No. 19-35386

IN THE UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

STATE OF OREGON, et al.,

Plaintiffs-Appellees,

v.

ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants-Appellants.

AMERICAN MEDICAL ASSOCIATION, et al.,

Plaintiffs-Appellees,

v.

ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON

ANSWERING BRIEF OF PLAINTIFFS-APPELLEES OREGON, NEW YORK, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, HAWAII, ILLINOIS, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, NEVADA, NEW JERSEY, NEW MEXICO, NORTH CAROLINA, PENNSYLVANIA, RHODE ISLAND, VERMONT, VIRGINIA, AND WISCONSIN

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INTRODUCTION

The plaintiff States—Oregon, New York, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Pennsylvania, Rhode Island, Vermont, Virginia, and Wisconsin, and the District of Columbia—brought this suit to challenge a new federal regulation (the Final Rule) that drastically changes the rules applicable to the Title X program. The district court (McShane, J.) issued a preliminary injunction to preserve the status quo and prevent irreparable harm to the plaintiff States, their residents, and the public health.

The Court should affirm. Title X funds vital family-planning and reproductive healthcare services for low-income patients. As the district court found, the Final Rule will reverse the rules that have governed Title X for decades and decimate the program by forcing providers to violate medical ethics and prevailing standards of medical care, or else leave the program. The resulting exodus of providers will cause more unwanted pregnancies, more abortions, and less disease screening. The district court properly exercised its broad discretion in concluding that these irreparable public-health harms warranted preliminarily enjoining the Rule—particularly given that the federal

government will not suffer any irreparable harm from simply maintaining the status quo pending judicial review.

The court also correctly concluded that the States are likely to prevail on the merits. The Final Rule is contrary to two federal statutes and is arbitrary and capricious, in violation of the Administrative Procedure Act (APA). Contrary to defendants' principal argument on appeal, *Rust v. Sullivan*, 500 U.S. 173 (1991), does not control. The statutes that the Final Rule violates were both enacted after *Rust*, and thus were not addressed by *Rust*. And *Rust* was based on a different and now-outdated administrative record.

STATEMENT OF JURISDICTION

Plaintiff States agree with defendants' statement of jurisdiction.

ISSUE PRESENTED

Did the district court abuse its discretion in granting a preliminary injunction in view of the plaintiff's likelihood of success on three independently sufficient grounds, the harm plaintiffs would suffer without an injunction, and the balance of harms and public interest?

BACKGROUND

A. Statutory and Regulatory Framework

1. Title X

Enacted in 1970, Title X funds grants to States and other entities to provide family-planning services and reproductive healthcare to patients who have low incomes, live in rural communities, or face other barriers to accessing medical care. (*See* SSER5–8, 52).[1] *See* Pub. L. No. 91-572, § 2(1), 84 Stat. 1504 (1970).[2] The contraceptive services provided by Title X have substantially reduced the number of unintended pregnancies and abortions in the plaintiff States. (PSER142; SSER22–24, 62–63, 79–81). And the vaccinations, tests for sexually transmitted infections, and cancer screenings that Title X enables significantly enhance patient health. (SSER4–5, 90–91).

Section 1008 of Title X precludes grants from being "used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6. Grantees are subject to rigorous audit and compliance programs to ensure that Title X funds are not used for any such prohibited activities. (ER190).

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[1] SSER refers to plaintiff States' supplemental excerpt of record and PSER refers to AMA/Planned Parenthood's supplemental excerpts.

[2] HHS, Office of Population Affairs, *Funding History*, https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/funding-history/index.html (last accessed 5/20/2019).

2. The 1981 Guidelines

For nearly fifty years, HHS has recognized that § 1008 allows Title X projects to provide the nondirective pregnancy counseling required by established standards of medical care and medical ethics. *See* 65 Fed. Reg. 41,270, 41,273–74 (2000).[3] These standards require the provision of information about prenatal care and delivery, adoption, and abortion in a neutral manner that does not steer the patient toward a particular option. *See* American Academy of Pediatrics, Committee on Adolescence, Options Counseling for the Pregnant Adolescent Patient ("AAOP Counseling"), Pediatrics Vol. 140(3), at 2–3 (2017).[4] The information provided during nondirective counseling includes

[3] *See* U.S. Dep't of Health & Human Services, Health Resources & Services Administration, *Report to Congress: The Infant Adoption Awareness Training Program* 4 (Nov. 2002) (review "revealed that every professional practice standard…specified non-directive counseling as part of the professional standard of care"); *id.* at 10–11 (collecting standards).

[4] American Academy of Pediatrics, Committee on Adolescence, Counseling the Adolescent About Pregnancy Options, Pediatrics Vol. 83(1), at 135–37 (1989); American Medical Association (AMA) Comment 2; American College of Obstetricians & Gynecologists (ACOG) Comment 6; American Academy of Nursing Comment 4.

Plaintiff States have included the pertinent comment letters in the addendum.

both "an unbiased discussion" of pregnancy options and referrals "to appropriate resources and services." AAOP Counseling 2017, *supra*, at 1.[5]

In 1981, HHS issued written guidelines requiring all Title X grantees to offer nondirective counseling, including referrals, to pregnant patients. U.S. Department of Health & Human Services, Program Guidelines for Project Grants for Family Planning Services (1981) ("1981 Guidelines") (States' Add. 12). As HHS explained at the time, nondirective counseling comports with § 1008 because evenhanded discussion of all legal pregnancy options does not fund abortions or promote abortion as a method of family planning.[6] *See National Family Planning & Reproductive Health Assoc., Inc. v. Sullivan* ("*NFPRHA*"), 979 F.2d 227, 229 (D.C. Cir. 1992).

3. The 1988 Regulations

In 1988, HHS reversed course and prohibited Title X projects from providing any counseling about abortion, including referrals. 53 Fed. Reg. 2922, 2954 (1988). The 1988 regulations further required that all Title X programs be physically and financially separated from any abortion-related

[5] *See also* ER28 (AMA code of ethics requires physicians to "cooperate in coordinating medically indicated care with other health care professionals").

[6] Although the text of §1008 does not prohibit Title X funds from being used to "promote" abortion, HHS has interpreted it to have that meaning based on the remarks of one of the sponsors of Title X. *See* 65 Fed. Reg. at 41,272; 116 Cong. Rec. 37,375 (1970) (remarks of Rep. Dingell).

activities. *Id.* at 2945. In promulgating the physical-separation requirement, HHS primarily relied on reports from the United States General Accounting Office (now the Government Accountability Office) and HHS's Office of Inspector General, which HHS claimed expressed concerns about potential confusion among Title X grantees about how to comply with § 1008. *Id.* at 2923–24.

The Supreme Court upheld the 1988 regulations in *Rust v. Sullivan*, 500 U.S. 173 (1991), concluding that § 1008 was ambiguous because Congress had not spoken "directly to the issues of counseling, referral, advocacy, or program integrity." *Id.* at 184. The Court also concluded that the regulations were sufficiently supported by the administrative record presented then. *Id.* at 187–89. Because of additional litigation, the regulations never went fully into effect. *See NFPRHA*, 979 F.2d at 241.

In 1993, HHS revoked the 1988 regulations, reinstated the 1981 Guidelines, and removed the physical-separation requirements. 58 Fed. Reg. 7464, 7465–66 (1993).

4. Congress's Mandate That All Pregnancy Counseling in Title X Be Nondirective (the Nondirective Mandate)

Starting in 1996, Congress enacted appropriations statutes every year requiring that "all pregnancy counseling" in Title X programs "shall be

nondirective" (the Nondirective Mandate).[7] The legislative history and context of the Nondirective Mandate make clear that Congress intended nondirective pregnancy counseling to have the meaning reflected in prevailing medical standards of care and adopted by the 1981 Guidelines.

After *Rust*, Congress twice passed legislation—ultimately vetoed—clarifying that § 1008 had always permitted nondirective counseling, including referrals, about all legal pregnancy options.[8] As both supporters and opponents of these and similar bills explained, nondirective counseling means providing factual information about all pregnancy options without steering a patient to "one option over another." 137 Cong Rec. 18,435 (1991) (Senator Chafee, sponsor of S. 323); *id.* at 18,491 (Senator Hatch, who opposed S. 323, explaining that "truly nondirective" counseling would not "counsel for one option over another"). And as legislators and advocates further explained,

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[7] Department of Health and Human Services Appropriations Act, 1996, Pub L. No. 104-134, 110 Stat. 1321-221 (1996); *see also*, *e.g.*, Department of Health and Human Services Appropriations Act, 2019, Pub. L. No. 115-245, 132 Stat. 2981, 3070–71 (2018).

