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July 31, 2018

**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  
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: HHS-OS-2018-0008, Comments on Proposed Rule: *Compliance With Statutory Program Integrity Requirements*, Docket No.: HHS-OS-2018-0008**

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

The undersigned, Attorneys General for the States of Washington, Oregon, and Vermont and the Commonwealth of Massachusetts, respectfully urge the Department of Health and Human Services (the Department) to withdraw its Proposed Rule: *Compliance with Statutory Program Integrity Requirements*, 83 Fed. Reg. 25,502 (June 1, 2018). We have grave concerns with the legality of the proposed rule, and do not believe it would survive judicial review in its current form.

The Title X family planning program was created to provide access to high-quality family planning and related preventive health care for low-income and underserved individuals. The proposed rule has a host of legal flaws. In some states, if implemented, it will eliminate from the Title X program many Title X providers and leave thousands of residents without reasonable options for critical family planning services. In other states, it will frustrate the ability of providers to deliver high-quality and complete care to their patients and will undermine the efficacy of the network as a whole. The proposed rule thus frustrates rather than promotes the purposes of Title X. The proposed rule shifts the burden and costs to the states, including myriad reproductive health services related to unintended pregnancies, treatment of sexually transmitted infections (STIs), cervical and breast cancer screening and treatment, and other public health

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services that the Title X program currently covers. The public health impact will fall the heaviest on our States' most vulnerable populations – including low-income and rural women and families, immigrants and people of color that the program is intended to help.

Further, the proposed rule requires directive counseling, which is in violation of a federal statute governing Title X.<sup>1</sup> It illegally injects the government into the Title X medical examination room, and it violates the constitutional rights of providers and patients under the First and Fifth Amendments. The proposed rule also violates the Department's current statutory interpretation of "acceptable and effective family planning methods and services" without mentioning the current interpretation or the evidence justifying it. Various parts of the rule are unsupported by any evidence and are thus arbitrary and capricious. Finally, the proposed rule violates Executive Orders 12866 and 13562.

**A. Relevant Background of Title X to the Public Health Service Act, 42 U.S.C. §§ 300-300a-6**

The Family Planning and Services Population Research Act of 1970, which added Title X to the Public Health Service Act, authorizes the Secretary of Health and Human Services:

to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services . . . .

42 U.S.C. § 300(a).

Title X projects serve an estimated four million women annually.<sup>2</sup> In 2015, 64 percent of U.S. counties had at least one safety-net family planning center supported by Title X, and 90 percent of women in need of publicly funded family planning care lived in those counties.<sup>3</sup> Title X clients are among the nation's most vulnerable populations: two-thirds have incomes at or below the Federal Poverty Level (FPL)(\$20,090 for a family of three in 2015), nearly half are uninsured—even after implementation of the Affordable Care Act's (ACA) major insurance

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<sup>1</sup> Public Law No. 115-141, § 118, <https://www.congress.gov/bill/115th-congress/house-bill/1625/text>.

<sup>2</sup> Fowler CI et al., Family Planning Annual Report: 2015 National Summary, Research Triangle Park, NC: RTI International, 2016, <http://www.hhs.gov/opa/sites/default/files/title-x-fpar-2015.pdf> (last accessed 7/17/18).

<sup>3</sup> Frost JJ and Zolna MR, Response to inquiry concerning the availability of publicly funded contraceptive care to U.S. women, memo to U.S. Senator Patty Murray, Senate Health, Education, Labor and Pensions Committee, New York: Guttmacher Institute, May 3, 2017, <https://www.guttmacher.org/article/2017/05/guttmacher-murray-memo-2017> (last accessed 7/17/18).

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expansions—and another 35 percent have coverage through Medicaid and other public programs.<sup>4</sup>

In 2015, the contraceptive care delivered by Title X–funded providers helped women avoid 822,000 unintended pregnancies, which would have resulted in 387,000 unplanned births and 278,000 abortions.<sup>5</sup> Without the contraceptive care provided by these health centers, the U.S. rates of unintended pregnancy and abortion would have been 31 percent higher, and the teen unintended pregnancy rate would have been 44 percent higher.<sup>6</sup> Title X is a vital program, especially for low-income women and teens as:

access to and consistent use of the most effective contraceptive methods are not enjoyed equally by all U.S. women. Disparities in contraceptive use are a major reason why half of U.S. pregnancies—3.2 million each year—are unplanned. . . . [U]nplanned and teen pregnancies occur disproportionately to poor women (those with incomes below the federal poverty level), whose unplanned pregnancy rate is five times that of higher income women.<sup>7</sup>

Concern for low-income women led President Nixon to push for national family planning assistance in the 1960s, stating that “unwanted or untimely childbearing is one of the several forces which are driving many families into poverty or keeping them in that condition.”<sup>8</sup> That remains a driving concern today. Studies have shown that access to family planning assistance makes it more likely that a teen will graduate high school, that a woman will achieve her educational and career goals, and that a woman will earn more money (positively impacting not only her life, but the lives of her family).<sup>9</sup> Access to family planning also leads to healthier

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<sup>4</sup> Fowler CI et al., Family Planning Annual Report: 2015 National Summary, Research Triangle Park, NC: RTI International, 2016, <http://www.hhs.gov/opa/sites/default/files/title-x-fpar-2015.pdf> (last accessed 7/17/18).

<sup>5</sup> Frost JJ, et al., Publicly Funded Contraceptive Services at U.S. Clinics, 2015, New York: Guttmacher Institute, 2017, <https://www.guttmacher.org/report/publicly-funded-contraceptive-services-us-clinics-2015> (last accessed 7/17/18).

<sup>6</sup> Hasstedt K, Why We Cannot Afford to Undercut the Title X National Family Planning Program, Guttmacher Institute, Jan. 30, 2017, <https://www.guttmacher.org/gpr/2017/01/why-we-cannot-afford-undercut-title-x-national-family-planning-program> (last accessed 7/17/18).

<sup>7</sup> Adam Sonfield, *What Women Already Know: Documenting the Social and Economic Benefits of Family Planning*, Guttmacher Institute (Mar. 2013), available at <https://www.guttmacher.org/gpr/2013/03/what-women-already-know-documenting-social-and-economic-benefits-family-planning>.

<sup>8</sup> Special Message to the Congress on Problems of Population Growth (Jul. 18, 1969), available at <http://www.presidency.ucsb.edu/ws/?pid=2132>.

<sup>9</sup> Adam Sonfield et al., *The Social and Economic Benefits of Women’s Ability To Determine Whether and When to Have Children*, Guttmacher Institute, available at <https://www.guttmacher.org/report/social-and-economic-benefits-womens-ability-determine-whether-and-when-have-children>, and Staff of J. Economic Comm., 114<sup>th</sup> Cong. *The Economic Benefits of Access to Family Planning*, available at

relationships, better health outcomes, and better parenting.<sup>10</sup> Title X is critical in assuring that teens and low-income women can achieve these same positive outcomes.

For many women, a visit to a family planning provider is about far more than birth control. During a visit for contraceptive services at a Title X site, women commonly receive other preventive sexual and reproductive health services, including preconception health care and counseling, STI testing and treatment, human papillomavirus (HPV) vaccinations, cancer screening, Pap tests for early detection of cervical cancer, and referrals for mammograms. Title X providers also screen for a host of other potential health issues, such as high blood pressure, diabetes, and depression, connecting clients to further care when needed.<sup>11</sup> For four in 10 women who obtain their contraceptive care from a safety-net family planning center that focuses on reproductive health, that provider is their only source of care.

Title X improves the health of our States' residents beyond helping them plan for their pregnancies. In 2010, the services provided within the Title X network prevented 87,000 preterm or low-weight births, 63,000 STIs and 2,000 cases of cervical cancer.<sup>12</sup>

**B. Title X Is a Critical Program That Provides High-Quality Care To Thousands of Residents of Washington, Massachusetts, Oregon, and Vermont Every Year.**

1. *Washington*

The Washington State Department of Health (DOH) is the sole grantee of Title X funds in Washington State and runs the program. Washington's current grant project period is one year and six months and ends August 31, 2018.

Washington's Title X expenditure for 2017 was approximately \$13 million. The state-funded amount was approximately \$9 million, and the federally funded amount was approximately \$4 million.

