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**Via Federal eRulemaking Portal**

Secretary Alex M. Azar II  
Assistant Secretary ADM Brett P. Giroir, M.D.  
Deputy Assistant Secretary Diane Foley, M.D., FAAP  
Office of the Assistant Secretary for Health  
Office of Population Affairs  
Attention: Family Planning  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 716G  
200 Independence Avenue SW  
Washington, DC 20201

**Re: Proposed Rule: Compliance with Statutory Program Integrity Requirements  
[Department of Health and Human Services, Office of the Assistant Secretary for  
Health RIN 0937-ZA00]**

Dear Secretary Azar, Assistant Secretary Giroir, and Deputy Assistant Secretary Foley:

The State of New York appreciates this opportunity to communicate our serious concerns with the above-referenced Proposed Rule, and to urge the Department of Health and Human Services ("HHS") to withdraw the rule in its entirety. Proposed Rule: Compliance With Statutory Program Integrity, 83 Fed. Reg. 25502 (June 1, 2018), makes regulatory changes to the Title X program that, if finalized, will reduce access to family planning services and harm Title X's intended beneficiaries in order to address entirely unfounded concerns that Title X recipients are misusing funds for abortion-related services.

The Proposed Rule would, if implemented, fundamentally alter the Title X program. Among its many changes, the Proposed Rule prohibits referrals for abortions, instead only permitting Title X clinics to provide lists of comprehensive health care providers, some of which perform abortions but may not be identified as abortion providers. The Proposed Rule imposes onerous physical and financial separation requirements on Title X projects, essentially forcing any provider that includes abortion among its services to create an independent clinic for Title X

services. The Proposed Rule eliminates existing requirements that Title X projects provide nondirective pregnancy options counseling, and instead directs all patients to prenatal care. It further eliminates the requirement that Title X clinics provide FDA-approved methods of contraception. The Proposed Rule also imposes additional monitoring provisions, including requiring documentation of efforts to encourage parents or guardians to participate in adolescents' decision-making.

This rule is both unnecessary and deeply problematic. As a threshold matter, there is simply no need or justification for issuance of revised regulations aimed at ensuring compliance with Title X's statutory requirements. Robust processes are already in place to ensure compliance with the statutory program requirements, and there is ample evidence both in New York and nationally that Title X grantees are appropriately segregating their Title X services and funding as required by statute – including as required by Section 1008, which prohibits the use of Title X funds in programs where abortion is a method of family planning.

Further, the proposed changes will be harmful to patients served by the program both in New York and elsewhere: many of the changes introduced will affirmatively reduce access to care (including, but not limited to, family planning care) and interfere with the patient-provider relationship. Moreover, the proposed regulatory language is often vague and ambiguous, thereby creating confusion regarding Title X compliance rather than providing clarification.

Finally, the Proposed Rule raises several serious legal concerns. First, it exceeds the authority of HHS under Title X insofar as it regulates providers and limits access to abortion outside of the Title X program, rather than making changes necessary to ensure compliance with the Title X statute. Second, the Proposed Rule raises significant constitutional concerns, as it prevents healthcare providers from giving patients accurate medical information and burdens constitutionally-protected access to abortion. Finally, HHS has ignored the federalism impacts of this Proposed Rule and has not adequately assessed the costs that the new regulatory changes will impose on Title X patients and providers.

Over many decades, the Title X program has been a tremendously successful federal program that annually provides over four million patients – most of whom are young low-income women and girls – with low-cost and confidential access to critical healthcare services, such as screening and treatment for sexually transmitted infections, cervical and breast cancer screenings, and effective contraception methods. The Proposed Rule unnecessarily jeopardizes the success of this program. To preserve Title X's successes and protect the vulnerable populations in need of its services, the Proposed Rule must be withdrawn in its entirety.

## **I. New York's Title X Programs Successfully Provide Family Planning Services Under the Current Regulations**

### **A. Overview of Title X in New York State**

Title X is a critical source of family planning funds in New York State. HHS's Office of Population Affairs ("OPA") provides Title X funding to two New York grantees: the New York State Department of Health ("DOH") and Public Health Solutions ("PHS"), a not-for-profit organization dedicated to advancing public health in New York City. For Fiscal Year 2017, OPA provided over \$14 million in Title X funding to the State of New York, of which \$9,912,000 was allocated to DOH and \$4,617,000 was allocated to PHS.<sup>1</sup> DOH and PHS in turn provide funding to a total of 50 sub-recipients at 178 service sites across the state.<sup>2</sup> These include Family Planning Health Centers, Federally Qualified Health Centers, hospitals, local health departments, and Planned Parenthood clinics.

Nationally, in 2016 the Title X program provided \$286.5 million in funding to a total of 48 state and local health departments and 43 nonprofit family planning and community health agencies. This funding helped support 3,898 service sites across the country in providing family planning and related health services to populations that are vulnerable and often lack access to such services.<sup>3</sup> Title X projects served over four million family planning clients in 2016, 64% of whom had incomes at or below the federal poverty level, and 89% of whom were female.<sup>4</sup> These demographics mirror those in New York, where, in 2017, 305,464 patients were served through the Title X program. Of those patients, almost 90% were female, and approximately 24% were black and 34% were Hispanic. Approximately 72% of patients served by the program had an educational attainment level of 12<sup>th</sup> grade or below and approximately 61% were at or below the federal poverty level (with approximately 83% of patients at or below 250% FPL).<sup>5</sup> Title X services are estimated to have prevented 59,200 unintended pregnancies in New York State in 2015 alone.<sup>6</sup>

In New York, funding from both DOH and PHS is used to provide family planning services and outreach to communities traditionally lacking access to such services. Title X

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<sup>1</sup> HHS, Office of Population Affairs, Recent Grant Awards, <https://www.hhs.gov/opa/grants-and-funding/recent-grant-awards/index.html> (Jan. 31, 2018).

<sup>2</sup> HHS, Office of Population Affairs, *Title X Family Planning Directory* (May 2018), available at <https://www.hhs.gov/opa/sites/default/files/Title-X-Family-Planning-Directory-May2018.pdf>.

<sup>3</sup> HHS, Office of Population Affairs, *Title X Family Planning Annual Report 2016 Summary*, <https://www.hhs.gov/opa/sites/default/files/OPA-FPAR-Infographic.pdf> (last accessed July 30, 2018).

<sup>4</sup> *Id.*

<sup>5</sup> National Family Planning & Reproductive Health Association, *The Title X Family Planning Program in New York* (November 2017), available at <https://www.nationalfamilyplanning.org/file/impact-maps-2017/NY.pdf>.