[8] *See* H.R. 2707, 102d Cong., § 514 (1992) (reported in Senate) (prohibiting HHS from using funds to implement 1988 counseling-related regulations); S. 323, 102nd Cong. (1992) (enrolled bill) (requiring Title X programs to provide "information regarding pregnancy management options," meaning "nondirective counseling and referrals" about prenatal care and delivery, adoption, and abortion).

nondirective counseling includes referrals—as the 1981 Guidelines had previously required. *See* H.R. Rep. 102-204 (1991) (1981 Guidelines "enumerated such [nondirective] options counseling to include information and referral").[9]

Congress applied this same understanding of nondirective pregnancy counseling in the Nondirective Mandate. Congress enacted the Mandate to preserve then-current "law and policy with respect to title X recipients and abortion funding, counseling, and lobbying." 141 Cong. Rec. H8252 (Aug. 2, 1995); *see id.* at H8250 (Representative Greenwood explaining that the appropriations "amendment restores the Title X planning program"). The appropriations statute reiterated § 1008's requirement that Title X funds "shall not be expended for abortions." *Id.* at H8249. And consistent with the 1981 Guidelines—which were then back in place—the appropriations statute made "clear that all counseling must be nondirective," i.e., all counseling must "lay out the legal options" available to pregnant patients. *Id.* at H8250.

[9] *See, e.g., Title X Regulations (The Gag Rule): Health Implications for Poor Women, Hr'g of the S. Comm. on Labor & Human Resources* 34 (May 16, 1991) ("*The Gag Rule*") (statement of Lee Minto, Planned Parenthood of Seattle-King County) (nondirective counseling insures that a patient "receives accurate information" and "gets appropriate referrals").

In 2000, HHS promulgated regulations implementing the Nondirective Mandate and formally adopting the nondirective counseling rules set forth in the 1981 Guidelines. 65 Fed. Reg. at 41,270–01. The 2000 regulations also provide that while grantees must financially separate their Title X programs from abortion-related serviced funded by non-Title X funds, physical separation is not required. *Id.* at 41,275–76. HHS explained that even without a physical-separation requirement, Title X grantees had been successfully separating their Title X and abortion-related services "for virtually the entire history" of Title X. *Id.* at 41,275.

5. The Affordable Care Act (ACA)

In 2010, Congress enacted § 1554 of the ACA to further protect patients' ability to receive medical information and services that are ethically and medically necessary. Section 1554 broadly prohibits HHS from promulgating "any regulation" that creates "unreasonable barriers" to obtaining appropriate medical care; impedes "timely access" to such care; interferes with patient-provider communications "regarding a full range of treatment options"; restricts providers from disclosing "all relevant information to patients making health care decisions"; or violates providers' ethical standards. 42 U.S.C. § 18114.

B. The Final Rule

In March 2019, HHS published the Final Rule at issue here. Despite the Nondirective Mandate, the Final Rule allows Title X grantees to give patients *directive* pregnancy counseling that discusses prenatal care and adoption while entirely omitting any information about abortion. 84 Fed. Reg. 7714, 7724, 7733, 7744–46 (2019). The Final Rule also places asymmetric burdens on abortion-related information—for example, by requiring that any counseling about abortion include counseling about another pregnancy option—regardless of the patient's wishes. *Id.* at 7747. The Rule also requires providers to refer every pregnant patient for prenatal care and prohibits providers from giving any referrals for abortion—regardless of what the patient wants. *Id.* at 7744–49, 7789–90.

The Final Rule further requires Title X-funded care to be physically separated from activities prohibited by the Final Rule, including referrals for abortion: i.e., entirely separate facilities, separate personnel and workstations, and separate healthcare records. *Id.*

C. Procedural Background

Immediately after HHS adopted the Final Rule, plaintiffs here—20 States and the District of Columbia—challenged the Final Rule as contrary to the Nondirective Mandate, contrary to § 1554, and arbitrary and capricious.

Plaintiffs then moved for a preliminary injunction, as did a group of individual medical providers and organizations of medical providers who sued in a consolidated case.

1. The Preliminary Injunction

The district court preliminarily enjoined the Rule's implementation.[10] The court first determined that plaintiffs are likely to succeed on the merits of their APA claims. The court concluded that the Final Rule likely contravenes Congress's Nondirective Mandate by, for example, requiring referrals for prenatal care while prohibiting referrals for abortion. The court rejected defendants' contention that the Nondirective Mandate does not encompass referrals, explaining that "common sense, the agency's own guidance, and Congress's statutory language indicate" that counseling includes referrals. (ER18–19). The court also determined that the physical-separation requirements likely violate § 1554 by disrupting Title X programs and creating unreasonable barriers to healthcare. (ER26–27).

[10] Three other district courts have also preliminarily enjoined the Final Rule. *See Washington v. Azar*, 2019 WL 1868362, at *9 (E.D. Wash. Apr. 25, 2019); *California v. Azar*, 2019 WL 1877392, at *44 (N.D. Cal. Apr. 26, 2019); *Mayor and City Council of Baltimore v. Azar*, 2019 WL 2298808, at *13 (D. Md. May 30, 2019).

Regarding the likely irrationality of the Rule, the court explained that the Rule requires Title X providers to violate established standards of medical care and ethics, and that HHS's contrary assertions lacked any evidentiary support or rational explanation. (ER27–31). The court also concluded that HHS had arbitrarily failed to consider the enormous costs and public-health harms that will result from the Final Rule, including harms to low-income women who already face barriers to obtaining care. (ER31–34).

The district court next found that the plaintiff States, their residents, and the public health would be irreparably harmed absent a preliminary injunction. (ER32–34). The court explained that by forcing state and private grantees to violate established standards of medical care and ethics, the Rule will compel most existing grantees to exit the Title X program. (ER33). That will devastate Title X and will reduce access to healthcare and family-planning services, decrease testing for sexually transmitted infections and cancer, and increase unintended pregnancies and abortions—imposing significant costs on the States and harming the health of their most vulnerable residents. (ER33).

Finally, the court determined that defendants would not suffer any irreparable harm from maintaining the status quo pending judicial review. The court emphasized that the current regulations' requirements for nondirective counseling and financial (but not physical) separation of Title X funds have

governed the Title X program "for nearly 50 years and have an excellent track record." (ER34).

2. The Motions Panel Stay Opinion

On June 20, 2019, based on limited expedited briefing and without any oral argument, a motions panel of this Court (Leavy, Callahan, Bea, JJ.) issued a published opinion granting defendants' motion to stay the preliminary injunction, thereby allowing HHS to implement the Final Rule immediately. Plaintiff States filed an emergency motion seeking en banc reconsideration of the stay order, as did the plaintiffs in several other cases covered by the motions panel's stay order. Those motions were pending when this brief was filed.

SUMMARY OF ARGUMENT

The district court properly exercised its discretion in issuing a preliminary injunction to preserve the status quo pending judicial review of the Final Rule.

A. The district court correctly concluded that plaintiffs are likely to prevail on the merits.

1. The Final Rule is likely contrary to an appropriations statute mandating that all Title X pregnancy counseling be nondirective (the Nondirective Mandate) and to § 1554 of the Affordable Care Act (ACA). In contravention of the Mandate, the Rule allows grantees to offer *directive*

counseling that discusses only prenatal care and adoption while omitting any information about abortion. The Rule also imposes asymmetric burdens on abortion-related information, including by prohibiting any abortion referrals. For substantially these same reasons, the Final Rule likely violates § 1554 of the ACA too—interfering with patient-provider communications regarding treatment, and forcing violations of medical ethics. As the district court correctly determined, the Rule will severely impede patient access to healthcare as well by forcing many providers to withdraw from Title X. Plaintiffs and other commenters raised each substantive way in which the Rule violates § 1554, and thus fully preserved their arguments regarding that provision.

Rust v. Sullivan does not control here because the Nondirective Mandate and the ACA were enacted after *Rust*. Those statutes eliminate the ambiguity that *Rust* found in § 1008 of Title X, which precludes grants from being "used in programs where abortion is a method of family planning." They do not overrule § 1008, but rather restrict what HHS may do in the name of enforcing § 1008.

2. The Final Rule likely is arbitrary and capricious because HHS did not adequately consider and address the significant harms it would inflict on the Title X program and public health. The administrative record shows that the Rule's requirement to provide counseling that violates medical ethics, and its

requirement to maintain physically separate facilities and personnel for any non-Title X abortion-related activities (including giving abortion referrals), will force many providers to leave the program, and that as a result many providers would leave the program. Yet HHS concluded, without support, that the rule would have no significant impact on access to Title X's essential healthcare services.

B. The district court properly exercised its discretion in finding that the balance of harms and public interest weigh heavily in favor of preliminarily enjoining the Rule. As the court found based on plaintiffs' unrebutted evidence, the Rule's forcing out of most existing Title X providers will reduce access to vital family-planning and healthcare services for vulnerable patients who have low incomes or live in rural communities. The result will be more unintended pregnancies, more abortions, less cancer detection, and less testing for sexually transmitted diseases. The plaintiff States will be irreparably harmed by the resulting damage to public health within their borders; and they will incur unrecoverable costs while coping with the gaps in care and negative health outcomes caused by the Final Rule.