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[https://www.jec.senate.gov/public/\\_cache/files/d0a67745-74ff-439c-a75a-aacc47e0abc1/jec-fact-sheet---economic-benefits-of-access-to-family-planning.pdf](https://www.jec.senate.gov/public/_cache/files/d0a67745-74ff-439c-a75a-aacc47e0abc1/jec-fact-sheet---economic-benefits-of-access-to-family-planning.pdf).

<sup>10</sup> *Id.*

<sup>11</sup> Frost JJ, Gold RB and Bucek A, Specialized family planning clinics in the United States: why women choose them and their role in meeting women's health care needs, *Women's Health Issues*, 2012, 22(6):e519–e525, [http://www.whijournal.com/article/S1049-3867\(12\)00073-4/pdf](http://www.whijournal.com/article/S1049-3867(12)00073-4/pdf) (last accessed 7/17/18).

<sup>12</sup> Sonfield A, Beyond preventing unplanned pregnancy: the broader benefits of publicly funded family planning services, *Guttmacher Policy Review*, 2014, 17(4):2–6, <http://www.guttmacher.org/gpr/2014/12/beyond-preventing-unplanned-pregnancy-broader-benefits-publicly-funded-family-planning> (last accessed 7/17/18). 2010 is the most recent year for which these data are available.

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Washington served 91,284 patients through Title X in 2017, with 128,296 patient visits. In 2017, 57 percent of Washington's Title X-funded patients were at or below the FPL, and 81 percent had incomes below 200 percent of the FPL. Sixteen percent of Title X clients were women of color. Nine percent of patients were under the age of 18. The DOH projects that Title X services prevented 16,233 unintended pregnancies in 2017; the resulting cost savings for Title X services (including STI, HIV, HPV, and Pap tests) was \$113,434,910.

DOH distributes Washington's Title X funds by an approved allocation process. DOH broadly distributes information about an upcoming competition for Title X funds toward the end of the project period. It conducts a formal Request for Proposals process to select providers. After the due date for proposals is past, they are reviewed by objective reviewers and scored on criteria that includes choosing the entities that can best utilize the available funding to carry out Title X requirements.

In addition to Title X funds, Washington separately funds contracted Title X health care providers for Title X-allowable services. Further, some Medicaid providers in Washington offer Title X-allowable services but are not Title X projects. The funding from Title X and Medicaid is separate and distinct. However, if an entity receives Title X funding, all clients that have received services according to Title X guidelines are counted as Title X clients in the data system regardless of their funding source.

There are 12 Title X sub-grantee agencies with 70 clinic sites across Washington State. Five of the 12 agencies that receive Title X funds in Washington perform abortions outside of the Title X project. There are several counties in Washington that only have one Title X provider, including Clallam, Grays Harbor, Pacific, Kitsap, Wahkiakum, Lewis, Thurston, Mason, Jefferson, Whatcom, Skagit, Clark, Skamania, Kittitas, Chelan, Ferry, Pend Oreille, Whitman, and Walla Walla. All sites have physicians on staff as medical directors, but nurse practitioners primarily provide care to patients. All sites have nurse practitioners accessible during all business hours.

Washington subjects Title X providers to numerous contractual requirements. These include: (1) they must be non-profit agencies; (2) they must be able to meet reporting requirements (including the ability to extract data from their Electronic Medical Records system to report to the contracted data vendor); (3) they must follow all regulations; (4) they must be able to separate abortion activities from Title X funding; and (5) they must have qualified personnel and licensed providers.

## 2. *Massachusetts*

Approximately \$6,155,000 in Title X funding flows into Massachusetts annually. These funds support, either directly or indirectly, 90 family planning providers. In 2016 alone, Title X

providers in Massachusetts served 66,072 people.<sup>13</sup> Data from fiscal year 2017 shows that 88 percent of all Title X visits were made by female patients, 50 percent of all patients were between 18 and 29 years old, and 88 percent of all patients were at or below 200 percent of the FPL.

Title X providers in Massachusetts offer a wide range of services and care, including pregnancy testing and options counseling; contraceptive services and supplies; pelvic exams; screenings for cervical and breast cancer; screenings for high blood pressure, anemia, and diabetes; screenings and treatment for STIs; infertility services; health education; and referrals for other health and social services. These services not only have a profound and positive impact on patients' lives, but also save Massachusetts and the federal government money. In fact, according to one estimate, Title X services save Massachusetts and the federal government approximately \$140 million per year in Massachusetts alone.<sup>14</sup> Beyond the significant fiscal impact, the services provided have a real and profound impact on the lives of Massachusetts women and their families. In 2014, Title X-funded centers met 15 percent of all contraceptive needs in Massachusetts<sup>15</sup> and helped avert 13,600 unintended pregnancies.<sup>16</sup>

Title X funds are crucial and must be spent wisely. Programs that currently receive these funds do so in a culturally competent and welcoming manner. They offer an array of services. They understand the health needs of their patients. The proposed rule does not advance Title X's purpose and undermines the ability of its recipients to do the important work that they do every day on behalf of some of Massachusetts' most vulnerable patients.

### 3. *Oregon*

The state of Oregon has been the umbrella grantee for Title X services throughout Oregon since 1970. The Oregon Health Authority's Reproductive Health Program administers the state's Title X grant. In fiscal year 2018, Oregon's Title X award was \$3,076,000. This funding provides direct support to a network of 35 agencies with 106 clinic sites and is comprised of local public

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<sup>13</sup> *Title X in Massachusetts: Improving Public Health and Saving Taxpayer Dollars*, National Family Planning & Reproductive Health Association, at 1 (Dec. 2017), available at <https://www.nationalfamilyplanning.org/file/state-snapshots-2017/Massachusetts.pdf>.

<sup>14</sup> *Contraception, Cost Savings at Title X-Funded Centers: From Contraceptive Services*, Guttmacher Institute Data Center, <https://data.guttmacher.org/states/table?state=MA&dataset=data&topics=96> (last visited July 30, 2018).

<sup>15</sup> *Contraception, Title X-Funded Centers: Percentage of Need Met By Title X-Funded Centers*, Guttmacher Institute Data Center, <https://data.guttmacher.org/states/table?state=MA&dataset=data&topics=257> (last visited July 30, 2018).

<sup>16</sup> *Contraception, Outcomes Averted By Title X-Funded Centers: From Contraceptive Services*, Guttmacher Institute Data Center, <https://data.guttmacher.org/states/table?state=MA&topics=120&dataset=data> (last visited July 30, 2018).

health authorities, federally qualified health centers (FQHCs), Planned Parenthood clinics, rural health centers, and other community health centers. Almost every county has at least one Title X Program provider, often with multiple clinic sites per provider.

A total of 37,012 unduplicated clients were served by Title X sub-recipient clinics in 2017. Of these clients, 15,225 (41 percent) were uninsured, meaning they have limited options for accessing affordable reproductive health services.

Oregon's Title X clinics provide essential, high-quality preventive reproductive health services to underserved individuals. Data from 2017 show that of the 37,012 clients served by Oregon's Title X clinics:

- 93 percent were female;
- 47 percent were females between the ages of 18 and 29;
- 95 percent were at or below 250 percent of the FPL and 66 percent were at or below 100 percent of the FPL; and
- 60,647 clinic visits were provided, including:
  - 6,511 cervical cancer screenings
  - 49,366 STI screenings
  - 12,649 annual/well-woman exams

Further evidence of the high quality of care in Oregon's Title X clinics comes from clients themselves. According to Oregon's 2015 Reproductive Health Client Satisfaction Survey, 99 percent of clients reported the following: that medical staff respected their values, they trust the medical staff to help them make decisions, and they would recommend the clinic to friends or family.

In addition to offering high quality care, Oregon's Title X program is also cost effective. In 2017, over 6,000 unintended pregnancies were averted through the provision of effective contraceptive methods and high-quality counseling services in Oregon's Title X clinics. Using a conservative estimate of \$16,000 for an average delivery and the first year of infant health care under Oregon's Medicaid program, even if less than half of these 6,000 unintended pregnancies resulted in births, the savings to the state were in excess of \$40 million in taxpayer funds in Oregon alone in 2017.

#### 4. *Vermont*

The Vermont Department of Health, the sole grantee for Vermont, has relied on Title X grant funding for decades. The Vermont Department of Health receives about \$775,000 annually from Title X, of which the majority is passed on directly to the sole sub-grantee, Planned Parenthood of Northern New England (PPNNE). With these funds, PPNNE provides reproductive health

services at 10 different clinics located throughout Vermont. These clinics serve a largely rural population—none are located in Chittenden County, the most populous county of Vermont.