<sup>6</sup> *Id.*

providers in New York provide a range of services, including general health screenings, screenings for domestic violence and depression, testing for sexually transmitted diseases, and Papanicolaou (Pap) testing. Patients also receive comprehensive counseling on a broad range of effective and medically approved family planning methods. These methods do not include abortion. Patients with a positive pregnancy test receive neutral, nondirective counseling on all pregnancy options, including adoption, continuation of the pregnancy, and termination of the pregnancy, and referrals are made as necessary.

**B. Title X Recipients and Sub-recipients are Currently Subject to Stringent Oversight to Ensure Compliance with Title X**

DOH, PHS, and their sub-recipients are subject to stringent oversight to ensure compliance with Title X's program requirements. DOH requires its Title X sub-recipients to submit annual work plans and budgets for DOH's review, which includes providing documentation sufficient for DOH to ascertain that Title X funds are not used to provide abortion services. DOH further requires sub-recipients to submit an Assurance of Compliance, wherein the sub-recipient certifies that it complies with key Title X requirements, including that it will not provide abortion as a method of family planning and will provide services without subjecting patients to any coercion to accept services or use any particular methods of family planning. DOH also maintains its own cost allocation schedules to ensure that no Title X funds are used for impermissible purposes, including the provision of abortion services.

PHS's oversight of its sub-recipients is similarly vigorous, beginning the moment the sub-recipient seeks funding. PHS's contracts with sub-recipients include a prohibition on the use of Title X funds for abortion, and receipt of funding requires a thorough review of all sub-recipients' policies. PHS also distributes an HHS-approved manual of policies and procedures to all sub-recipients and conducts on-site program reviews of each sub-recipient to ensure clinical, fiscal and administrative compliance with all Title X policies and requirements. This review includes a thorough examination of accounting procedures to ensure that Title X funds are not misused. Each sub-recipient is reviewed once during each project period.

Moreover, HHS provides grantees with numerous guidance documents to facilitate compliance, and its historic oversight and monitoring of grantees has been rigorous and searching. In 2014, OPA released updated Title X guidelines that provide detailed guidance on program compliance.<sup>7</sup> It also developed a "Program Review Tool" intended for use by OPA to assess compliance with key aspects of Title X and the newly-released guidelines, as well as by Title X grantees for self-assessment and monitoring of sub-recipients.<sup>8</sup> OPA administers this

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<sup>7</sup> Office of Population Affairs, *Program Requirements for Title X Funded Family Planning Projects* (April 2014), available at <https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf>.

<sup>8</sup> Office of Population Affairs, *Title X Program Review – Grantee Q&A* (July 14, 2016), available at <https://www.hhs.gov/opa/sites/default/files/program-review-tool-grantee-qa-vupdated-remediated.pdf>.

tool every three years, contacts grantees with findings, and monitors any required corrective action plans. This review tool specifically assesses compliance with Section 1008, with the 2017 review tool providing:

8.2: Prohibition of Abortion

Title X grantees and sub-recipients must be in full compliance with Section 1008 of the Title X statute and 42 CFR 59.5 (a)(5) which prohibit abortion as a method of family planning. Systems must be in place to assure adequate separation of any non-title X activities from the Title X project. Grantee has documented processes to ensure that they and their sub-recipients are in compliance with Section 1008. Grantees should include language in sub-recipient contracts addressing this requirement.

The HHS reviewer administering the tool must specifically assess compliance with these requirements, including that “[f]inancial documentation at service sites demonstrates that Title X funds are not being used for abortion services and adequate separation exists between title X and non-Title X activities.”<sup>9</sup>

Indeed, OPA itself reported to the Congressional Research Service (“CRS”) on the robustness of its oversight to ensure compliance with the statutory prohibition on the use of Title X funds in programs where abortion is a method of family planning. In 2017 and 2018, the CRS released reports on Title X, both of which stated that “[a]ccording to OPA, family planning projects that receive Title X funds are closely monitored to ensure that federal funds are used appropriately and that funds are not used for prohibited activities such as abortion.”<sup>10</sup> Both reports describe HHS’s “safeguards” for keeping abortion activities “separate and distinct” from Title X project activities, relying specifically on a May 1, 2017 email from HHS’s Office of the Assistant Secretary for Legislation. HHS’s identified “safeguards” include:

(1) careful review of grant applications to ensure that the applicant understands the requirements and has the capacity to comply with all requirements; (2) independent financial audits to examine whether there is a system to account for program-funded activities and nonallowable program activities; (3) yearly comprehensive reviews of the grantees’ financial status and budget report; and (4) periodic and comprehensive program reviews and site visits by OPA regional offices.<sup>11</sup>

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<sup>9</sup> *Id.*

<sup>10</sup> Angela Napili, Congressional Research Service, *Title X (Public Health Service Act) Family Planning Program*, (“2017 CRS Report”) at 22 (Aug. 31, 2017), available at <https://fas.org/sgp/crs/misc/RL33644.pdf>; Angela Napili, Congressional Research Service, *Title X (Public Health Service Act) Family Planning Program* (“2018 CRS Report”) at 16 (April 27, 2018), available at <https://fas.org/sgp/crs/misc/R45181.pdf>.

<sup>11</sup> *Id.*

None of these numerous internal and external reviews revealed evidence of misuse or co-mingling of funds. In conducting extensive reviews of its sub-recipients, DOH has never found any indication that Title X funds in New York have been used for the provision of abortion services. DOH was last monitored by HHS in September of 2017, and neither DOH nor any sub-recipients were informed by HHS that it believed DOH or its sub-recipients inappropriately co-mingled Title X funds with those used to provide abortion services or otherwise misused Title X funds (nor have they ever been so informed). Similarly, PHS has not found any indication that any Title X funds it distributed were used for the provision of abortion services. PHS was most recently inspected by HHS in Fall 2017 and was given no indication that HHS believed PHS or its sub-recipients were inappropriately using Title X funds; on the contrary, PHS received a written assessment with no adverse findings.

## **II. The Proposed Rule is Unnecessary to Protect Against Misuse of Funds**

The Proposed Rule suggests that additional regulation is necessary ensure compliance with Section 1008, which prohibits the use of Title X funds in programs where abortion is a method of family planning. However, existing regulations, guidance, and oversight have resulted in broad compliance with Section 1008, and HHS has not pointed to any evidence or findings indicating grantees or sub-grantees – including, as demonstrated in Section I, recipients in New York – are confused about compliance or are in any way misusing Title X funds for abortion-related services.