By contrast, HHS will not suffer any irreparable harm from maintaining the status quo that has governed Title X for nearly fifty years. Indeed, defendants' claims of harm were generic, speculative, and unsupported.

C. The district court also properly exercised its discretion in issuing a preliminary injunction that essentially postpones the effective date of the Final Rule—an interim remedy that the APA expressly authorizes when necessary to prevent irreparable injury. And the same equities that make it appropriate to enjoin the Rule as to the plaintiff States also make it appropriate for the preliminary relief to extend nationwide and to nonparties.

ARGUMENT

THE PRELIMINARY INJUNCTION PROPERLY PRESERVES THE STATUS QUO

A preliminary injunction is a matter of equitable discretion. *California v. Azar*, 911 F.3d 558, 575 (9th Cir. 2018). The party seeking an injunction must show that "(1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in its favor, and (4) an injunction is in the public interest. *Id.* at 568. Here, the district court properly exercised its discretion in granting a preliminary injunction, because plaintiffs demonstrated that all four factors weighed strongly in their favor.[11]

[11] The motion panel's opinion does not control the issues presented here. The question for the motions panel was whether to grant a temporary stay until a merits panel could rule. And the motions panel could make only a preliminary *prediction*, based on limited briefing and without oral argument, about how the appeal will turn out. This merits panel, by contrast, is being asked to rule

Footnote continued…

A. The States Are Likely to Succeed on the Merits

1. The Final Rule is likely contrary to law.

The district court correctly concluded that the Final Rule is likely contrary to Congress's mandate that "all pregnancy counseling" in Title X projects "shall be nondirective," 132 Stat. at 3070-71, and to § 1554 of the Affordable Care Act. (ER18–32); *see also California*, 2019 WL 1877392, at *14–26; *Washington*, 2019 WL 1868362, at *7–9; *Baltimore*, 2019 WL 2298808, at *8-11. These statutes were enacted after the Supreme Court's decision in *Rust v. Sullivan*, and thus *Rust* does not address their constraints on HHS.

a. The Final Rule likely violates Congress's mandate that "all pregnancy counseling" in Title X be "nondirective."

Under long-settled standards of medical care and ethics, nondirective pregnancy counseling requires the neutral presentation of all legal pregnancy

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(…continued)
definitively on the question presented, on full briefing and with the benefit of argument if the panel permits.

Lair v. Bullock, 798 F.3d 736 (9th Cir. 2015), is not to the contrary. *Lair* noted that a motions panel can issue published decisions that constitute binding Ninth Circuit precedent. *Id.* at 747. But the only holding from the motions panel that the *Lair* Court treated as binding was one that had already been established by another binding three-judge panel opinion. *See id. Lair* thus had no occasion to consider the question presented here, which is whether there is a difference between a prediction of success on appeal and actual success after full briefing and argument.

options about which the patient inquires, with referrals on request. See *supra*, at 4–9. The Final Rule violates this Nondirective Mandate by (i) allowing providers to omit all information about abortion; (ii) requiring providers that discuss abortion to omit certain abortion-related information and to force patients to receive information about non-abortion options they do not want; and (iii) prohibiting providers from referring patients for abortion while requiring providers to refer every pregnant patient for prenatal care.

(i) Omitting Abortion Information: The Final Rule allows Title X providers to steer a patient towards prenatal care and adoption by discussing only those options while omitting all information about abortion, giving a list of primary care providers that do not offer abortions, and supplying referrals only for prenatal care and adoption agencies—even if the patient has specifically requested abortion-related information. *See* 84 Fed. Reg. at 7789; *id* at 7745 ("Title X projects will not be required to offer nondirective pregnancy counseling in general, *or abortion information and counseling specifically*." (emphasis added)). As the motions panel recognized, the Final Rule states that Title X providers "*may* include neutrally-presented information abortion" (Op. 18 (emphasis added)), but does not require that. And as defendants' acknowledge (Br. 19), providers are permitted but not required to disclose that they are actively withholding abortion-related information.

But "removing an option from the client's consideration necessarily steers her toward the options presented and is a directive form of counseling" that plainly contravenes the Nondirective Mandate. 65 Fed. Reg. at 41,274; *see, e.g.*, 137 Cong. Rec. 18,453 (counseling impermissibly directive if provider "does not have to give" information about abortion). Mistakenly regarding counseling as nondirective even if it omits any information about abortion, the motions panel erroneously accepted that the Final Rule requires that "such counseling as is given shall be nondirective" (Op. 18). *See* 84 Fed. Reg. at 7716 (stating that Final Rule "permits the use of Title X funds in programs that provide pregnancy counseling, so long as it is nondirective"). But the failure of the Final Rule to require that all Title X counseling is in fact nondirective is fatal to the Rule because Congress required that "*all* pregnancy counseling" in the Title X program must be nondirective.. This broad mandate does not authorize HHS to allow directive pregnancy counseling, as HHS recognized in its 2000 regulations. *See* 65 Fed. Reg. at 41,273.

(ii) Asymmetrical Burdens on Abortion Information: The Final Rule forces providers that include abortion-related information in counseling to give patients information about pregnancy options that the patients do not want—and prevents patients from receiving abortion-related information that they do want. For example, the Final Rule prohibits a provider from counseling a

patient about abortion without also counseling the patient about at least one other pregnancy option—regardless of the patients' wishes. *See* 84 Fed. Reg. at 7747. By contrast, a patient who wants information about only prenatal care or adoption may receive that information alone. Moreover, a patient who wants to learn about only abortion must nonetheless receive "information about maintaining the health of the mother and unborn child during pregnancy." *Id.* And such a patient may receive a list of "comprehensive primary health care providers," but more than half of those providers cannot offer abortion and none of those providers can be identified as offering abortion. *Id.* at 7789.

Steering patients away from abortion in this manner violates the Nondirective Mandate. The motions panel adopted defendants' argument (Br. 24, 28) that requiring clinics to present information in a selective way comports with the Nondirective Mandate so long as the provider does not "affirmatively endorse one option over another" (Op. 19). But requiring clinics to provide information on some options but not others *is* directive counseling. *See, e.g.*, *Gag Rule*, *supra*, at 3 ("requiring clinics to provide information on some options but not others" impermissibly skews patient decision making).

Equal presentation of all options about which the patient wants to learn is fundamental to nondirective counseling. Otherwise, a provider could impermissibly favor one option over another simply by presenting selective

information. *See* 138 Cong. Rec. H2826 (Apr. 30, 1992) (nondirective counseling means "not suggesting or advising one option over another"). Congress could not plausibly have allowed providers to evade the Nondirective Mandate so easily. As HHS recognized in the Final Rule, counseling in which providers give information about only abortion, or in which providers conceal which primary care providers offered prenatal care, would be impermissibly directive. *See* 84 Fed. Reg. at 7716. The same weighting of information against abortion and in favor of other options likewise contravenes the Nondirective Mandate's broad requirement that "all pregnancy counseling" in Title X programs "shall be nondirective." 132 Stat. at 3070–71.

Contrary to defendants' arguments, a statutory provision known as the Infant Adoption Awareness Act (IAAA) further demonstrates that Congress understood nondirective counseling to require the equal treatment of pregnancy options. The IAAA created a program to train Title X and other providers "in providing adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women." 42 U.S.C. § 254c-6(a)(1). Congress's use of the word "equal" did not establish an equal-treatment requirement for adoption that was previously absent. Rather, Congress allocated resources for a training program to ensure that providers were able to satisfy the Nondirective Mandate's

preexisting requirement to treat adoption and all other legal pregnancy options equally during counseling. *See*, *e.g.*, 146 Cong. Rec. H2718 (May 9, 2000). The motions panel was thus incorrect in asserting that plaintiffs' interpretation of the Nondirective Mandate strips the IAAA of meaning (Op. 19).

(iii) Directive Referrals: The Final Rule further violates the Nondirective Mandate by requiring Title X providers to refer *every* pregnant patient for prenatal care and prohibiting providers from referring *any* pregnant patient for an abortion, regardless of the patients' wishes. 84 Fed. Reg. at 7788–89.

Defendants incorrectly assert that nondirective counseling excludes referrals. (Br. 24–28). Referrals—i.e., giving the names, locations, and contact information of providers of postconception services—have long been an integral part of the factual information provided during pregnancy counseling, as Congress well understood when enacting the Nondirective Mandate.

Each year that Congress enacted the Nondirective Mandate, established standards of medical care and ethics required that nondirective counseling include referrals See *supra* at 6–9. In the 1981 Guidelines, HHS formally applied this settled medical understanding. Specifically, in a section entitled "Pregnancy Diagnosis and Counseling," the 1981 Guidelines directed Title X providers to offer pregnant patients "information and counseling regarding their pregnancies," including nondirective counseling "*and referral upon request*."