Through these clinics, Title X provided family planning services to 9,808 Vermonters in 2016. Of these, 44 percent reported income of less than 100 percent of the FPL, and 76 percent had income less than 250 percent of the FPL. Vermont’s Title X patients were 11 percent male, and 20 percent were under age 20. And 22 percent had no health insurance.<sup>17</sup>

Services provided by Title X funds in Vermont include “a broad range of family planning and related preventive health services for Vermont women, men, and their partners.”<sup>18</sup> As required in 42 C.F.R. Part 59, all pregnancy counseling at Title X clinics in Vermont is nondirective.<sup>19</sup> In addition, Title X funds provided “patient education and counseling; breast and pelvic examinations; breast and cervical cancer screening according to nationally recognized standards of care; STI and Human Immunodeficiency Virus (HIV) prevention education, counseling, testing and referral; and pregnancy diagnosis and counseling.”<sup>20</sup>

Title X funding has been an essential part of the success that Vermont has seen in reproductive health outcomes over time. For example, while the current Title X rules and program have been in place, the number of teen pregnancies in Vermont has steadily declined.<sup>21</sup> And, the number of teen abortions occurring in Vermont has steadily declined.<sup>22</sup> This is consistent with the overall drop in abortion rates in Vermont and nationwide.<sup>23</sup> Title X-specific analyses show that these trends over time are at least partly attributable to Title X funding. One estimate shows that approximately 1900 unintended pregnancies were averted by Title X-funded clinics in Vermont

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<sup>17</sup> Office of Population Affairs, Title X Family Planning Annual Report: Vermont (April 2017) (on file with Vermont Attorney General’s Office).

<sup>18</sup> Office of Population Affairs, Program Review: Title X Family Planning Project: Vermont Department of Health, 1, 33 (May 2017) (on file with Vermont Attorney General’s Office).

<sup>19</sup> *Id.* at 34-35.

<sup>20</sup> *Id.* at 1.

<sup>21</sup> Kathryn Kost et al., *Pregnancies, Births and Abortions Among Adolescents and Young Women in the United States, 2013: National and State Trends by Age, Race and Ethnicity*, 36 (Guttmacher Inst. Aug. 2017) (data going back to 1988), available at [https://www.guttmacher.org/sites/default/files/report\\_pdf/us-adolescent-pregnancy-trends-2013.pdf](https://www.guttmacher.org/sites/default/files/report_pdf/us-adolescent-pregnancy-trends-2013.pdf)

<sup>22</sup> *Id.* at 40.

<sup>23</sup> Vt. Dept. of Health, “Fig. 11: Vermont and U.S. Abortion Ratios 1980 – 2016,” *2016 Vital Statistics: 132nd Report Relating to the Registry and Return of Births, Deaths, Marriages, Divorces, and Dissolutions*, 129 (Agency of Human Servs. 2016) (data going back to 1980), available at <http://www.healthvermont.gov/sites/default/files/documents/pdf/Vital%20Statistics%20Bulletin%202016.pdf>



in 2014.<sup>24</sup> Of those, 400 would have been teen pregnancies.<sup>25</sup> In addition, Title X's successes have not been limited to pregnancy outcomes. Although Title X is not the only public health program addressing these issues, cervical cancer rates<sup>26</sup> and new HIV/AIDS diagnoses<sup>27</sup> in Vermont have been generally declining as well. In 2016, Title X clinics screened 1,344 clients for cervical cancer and 2,834 clients for HIV.<sup>28</sup>

The successes of the Title X program translate from public health to the public fisc. By one estimate, Title X services in Vermont saved the state and federal governments \$7,868,000 in 2010.<sup>29</sup> Of that money, the majority (\$7,520,000) was saved in annual maternity and birth-related costs as a result of contraceptive services.<sup>30</sup> An additional \$215,000 was saved in annual miscarriage and ectopic pregnancy costs.<sup>31</sup> Tens of thousands of dollars in public health costs were saved from STI and cancer screening at Title X clinics.<sup>32</sup>

### C. The Fatal Deficiencies in the Proposed Rule

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<sup>24</sup> *Number of Unintended Pregnancies Averted by Title X-Funded Centers*, Data Ctr., Guttmacher Inst., <https://data.guttmacher.org/states/table?state=VT&topics=114> (last visited July 30, 2018).

<sup>25</sup> *Number of Unintended Pregnancies Averted to Clients Aged <20 by Title X-Funded Centers*, Data Ctr., Guttmacher Inst., <https://data.guttmacher.org/states/table?state=VT&topics=114> (last visited July 30, 2018).

<sup>26</sup> Vermont Cancer Registry, *HPV Associated Cancers—Data Brief*, 1 (Vt. Dept. of Health May 2018) (data going back to 1994), available at [http://www.healthvermont.gov/sites/default/files/documents/pdf/stat\\_cancer HPV Assoc Ca Data Brief.pdf](http://www.healthvermont.gov/sites/default/files/documents/pdf/stat_cancer HPV Assoc Ca Data Brief.pdf).

<sup>27</sup> Decrease seen since the height of the epidemic, and the introduction of the first effective treatments, in the early 1990s. Vt. Dept. of Health, "History of the HIV/AIDS epidemic, Vermont residents at diagnoses 1984 – 2014," *Vermont HIV/AIDS Annual Report*, 2 (May 2015), available at [http://www.healthvermont.gov/sites/default/files/documents/pdf/ID\\_HIV\\_surveillance\\_Vt%20HIV%20Annual%20Rep%202014.pdf](http://www.healthvermont.gov/sites/default/files/documents/pdf/ID_HIV_surveillance_Vt%20HIV%20Annual%20Rep%202014.pdf); see also Vt. Dept. of Health, *2016 Vermont HIV Annual Report*, 2-3 (May 2018), available at [http://www.healthvermont.gov/sites/default/files/documents/pdf/ID\\_HIV\\_VermontHIVAnnualReport2016.pdf](http://www.healthvermont.gov/sites/default/files/documents/pdf/ID_HIV_VermontHIVAnnualReport2016.pdf).

<sup>28</sup> Office of Population Affairs, *Title X Family Planning Annual Report: Vermont*, 10, 13 (April 2017) (on file with Vermont Attorney General's Office).

<sup>29</sup> *Total Annual Gross Savings from Services Provided During Family Planning Visits at Title X-Funded Centers*, Guttmacher Institute Data Center, <https://data.guttmacher.org/states/table?state=VT&topics=98> (last visited July 30, 2018).

<sup>30</sup> *Annual Maternity and Birth Related Costs (Through 60 Months) Saved from Contraceptive Services*, Guttmacher Institute Data Center, <https://data.guttmacher.org/states/table?state=VT&topics=96> (last visited July 30, 2018).

<sup>31</sup> *Annual Miscarriage and Ectopic Pregnancy Costs Saved from Contraceptive Services*, Guttmacher Institute Data Center, <https://data.guttmacher.org/states/table?state=VT&topics=96> (last visited July 30, 2018).

<sup>32</sup> *Annual Costs Saved From Chlamydia, Gonorrhea and HIV Testing at Title X-Funded Centers; Annual Costs Saved from Pap and HPV Testing at Title X-Funded Centers*, Guttmacher Institute Data Center, <https://data.guttmacher.org/states/table?state=VT&topics=97> (last visited July 30, 2018).

1. *The proposed rule requires directive counseling in violation of the Consolidated Appropriations Act, 2018.*

In numerous ways, the proposed rule imposes unethical requirements to provide directive, mandatory patient counseling. This is contrary to the Consolidated Appropriations Act, 2018, which states that, with respect to the amounts appropriated “for carrying out the program under title X of the PHS Act to provide for voluntary family planning projects, . . . all pregnancy counseling shall be nondirective.”<sup>33</sup> While Congress is free to “make a value judgment favoring childbirth over abortion,”<sup>34</sup> once Congress makes a policy choice executive agencies are not at liberty to ignore it. Here Congress has required that counseling of patients using Title X funds may not be slanted, and HHS may not direct Title X providers to disregard Congress’s directive.