HHS's and grantees' robust oversight mechanisms and HHS's own guidance documents and review tools, described in Section I, *supra*, have resulted in widespread understanding of Title X's requirements and successful compliance by its grantees and sub-grantees – including in New York State, where grantees have successfully complied with these requirements for decades. It is presumably for that reason that HHS cites no governmental reports from the past three decades expressing any concern over misuse of Title X funds. For example, the 2017 and 2018 CRS reports did not reflect any concerns about non-compliance, nor did a 2009 Institute of Medicine report studying the Title X program, which made various recommendations for improving the program, none of which in any way addressed any potential misuse of Title X funds for abortion-related services.<sup>12</sup>

Moreover, HHS does not support its claims that Title X funds are at risk of misuse with any of its own data. As the CRS reports highlighted, HHS has access to independent financial audits, yearly comprehensive reviews of financial status and budget reports, and the findings from its own onsite program reviews. Yet despite having access to years' worth of data on compliance efforts and potential misuse or co-mingling of funds, the Proposed Rule does not

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<sup>12</sup> *A Review of the HHS Family Planning Program: Mission, Management, and Measurement of Results*, INSTITUTE OF MEDICINE, 2009, available at <https://www.nap.edu/read/12585/chapter/1>.

provide any discussion or analysis of this information and data as a basis for the proposed regulatory changes. At the very least, the Proposed Rule should be withdrawn and resubmitted only once HHS has reviewed and conducted an internal analysis of the wealth of information and data in its possession that directly bears on the subject matter of these proposed regulations.

Indeed, the Proposed Rule does not provide relevant factual support or any other substantiation for its purported concerns that Title X projects are misusing funds for non-Title X abortion-related services or otherwise co-mingling Title X and non-Title X funds. To the extent HHS cites to actual examples of improper billing under government programs, they are nearly all completely irrelevant instances of allegedly improper Medicaid billing, which has different program requirements and billing systems.<sup>13</sup> Of all the examples relied upon by HHS, only two seem to actually involve Title X – only one of which concerns abortion-related expenses and the other of which dates back to 2000.

Rather than relying on relevant examples, data, or other findings of misuse or commingling of funds to justify the regulatory changes, HHS engages in pure speculation about the possibility that Title X funds could be misused by grantees. In the Proposed Rule, HHS claims that the concern of “comingling” Title X and non-Title X funds is “particularly acute” because of reports that abortions are increasingly performed at facilities “that *could themselves be the recipients of Title X funds*.”<sup>14</sup> Clearly, the mere fact that abortion providers receive Title X funds has no bearing on whether those providers are improperly using Title X funds outside of the Title X program. Indeed, Section 1008 would only be considered necessary if providers of abortion-related services are the recipients of some of Title X’s funds. The Proposed Rule similarly relies on the irrelevant, unsupported and factually inaccurate statement: “Organizations that actively include abortions as a method of family planning have consistently received Title X funding.”<sup>15</sup> HHS has failed to identify a single Title X recipient that includes abortions as a method of family planning – which, as discussed in Section IV.A, *infra*, it is unlikely to be able to do since abortion is not considered a method of family planning by healthcare providers. Further, even if a Title X recipient *did* include abortion as a method of family planning outside of the Title X program, that would not on its own indicate any misuse of funds or otherwise justify the issuance of these regulations. The Proposed Rule also claims as justification for the Proposed Rule that the current regulations have resulted in public confusion about the scope of Title X services and whether Title X projects include abortion, without even so much as an

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<sup>13</sup> 83 Fed. Reg. at 25509. For example, HHS improperly cites New York when attempting to explain why the new regulations are necessary to protect against misuse of Title X funds, yet these alleged billing errors involved Medicaid reimbursement and are not at all analogous to Title X funding. *Id.* As HHS itself notes: “[U]nlike Title X, which is a grant program, Medicaid is a reimbursement program. By their very nature, grants afford considerably greater latitude and versatility to grantees on how funds are used.” 83 Fed. Reg. at 25508.

<sup>14</sup> 83 Fed. Reg. at 25507 (emphasis added).

<sup>15</sup> *Id.*



anecdotal example of such confusion (which would still be insufficient to justify the regulations).<sup>16</sup>

HHS's reliance on speculation concerning the potential for misuse and comingling of funds and a handful of isolated findings of allegedly improper years-old Medicaid billing demonstrate that additional relevant fact-finding should have been performed before release of the Proposed Rule, and absolutely must be performed before any final regulations are issued. HHS's failure to engage in such fact-finding, as well as its reliance on plainly irrelevant information and speculation, is a dangerous and reckless way to regulate – particularly when those regulations directly impact access to needed health care services by already vulnerable populations.

### **III. The Proposed Rule Will Harm Title X's Intended Beneficiaries: Patients**

Some of the key ways in which the Proposed Rule will harm patients by **reducing access to care** include:

- Drives providers out of the program: The proposed regulations will drive longstanding Title X providers out of the program, eliminating access to providers that have a demonstrated history of successfully providing family planning services to their communities and jeopardizing continuation of care for patients who have existing relationships with these providers through Title X. This is problematic since, “[f]or many clients, Title X providers are their only ongoing source of health care and health education.”<sup>17</sup> Many current Title X providers may decide that the regulations will compromise the quality of care provided to patients and withdraw from the program. In addition, many Title X providers offering abortion-related services outside of the project will not be able to afford the substantial costs they would have to incur in order to comply with the program integrity requirements, which will require them to create an entirely separate facility with separate personnel, medical records, and accounting records. Moreover, the “facts and circumstances” review that will determine whether a facility meets HHS’s “integrity and independence” standards is so vague and confusing that providers that perform abortion-related services outside of the Title X project will be dissuaded from even attempting to comply.<sup>18</sup> It is unlikely providers will undertake such dramatic changes to their operations when there is the very real risk that HHS would still

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<sup>16</sup> *Id.*

<sup>17</sup> HHS, Office of Population Affairs, *Title X Family Planning Annual Report, 2016 National Summary*, at ES-1 (August 2017), available at <https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf>.