Id. at 12–13 (emphasis added). HHS again set forth this understanding of nondirective counseling in the 2000 regulations. *See* 65 Fed. Reg. at 41,274, 41,279. Defendant Office of Population Affairs, a subdivision of HHS, continues to require grantees to follow established medical standards in conducting nondirective counseling, emphasizing that "[r]eferral to appropriate providers of follow-up care should be made" for pregnant patients.[12] And Congress has repeatedly recognized in other statutes that medical and other professional counseling includes referrals.[13]

Congress was well aware of the settled understanding that nondirective counseling includes referrals, and of HHS's position, when it enacted the Nondirective Mandate. After *Rust*, Congress debated statutes that would have reinstated the 1981 Guidelines. See *supra*, at 7–8. During this time period, a

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[12] Loretta Gavin, Susan 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, 14 (April 25, 2014) ("QFP"); *see also id.* at 4, 13.

[13] *See* 42 U.S.C. § 300ff-33(g)(1)(B)(ii) ("post-test counseling (including referrals for care)" provided to individuals with positive HIV/AIDS test); 38 U.S.C. § 1720D(b)(2) (counseling for sexual-trauma treatment includes "referral services"); 42 U.S.C. § 3020e-1(b) (pension counseling includes "information, counseling, referral, and other assistance"); 20 U.S.C. § 1161k(c)(4)(A) (college counseling includes "referrals to and follow-up with other student services staff").

Senate Report observed that counseling in Title X program should follow "medical and professional ethics of the American Medical Association and the American College of Obstetricians and Gynecologists." S. Rep. 102-86 (1991). Senators made the same observations on the Senate floor. *See, e.g.*, 137 Cong Rec. at 18,439 (Senator Packwood) (Title X program should give "quality and type of counseling" that "organizations such as the American Medical Association state in their guidelines that physicians should give"). And legislators, representatives of medical associations, and advocates made clear that referrals fell within the settled meaning of nondirective counseling adopted by both medical standards of care and the 1981 Guidelines. *See e.g.*, H.R. Rep. 102-240 (1991) (1981 Guidelines required "nondirective options counseling" and "enumerated such options counseling to include information and referral").[14]

Although these bills were vetoed or otherwise not enacted, Congress later adopted the same settled meaning of nondirective pregnancy counseling when it

[14] *See also 1991 Reauthorization Hr'g*, at 10 (Representative Porter) (during nondirective counseling, "[h]onest information is given, referral provided"); 137 Cong Rec. at 18,453 (failing to provide referrals for abortion does not ensure that each patient "receives nondirective counseling"); *id.* at 18,435 (directive counseling includes requiring referral "only for prenatal care," prohibiting referrals for abortion, and providing "list of providers that promote the welfare of the mothers and unborn child").

imposed the Nondirective Mandate.[15] In response to efforts to defund Title X, Congress adopted the Nondirective Mandate to preserve the program and the then-existing "law and policy" about "abortion funding, counseling, and lobbying," 141 Cong. Rec. at H8252. At that time, existing law and policy—including the 1981 Guidelines then in place—required all Title X providers to offer referrals as part of nondirective pregnancy counseling. The Nondirective Mandate should be read to incorporate that established understanding of HHS and the medical community. *See McDermott Int'l, Inc. v. Wilander*, 498 U.S. 337, 342 (1991) (courts "assume that when a statute uses [a term of art], Congress intended it to have its established meaning").

Defendants misread HHS's prior rules as having treated referrals as separate from counseling, based on HHS's reference in those rules to both nondirective counseling "and" referrals. (*See* Br. 26–27). But read in context,

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[15] Defendants misplace their reliance (Br. 25–26) on the text of one of the unenacted bills, the Family Planning Amendment Acts of 1992. Consistent with the approach in HHS' 1981 guidelines, that bill treated "information" and "referrals" as elements of pregnancy counseling by requiring Title X providers to offer "nondirective counseling *and* referrals." *See* S. 323, 102nd Cong. § 2 (1992). The bill's drafters did so to specifically address (and overrule) the 1988 regulations in effect at the time, which separately prohibited *both* nondirective counseling and referrals. 53 Fed. Reg. at 2928, 2936. Congress did not need to include any similar specification concerning referrals when enacting the Nondirective Mandate in 1996, because HHS had by that time returned to the long-settled understanding that nondirective counseling includes referrals. *See California*, 2019 WL 1877392, at *17–18.

the word "and" specified that a referral, like the provision of factual information, is one of several pieces of the counseling process—in keeping with the medical establishment's understanding. Indeed, the 2000 regulations specified that counseling includes "factual information *and* nondirective counseling . . . *and* referral." 65 Fed. Reg. at 41,279. Defendants do not dispute that this regulation treated factual information about pregnancy options as part of nondirective counseling, notwithstanding the regulation's use of the term "and" between "factual information" and "nondirective counseling." The regulation likewise treated referrals as part of nondirective counseling, notwithstanding its use of the term "and" between "nondirective counseling" and "referrals."

Congress again expressed its understanding that nondirective counseling includes referrals when it enacted the IAAA as an amendment to the Public Health Service Act—the same law that contains Title X. The IAAA funded training "in providing adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women." 42 U.S.C. § 254c-6(a)(1). Both Congress and HHS made clear that the IAAA ensures staff will be trained to include "adoption information and referrals" in nondirective counseling on an equal basis with the nondirective counseling provided about other options. For

example, legislators explained that "the [IAAA] refers to pregnancy counselors providing adoption information and referrals as a part of pregnancy counseling." 146 Cong. Rec. at H2719. In assessing whether the IAAA was fulfilling its purpose "to promote training for presenting the option of infant adoption as part of a course of non-directive counseling," HHS evaluated "the extent to which adoption information and referral, upon request," were being provided. *Report to Congress*, *supra*, at 2. And in the Final Rule here, HHS reaffirmed that the IAAA expressed Congress's "intent that postconception adoption information and referrals be included as part of any nondirective counseling in Title X projects." 84 Fed. Reg. at 7730.[16]

Defendants' interpretation of § 254c-6(a)(1) to exclude the provision of "information and referrals" from "nondirective counseling" (Br. 27) contradicts the settled "presumption that a given term [i.e., nondirective counseling] is used to mean the same thing throughout a statute." *Brown v. Gardner*, 513 U.S. 115, 118 (1994).

Defendants' bald assertion that neither Congress nor HHS understood nondirective counseling to include referrals is further belied by the Final Rule,

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[16] *See also* 84 Fed. Reg. at 7744 (grantees "may provide adoption information and referrals" during postconception nondirective counseling because IAAA specified that Title X clinics "should receive training on providing adoption information and referrals").

in which HHS repeatedly "includes referrals within pregnancy counseling." (ER18). As the district court correctly observed, the Rule states that "Title X projects should not use nondirective pregnancy counseling, *or referrals* made for prenatal care or adoption *during such counseling*" to encourage or promote abortion as a method of family planning. 84 Fed. Reg. at 7747 (emphasis added). And it states that "nondirective pregnancy *counseling can include* counseling on adoption, and corresponding *referrals* to adoption agencies." *Id.* at 7730 (emphasis added). These statements do not remotely suggest that referrals are "something that merely may occur at the same time as counseling" (Br. 27–28), particularly given that HHS specified that "counseling, information, and referral" are "*part of* nondirective postconception counseling," 84 Fed. Reg. at 7733–34. Nor can these statements plausibly be dismissed as "preamble" (Br. 27) when HHS reiterated that nondirective counseling includes referrals throughout critical portions of the Final Rule explaining counseling.

Providing referrals for postconception services is particularly important for nondirective counseling in the context of Title X, because, as defendants emphasize (Br. 1, 38), Title X does not fund *any* postconception care. Thus, for a Title X provider, the fundamental purpose of nondirective counseling is to enable pregnant patients to make their own well-informed decisions about postconception care outside of the Title X program—whether that entails

prenatal, adoption, or abortion services. *See* 84 Fed. Reg. at 7716 (Final Rule explaining that nondirective counseling must "empower the client to be informed" about all postconception options). Denying a patient information about abortion services while forcing her to receive information about prenatal services impermissibly controls the "information she needs to make her own decision." 137 Cong. Rec. at 18,493; *see also id.* at 18,435 (Senator Chafee) (requiring referrals for prenatal care while prohibiting referrals for abortion "is not nondirective counseling" and is instead "forcing a woman to choose a particular option"). Title X's "limited" focus on preconception family-planning services (Br. 1) thus reinforces the importance of even-handed referrals for all postconception options during nondirective counseling. It does not provide any basis to treat postconception referrals as separate from counseling, or to prohibit referrals for only one postconception option (abortion) while requiring referrals for another postconception option (prenatal services).

b. The Final Rule's separation requirements and the counseling requirements likely violate § 1554 of the ACA

i. The Final Rule likely violates § 1554

As the district court properly concluded (ER23–26), the Final Rule's separation requirements and counseling requirements likely contravene § 1554 of the ACA, which broadly prohibits HHS from issuing "any regulation" that creates "unreasonable barriers" to medical care; impedes "timely access" to

such care; interferes with patient-provider communications "regarding a full range of treatment options"; restricts providers from giving "full disclosure of all relevant information to patients making health care decisions"; or violates healthcare providers' ethical standards. 42 U.S.C. § 18114. The separation requirements will force any provider that engages in abortion-related activities with non-Title X funds—including providers that simply refer patients for abortion as part of truly nondirective counseling—to maintain separate facilities, separate personnel and workstations, and separate healthcare records for such activities. And the counseling requirements interfere with patient-provider communications and require violations of ethical standards. *See, e.g.*, ACOG Comment 6 (physicians have an ethical obligation to "provide a pregnant woman who may be ambivalent about her pregnancy full information about all options in a balanced manner").