The proposed rule requires Title X funds be used for directive counseling in several ways. First, the rule prohibits Title X providers from referring a patient who discovers she is pregnant to abortion providers, except in the narrow circumstances where the patient “clearly states” that she has “already decided” she will have an abortion.<sup>35</sup> Of course, such a “clear decision” for someone who learned minutes earlier that she was pregnant would be unlikely, meaning the vast majority of patients will be referred away from abortion providers. Second, providers are prohibited from even “present[ing]” the option of abortion. Third, providers must refer patients for “appropriate prenatal and/or social services (such as prenatal care and delivery, infant care, foster care, or adoption)” whether or not the patient desires such referrals.<sup>36</sup> Fourth, providers are required to assist in setting up these referral appointments—unless the patient wants an abortion.<sup>37</sup> In short, if a pregnant patient says that she wants advice on birth or adoption options the provider is unencumbered, but if she wants to discuss the option of abortion, the provider may not assist her. Only if the patient states she wants an abortion may the provider offer her a list that includes abortion providers, but that list must obfuscate which clinics offer what she seeks and which do not.<sup>38</sup>

These provisions are intended to, and do, slant Title X counseling against termination and in favor of childbirth, in violation of Congress’s directive otherwise. Indeed, the text of the proposed rule says nothing about nondirective counseling, instead eliminating the former

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<sup>33</sup> Pub. L. No. 115-141, div. H, tit. II, 132 Stat. 348, 716 (2018), <https://www.congress.gov/bill/115th-congress/house-bill/1625/text>.

<sup>34</sup> *Rust v. Sullivan*, 500 U.S. 173, 192 (1991) (quoting *Maher v. Roe*, 432 U.S. 464, 474 (1977)).

<sup>35</sup> 83 Fed. Reg. 25,531 (proposed § 59.14(a), (c)).

<sup>36</sup> 83 Fed. Reg. 25,531 (proposed § 59.14(b)).

<sup>37</sup> *Id.*

<sup>38</sup> 83 Fed. Reg. 25,531 (proposed § 59.14(c)).

requirement to provide “neutral, factual information and nondirective counseling . . .” 42 C.F.R. 59.5(a)(5)(ii). Through the repeal of the nondirective counseling requirement and the addition of severe restrictions on referrals, the proposed rule seeks to replace what has been a patient-guided, provider-informed approach to care with a system that jeopardizes both providers’ ethical obligations and patients’ health.

2. *The proposed rule illegally injects the government into the provider-patient relationship.*

We are deeply troubled by the Department’s proposed government interference in the relationship between a medical provider and a patient, and not only because it violates a federal law. The proposed rule purports to tell providers paid with Title X funds what they can and cannot say when a patient discovers she is pregnant. The government should have no role telling a health care provider what to say to a patient. Here, the proposed rule prohibits nurses and nurse practitioners, who see the majority of Title X patients, from mentioning abortion, and doctors may do so only in the very limited circumstances permitted in proposed section 59.14(c) and (d).<sup>39</sup> Under the proposed rule, Title X providers could not simply take off their “Title X hats” and offer the same nondirective advice that they currently offer because the rule would require Title X providers to comply with Title X requirements, whether or not Title X funds a particular patient’s service.

As America’s women’s health providers have jointly stated in opposing the proposed rule, “[p]oliticians have no role in picking and choosing among qualified providers.”<sup>40</sup> This government script for providers when addressing their Title X patients violates the American Medical Association’s Code of Ethics, which states that “withholding information without the patients’ knowledge or consent is ethically unacceptable.”<sup>41</sup> Similarly, the Code of Ethics for Nursing requires nurses to give complete – not slanted – information to patients.<sup>42</sup>

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<sup>39</sup> 83 Fed. Reg. 25,531.

<sup>40</sup> “America’s Women’s Health Providers Oppose Efforts to Exclude Qualified Providers from Federally-Funded Programs,” Join Statement of the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the American College of Nurse-Midwives, the American College of Physicians, the Association for Physician Assistants in Obstetrics and Gynecology, the National Association of Nurse Practitioners in Women’s Health, Nurses for Sexual and Reproductive Health, and the Society for Adolescent Health and Medicine (May 23, 2018), <https://www.acog.org/About-ACOG/News-Room/Statements/2018/Health-Providers-Oppose-Efforts-to-Exclude-Qualified-Providers-from-Federally-Funded-Programs> (last accessed on July 17, 2018).

<sup>41</sup> American Medical Association, Code of Medicaid Ethics Opinion 2.1.3, Withholding Information from Patients, available at <https://www.ama-assn.org/delivering-care/withholding-information-patients> (last accessed on July 17, 2018).

<sup>42</sup> Code of Ethics for Nursing, Provision 1.4, [www.bc.edu/content/dam/files/schools/son/pdf2/ANA\\_code\\_of\\_ethics.pdf](http://www.bc.edu/content/dam/files/schools/son/pdf2/ANA_code_of_ethics.pdf) (last accessed on July 17, 2018) (patients must be given “accurate, complete, and understandable information in a manner that facilitates an informed decision”).

Further, the proposed rule is arbitrary and capricious because it only permits “a medical doctor” to provide the very limited referral for abortion the proposed rule allows.<sup>43</sup> In our States, this severely restricts the nondirective counseling Title X patients would receive. In Oregon, for example, over 93 percent of visits to Title X clinics in 2017 were conducted by non-physician caregivers such as nurse practitioners and physician assistants. The preamble to the proposed rule itself recognizes that only 22 percent of clinical service FTEs delivered to Title X patients were provided by medical doctors.<sup>44</sup> As a result, the proposed rule would prevent 78 percent of the medical professionals who see patients at Title X providers from providing even the limited and intentionally obfuscated abortion referral it claims to authorize. The Department does not explain why prohibiting such a large percentage of Title X caregivers from providing any kind of counseling on the legally available option of abortion comports with the statutory requirement that Title X funds be used only for nondirective counseling, and we request such an explanation.

The proposed rule’s roadblocks for a patient seeking complete and accurate health information also are arbitrary and capricious. First, the patient must already know that she wants an abortion. This precludes the patient from engaging in an important conversation with her health care provider about the pros and cons of abortion. The Department fails to address the fact that many women do not ask directly about abortions immediately upon learning they are pregnant, and instead consider it as one of many medical options. We ask that the Department explain how its proposed restrictions can be reconciled with this experience of clinicians. Second, only a doctor can give the patient the referral list. This appears designed to undermine the provision of healthcare. Moreover, it is not clear what, if any, counseling a physician is entitled to provide to a woman who has decided to have an abortion given that the proposed rules prohibit providers from “promot[ing]” and “support[ing]” abortion as a method of family planning. Limiting the medical information that physicians can offer their patients unreasonably intrudes upon the physician-patient relationship and undermines ethical standards of care.

The preamble to the proposed rule relies on “Federal conscience statutes” to justify its diverging from the requirement in the Consolidated Appropriations Act that Title X-funded counseling must be nondirective.<sup>45</sup> This reliance is misplaced. The proposed rule does not merely create an exception to nondirective counseling for conscience objectors. Instead, it allows conscience objectors to dictate what all Title X providers may say. Purportedly to uphold conscience protections, the proposed rule prohibits nearly 80 percent of the medical professionals who treat patients at Title X clinics from saying anything about abortion, regardless of their religious or moral beliefs. Likewise, it severely restricts the information medical doctors can impart, again regardless of their religious or moral convictions. In doing so, it makes no accommodation for providers who have religious or moral convictions contrary to the proposed rule, for instance

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<sup>43</sup> 83 Fed. Reg. 25,531 (§ 59.14(a); *see also*, § 59.14(c)).

<sup>44</sup> 83 Fed. Reg. 25,523.

<sup>45</sup> 83 Fed. Reg. 25,506-507.

those whose convictions align more closely with professional ethics rules. These prohibitions go substantially further than necessary to vindicate a select number of providers' conscience objections, and we ask the Department to better explain its reasoning.