<sup>18</sup> See *infra* Section IV.A.



not consider the Title X clinic sufficiently distinct because of some tenuous connection that might continue to exist with the organization's abortion-related services.<sup>19</sup>

- Reduces access to prenatal providers: Under the Proposed Rule, if a patient asks for a list of prenatal providers, that list must exclude providers *who also* perform abortions.<sup>20</sup> This requirement will unnecessarily limit the universe of providers from whom the patient can receive timely prenatal care – a universe already limited by distance, hours of service, insurance coverage/Medicaid participation, and availability to take on more patients. Patients in rural areas will be particularly impacted by this unnecessary limitation. This limit is unjustifiable, and is certainly not supported by any facts or analysis in the Proposed Rule.
- Deprives patients of evidenced-based care: The Proposed Rule eliminates the current requirement that Title X projects offer “medically approved” family planning methods. Under the current rules, all Title X projects must “[p]rovide a broad range of acceptable and effective medically [i.e., FDA] approved family planning methods.”<sup>21</sup> There is no medical or other rational basis for eliminating the requirement that Title X projects offer FDA-approved contraceptive methods, and indeed the Proposed Rule does not provide any such justification. This language change is inconsistent with OPA and the Centers for Disease Control and Protection's joint recommendations for “providing quality family planning services,” which states that “[c]ontraceptive services should include consideration of a full range of FDA-approved contraceptive methods.”<sup>22</sup> Moreover,

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<sup>19</sup> See, e.g. Nicole Knight, *To See the Potential ‘Devastating’ Effect of Trump’s Domestic Gag Rule, Look to Colorado*, REWIRE.NEWS, May 30, 2018 (reporting that, in response to Colorado’s insistence on complete separation between abortion services and Title X clinics, one woman’s health center created a separate corporation for abortion services in order to comply and another created separate entrances and waiting rooms, and yet both were *still* disqualified on the grounds of inadequate separation).

<sup>20</sup> 83 Fed. Reg. at 25531 (Proposed § 59.14) (“All other patients [who did not state an intention to have an abortion] will be provided, upon request, a list of licensed, qualified, comprehensive health service providers (including providers of prenatal care) who do not provide abortion as a part of their services.”).

<sup>21</sup> 42 C.F.R. § 59.5.

<sup>22</sup> Jami S. Leichter, et al., *Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, April 25, 2014, Providing Quality Family Planning Services[:]* Recommendations of CDC and the U.S. Office of Population Affairs at 7, available at <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>. OPA’s website still states that this document “provide[s] recommendations for use by all reproductive health and primary care providers with patients who are in need of services related to preventing or for achieving pregnancy.” HHS, OPA, *Quality Family Planning*, <https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html> (Jan. 24, 2018).

better access to effective birth control methods *reduces* rates of unwanted pregnancies, which is a core goal of providing family planning.<sup>23</sup>

The Proposed Rule would further cause harm to patients by **impairing the patient-provider relationship** in a number of different ways, including:

- Preventing providers from complying with state law requirements concerning patient care: Prohibiting Title X providers from providing meaningful referrals for abortion services undermines the patient-provider relationship by forcing providers to withhold and delay access to medically appropriate services desired by their patients. Indeed, the rule conflicts with New York State law prohibiting patient abandonment. Complying with the Proposed Rule's referral prohibition would constitute "abandoning...a patient under and in need of immediate professional care, without making reasonable arrangements for the continuation of such care..." N.Y. Educ. Law § 6530. By not being able to expressly refer patients in need of abortion care, New York doctors could be put in the position of either abandoning or neglecting patients in need of immediate medical care or violating the new Title X regulations. Abortion, by its very nature, is a time-sensitive procedure, and access to abortion becomes more difficult as weeks pass. For example, medication abortions are only available up to ten weeks of pregnancy,<sup>24</sup> and it can be harder to find a health care provider who will provide a woman with an abortion after the 12<sup>th</sup> week of pregnancy.<sup>25</sup> Moreover, it is widely recognized that while abortion is safe, there is nevertheless an increased mortality risk after the 8<sup>th</sup> week of pregnancy with the risk of complications increasing each week thereafter.<sup>26</sup> Thus, for women who have chosen to have an abortion, forcing them to delay their care needlessly increases their health risks. As set forth above, if a doctor is prevented from referring a patient to another doctor who can provide abortion services, the doctor may be deemed to have abandoned a patient in need of immediate care in violation of New York State law. As the CDC's *Providing Quality Family Planning Services* states with respect to all post-

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<sup>23</sup> See, e.g. Jeffrey F. Piepert, et al., *Preventing unintended pregnancy by providing no-cost contraception*, 120(6) OBSTET GYNECOL 1291-1297 (2012) (finding that adolescents and women at risk for unintended pregnancy had substantially lower abortion rates and teenage birth rates as compared to national rates if provided with free prescription birth control methods of their choice, particularly long-acting birth control such as IUDs and implants, and concluding: "unintended pregnancies may be reduced by providing no-cost contraception and promoting the most effective contraception methods.").

<sup>24</sup> Planned Parenthood, The Abortion Pill, <https://www.plannedparenthood.org/learn/abortion/the-abortion-pill> (last visited July 30, 2018).

<sup>25</sup> Planned Parenthood, In-Clinic Abortion, <https://www.plannedparenthood.org/learn/abortion/in-clinic-abortion-procedures> (last visited July 30, 2018).

<sup>26</sup> See, e.g. Planned Parenthood, *Abortion After the First Trimester*, [https://www.plannedparenthood.org/uploads/filer\\_public/99/41/9941f2a9-7738-4a8b-95f6-5680e59a45ac/pp\\_abortion\\_after\\_the\\_first\\_trimester.pdf](https://www.plannedparenthood.org/uploads/filer_public/99/41/9941f2a9-7738-4a8b-95f6-5680e59a45ac/pp_abortion_after_the_first_trimester.pdf) (last updated Jan. 2015).

conception care: “Every effort should be made to expedite and follow through on all referrals.”<sup>27</sup> The Supreme Court has long recognized that “[t]ime, of course, is critical in abortion,” since “[r]isks during the first trimester of pregnancy are admittedly lower than during later months.”<sup>28</sup> By intervening in the care that doctors can provide their patients in what is clearly a time-sensitive procedure, the Proposed Rule conflicts with New York state law and interferes with the patient-provider relationship.

- Forcing providers to violate professional guidelines concerning the provision of information on reproductive health and abortion: Professional medical organizations have long recognized that providing information and timely referrals for abortion if requested are part of medical professionals’ obligations to their patients. The American College of Obstetrics and Gynecologists, American Academy of Pediatrics, and Association of Women’s Health, Obstetric and Neonatal Nurses have issued statements affirming the professional obligation to provide patients with unbiased information about all available medical options and to make appropriate referrals, and further affirming that a clinician’s personal values should not interfere with patient care.<sup>29</sup>
- Compromising patients’ confidentiality and trust in Title X providers: The cumulative effect of the foregoing is that patients will no longer place their confidentiality and trust in Title X providers. If patients are not confident that they will receive counseling on and access to the most effective contraceptive options and will not receive meaningful referrals for abortions upon request, they are likely to stop seeking care with those providers. These effects will be compounded for adolescents who will be subject to more searching inquiries regarding parent or guardian participation in their decision-making (because clinicians would have to document such efforts for adolescent patients under the Proposed Rule).<sup>30</sup> As there is increased knowledge within a community about these

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<sup>27</sup> Gavin L. Moskosky, et al., *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*, Morbidity and Mortality Weekly Report, 63 Recommendations and Reports No. 4 (April 25, 2014), available at <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>.