As many commenters warned, the physical separation requirements and counseling requirements will force many Title X providers to exit the program, thereby decimating States' Title X networks. This exodus of providers will severely impede patients' access to critical family-planning and health-care services. *See infra* at 40–45. Most Title X patients have low incomes, lack health insurance, and live in rural communities or face other substantial hurdles to accessing quality and timely healthcare. Such patients already have few

options and often rely on "Title X providers [as] their only ongoing source of health care and health education." HHS, Office of Population Affairs, Title X Family Planning Annual Report, 2016 National Summary, at ES-1 (Aug. 2017). The disruption caused by the separation and counseling requirements will thus impede access to care for many of the country's most vulnerable patients.

Defendants do not dispute that the Final Rule's limitations on nondirective counseling—including the prohibition against referrals for abortion and the rules about lists of primary care physicians—restrict grantees ability to communicate with patients and provide relevant information about pregnancy options. *See California*, 2019 WL 1877392, at *24. HHS asserted in the Final Rule that such information-sharing restrictions were appropriate because "[i]nformation about abortion and abortion providers is widely available and easily accessible, including on the internet." 84 Fed. Reg. at 7746. But blocking patients from receiving information from trusted medical professionals on the ground that patients can search the internet instead is precisely the type of interference with provider-patient communications that § 1554 prohibits.

Indeed, pregnant patients who are given directive counseling or referrals that omit abortion may have little reason to conduct their own internet research unless the Title X provider discloses that it has omitted abortion as an option—a

disclosure that the Final Rule does not require. *See* 84 Fed. Reg. at 7716. Instead, the patient will likely begin making appointments and visiting the providers to which she was referred. Such impediments to timely healthcare are particularly problematic because patients often must obtain an abortion quickly or lose their opportunity to do so.

ii. Plaintiffs did not waive their § 1554 claim.

The motions panel incorrectly accepted defendants' assertion (Br. 33–34) that plaintiffs waived their ACA challenge by not citing § 1554 by name during notice and comment. As an initial matter, the waiver doctrine is inapplicable where, as here, an agency's rulemaking is outside the scope of its statutory authority. *See Sierra Club v. Pruitt*, 293 F. Supp. 3d 1050, 1061 (N.D. Ca. 2018). The waiver doctrine ensures that an agency has a fair opportunity to "apply its expertise, to correct its own errors, and to create a record for" appellate review. *Portland Gen. Elec. Co. v. Bonneville Power Admin.*, 501 F.3d 1009, 1024 (9th Cir. 2007). But determining whether HHS has acted ultra vires falls squarely within the expertise of the courts rather than the agency—particularly when defendants do not contend that there is any ambiguity in § 1554. *See United States v. Able Time, Inc.*, 545 F.3d 824, 835–36 (9th Cir. 2008). The judicially created waiver doctrine thus does not give HHS license to maintain an ultra vires regulation that is plainly contrary to law.

In any event, commenters raised the "specific argument[s]" raised by plaintiffs here, *Koretoff v. Vilsack*, 707 F.3d 394, 398 (D.C. Cir. 2013) (per curiam), by identifying each substantive way in which the Final Rule contradicts § 1554.[17] For example, commenters emphasized that the Final Rule will "create barriers to access to women's healthcare," California Attorney General et al., Comment at 4 (July 30, 2018); "harm patients by reducing access to care" for time-sensitive procedures like abortion, New York Attorney General, Comment at 8, 11 (July 31, 2018); restrict "the provision of information on reproductive health and abortion," *id.* at 11; and force providers "to violate their ethical obligations," California Medical Association, Comment 4 (July 31, 2018). Indeed, HHS acknowledged comments "objecting that the Final Rule created barriers to patients' access to care, interfered with provider-patient communications, and violated principles of medical ethics." *California*, 2019 WL 1877392, at *21. HHS thus had ample "opportunity to consider the issue[s]." *Portland Gen.*, 501 F.3d at 1024; *see also Native Ecosystems Council*

[17] In *Koretoff*, no commenter had raised the underlying substantive issue of whether the agency had properly required treatment of food products "irrespective of whether they [were] contaminated." 707 F.3d at 398. Here, by contrast, commenters specifically raised each of the issues underlying whether HHS violated § 1554.

v. Dombeck, 304 F.3d 886, 899 (9th Cir. 2002) (no waiver where "administrative decisionmaker understood plaintiffs to raise the issue").

This is especially so because HHS was fully aware of § 1554 and that provision's relevance to regulatory provisions impeding access to contraception and abortion. Before HHS issued the Final Rule, it had already analyzed whether § 1554 was violated by a regulation allowing insurance plans to refuse to cover contraceptive care based on religious or moral objections—a regulation that is directly connected to the Final Rule's redefinition of "low income family" to include women whose insurance plans invoked such objections. *See* 83 Fed. Reg. 57,546, 57,551–52 (2018); 84 Fed. Reg. at 7734–39, 7787. Given that HHS was on notice of § 1554 and the substantive ways in which the Final Rule likely violates § 1554, defendants' argument boils down to the contention that commenters waived their § 1554 contrary-to-law argument by failing to cite that statute specifically. But this Court has already rejected such a formalistic approach, making clear that commenters "need not raise an issue using precise legal formulations" and that "alerting the agency in general terms will be enough." *Lands Council v. McNair*, 629 F.3d 1070, 1076 (9th Cir. 2010); *see also, e.g.*, *Idaho Sporting Cong., Inc. v. Rittenhouse*, 305 F.3d 957, 966 (9th Cir. 2002) (no waiver where commenters "expressed concern" without citing regulation).

iii. Defendants' other arguments are meritless

There also is no merit to defendants' other objections to § 1554's applicability here. First, defendants contend (Br. 35–36) that § 1554 applies to regulations issued under only the ACA and not to regulations issued under Title X. But by its plain terms, § 1554 broadly precludes HHS from promulgating "*any* regulation" that contravenes § 1554's terms. 42 U.S.C. § 18114 (emphasis added). By contrast, where Congress wanted a provision to apply to actions taken under only the ACA, it said so expressly. *See*, *e.g.*, 42 U.S.C. § 18112 (directing HHS to publicly list all "authorities provided to the Secretary under this Act"); *id.* § 18113 (prohibiting providers that receive "Federal financial assistance under this Act" from engaging in certain discrimination). Congress thus knew "how to limit" the ACA's application but declined to limit § 1554's reach. *See Miller v. Clinton*, 687 F.3d 1332, 1340 (D.C. Cir. 2012).

Defendants are incorrect that Congress limited § 1554 by using the prefatory phrase "[n]otwithstanding any other provision of this Act," 42 U.S.C. § 18114. This prefatory clause means that HHS "cannot engage in the type of rulemaking proscribed," i.e., issue any regulation that violates § 1554, "even if another provision of the ACA could be construed to permit" such a regulation. *California*, 2019 WL 1877392, at *21; *see also Cisneros v. Alpine Ridge Group*, 508 U.S. 10, 16 (1993) (clause "notwithstanding any other provision of

this Contract" applies "even if other provisions of the contracts might seem" to require different result).

Contrary to defendants' suggestion (Br. 34–35), Congress's decision to constitute Title X as a federal funding statute does not exempt the Final Rule from § 1554. Section 1554's broad application to "any regulation" promulgated by HHS easily encompasses regulations issued under funding statues, 42 U.S.C. § 18114. The purported distinction that defendants draw between federal funding programs and other congressional programs comes from an entirely different context: *Rust*'s discussion of the First and Fifth Amendment right to choose whether to obtain an abortion, *see* 500 U.S. at 202. The distinction thus lacks any grounding in the ACA provision at issue here or the APA. *See California*, 2019 WL 1877392, at *23. Accordingly, the district court properly determined that the Final Rule likely violates § 1554.

c. Defendants misplace their reliance on *Rust* and the presumption against implied repeal.