3. *The proposed rule is contrary to, and ignores, the Department's authoritative recommendations for evidence-based "family planning methods and services" without reason or explanation.*

A federal agency cannot simply ignore its prior statutory interpretations. This is especially true where, as here, the prior interpretation is based on factual findings or cited evidence, and the new interpretation fails to consider that evidence. "[T]he consistency of an agency's position is a factor in assessing the weight that position is due." *Good Samaritan Hospital v. Shalala*, 508 U.S. 402, 417 (1993). "To be sure, the requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it is changing position." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

In 2014, the Department's Centers for Disease Control and Prevention (CDC) issued a Recommendations and Report entitled "Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs."<sup>46</sup> The report provided the agency's view on what are "acceptable and effective family planning methods and services."<sup>47</sup> The CDC stated:

This report provides recommendations developed collaboratively by CDC and the Office of Population Affairs (OPA) of the U.S. Department of Health and Human Services (HHS). The recommendations outline how to provide quality family planning services, which include contraceptive services, pregnancy testing and counseling, helping clients achieve pregnancy, basic infertility services, preconception health services, and sexually transmitted disease services. The primary audience for this report is all current or potential providers of family planning services, including those working in service sites that are dedicated to family planning service delivery as well as private and public providers of more comprehensive primary care.<sup>48</sup>

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<sup>46</sup> Gavin, L, Moskosky, S, Carter, M, Curtis, K, Glass, E, Godfrey, E, Marcell, A, Mautone-Smith, N, Pazol, K, Zapata, L, "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> (last accessed July 19, 2018) (hereinafter "CDC Report and Recommendations").

<sup>47</sup> 42 U.S.C. § 300(a).

<sup>48</sup> CDC Report and Recommendations at 1.

The report provided “recommendations for how to help prevent and achieve pregnancy, emphasize[d] offering a full range of contraceptive methods for persons seeking to prevent pregnancy, highlight[ed] the special needs of adolescent clients, and encourage[d] the use of the family planning visit to provide selected preventive health services for women, in accordance with the recommendations for women issued by the Institute of Medicine and adopted by HHS.”<sup>49</sup> In other words, it was a careful, evidence-based description of the best practices for family planning in the United States.

Without explanation, the proposed rule contradicts this report in numerous ways, and it does so without mentioning the report. The CDC report’s “recommendations support offering a full range of Food and Drug Administration (FDA)-approved contraceptive methods,”<sup>50</sup> while the proposed rule eliminates “medically approved” from the requirement that projects provide a broad range of family planning methods.<sup>51</sup> The CDC report advocates a “[c]lient-centered approach” where the patient is offered a “broad range of contraceptive methods so that clients can make a selection based on their individual needs and preferences,”<sup>52</sup> while the proposed rule offers Title X funds to a clinic that chooses to offer only a single method of family planning.<sup>53</sup> The CDC report states that a provider, after administering a pregnancy test, should present “options counseling” and “appropriate referrals,”<sup>54</sup> while the proposed rule mandates concealing the full range of options available to the patient, including abortion, and directs omitting abortion providers from referral lists.<sup>55</sup> These changes undermine long-held, evidence-based standards of care.

The Department fails to explain why it is rejecting its own recommendations expressly “based on scientific knowledge.”<sup>56</sup> Indeed, it fails even to acknowledge the existence of those

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

<sup>50</sup> CDC Report and Recommendations at 2.

<sup>51</sup> 83 Fed. Reg. 25,530 (proposed § 59.5).

<sup>52</sup> CDC Report and Recommendations at 2.

<sup>53</sup> 83 Fed. Reg. 25,530 (proposed § 59.5). Without doubt, the proposed regulations’ emphasis on fertility awareness-based methods of family planning over all other forms of contraception will result in increased numbers of unintended pregnancies, including teen pregnancies. Table 3-2, Contraceptive Technology, <http://www.contraceptivetechnology.org/wp-content/uploads/2013/09/CTFailureTable.pdf> (last visited July 30, 2018) (listing a 24% failure rate for typical use of fertility awareness-based methods, compared to a less than 10% failure rate for typical use of hormonal contraceptives and less than 1% failure rate for long-acting reversible contraceptives).

<sup>54</sup> CDC Report and Recommendations at 14.

<sup>55</sup> 83 Fed. Reg. 25,531 (proposed § 59.14).

<sup>56</sup> CDC Report and Recommendations at 4.

recommendations. The proposed rule lacks the “reasoned analysis” the Department concedes is required.<sup>57</sup>

4. *The financial separation requirement reverses a prior agency interpretation and is unsupported by any evidence.*

The proposed rule imposes a new requirement of physical separation between Title X projects and the abortion activities of the Title X grantee/sub-recipient.<sup>58</sup> This requirement reverses the Department’s prior interpretation, is imposed without supporting evidence, and does not reflect agency consideration of substantial evidence contradicting the Department’s conclusion.

The proposed rule reverses the Department’s longstanding interpretation that, “[i]f a Title X grantee can demonstrate [separation] by its financial records, counseling and service protocols, administrative procedures, and other means. . . ., then it is hard to see what additional statutory protection is afforded by the imposition of a requirement for ‘physical’ separation.”<sup>59</sup> The Department states that this reversal is necessary to avoid the risk of (i) intentional or unintentional use of Title X funds for impermissible purposes or the commingling of funds, and (ii) public confusion that Title X funds being used by a family planning organization may be supporting the program’s abortion activities.<sup>60</sup>

Despite the need for *evidence* to justify an agency’s reversal of course, the preamble to the proposed rule cites no evidence of commingled funds or public confusion. The preamble states that the Department’s concerns are “acute” because, according to a Guttmacher Institute report, the percentage of “nonspecialized clinics” such as doctors’ offices accounting for abortions performed in the United States inched up 6 percent from 2008 to 2014, which may increase the risk of confusion and misuse of Title X funds.<sup>61</sup> However, the Department has no evidence that any of these nonspecialized clinics receive Title X funds. The Guttmacher Institute itself noted that the data its report relied on included inaccuracies and out-of-date information.<sup>62</sup> This is the only evidence the Department cites of potential public confusion and commingling of funds, yet

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<sup>57</sup> 83 Fed. Reg. 25,505.

<sup>58</sup> 83 Fed. Reg. 25,532 (proposed § 59.15).

<sup>59</sup> Standards of Compliance for Abortion Related Services in Family Planning Services Projects, 65 Fed. Reg. 41,270, 41,276 (Jul. 3, 2000).

<sup>60</sup> 83 Fed. Reg. 25,507.

<sup>61</sup> *Id.*

<sup>62</sup> Jones, RK, Jerman, J, Abortion Incidence and Service Availability In the United States, 2014, Guttmacher Institute Perspectives on Sexual and Reproductive Health (March 2017) (“Limitations”), <https://www.guttmacher.org/journals/psrh/2017/01/abortion-incidence-and-service-availability-united-states-2014> (last accessed July 18, 2018).



it evinces no actual *use* of Title X funds.<sup>63</sup> In fact, unlike the Title X regulations proposed in 1988—which relied in part on two reports, one from the Department’s Office of Inspector General (OIG) and the other from The General Accounting Office—the Department currently points to no reports or relevant evidence as justification for the proposed rule.

The Department fails to cite its own safeguards it already has in place to ensure that Title X funds are kept separate from abortion-related services. “According to [the Office of Population Affairs], 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>64</sup> These “[s]afeguards to maintain this separation 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 non-allowable 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>65</sup> Despite this thorough monitoring, the Department fails to provide any evidence of actual threats to Title X funding and instead relies on reports from the 1980s, old Medicaid audits, and unsupported assertions.

The Department’s monitoring has been thorough. For example, the 2017 OPA Program Review Report for the Vermont Department of Health found the following:

Financial 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. (42 C.F.R. § 59.5(a)(5))

#### REVIEW OF EVIDENCE

The grantee does not provide abortion services. However, the sub-recipient does provide these services. The sub-recipient has established policies, procedures, and practices to ensure the adequate separation of Title X activities from non-Title X activities. Staff separates their time, after the fact, into clearly defined cost centers in the TimeForce system. This is done each day, is checked by the site supervisor,

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<sup>63</sup> In a separate part of the preamble addressing the purported need for monitoring of the use of Title X funds, the Department cites a Washington Medicaid Fraud Control Unit investigation. 83 Fed. Reg. 25,509. The Medicaid Fraud Control Unit is part of the Washington Attorney General’s Office. Our investigation found that the individuals reporting the alleged violations relied only a newsletter sent out by American Life League and had no additional information or any firsthand knowledge, the state Medicaid agency auditor did not see any indication of fraudulent billing, and there was no pattern of intentional billing misconduct.

<sup>64</sup> Angela Napili, Cong. Research Serv., R45181, *Family Planning Program Under Title X of the Public Health Service Act* 16 (2018), available at <https://fas.org/sgp/crs/misc/R45181.pdf>.

<sup>65</sup> *Id.*



and is further checked through an analysis of the number and type of services provided each day in the clinic setting by administrative staff.