<sup>28</sup> *Doe v. Bolton*, 410 U.S. 179, 198 (1973).

<sup>29</sup> American College of Obstetricians and Gynecologists (ACOG), *Informed Consent, Committee Opinion No. 439*, 114(2) OBSTETRICS & GYNECOLOGY 401–408 (2009), <https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Ethics/Informed-Consent>; American Academy of Pediatrics, Committee on Adolescence, *Counseling the adolescent about pregnancy options*, 101(5) PEDIATRICS 938–940 (1998), <http://pediatrics.aappublications.org/content/pediatrics/101/5/938.full.pdf>; Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN), *AWHONN position statement: Health care decision making for reproductive care*, 45(5) JOURNAL OF OBSTETRIC, GYNECOLOGIC & NEONATAL NURSING 718 (2016), [https://www.jognn.org/article/S0884-2175\(16\)30229-5/pdf](https://www.jognn.org/article/S0884-2175(16)30229-5/pdf).

<sup>30</sup> 83 Fed. Reg. at 25530 (Proposed § 59.5(a)(14)).

changes, many individuals most in need of care – particularly adolescents – will simply forego care altogether, increasing the risk of adverse health outcomes.<sup>31</sup>

As a whole, the proposed regulations will erode the quality of care provided through the Title X program and undermine the patient-provider relationships that Title X clinics have cultivated with their patients, thus compromising the program as a whole. This will have significant public health consequences. If patients are unable or unwilling to go to Title X clinics due to concerns about confidentiality, availability of effective contraception options, and unwillingness to provide meaningful abortion referrals if pregnant, they may have no other affordable options for receiving the critical family planning services funded through Title X. This could result in an increase in sexually-transmitted diseases, unhealthy pregnancies due to a delay in both preconception and prenatal care, an increase in unintended pregnancies brought to term against the wishes of the patient, and an increase in unintended pregnancies resulting in termination.

These consequences are particularly destructive because they will disproportionately impact low-income families, women, and communities of color – populations that are already vulnerable and most reliant on Title X for affordable and confidential access to family planning and related services. As set forth above in Section I, *supra*, the majority of Title X patients are low-income women: both nationally and in New York State, approximately 90% of Title X patients are female and approximately 60% are at or below the federal poverty level. In New York, approximately 58% of Title X patients are black or Hispanic. The Title X program is needed precisely because these populations are already at risk for poor health outcomes due to, among other factors, reduced access to high-quality comprehensive health care. In the United States, black women have the highest cervical cancer mortality rate of any racial or ethnic group, and therefore access the cervical cancer screenings offered through Title X clinics is absolutely critical.<sup>32</sup> The United States also has the highest rate of maternal mortality among wealthy countries, and black women’s risk of pregnancy-related death is three to four times higher than

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<sup>31</sup> Patients are less likely to seek out care if they have concerns about confidentiality, especially adolescents, resulting in worse health outcomes. See, e.g. Jami S. Leichter, et al., *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*, Morbidity and Mortality Weekly Report, 66 Recommendations and Reports No. 9 (March 10, 2017), available at <https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6609a1.pdf> (finding that “12.7% of sexually experienced youths... would not seek sexual and reproductive health care because of concerns that their parents might find out,” and further finding that “[f]emales with confidentiality concerns regarding seeking sexual and reproductive health care reported a lower prevalence of receipt of chlamydia screening (17.1%) than did females who did not cite such concerns (38.7%).”); see also Liza Fuentes, et al., *Adolescents’ and young adults’ reports of barriers to confidential health care and receipt of contraceptive services*, 62(1) JOURNAL OF ADOLESCENT HEALTH 36-43 (Jan. 2018) (finding that 18% of 15 – 17 year olds would forego sexual or reproductive health care because their parents might find out; and critically, youth from lower socioeconomic positions reported *less* concerns about confidentiality issues – possibly in part because they receive care through Title X clinics that guarantee confidential care).

<sup>32</sup> Wonsuk Yoo, et al., *Recent trends in racial and regional disparities in cervical cancer incidence and mortality in United States*, 12 PLOS ONE 2 (Feb. 2017).

that of white women.<sup>33</sup> Reducing access to comprehensive family planning services, which can facilitate healthy pregnancies by promoting the preconception health of the mother and ensuring seamless access to prenatal care, will only exacerbate this already devastating public health problem.

#### **IV. The Proposed Rule Has Numerous Fatal Drafting Deficiencies**

Not only is the Proposed Rule unnecessary and detrimental to Title X patients, but the proposed regulatory language is vague and confusing, making compliance with the regulations as drafted impossible. In particular, the Proposed Rule: (1) does not distinguish between “abortion” and “abortion as a method of family planning,” and (2) sets out circumstances under which a clinic may provide a list of abortion providers that are impermissibly vague and confusing.

##### **A. The Proposed Rule Conflates “Abortion” and “Abortion as a Method of Family Planning”**

One of the most critical flaws in the Proposed Rule is that it seems to equate all abortion – including abortion-related services occurring entirely outside of the Title X program – with “abortion as a method of family planning.”<sup>34</sup> However, providers do not consider abortion a method of family planning and do not present abortion to patients as such. And patients seeking abortions often have purposes quite separate from family planning, including preservation of their own health or avoidance of a pregnancy that is incapable of resulting in a live birth. Moreover, a patient’s motivation for seeking an abortion is deeply personal, complex, and multifaceted. There is no basis for HHS’s apparent conclusion that abortion must be construed, in all circumstances, as a method of family planning. Congress’s prohibition on using Title X funds in programs that use “abortion as a method of family planning” seemingly acknowledges as a factual matter that abortion may be used for other purposes, or may be used for family planning outside of Title X, but it may not be treated as a method of family planning that qualifies for Title X family planning funds. HHS’s improper conflation of “abortion” and “abortion as a

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<sup>33</sup> Centers for Disease Control and Prevention, *Pregnancy-Related Deaths*, <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pregnancy-relatedmortality.htm> (last updated May 9, 2018); *Focus on Infants During Childbirth Leaves U.S. Moms in Danger*, NPR (May 12, 2017), <https://www.npr.org/2017/05/12/527806002/focus-on-infants-during-childbirth-leaves-u-s-moms-in-danger>; *Black Mothers Keep Dying After Giving Birth*, NPR, <https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why>.