The repeated reliance on *Rust* by defendants (Br. 1–2, 15–21, 30–31) misses the mark because the Supreme Court's 1991 decision in *Rust* did not address either the Nondirective Mandate, which dates from 1996, or the ACA, which was enacted in 2010. As the district court correctly observed (ER16–17), the Court in *Rust* concluded that § 1008's prohibition on providing "abortion [as] a method family planning" was ambiguous under then-existing statutes

because "[a]t no time did Congress directly address the issues of abortion counseling, referral, or advocacy." 500 U.S. at 185. But "[t]he relevant statutory text" (Br. 21) has since changed. Congress in 1996 directly addressed the issues that were previously ambiguous by requiring that "all pregnancy counseling" in Title X be "nondirective," 132 Stat. at 3070–71, and prohibiting HHS from issuing regulations that impose unreasonable barriers to care or interfere with patient-provider communications, 42 U.S.C. § 18114.

Indeed, HHS has conceded that the Nondirective Mandate "imposed additional requirements" not at issue in *Rust*, 84 Fed. Reg. at 7720, and that HHS "must enforce" Congress's requirement that all Title X "pregnancy counseling be nondirective," *id.* at 7747. And defendants do not dispute that in 2010, Congress precluded HHS from issuing any regulations that violate § 1554. Far from abrogating *Rust* (Br. 2, 22), the district court properly gave effect to statutory provisions not considered in *Rust*.

Defendants' reliance on the presumption against implied repeals (Br. 22–23, 29–32) misconstrues the district court's decision. That presumption applies where two statutes might be interpreted as "in irreconcilable conflict," *Branch v. Smith*, 538 U.S. 254, 273 (2003) (quotation marks omitted), and requires courts to avoid such conflict by adopting a "reading that harmonizes the statutes," *National Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S.

644, 662 (2007). The district court correctly applied these principles here—as the motions panel acknowledged (Op. 17). As the district court explained, § 1008 continues to prohibit providers from using Title X funds for abortions. The Nondirective Mandate clarifies that, unlike funding for abortions, nondirective counseling is allowed by § 1008.[18] And the ACA limits HHS's discretion to enact certain regulations, without repealing § 1008. The statutes thus do not conflict with one another and instead work together "as a harmonious whole." *Epic Systems Corp. v. Lewis*, 138 S. Ct. 1612, 1619 (2018). It is the Final Rule—not § 1008—that conflicts with both the Nondirective Mandate and the ACA.

Defendants' arguments find no support in *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984). Defendants contend that any congressional enactment that clarifies ambiguity in a preexisting statute necessarily affects an implied repeal because it removes an agency's prior "authority" to interpret that statute reasonably. (*See* Br. 31–32). But this contention upends basic principles

[18] Defendants incorrectly contend (Br. 23) that interpreting the Nondirective Mandate to include referrals must impliedly repeal § 1008 because there is no "alternative interpretation of § 1008 under which a program that makes referrals" does not violate § 1008. But § 1008 is easily reconcilable with an interpretation of the Nondirective Mandate that includes referrals. (*See* ER16–17). As HHS explained both before and after *Rust*, providing referrals during pregnancy counseling does not promote abortion so long as referrals are provided in a nondirective manner. *See* 65 Fed. Reg. 41,270–75.

of statutory construction and separation of powers. *Chevron* deference comes into play when traditional tools of statutory construction leave courts with ambiguity that Congress did not resolve. *See Epic*, 138 S. Ct. at 1630. It has no application where, as here, Congress's later enactments remove statutory ambiguity and foreclose previously permissible interpretations that an agency preferred.

Contrary to defendants' contention (Br. 30, 35), there is nothing unusual about Congress using an appropriations statute to clarify the proper interpretation of an existing law. Using the appropriations process to clarify Title X makes sense because Congress wanted to preserve, rather than alter, its existing enactment and insulate that enactment from being interpreted differently going forward.

Nor is there anything surprising about Congress using § 1554 to limit HHS's authority to issue "any regulation" that imposes unreasonable barriers to healthcare or unduly interfere with patient-provider communications. 42 U.S.C. § 18114. The ACA broadly overhauled the nation's entire healthcare system and contains other provisions that, like § 1554, apply to actions taken under preexisting statutory regimes. *See id.* § 18116(a) (nondiscrimination provision extends to all federally funded health programs). Again, Congress was merely maintaining the status quo.

2. The Final Rule is arbitrary and capricious because HHS failed to adequately address the significant detriment it would cause to the Title X program and public health.

Under the APA, an agency acts arbitrarily and capriciously where it fails to engage in "reasoned decision-making" that rests on a logical "consideration of relevant factors." *Michigan v. EPA*, 135 S. Ct. 2699, 2706 (2015). Here, the district court correctly found that plaintiffs had established serious questions regarding whether the Final Rule satisfied this reasoned decision-making standard. (ER27). These serious questions amply supported the preliminary injunction given the irreparable harm to plaintiff States and the public absent the injunction. *See Alliance for the Wild Rockies*, 632 F.3d at 1131–35. In any event, plaintiffs established that the Final Rule is likely arbitrary and capricious.

First, HHS failed to provide any evidentiary support or rational explanation for its conclusion that the Rule will not "have a significant impact on access to services." 84 Fed. Reg. at 7782. *See Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Auto Ins. Co.*, 463 U.S. 29, 43 (1983). Overwhelming evidence submitted to HHS demonstrates that the Final Rule will force many state and private providers to leave Title X. For example, state grantees—including Washington, New York, Hawaii, and Oregon, which together serve 427,000 Title X patients—will likely exit Title X. (Governor Cuomo Letter 2; Governor Ige Letter 1; PPFA Comment 15). And the Rule will

force Planned Parenthood to exit the program—stripping approximately 40% of all Title X patients of their trusted family-planning and healthcare providers. (ER31; PPFA Comment 15–16). Planned Parenthood's exit will be particularly devastating in States like Vermont, where Planned Parenthood is the *only* Title X provider. (Washington AG et al. Comment 24).

This mass exodus of providers will be devastating for plaintiff States, their residents, and public health. (*See* ER31–32). Providers that remain will not be able to fill the extreme gaps in Title X services. (AMA Comment 11–13; Guttmacher Comment 20; Washington AG et al. Comment 23–26; California AG et al. Comment 14). The result will be more unintended pregnancies, riskier pregnancies, more abortions, more sexually transmitted infections, and worse health outcomes. (ER31–32; NYDOH Comment 7–9; California AG Comment 14, 16).

Faced with this evidence, HHS speculated—with no support—that such harms may not occur because new providers will materialize to fill gaps in services. 84 Fed. Reg. at 7782; *see also* Tr. 60 (HHS unable to identify any new providers who might apply for Title X funding). Such "conclusory statements" do not constitute reasoned decision-making. *Getty v. Fed. Savs. & Loan Ins. Corp.*, 805 F.2d 1050, 1057 (D.C. Cir. 1986). Contrary to HHS's assertions, the current nondirective counseling requirements provide no plausible reason for

providers to refrain from joining the Title X program, because HHS does not enforce the 2000 regulations against providers or applicants with religious or moral objections to abortion. *See* 84 Fed. Reg. 23,170, 23,191 n.64 (2018). And even if a handful of providers previously stayed out of Title X for religious reasons despite the nonenforcement policy, nothing suggests that there are enough such providers to fill the void created by the exit of Planned Parenthood and other established Title X providers.

Second, the evidence that HHS possessed belies its conclusion that the Final Rule will not force medical professionals to violate medical standards of care and ethics. The Rule's counseling requirements flatly violate medical standards and ethics by requiring providers to withhold abortion-related information from patients, force patients to receive information that they have stated they do not want, and make referral decisions inconsistent with a patient's medical needs. (ER28–29; NYDOH Comment 1, 8–9; Washington AG et al. Comment 11–13; California AG et al. Comment 5–6).

There is no support for HHS's contention that the Final Rule comports with medical ethics on the ground that providers are not completely foreclosed from discussing abortion. *See* 84 Fed. Reg. at 7724. By prohibiting abortion referrals, forcing providers to hide the identities of primary care providers that offer abortion, and otherwise restricting abortion-related information, the Final

Rule prevents medical professionals from giving patients complete information. HHS's failure to grapple with such fundamental violations of medical ethics renders the Rule arbitrary and capricious. *See State Farm*, 463 U.S. at 43 (agency's decision is arbitrary and capricious if it "runs counter to the evidence before the agency").

HHS's assertions about medical ethics find no support in refusal-of-care statutes, *see* 84 Fed. Reg. at 7748, because these statutes do not address medical ethics. They restrict the government from compelling providers to conduct or refer for abortion, and prohibit certain actions against providers who refuse to give such services due to religious or moral convictions. *See* 42 U.S.C. § 300a-7; 42 U.S.C. § 238n; Weldon Amendment, Consolidated Appropriations Act, 2009, Pub. L. No. 111-117, 123 Stat 3034 (2009). Refusal-of-care laws reflect that *even if* refusing to refer for abortion violates medical ethics, a provider who does so for religious or moral reasons will be protected from certain disciplinary actions.