The sub-recipient demonstrated that no abortion-related activities were provided as part of the Title X project. This included policies and procedures and the actual practices in the clinic setting, counseling and service protocols, intake and referral procedures, and fiscal and other administrative procedures.

This requirement [compliance with Section 1008] was MET.<sup>66</sup>

No evidence indicates that the Vermont Department of Health has ever had any issues complying with Section 1008.

In addition, the Department does not address the steps states like ours take to ensure sub-recipients' separation of Title X funds from any abortion-related activities. In Washington, the State Department of Health Family Planning Program ensures the separation of Title X funds from abortion services through contract language, desk reviews, and on-site monitoring. The goal of monitoring is to document the extent of sub-recipient agencies' compliance with state and federal laws and regulations. Monitoring helps the Family Planning Program assist local agencies with compliance with Federal Title X and state rules related to funding. This ensures accountability.

The Washington Department of Health (DOH) does three types of monitoring: Administrative, Clinical, and Fiscal. As federal grant funds flow through the Family Planning Program to a sub-recipient, the Family Planning Program maintains primary responsibility for ensuring enforcement of federal and state requirements. Those requirements pertain to sub-recipients as they receive state and federal funds. When a sub-recipient signs the Family Planning Program contract with the DOH, they agree to enforce those same certifications, assurances, cost principles, and administrative rules. All of these requirements are incorporated in contract language. Title X sub-recipient contract standard clauses include that the Contractor does "not provide abortion as a method of family planning within the Title X Project. (42 CFR 59.5(5))," and "[t]he Title X Project must not include sterilizations, abortions, or any flat rated service (for instance some STD or HIV testing) or income/revenue generated from them."

Furthermore, the DOH Fiscal Monitoring and Review Guide and On-site Monitoring Tool is used by site consultants and agency fiscal experts to perform on-site reviews every three years or more often if needed. They monitor for documentation that:

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<sup>66</sup> Office of Population Affairs, Program Review: Title X Family Planning Project: Vermont Department of Health, 21 (May 2017) (on file with Vermont Attorney General's Office).

- i. The financial system provides for financial separation of Title X family planning service dollars and abortion service dollars;
- ii. Agency personnel must be informed that they could be prosecuted, under Federal law, if they coerce, or try to coerce, anyone to undergo abortion or a sterilization procedure, and the agency has a policy in place to this end;
- iii. The agency has written policies that clearly state that no Title X funds will be used in programs where abortion is a method of family planning;
- iv. The agency is in compliance with Title X, specifically calling out Section 1008; and
- v. Staff members have been trained about separating Title X family planning services and abortion services.

The site consultant verifies this onsite through the sub-recipients' policies and procedures, personnel records, and a review of the accounting system.

In addition, the Washington State Family Planning Manual<sup>67</sup> advises about separating Title X services from abortion, including that Contractors must be in full compliance with Section 1008 prohibiting the use of Title X funds for abortion as a method of family planning.

Oregon's Reproductive Health Program maintains a robust process for monitoring compliance among its Title X agencies. Ongoing and routine compliance reviews ensure that Title X agencies adhere to administrative, clinical, and fiscal requirements. The monitoring process includes:

- i. Annual recertification of agencies;
- ii. Onsite compliance reviews of consent forms, policies, procedures and protocols; chart audits; onsite clinical observation; and onsite observation of patient and physical environment; and
- iii. Regular billing, client enrollment, and quality assurance reviews.

Like Washington's DOH, Oregon's Reproductive Health Program uses a comprehensive Program Certification Verification Tool to monitor its Title X agencies. Specific policies relating to abortion, including the requirement that no federal funds are used for abortion services and that abortion is not provided as a birth control method, are reviewed and verified.

In Massachusetts, the Department of Public Health's robust oversight of sub-recipients providing abortion services ensures compliance with current Title X requirements. The Department of Public Health requires that these sub-recipients establish and follow written policies that clearly indicate that Title X funds will not be used for abortion services, clearly segregate Title X funds to prevent allocation of Title X funding to abortion services; maintain separate inventory for

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<sup>67</sup> *Family Planning Manual*, Washington State Department of Health, September 2016, available at <https://www.doh.wa.gov/portals/1/Documents/Pubs/930-122-FPRHManualComplete.pdf> (last visited July 30, 2018)

abortion and non-abortion services; and implement fiscal review and oversight procedures to assure that no Title X funds are used for abortion services. The Massachusetts Department of Public Health also engages in regular monitoring, and requires all providers to inform them of any changes in their practice.

In Vermont, in addition to the safeguards noted above, PPNNE undergoes an annual financial audit, which specifically examines its Title X expenditures. PPNNE passes its audit every year, including its accounting of Title X funds.<sup>68</sup>

The Department has not explained why these thorough guidance, monitoring, and auditing steps taken by our state agencies and by the Department itself are insufficient to prevent commingling of funds, and we ask the Department to provide this explanation.

5. *The proposed rule would violate the constitutional rights of Title X providers and their patients.*

The proposed rule imposes government restrictions on speech and denies women freedom from government interference in their most intimate and personal decisions that courts will find fatal under the First and Fifth Amendments. It should be withdrawn for these reasons.

In *Rust v. Sullivan*, the Supreme Court recognized that “funding by the government, even when coupled with the freedom of the fund recipients to speak outside of the scope of the Government-funded project,” is not “invariably sufficient to justify Government control over the content of expression.” 500 U.S. at 199. In some areas, particularly rural areas, the proposed rule is likely to drive all Title X providers from the program, leaving patients without reasonable access to any Title X services. And for those Title X providers remaining in the program, the Department’s restriction on speech will extend beyond the Title X program to every patient encounter by every Title X provider, whether or not Title X funds are used. As a consequence, the proposed rule will force all Title X grantees to give up neutral abortion-related speech, whether or not they are wearing a “Title X hat.” These facts are different from those presented in *Rust v. Sullivan*, which makes that decision distinguishable.

The massive contraction of the Title X program that would occur under the proposed rule, and is shown herein as to our States, results in a violation of the unconstitutional conditions doctrine and the vagueness and overbreadth doctrines of the First Amendment. The proposed rule interferes with a doctor’s ability to provide, and a woman’s right to receive, information concerning abortion and abortion-related services, both within and outside of the Title X program. This violates women’s Fifth Amendment rights to be free of government interference

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<sup>68</sup> Financial audits for 2015 – 2017 may be downloaded at the Federal Audit Clearinghouse, <https://harvester.census.gov/facdissem/Main.aspx>. Financial audits for 2013 and 2014 on file with the Vermont Attorney General’s Office. Financial audits older than five years were not readily available.

Secretary Alex M. Azar II  
Assistant Secretary ADM Brett P. Giroir, M.D.  
Deputy Assistant Secretary Diane Foley, M.D., FAAP  
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in their decisions whether to continue pregnancies to term. It is also contrary to the First Amendment, especially given the Supreme Court’s recent recognition that “[a]s 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.’” *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2374 (2018) (quoting *Turner Broadcasting System v. FCC*, 512 U.S. 622, 641 (1994)). And it contravenes Supreme Court cases that reject “confin[ing] the attending physician in an undesired and uncomfortable straitjacket in the practice of his profession.” *Planned Parenthood of Central Mo. v. Danforth*, 428 U.S. 52, 67 n.8 (1976). Finally, it interferes in the states’ rights to design and implement health care programs in their states by causing the Title X regulations to be applicable outside the Title X program.

If the Department does not voluntarily withdraw the proposed rule, we ask it to explain, in light of these facts, how the proposed rule is consistent with the Constitution.

6. *The proposed rule includes many requirements that are unsupported by any evidence and, if not abandoned, will be found to be arbitrary and capricious.*

a. *The primary care requirement is unsupported and arbitrary.*

The proposed rule requires that Title X providers “should offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site.”<sup>69</sup> This requirement is supposedly meant to “promote holistic health and provide seamless care.”<sup>70</sup> This call for holistic and seamless care rings hollow considering that the Department is simultaneously proposing specific steps to limit the provision of complete health information and seamless care to patients through abortion counseling and referral restrictions. Instead, the primary care requirement appears intended to push out long-standing Title X providers who have specialized in family planning services and rural Title X providers who may not have “robust referral linkage[s] . . . in close physical proximity.”<sup>71</sup>

This requirement alone could dramatically reduce the scope of the Title X program in our States depending upon how the Department defines “close physical proximity.” This requirement is not stated in the statute. The Department must explain how it can be reconciled with the goals of the Title X program.

