests on complex assumptions.[127] To calculate the number of unintended pregnancies, the Institute adopted the failure rates of contraception used by women "similar" to those for whom Title X services became unavailable.[128] However, the data relate to contraception and pregnancy rates that are more than a decade old, and the proxy population did not use publicly funded contraceptive services in the prior year, but were presumed to be "likely to need them in the future."[129]

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[122] 86 Fed. Reg. at 19825.
[123] *Id.*
[124] Rebecca Peters et al., *Birth Control is Transformative*, URBAN INST., https://www.urban.org/sites/default/files/publication/99912/birth_control_is_transformative_1.pdf.
[125] *Id.*
[126] 86 Fed. Reg. at 19815.
[127] For example, failure rates were discounted based on the difference between the number of pregnancies predicted by those rates and the actual number of pregnancies experienced by all contraceptive method users in the United States in 2011—that is, a decade ago. Memorandum from Jennifer J. Frost and Lawrence B. Finer re Unintended Pregnancies Prevented by Publicly Funded Family Planning Services: Summary of Results and Estimation Formulation (updated June 23, 2017), https://www.guttmacher.org/sites/default/files/pdfs/pubs/Guttmacher-Memo-on-Estimation-of-Unintended-Pregnancies-Prevented-June-2017.pdf.
[128] *Id.* at 3.
[129] *Id.* at 2.

11. ***Assuming providers will not drop out under proposed regulations.*** The proposed rule also assumes that all the current Title X providers will remain in the program, which does not take into account those providers which joined with the advent of the 2019 Rule and may be forced out if the new regulations adopted ignore conscience rights and require abortion counseling and referrals. The Department acknowledges (only in passing) that at least seven states had a "meaningful increase" in the number of Title X clinics in their states after the 2019 Rule (CO, DE, KY, ND, NM, NV, TX),[130] but does not explain whether this increase will remain if Title X's regulations are again changed.

12. ***Erroneously attributing Planned Parenthood cost saving to the proposed rule.*** Footnote 54 of the proposed rule acknowledges that Planned Parenthood used the 2019 Rule as an effective fundraiser, demonstrating that Planned Parenthood does not need Title X taxpayer dollars to provide family planning services to its clients.[131] Shockingly, footnote 54 also states: "If funds are more efficiently gathered and distributed via a program such as Title X than through such private campaigns, the efficiency would represent a cost savings attributable to the proposed rule."[132] This is absurd. This is not a cost savings that HHS can claim as its own; the cost savings would solely be Planned Parenthood's. It is inappropriate and illegal to direct federal funds to financially benefit private interests. Their fundraising was to Planned Parenthood's own benefit, not to clients served in the Title X program. The Department provides no evidence that funds are more efficiently gathered and distributed via the government's Title X program than a private campaign. Indeed, in a private campaign funds are given directly to the organization and it cuts out costs associated with Title X applications, review, distribution, compliance, and reporting. The Department's statement is also very concerning and completely inappropriate as it prejudges that Planned Parenthood will be awarded future Title X grants, indicating that HHS will not be impartial when it comes to evaluating Planned Parenthood Title X project applications and that the aim of HHS under this administration is to fund Planned Parenthood, not further the public interest in family planning services.

VI. Conclusion

In sum, I urge HHS to withdraw proposed rule and retain the 2019 Rule. But if HHS chooses to move forward, I recommend the abovementioned changes.

Sincerely,

Rachel N. Morrison, Esq.
Policy Analyst | HHS Accountability Project
Ethics & Public Policy Center

[130] 86 Fed. Reg. at 19816, 19822 n.43.
[131] *Id.* at 19826 n.54.
[132] *Id.*