Third, the Final Rule's separation requirements were unnecessary to ensure that grantees do not use Title X funds for improper purposes. *See* 84 Fed. Reg. at 7763–68; 83 Fed. Reg. 25,502, 25,507 (2018). HHS identified no evidence that grantees are improperly using Title X funds or are confused by proper separation procedures. Rather, the record demonstrates that HHS and

grantees maintain robust monitoring and auditing procedures that "ensure that federal funds are used appropriately and that funds are not used for prohibited activities such as abortion."[19] (NYDOH Comment 18–19, 24–26; Washington AG et al. Comment 15–19; California AG et al. Comment 19–20). For example, HHS conducts in-depth audits of grantees and subgrantees, including onsite monitoring. (NYDOH Comment 18–19; Washington AG et al. Comment 15–17). And many States have implemented additional oversight mechanisms. (NYDOH Comment 15; Washington AG et al. Comment 17–19). Thus, unlike in *Rust*, HHS possessed decades of evidence demonstrating that Title X funds are not being used for impermissible purposes. HHS's contrary assertion in the Final Rule "runs counter to the evidence before it." *State Farm*, 463 U.S. at 43.

Fourth, HHS improperly ignored that complying with the physical-separation requirements is cost-prohibitive for many providers. (PPFA Comment 21, 30–34; Washington AG et al. Comment 23–24; NYDOH Comment 18–19). The cost estimates that HHS considered lacked any factual basis. HHS estimated—without identifying any support—that the separation requirement would cost providers $20,000 to $40,000. 84 Fed. Reg. at 7781–82.

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[19] Angela Napili, Cong. Research Serv., R 45181, *Family Planning Program under Title X of the Public Health Service Act* at 14 (Updated October 15, 2018).

The administrative record, however, shows that many providers' expenditures will approach $625,000—more than fifteen times the highest figure HHS cited. (PPFA Comment 30–31). As a number of State Attorneys Generals explained, many providers "will effectively have to open a second clinic for every site to obtain Title X funding." (California AG et al. Comment 23). The lack of any rationale for HHS's cost figures violates the APA and further distinguishes this case from *Rust*, which was decided based on a different, now-outdated record.

HHS's lack of reasoned explanation is particularly egregious given that the Final Rule's radical departure from long-established policy will upend strong reliance interests. Title X providers have built clinics, hired personnel, and otherwise structured their operations around HHS's longstanding view that § 1008 requires only financial (but not physical) separation. (NYDOH Comment 17–19; Washington AG et al. Comment 17–19; California AG et al. Comment 10–11). And the mass exodus of providers that will result from providers exiting the program rather than restructuring their entire operations will hinder access to family-planning and medical care, and increase the cost of such care. (Washington AG et al. Comment 23–26; NYDOH Comment 18–20). HHS acted arbitrarily and capriciously in disregarding these strong reliance interests of Title X providers and the low-income patients whom Title X is

designed to serve. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (agency regulation should account for serious reliance interests).[20]

B. The district court did not abuse its discretion in finding that plaintiffs and the public will suffer irreparable harm.

The district court's preliminary injunction merely maintains a status quo that has been in place for nearly half a century. Neither HHS nor the public at large are likely to suffer *any* irreparable harm from the preliminary injunction—let alone a harm greater than the harm that plaintiffs are likely to suffer if the Final Rule takes effect while this case is pending. Other than a single declaration in support of their motion for a stay pending appeal, defendants submitted *no* evidence to the district court on any of the factors bearing on the balance of harms or the public interest. Plaintiffs, by contrast, submitted

[20] The motion panel incorrectly suggested that HHS adequately explained its reason for adopting the counseling requirements by simply stating that it was *a* "reasonable reading of § 1008." (Op. 23). *Rust* recognized that § 1008 was ambiguous and that HHS's 1988 rule was one reasonable interpretation. But HHS has adhered to a contrary reading for most of the last fifty years. Faced with the significant damage the Rule will cause to the Title X program, HHS had to provide a reasoned explanation for why it chose *that* reading over others. *See Encino Motorcars*, 136 S. Ct. at 2125–26 (when an agency changes policy a "reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy"); *Judulang v. Holder*, 565 U.S. 42, 53 (2011) (courts "retain a role, and an important one, in ensuring that agencies have engaged in reasoned decisionmaking" based on relevant factors).

extensive evidence of the harms they and the public would suffer without a preliminary injunction. (ER6).

When the Final Rule takes effect, plaintiff States and the public will be irreparably harmed by the dismantling of their current Title X networks. As the district court correctly found, the harms that the Final Rule threaten to plaintiffs "are extensive and not rebutted by the government." (ER6, 32–33).

The "elimination of Title X providers [will] be detrimental to public health." (ER31–32); *see California v. Azar*, 911 F.3d 558, 581–82 (9th Cir. 2018) ("potentially dire public health" consequences from rule that would decrease contraceptive coverage). The Title X providers that remain will be unable to maintain the same quality of care due to the dramatic increase in their patient load, restrictions on counseling and referral, and the need to shift spending from patient care to administrative costs. (PSER22–23; SSER42, 83–84, 96–97). Patients will lose access to the providers they trust and rely on for care. (PSER97; SSER2–4, 28–29, 44–45, 69–71, 97).

Because the availability and quality of comprehensive preventive healthcare will decrease, the Final Rule "will result in less contraceptive services, more unintended pregnancies, less early breast cancer detection, less screening for cervical cancer, less HIV screening, and less testing for sexually transmitted disease." (ER6, 31–34; *see* PSER118–124, 172; SSER28, 47–49).

These harms will fall especially hard on patients who have low incomes, or live in rural areas or communities of color—conditions that already impose barriers to quality healthcare. (PSER3, 7, 25–28, 92; SSER52, 97). Patients in regions where affordable healthcare is scarce will thus be left with few or no options. (PSER3, 22–23; SSER52, 54, 97).

States will also suffer irreparable economic harm from the exodus of Title X providers. *See Azar*, 911 F.3d at 581–82 (9th Cir. 2018) (State's economic interest threatened by reduction in contraceptive coverage). States that are direct Title X grantees risk losing all Title X funding and every Title X clinic in their current network. *Id.* (lost Title X fund cannot be recouped from federal government); (SSER2–4, 67–68, 96–98). States that attempt to maintain their Title X programs will face significant administrative costs to do so. For example, the Oregon Health Authority estimates that it would incur almost $1 million in administrative costs to impose the structural changes required by the Final Rule. (SSER68). And States will face an increase in costs to state programs like Medicaid that will necessarily try to fill the gaps in care and address the negative health outcomes caused by the loss of Title X providers, such as more unintended pregnancies and delayed cancer diagnoses. (SSER13–16, 52, 83–84, 97–98).

Defendants brush aside all that unrebutted evidence as speculative (Br. 42–43) and the motions panel dismissed these harms as "comparatively minor" (Op. 24). But the evidence was compelling—as the district court found (ER 5–6)—and there is nothing minor about eliminating necessary healthcare for millions of low-income individuals (ER5–6, 31–32; PSER3). This case does not simply concern "ordinary compliance costs" while the appeal is pending (Br 43); it is about maintaining a stable network of providers to ensure access to reproductive healthcare. In light of the dire consequences to plaintiffs and the public, the balance of equities tips in favor of plaintiffs.

Defendants identified two supposed harms to HHS, but neither withstands scrutiny. First, HHS faces no harm in spending taxpayer dollars to enforce § 1008 as that statute has been interpreted for decades. (Br. 44–45). Defendants' contention that such spending violates § 1008 by "fund[ing] or subsidiz[ing] abortions" is predicated solely on their view of the merits. As *Rust* reflects, § 1008 itself is ambiguous on that point; HHS's new interpretation is contrary to law and arbitrary and capricious; and in any event there is *zero* evidence in the record that any Title X funds have ever been illegally diverted to funding abortions. The government "cannot suffer harm from an injunction that merely ends an unlawful practice." *Rodriguez v. Robbins*, 715 F.3d 1127, 1145 (9th Cir. 2013).

Second, the record does not support the conclusion that HHS needs a stay to avoid "significant administrative costs" or "uncertainty for the Title X program" (Br. 45)—much less that the district court abused its discretion in concluding otherwise. Defendants submitted no evidence whatsoever about any administrative costs. *See, e.g.*, *Hernandez v. Sessions*, 872 F.3d 976, 995 (9th Cir. 2017) (rejecting the government's "conclusory assertions" of harm in a declaration submitted on appeal when they were not "supported by any actual evidence"). And it is hard to imagine what those costs would be, when HHS need not do anything differently from what it has already been doing for years. As for avoiding uncertainty in the Title X program, maintaining the status quo—not disrupting it—is the surest way to protect that interest.