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<sup>69</sup> 83 Fed. Reg. 25,530.

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

- b. *The provisions requiring reporting on minors are unsupported and irrational.*

Currently, Title X providers must attempt to encourage a minor to involve her or his family in the decision-making process when the minor seeks contraceptive services. Under the proposed rule, this “encouragement” would be replaced with undue pressure on both the provider and the minor. The proposed rule requires that a Title X provider document “in the minor’s medical records the 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.”<sup>72</sup> The only exception to this requirement, which must be documented in the minor’s medical record, is if the provider “suspects the minor to be the victim of child abuse or incest” and this has been reported in compliance with state or local law.

Today, if a minor explains to a Title X provider that she wishes not to involve her family, that wish is respected. Minors may choose not to involve their families in their health care decisions due to differences of religious belief, fear of violence, fear of abandonment, lack of a suitable adult to involve, or simply a desire for confidential care. By requiring that the providers’ efforts to encourage family involvement be recorded in the medical record, the proposed rule could force providers to apply pressure on minor patients to involve their families even when doing so is not in the minor’s best interests. The proposed rule could ultimately have a chilling effect on honest and open conversations between providers and minor patients. Further, the proposed rule imperils patient confidentiality to such a degree that minors could be discouraged from seeking care altogether.<sup>73</sup> This will serve neither the purposes of the Title X program nor patients.

- c. *The other reporting requirements are unsupported, vague, and beyond the Department’s legal authority.*

The proposed rule would bury Title X projects and sub-recipients in overly burdensome reporting requirements. For example, a Title X project would need to report for each sub-recipient and referral agency not only the exact services provided, but also a “[d]etailed description of the extent of the collaboration” even down to the individuals involved and inclusive of undefined “less formal partners within the community.”<sup>74</sup>

Along with the inclusion of the “less formal partners,” the proposed rule’s definition of “referral agency” makes the reporting requirements overly broad. The proposed rule suggests that even if a referral agency does not receive Title X funds, it may still be “subject to the same reporting

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<sup>72</sup> *Id.*

<sup>73</sup> See, e.g., *Planned Parenthood Fed’n of Am. v. Heckler*, 712 F.2d 650, 659-61 (D.C. Cir. 1983) (describing Congress’s decision not to mandate family involvement in Title X care for minors).

<sup>74</sup> 83 Fed. Reg. 25,530.

requirements as a grantee or sub-recipient.”<sup>75</sup> These requirements improperly overreach into relationships not otherwise governed by Title X regulations and burden projects, sub-recipients, and referral agencies. Rather than achieving the stated goal of creating a robust referral system, these requirements will cause projects and sub-recipients to limit their referral networks in order to control the amount of reporting.

These changes will have significant impacts. For example, the proposed regulations’ applicability to “referral agencies”<sup>76</sup> of Title X clinics would impact a significant number of Vermont’s health care providers. As a small and rural state, Vermont’s pool of available health care referral partners is also small. PPNNE maintains a “comprehensive referral data base” of other local health care providers.<sup>77</sup> But the proposed regulations would be unnecessarily and prohibitively restrictive on those health care providers that do not receive Title X funds, interfering with those providers’ and their patients’ rights and their ability to provide ethical and professional care.

7. *The proposed rule does not comply with Executive Orders 12866 and 13562.*

Executive Orders 12866 and 13562 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.” 83 Fed. Reg. 25521. Executive Order 12866 requires that a “significant regulatory action” comply with additional regulatory requirements. This proposed rule meets all the definitions of a “significant regulatory action” because it would (1) have an annual effect on the economy of \$100 million or more and will “adversely and materially affect” the health sector of the economy, public health, and state and local governments; (2) create a serious inconsistency and interfere with an action taken or planned by another agency; (3) materially alter budgetary impacts of entitlement grants or the right and obligations of recipients thereof; and (4) raise novel legal or policy issues arising out of legal mandates.

The restrictive requirements of the proposed rule disqualify many current Title X grantees from the program across the country. Some Title X patients currently served by these providers will lose access altogether to family planning services, particularly among the uninsured and those residing in rural areas. In 2017, Title X services saved our four States alone many millions of dollars in costs for health care services. Extrapolating those cost savings across all states, the fiscal impact of the proposed rule on the economy will exceed \$100 million and will adversely affect public health, the health care sector, and state treasuries. Additionally, the proposed rule materially changes the outflow of entitlement grants and the rights and obligations of grant

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<sup>75</sup> 83 Fed. Reg. 25,514.

<sup>76</sup> 83 Fed. Reg. 25514.

<sup>77</sup> Office of Population Affairs, Program Review: Title X Family Planning Project: Vermont Department of Health, 11 (May 2017) (on file with Vermont Attorney General’s Office).

applicants and recipients. It also raises novel legal and policy issues because of new restrictions on speech. The preamble wrongly concludes that the proposed rule is not economically significant and fails to address these considerations.

8. *The proposed rule is contrary to Congress's intent because it would exclude qualified and experienced Title X providers from the program and reduce access to essential preventive health services.*

The impact of the proposed rule is contrary to the Title X statute. The proposed rule appears to be designed to deny Title X funds to many of the current Title X providers in our States and nationwide, and it does not address the impact this rule will have on our States' residents and budgets. The proposed rule, if implemented, will leave many counties without a Title X provider. Because the proposed rule will undermine the quality of health care provided and impose burdensome and counterproductive separation and reporting requirements, many providers in our States will be unable or unwilling to comply. Further, the proposed rule falls particularly hard on uninsured patients and those in rural areas, who in some cases will have no other reasonable option for obtaining family planning services. As a result, thousands of people who rely on Title X providers for contraception and other family planning services will lose access to those services. The proposed rule thus frustrates, rather than promotes, the purpose of Title X.

It is no secret that the Department wants to expel Planned Parenthood from the network of Title X providers. As then-candidate Donald Trump stated, "We're not going to allow, and we're not going to fund, as long as you have the abortion going on at Planned Parenthood."<sup>78</sup> More recently, when introducing the proposed rule, President Trump stated: "For decades American taxpayers have been wrongfully forced to subsidize the abortion industry through Title X federal funding so today, we have kept another promise. My administration has proposed a new rule to prohibit Title X funding from going to any clinic that performs abortions."<sup>79</sup> The proposed rule would certainly achieve the President's goal, but as described herein, it would go much further than that.

For some Title X providers, creating a separate corporate entity with complete physical and financial separation will be prohibitively expensive. In Massachusetts, at least one Title X provider, if forced to create a separate corporate entity to continue providing abortion care, will have to stop participating in Title X at one of its locations, resulting in the loss of a geographically important Title X clinic. In Oregon, two major Title X agencies with 12 clinic sites would likely be unable to continue as Title X providers due to the onerous physical

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<sup>78</sup> Danielle Paquette, "Donald Trump's Incredibly Bizarre Relationship with Planned Parenthood," *Washington Post* (Mar. 2, 2016), [https://www.washingtonpost.com/news/wonk/wp/2016/03/02/donald-trumps-incredibly-bizarre-relationship-with-planned-parenthood/?utm\\_term=.db131f627e96](https://www.washingtonpost.com/news/wonk/wp/2016/03/02/donald-trumps-incredibly-bizarre-relationship-with-planned-parenthood/?utm_term=.db131f627e96) (last accessed 7/13/18).

<sup>79</sup> <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-susan-b-anthony-list-11th-annual-campaign-life-gala/> (last accessed 7/13/18).

separation requirements set forth in the rules. The same is true in Washington and Massachusetts. All of Vermont's Title X clinics would be ineligible to continue under the program. A wide range of Title X provider types will have no choice but to forgo Title X funds, thus reducing their capacity to provide much needed family planning services. For example, it is unclear whether a hospital that runs a Title X clinic (on or off site) that also provides abortion would be able to comply with the requirement to have "separate, accurate accounting records" or "separate personnel, electronic or paper-based health care records."<sup>80</sup> Would funds attributed to the clinic also be attributable to the hospital as a whole? In addition to the practical issues created by the proposed rule's separation requirement, it also creates serious risk to patient safety by requiring separate medical record systems and further stigmatizes legal medical procedures.