<sup>34</sup> Moreover, the Proposed Rule’s definition of “family planning” is logically inconsistent with the rest of the proposed regulation. The proposed definition states: “Family planning does not include postconception care (including obstetric or prenatal care) or abortion as a method of family planning.” 83 Fed. Reg. at 25529. Yet the Proposed Rule prohibits clinics from engaging in a range of activities related to “abortion as a method of family planning,” including not providing, promoting, referring for, supporting, or presenting abortion as a method of family planning. 83 Fed. Reg. at 25530. In short: as drafted, HHS is prohibiting something it has defined not to exist. This drafting error could be corrected by simply stating that abortion may not be included as a method of family planning in the Title X project.

method of family planning” is pervasive throughout the Proposed Rule, and its failure to make this critical distinction creates ambiguity and confusion about what exactly HHS believes the Proposed Rule prohibits.

A paradigmatic example appears in HHS’s estimate of the number of existing Title X clinics that would have to change their practices to comply with the new physical separation requirements. In this discussion, HHS cites the 2017 CRS report as estimating “that 10% of clinics that receive Title X funding offer abortion *as a method of family planning* separately from their Title X-funded activities.”<sup>35</sup> Yet, the 2017 CRS report cites a 2015 Guttmacher Institute survey finding that “an estimated 10% of clinics that received any Title X funding reported *offering abortions separately from their Title X project*.”<sup>36</sup> HHS simply converted “abortion separately from their Title X project” to “abortion as a method of family planning” without any recognition that they are not interchangeable. This obfuscation of “abortion” and “abortion as a method of family planning” is itself enough to necessitate withdrawal of the Proposed Rule, as it creates ambiguity about the core activity that is subject to regulation.

The Proposed Rule’s physical and financial separation requirements demonstrate how this conflation creates confusion. In the preamble, HHS states that proposed § 59.15 is intended to “create a requirement of both physical and financial separation between Title X services and any abortion services provided by the Title X grantee or subrecipient,” *and* that HHS “wishes to ensure, among other things, that there is a clear separation between Title X services and any abortion services provided by a Title X grantee or subrecipients.”<sup>37</sup> However, the preamble then states that “Proposed § 59.15 would require that Title X projects be physically and financially separate from programs in which abortion is provided or presented *as a method of family planning*.”<sup>38</sup> And indeed, the final regulatory language requires separation from an organization’s activities that would be prohibited if they were provided through the Title X program – all of which concern activities related to abortion as a method of family planning.<sup>39</sup> If a provider operates a Title X clinic that is in every way compliant with proposed §§ 59.13, 59.14, and 59.16, but, outside of the Title X program provides abortion-related services and information that *is not* for family planning purposes, such services should not have to be physically and financially separate under the text of § 59.16. However, it appears that HHS believes such separation is nonetheless required.

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<sup>35</sup> 83 Fed. Reg. at 25525.

<sup>36</sup> 2017 CRS Report at 22. Notably, the report further states that it is “unclear precisely how many Title X clinics also provide abortions through their non-Title X activities.” *Id.*

<sup>37</sup> 83 Fed. Reg. 25519.

<sup>38</sup> *Id.* (emphasis added).

<sup>39</sup> 83 Fed. Reg. at 25532 (proposed § 59.15).

Similarly, in an effort to treat all referrals for abortion as referrals for “abortion as a method of family planning,” the Proposed Rule relies on the circular reasoning that referrals within the Title X program are an “integral part of family planning,” and thus when referrals are “provided for abortion, a referral necessarily treats abortion as a method of family planning and runs afoul of the statute.”<sup>40</sup> In other words: services provided *outside* the Title X program become methods of family planning if the referral for those services came from *within* the Title X program. Yet referrals are warranted specifically because the services sought cannot be provided within the Title X program because they are *not* family planning services! Under HHS’s logic, all other referrals from a Title X clinic – such as those for prenatal care or cancer screenings – should also “run[] afoul of the statute” because the referral transforms the service into an “impermissible” family planning service.

Yet another example is that the Proposed Rule allows a Title X clinician to refuse to provide patients with a positive pregnancy test a list that includes abortion providers on the grounds that the project “does not consider abortion a method of family planning.”<sup>41</sup> This again reflects HHS’s incorrect treatment of abortion as necessarily a method of family planning. That the project does not consider abortion a method of family planning does not authorize the project to limit a patient’s medical options *outside* of the Title X program where abortion is not a method of family planning.

This inconstancy and obfuscation appear to be a deliberate attempt to regulate outside the scope of Title X. Indeed, it appears that HHS seeks to force complete separation between Title X services and a Title X recipient’s non-Title X activities and to prohibit all abortion referrals, but recognizes that it may not regulate activities outside the Title X program; it thus seeks to reach activities outside the scope of the grant through ambiguous and inaccurate regulatory language.

In the event HHS does not withdraw this rule in its entirety – which it should, for all of the other reasons outlined in this letter – it must at least be clear about what it is regulating and must not target the activities of Title X providers outside of the Title X program, as it has no legal authority to do so.

## **B. The Circumstances Under Which a Clinic May Provide a List of Abortion Providers Is Ambiguous**

The limited circumstances under which a Title X clinic can provide a list of providers that includes (without identifying) clinicians that provide abortion-related services is impermissibly vague and should be amended to permit referrals. Proposed § 59.14(a) provides: “If asked, a medical doctor may provide a list of licensed, qualified, comprehensive health

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<sup>40</sup> 83 Fed. Reg. at 25506.

<sup>41</sup> 83 Fed. Reg. at 25532.



service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care), but only if a woman who is clearly pregnant states that she has already decided to have an abortion,” and the list cannot identify which of the providers perform abortion.<sup>42</sup> HHS defends this shell game as consistent with HHS’s apparent “recogni[tion] of . . . the duty of a physician to promote patient safety.”<sup>43</sup> However, the proposed regulation does the opposite: by hiding which provider provides abortion services, patients are delayed in seeking care that is time-sensitive. Moreover, the Proposed Rule is drafted in such a manner that it is difficult to understand what exactly is required for a patient to receive this list, as well as which providers can be included on the list. Some of the questions this provision raises are:

- What must a patient ask in order to be provided with this list? Must the patient ask for a list in addition to stating a desire to have an abortion? Is a request for a referral or more information about abortion sufficient?
- Are only physicians permitted to provide this list? Are other medical providers authorized to provide referrals without having to use such a list?
- While the list itself may not identify which providers perform abortion, are clinicians barred from identifying such providers?
- Must the abortion providers eligible for inclusion offer both comprehensive prenatal care and comprehensive health services?
- If an abortion provider is legally distinct from the comprehensive health and prenatal services it previously provided in order to comply with the new regulations, may it be included on the list?