In 2017, in Washington, over 14,000 Title X-funded patients received their Title X services at Planned Parenthood or other clinics that provided abortions outside the Title X project. In fact, in 20 of Washington's 39 counties, the only Title X provider is one that performs abortions outside the Title X project.<sup>81</sup> If these Title X providers no longer could offer Title X-funded family planning services due to the separation and other requirements, these patients would need to either locate new Title X providers for their contraception and other family planning services, or forego the benefits of the Title X program. In all of eastern Washington, which is comprised of 20 counties, only four of those counties would have any Title X provider at all. In western Washington, the proposed rule would drive out the Title X providers in 10 additional counties. This includes six of the 10 most populous counties in Washington.

If the proposed regulations take effect, for the first time in the history of Title X, the Vermont Department of Health's Title X funding will be jeopardized. None of the current Title X clinics in Vermont will be eligible for Title X funds. Nor does Vermont have the health care infrastructure to make up for the anticipated loss in funding. Although Vermont has several FQHCs and rural health centers, they are not equipped to absorb all the family planning patients currently served by Title X clinics. Vermont FQHCs saw a total of 4,047 patients for contraceptive management in 2016.<sup>82</sup> By comparison, Vermont's Title X clinics served 9,808 family planning patients in 2016. The FQHCs would have to more than double their family planning patient services in rural areas to absorb the needs of all Title X patients. FQHCs in Vermont are not equipped to do this.

In the Department's zeal to punish providers that perform abortions *outside* of the Title X project, the Department is harming many recipients of Title X services in our States. The

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<sup>80</sup> 83 Fed. Reg. 25,519.

<sup>81</sup> See Attachment 1 (map of Washington counties without Title X services if organizations that also provide abortions are removed from Title X).

<sup>82</sup> 2016 Health Center Data: Vermont Data, Health Resources & Servs. Admin., <https://bphc.hrsa.gov/uds/datacenter.aspx?q=tall&year=2016&state=VT> (last visited July 30, 2018).



Department has not explained why issuing a rule to govern Title X that requires thousands of Title X-funded patients to search for a new Title X family planning provider—or go without one entirely—is consistent with Congress’s intent in establishing the Title X program, and we ask the Department to provide this explanation.

The harmful consequences of the proposed rule uniquely impact rural and uninsured patients. In five Washington counties, for example, one quarter or more of Title X patients are uninsured, and the only Title X providers are ones that perform abortions outside the Title X project.<sup>83</sup> And in five other counties in rural Washington, Title X patients are served by small Title X clinics associated with providers that perform abortions outside the Title X project. These clinics are in Ellensburg (in Kittitas County), Walla Walla (in Walla Walla County), Wenatchee (in Chelan County), Pullman (in Whitman County), and Moses Lake (in Grant County). We are advised that, because they are so small and a significant amount of their work involves Title X-funded services, at least some of these clinics would not survive the loss of Title X funds. If these current Title X providers are driven from the Title X program, many of these patients will not be able to shift to another provider.<sup>84</sup> Even if some current Title X providers remain in the program, the distance these patients would have to travel to another Title X provider is impracticable. We ask that the Department explain how it reconciles the significant impact the proposed rule will have on rural and uninsured patients with the mission of the Title X program.

In Oregon, significant portions of the state, primarily the rural and frontier areas, are designated as Medically Underserved Areas because they have a shortage of primary health care providers and facilities coupled with high levels of need. The proposed rule will likely cause providers to decline Title X funds in order to maintain their quality of care, further straining access to reproductive health care for Oregonians in these areas. For the 40 percent of Oregon’s Title X clients who are uninsured, this burden is heightened because the high quality of care at Title X clinics may not be available to them at other clinics. Title X clinics currently are required to provide the same high quality of care to all clients regardless of ability to pay, whereas other clinics may limit services for patients without coverage sources.

A remarkably broad coalition of Vermont health care providers has joined the nationwide medical community’s condemnation of the proposed rule.<sup>85</sup> This Vermont coalition “strongly

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<sup>83</sup> These counties are Mason (24 percent of Title X patients were uninsured in 2017), San Juan (30 percent), Skagit (29 percent), Douglas (28 percent), and Whitman (27 percent). These counties do not have local health jurisdictions providing family planning services.

<sup>84</sup> In addition, under the proposed rule, eliminating Planned Parenthood and other abortion providers from Title X will cause the following colleges and universities in Washington to lose their Title X providers: Washington State University, Western Washington University, Central Washington University, Eastern Washington University, Big Bend Community College, Columbia Basin College, and Yakima Valley Community College.

<sup>85</sup> *Vermont Health Care Coalition Title X Statement*, Vt. Ass’n of Hosps. and Health Sys. (June 15, 2018), <https://vahhs.org/title-x-statement.html> (endorsing, among other things, a statement from the American Nurses Association stating, “The Code of Ethics for Nurses outlines that the nurse’s primary commitment is to the patient,

opposes” the proposed regulations and warns that those regulations “will significantly restrict access to necessary care for both women and men particularly in rural, hard to serve areas of Vermont.”<sup>86</sup> Vermont is a small state, and the Vermont coalition represents a significant majority of all health care providers in Vermont. It is therefore unlikely that the number of Vermont medical professionals who would consent to work in a clinic governed by the proposed regulations would be sufficient to replace the current robust number of Title X-funded providers statewide.

9. *The proposed rule would impose tens of millions of dollars of costs on the treasuries in Washington, Massachusetts, Oregon, and Vermont.*

The costs imposed on our States, along with all other states, by the proposed rule will be well over \$100 million. Because the cost or burdens of compliance with the proposed rule will be prohibitively high for many providers, the network of Title X providers will shrink in our States and around the country. Further, some Title X patients will lose all access to family planning services as a result of the proposed rule. As mentioned, in Oregon 41 percent of Title X patients were uninsured in 2017, and in Washington there are counties where upwards of 30 percent of Title X patients are uninsured.

Yet the Department fails to analyze either the significant public health impact or the fiscal impact to states. The Department fails to grapple with the fact that, unless it is expecting the states to step in to plug the fiscal hole created by the loss of Title X funding, unplanned pregnancies and births will occur, cervical cancers will not be diagnosed in early stages, and complications will occur due to untreated STIs, among other things, all resulting in significant increased health care costs for states that Title X is meant to address.

The Department provides no analysis explaining why these impacts are consistent with the fundamental mission of the Title X program. In fact, they are not. Analyses show that significant cost savings are achieved by funding family planning services. Nationally, an estimated \$7.09 is saved for every dollar spent.<sup>87</sup> In short, a significant portion of the cost savings created by

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whether an individual, family, group, community, or population. This proposed rule interferes with that relationship and violates the basic ethics of the profession.”); *see also* Mike Faher, *Vermont health care coalition protests Title X change*, VTDigger.com (June 12, 2018), <https://vtdigger.org/2018/06/12/vermont-health-care-coalition-protests-title-x-change/> (calling the Vermont Health Care Coalition opposing the proposed regulations “an unlikely group of allies in Vermont”).

<sup>86</sup> *Vermont Health Care Coalition Title X Statement*, Vt. Ass’n of Hosps. and Health Sys. (June 15, 2018), <https://vahhs.org/title-x-statement.html>

<sup>87</sup> Jennifer J. Frost, *Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program*, *Milbank Quarterly*, Vol. 92, No. 4, p. 668 (2014) (available at [https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/MQ-Frost\\_1468-0009.12080.pdf](https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/MQ-Frost_1468-0009.12080.pdf)).

Secretary Alex M. Azar II  
Assistant Secretary ADM Brett P. Giroir, M.D.  
Deputy Assistant Secretary Diane Foley, M.D., FAAP  
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funding family planning services is jeopardized by the proposed rule and would fall on our States, among others.

#### **D. Conclusion**

The proposed rule will drive many family planning providers from the Title X program. As a result, thousands of patients will lose reasonable access to family planning services and other critical reproductive health services. The Title X providers that remain will be prevented from delivering the high-quality and complete medical care that they have always provided. This frustrates rather than achieves the purposes of Title X, and the courts will strike down the proposed rule, if implemented, accordingly. The proposed rule would limit health care services to vulnerable populations that Congress intended to help. It also would shift the costs of reproductive health care, including services for unintended pregnancies, breast and cervical cancer diagnoses, spread of STIs, and other serious health conditions to our states. For these and the other reasons stated in our comments, we urge the Department to withdraw the proposed rule.

Thank you for considering our views.

Sincerely,



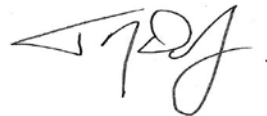
Bob Ferguson  
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Attachment 1