## **V. The Proposed Rule Conflicts With Title X**

### **A. The Proposed Rule Conflicts With the Title X Appropriations Language**

The Title X appropriations statute mandates, and has long mandated, that “all pregnancy counseling shall be nondirective.”<sup>44</sup>

Consistent with this statutory requirement, the existing regulations explicitly require that Title X clinics provide “neutral, factual information and nondirective counseling” on all options related to a pregnancy diagnosis, including prenatal care, adoption, and pregnancy termination.<sup>45</sup> Incredibly, the Proposed Rule actually *eliminates* this regulatory language requiring nondirective pregnancy options counseling. Moreover, while the preamble states that the Proposed Rule

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<sup>42</sup> 83 Fed. Reg. at 25531.

<sup>43</sup> *Id.*

<sup>44</sup> See Consolidated Appropriations Act, 2018, Public Law 115–141, Div. H, Title II, 132 Stat. at 716–17 (“all pregnancy counseling shall be nondirective”); Omnibus Consolidated Rescissions and Appropriations Act, 1996, Public Law 104-134, Title II, 110 Stat. 1321, 1321-221 (1996).

<sup>45</sup> 42 C.F.R. § 59.5.

permits nondirective counseling on abortion,<sup>46</sup> the proposed regulatory language provides no such protection. To the contrary, it expressly prohibits the dissemination of materials that “advocate[es] abortion as a method of family planning or otherwise promot[es] a favorable attitude towards abortion,” which apparently includes even having brochures advertising that a clinic provides abortion.<sup>47</sup>

Not only does the Proposed Rule eliminate the existing regulation’s requirement that “nondirective” counseling options be provided in order to ensure compliance with the appropriations statute, but in fact it mandates directive counseling by steering patients away from abortion through the referral provisions, the provisions prohibiting activities that “encourage, promote or advocate for abortion” – which could easily be construed as referencing abortion as a pregnancy option – and provisions permitting the withholding of information about abortion. Indeed, the Proposed Rule *requires* Title X projects to refer patients confirmed to be pregnant for prenatal and/or social services.<sup>48</sup> Further, the patient must “be given assistance with setting up a referral appointment to optimize the health of the mother and unborn child,” and “provided with information necessary to protect her child and the health of the unborn child until such time as the referral appointment is kept.”<sup>49</sup> It is hard to imagine what could be more directive than a provider giving a pregnant patient information only about prenatal care and then arranging an appointment for prenatal care with a provider that solely provides prenatal care.

As the Proposed Rule does not comply with the appropriations statute, it must be withdrawn or substantially revised.

## **B. The Proposed Rule Ignores Congressional Ratification of the Existing Rule**

As the Supreme Court has explained, “[w]here an agency’s statutory construction has been ‘fully brought to the attention of the public and the Congress,’ and the latter has not sought to alter that interpretation although it has amended the statute in other respects, then presumably the legislative intent has been correctly discerned.”<sup>50</sup>

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<sup>46</sup> 83 Fed. Reg. at 25507.

<sup>47</sup> 83 Fed. Reg. at 25532 (proposed § 59.16(a)(6)). Once again, the conflation of abortion and “abortion as a method of family planning,” fosters confusion over when Title X providers will run afoul of the new regulations. Provision of nondirective counseling on abortion necessarily includes providing information, yet the Proposed Rule prohibits making available information on abortion as a method of family planning, which HHS is incorrectly treating as inclusive of all abortion.

<sup>48</sup> 83 Fed. Reg. at 25531 (proposed § 59.14(b)).

<sup>49</sup> *Id.*

<sup>50</sup> *N. Haven Bd. of Educ. v. Bell*, 456 U.S. 512, 535 (1982) (citation omitted); *see also*, *Commodity Futures Trading Comm’n v. Schor*, 478 U.S. 833, 846 (1986) (“It is well established that when Congress revisits a statute giving rise to a longstanding administrative interpretation without pertinent change, the ‘congressional failure to revise or repeal the agency’s interpretation is persuasive evidence that the interpretation is the one intended by Congress.’”) (citation omitted).

Such is the case here. Congress has appropriated funds for Title X every year since the statute was passed. For more than two decades, Title X projects had the ability to make referrals for abortion and to share physical space with clinics that provided abortion as long as all funds were kept separate. Indeed, Congress appropriated the funds as recently as 2018, and Rep. Tom Cole commented that he was glad that the appropriations bill maintained “all existing pro-life provisions, including the Hyde Amendment . . . the Dickey-Wicker amendment . . . and the Weldon amendment.”<sup>51</sup>

This overall history of funding provides evidence that Congress has implicitly ratified the existing regulations ensuring compliance with Section 1008, without concern that Title X programs referred for abortions when appropriate or that existing separation requirements were inadequately safeguarding against misuse and comingling of funds.

## **VI. The Proposed Rule Infringes Upon Patients’ and Providers’ Constitutional Rights**

In addition to harming the patients the program is intended to serve in order to solve problems HHS has not actually determined exist, the Proposed Rule also interferes with the constitutional rights of both patients and providers participating in the Title X program.

First, the Proposed Rule impermissibly regulates physicians’ speech in violation of the First Amendment. The Proposed Rule would make it impossible for physicians providing care through Title X to do their job by imposing content-based restrictions on their private, professional speech.<sup>52</sup> Specifically, the regulations would restrict clinicians’ ability to provide information about abortion and abortion referrals as appropriate and necessary – even when the information and referral is *not* to provide family planning options but rather to present *pregnancy options* for referrals to care outside of the Title X clinic. The recent Supreme Court case *NIFLA v. Becerra* described the danger that content-based restrictions pose in a medical context, with Justice Thomas writing:

Moreover, this Court has stressed the danger of content-based regulations “in the fields of medicine and public health, where information can save lives.” *Sorrell, supra*, at 566.

The dangers associated with content-based regulations of speech are also present in the context of professional speech. As with other kinds of speech, regulating the content of professionals’ speech “pose[s] the inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to suppress unpopular ideas or information.” *Turner Broadcasting*, 512 U. S., at 641. Take medicine, for example. “Doctors help patients make deeply personal decisions, and their candor is crucial.” *Wollschlaeger v. Governor*

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<sup>51</sup> Congressional Record – House, March 22, 2018, H1875 (Title X funding appropriation language); H2025 (Rep. Cole’s comments), <https://www.congress.gov/crec/2018/03/22/CREC-2018-03-22-pt1-PgH1769-2.pdf>.

<sup>52</sup> See, e.g. *Legal Services Corp v. Velazquez*, 531 U.S. 533, 542-544 (2001).

*of Florida*, 848 F. 3d 1293, 1328 (CA11 2017) (en banc) (W. Pryor, J. concurring). Throughout history, governments have “manipulat[ed] the content of doctor-patient discourse” to increase state power and suppress minorities . . . <sup>53</sup>

Here, the Proposed Rule goes beyond regulating the family planning options that can be presented to a patient, and seeks to regulate how providers refer patients *out* of the Title X program in a manner that is explicitly content-based by distinguishing referrals for abortion services from all other referrals for post-Title X medical care.

Moreover, the Proposed Rule creates an undue burden on access to abortions, as patients who receive family planning services at a Title X clinic will, under the best of circumstances, receive a largely useless list from which they must attempt to track down an abortion provider before it is too late to receive an abortion at all. Under any circumstances – i.e., whether patients request an abortion referral or not – patients will be actively diverted away from abortion as a pregnancy option, and their ability to access an abortion at all may ultimately be dictated by whether they went to a Title X provider. Such government interference with a woman’s ability to access abortions is an “undue burden” under *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992).

While the federal government cannot be forced to fund abortion services, it also may not withhold funding because of an organization’s abortion-related activities performed entirely outside of the Title X program. The Proposed Rule goes far beyond limiting use of Title X funds and instead imposes “conditions that seek to leverage funding to regulate speech outside the contours of the program itself.”<sup>54</sup> In doing so, it infringes upon the constitutional rights of both providers and patients.

## **VII. HHS Has Not Conducted the Federalism and Economic Analyses Required to Promulgate the Proposed Rule**

In proposing these dramatic and onerous changes to the Title X program, HHS has failed to perform any federalism analysis, as required by Executive Order 13132, and its economic analysis is wholly inadequate and does not meaningfully or accurately consider many of the costs that will be incurred by patients and providers as a result of the regulatory changes.

First, HHS erred in concluding that it need not conduct any analysis of the federalism impacts, as required by Executive Order 13132, on the grounds that the Proposed Rule “does not contain policies that have federalism implications.”<sup>55</sup> The Proposed Rule forces participating providers to choose between complying with the new grant terms or state laws regulating the practice of medicine. Further, state and local governments are themselves grantees and/or sub-

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<sup>53</sup> *NIFLA v. Becerra*, No. 16-1140, Slip Op. at 12 (2018).

<sup>54</sup> *Agency for International Development v. Alliance for Open Society International*, 570 U.S. 205, 214-15 (2013).

<sup>55</sup> 83 Fed. Reg. at 25521-25522.

grantees *and*, separately, may be forced to shoulder additional costs for providing access to the services formerly provided through Title X and for the public health costs associated with reduced access to the screenings and family planning services that Title X clinics provided. The mere fact that the regulation concerns a federal grant program is insufficient grounds for an agency to excuse itself from the Executive Order's requirements. HHS should collaborate with the states to ensure state laws governing the practice of medicine and safeguarding the patient-provider relationship are not impaired through the revised Title X regulations, as well as to address the costs to the states.

Second, the Proposed Rule fails to comply with the requirement that federal agencies accurately assess the costs and benefits of their proposed regulations. Specifically, Executive Orders 12866 and 13563 require agencies to "assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits."<sup>56</sup> Executive Order 12866 requires that a "significant regulatory action" comply with additional regulatory requirements.

While the Proposed Rule provides an "analysis of economic impacts," this analysis does not address the cost to patients at all, and provides no substantiation for its estimates of the financial impact on affected providers, particularly with respect to the costs of complying with the physical separation provisions. Astonishingly, HHS estimates, without any support, that "an average of between \$10,000 and \$30,000, with a central estimate of \$20,000, would be incurred to come into compliance with the physical separation requirements" in the first year following the rule.<sup>57</sup> However, for a provider that performs abortion-related services entirely outside of the Title X program to comply with the new regulations, it would be required to, at a minimum, establish separate examination and waiting rooms, office entrances and exits, phone numbers, email addresses, educational services, and websites, as well as ensure separate personnel, electronic or paper-based health care records, and workstations. Such providers will effectively have to open a second clinic that does not share any of the same overhead services with its principal location in order to obtain Title X funding. It is a preposterous assumption this would cost at most \$30,000, as the actual number could easily be hundreds of thousands of dollars for a single provider. HHS must conduct an analysis of the estimated cost associated with each of the physical and financial separation requirements that it seeks to impose through the new rule and provide the supporting data and figures used to reach those cost estimates.

Additionally, the Proposed Rule does not provide an economic analysis for other changes imposed by the rule that will necessarily have a financial impact on Title X providers. For example, the requirements for additional documentation in electronic health record systems (such as those for adolescent visits) would alone require a systems update that could cost \$10,000 –

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<sup>56</sup> 83 Fed. Reg. at 25521.

<sup>57</sup> 83 Fed. Reg. at 25525.

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which is not accounted for at all in this analysis.<sup>58</sup> Similarly, its proposed definition change to “low income family” to include any woman, regardless of income, who is unable to receive contraceptive coverage as a result of HHS’s separate regulations restricting insurance coverage for contraception is not accounted for. This change will inevitably increase costs for Title X providers tasked with providing low-cost or cost-free contraception, yet the Proposed Rule does not address this cost.

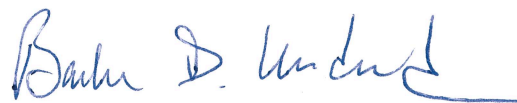
The failure to quantify the costs to patients and clinics not only reflects HHS’s failure to engage in reasoned decision-making in issuing the Proposed Rule, but also hinders meaningful comment on the proposal, as it is impossible to accurately weigh the costs against the purported benefits of the regulatory changes.

### **VIII. Conclusion**

We urge HHS to reconsider issuance of this regulation for the reasons outlined herein. While Section 1008 undeniably prohibits the use of Title X funds in programs where abortion is a method of family planning, HHS uses that limited statutory provision as a vehicle for broadly regulating the availability of abortion-related services, information, and referrals outside of the Title X program and far beyond what is reasonably necessary or justified to ensure compliance with Section 1008. HHS may not leverage its rulemaking authority to issue regulations that effectuate policy changes outside the scope of the program it is charged with administering, yet that is what it does in this Proposed Rule: effectuate abortion-related policy goals outside of the Title X program.

In its effort to regulate beyond its scope of authority, HHS has issued a Proposed Rule that is unnecessary, not informed by any relevant fact-finding, harmful to Title X patients, impermissibly confusing and vague, contrary to law, unconstitutional, and lacking critical federalism and economic analyses. For any one of these reasons alone, the Proposed Rule is fatally deficient and must be withdrawn.

Sincerely,



Barbara D. Underwood  
Attorney General of the State of New York

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<sup>58</sup> Robin Summers, *Analysis of 2018 Proposed Title X Regulation*, Nat’l Family Planning & Reproductive Health Ass’n, at 18 n. 69 (July 5, 2018), available at <https://www.nationalfamilyplanning.org/file/documents---policy--communication-tools/NFPRHA-Title-X-NPRM-Analysis-FINAL.pdf>.