C. The district court did not abuse its discretion over the scope of the injunction.

The scope of the district court's preliminary injunction matches what the APA contemplates for cases like this. Under 5 U.S.C. § 705, when a reviewing court concludes that it is "necessary to prevent irreparable injury," the court is authorized "to postpone the effective date of an agency action . . . pending conclusion of the review proceedings." That is effectively what the preliminary injunction does here. The injunction preserves the status quo by prohibiting defendants from implementing the Rule while the case is pending. There is no practical difference between what the district court did here and an order

"postpon[ing] the effective date" of the Rule under 5 U.S.C. § 705. That is a complete answer to defendants' arguments about the scope of the injunction. (Br. 46–51). A nationwide injunction is appropriate because the Rule applies nationwide; postponing its effective date pending judicial review necessarily prevents its implementation anywhere. Similarly, enjoining the Rule's application to nonparties and enjoining the entire rule, not just particular sections, is appropriate because a Rule that has not come into effect cannot be applied. Because, as explained above, the Rule will cause irreparable injury if it is allowed to take effect before judicial review is complete, the district court did not abuse its discretion in adopting the interim remedy suggested by the APA itself, rather than some narrower remedy that might theoretically have been available.

But even without considering 5 U.S.C. § 705, the district court had the authority to preserve the status quo for the entire Title X program, including as to nonparty providers. *See Trump v. Int'l Refugee Assistance Project (IRAP)*, 137 S. Ct. 2080, 2087 (2017) (Supreme Court refusing to stay the portion of a preliminary injunction that covered "not just respondents, but parties similarly situated to them," because the same equities that justified relief for the parties also justified extending that relief nationwide). If plaintiffs succeed on the merits of their APA claim, they will be entitled to an order that "set[s] aside"

the agency action—here, the Rule. 5 U.S.C. § 706(2); *see Earth Island Inst. v. Ruthenbeck*, 490 F.3d 687, 699 (9th Cir. 2007), *aff'd in part, rev'd in part sub nom. Summers v. Earth Island Inst.*, 555 U.S. 488 (2009). And plaintiffs submitted unrebutted evidence that the Final Rule will have an adverse impact on public health everywhere, not just in the 21 States that sued. (*See* SSER44–49; PSER118–126, 133–138) (discussing nationwide harms). Because the ultimate relief would extend nationwide to nonparties and the equities are the same for those nonparties, it is appropriate for the preliminary injunction to cover the same scope.

The district court also did not abuse its discretion by rejecting defendants' passing request that it limit the preliminary injunction to particular provisions. (C.R. 83 p 65; Tr. 131–33). The district court correctly found problems with *both* the counseling requirements and the separation requirements, and it permissibly concluded that the rest of the Rule—the more ancillary provisions, as defendants had characterized them—could not function on their own. *See MD/DC/DE Broadcasters Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001) ("Whether the offending portion of a regulation is severable depends upon the intent of the agency *and* upon whether the remainder of the regulation could function sensibly without the stricken provision.") (emphasis in original); *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2319

(2016) ("[A] severability clause is an aid merely; not an inexorable command.").

CONCLUSION

The district court did not abuse its discretion in entering a preliminary injunction. This Court should affirm.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7), Federal Rules of Appellate Procedure, I certify that the Appellee's Brief is proportionately spaced, has a typeface of 14 points or more and contains 11,513 words.

DATED: June 28, 2019

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IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

STATE OF OREGON, et al., Plaintiffs-Appellees, v. ALEX M. AZAR, in his official capacity as Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants-Appellants.	U.S.C.A. No. 19-35386
AMERICAN MEDICAL ASSOCIATION, et al., Plaintiffs-Appellees, v. ALEX M. AZAR, in his official capacity as Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants-Appellants.	U.S.C.A. No. 19-35386 STATEMENT OF RELATED CASES

The following related cases, involving preliminary injunctions of the same Final Rule, are currently pending in this Court: *National Family Planning*

& Reproductive Health Ass'n v. Azar, No. 19-35394; *State of Washington v. Azar*, No. 19-353-94; *Essential Access Health Inc. v. Azar*, No. 19-15979.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 28, 2019, I directed the Appellee's Brief to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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No. 19-35386

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v.

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Defendants-Appellants.

AMERICAN MEDICAL ASSOCIATION, et al.,

Plaintiffs-Appellees,

v.

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Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON

ADDENDUM TO STATES' ANSWERING BRIEF

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 59

RIN: 0940–AA00

Standards of Compliance for Abortion-Related Services in Family Planning Services Projects

AGENCY: Office of Population Affairs, OPHS, DHHS.

ACTION: Final rules.

SUMMARY: The rules issued below revise the regulations that apply to grantees under the federal family planning program by readopting the regulations, with one revision, that applied to the program prior to February 2, 1988. Several technical changes to the regulation are also made to remove and/or update obsolete regulatory references. The effect of the revisions made by the rules below is to revoke the compliance standards, promulgated in 1988 and popularly known as the "Gag Rule," that restricted family planning grantees from providing abortion-related information in their grant-funded projects.

DATES: These rules are effective July 3, 2000.

FOR FURTHER INFORMATION CONTACT: Samuel S. Taylor, Office of Population Affairs, (301) 594–4001.

SUPPLEMENTARY INFORMATION: The Secretary of Health and Human Services issues below regulations establishing requirements for recipients of family planning services grants under section 1001 of the Public Health Service Act, 42 U.S.C. 300. The rules below adopt, with minor technical amendments and one substantive modification, the regulations proposed for public comment on February 5, 1993, at 58 FR 7464. They accordingly revoke the compliance standards, known as the "Gag Rule," promulgated on February 2, 1988.

By notice published elsewhere in this issue of the **Federal Register**, the Department is separately acting to reinstitute, with minor changes, the interpretations of the statute relating to the provision of abortion-related information and services that applied to grantees prior to the issuance of the Gag Rule. The Secretary had previously proposed reinstituting these interpretations in the notice of February 5, 1993 and requested public comment on this proposed action; the public comment period was subsequently reopened by notice of June 23, 1993, 58 FR 34024.

I. Background

In 1988, the Secretary of Health and Human Services issued rules, widely known as the "Gag Rule," which substantially revised the longstanding polices and interpretations defining what abortion-related activities were permissible under Title X's statutory limitation on abortion services. That statutory limitation, section 1008 (42 U.S.C. 300a–6), provides that "[n]one of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." The rules issued on February 2, 1988 (53 FR 2922) set out detailed requirements that (1) Prohibited the provision to Title X clients of nondirective counseling on all pregnancy options and referral to abortion providers, (2) required physical and financial separation of abortion-related activities from Title X project activities, and (3) prohibited Title X projects from engaging in activities that encourage, promote, or advocate abortion. These requirements are presently codified principally at 42 CFR 59.7–59.10.

The February 2, 1988 "Gag Rule" was extremely controversial: The proposed rules generated approximately 75,000 public comments, many of which were negative. 53 FR 2922. The rules were subsequently challenged in several district courts by a variety of providers, provider organizations, and others. Although the requirements embodied in the Gag Rule were upheld by the Supreme Court in 1991 as a permissible construction of section 1008, the rules continued to be a source of controversy, with the provider and medical communities litigating after 1991 to prevent enforcement of the rules. Following his inauguration in 1993, President Clinton ordered the Secretary to suspend the rules and initiate a new rulemaking:

> The Gag Rule endangers women's lives and health by preventing them from receiving complete and accurate medical information and interferes with the doctor-patient relationship by prohibiting information that medical professionals are otherwise ethically and legally required to provide to their patients. Furthermore, the Gag Rule contravenes the clear intent of a majority of the members of both the United States Senate and House of Representatives, which twice passed legislation to block the Gag Rule's enforcement but failed to override Presidential vetoes.
>
> For these reasons, you have informed me that you will suspend the Gag Rule pending the promulgation of new regulations in accordance with the "notice and comment" procedures of the Administrative Procedure Act. I hereby direct you to take that action as soon as possible. I further direct that, within 30 days, you publish in the **Federal Register** new proposed regulations for public comment.

Presidential Memorandum of January 22, 1993, published at 58 FR 7455 (February 5, 1993). The Secretary subsequently suspended the 1988 rules on February 5, 1993 (58 FR 7462) and issued proposed rules for public comment (58 FR 7464).

The notice of proposed rulemaking proposed to revise the program regulations by readopting the program regulations as they existed prior to the adoption of the Gag Rule, which would have the effect of revoking the Gag Rule. It also proposed that the policies and interpretations in effect prior to the issuance of the Gag Rule be reinstated, both in substance and in form. As noted in the proposed rules, these policies and interpretations, which had been in effect for a considerable time prior to 1988, were set out largely, "in the 1981 Family Planning Guidelines and in individual policy interpretations." 58 FR 7464. The pre-1988 interpretations had been developed during the 1970's and early 1980's in response to questions arising out of the Department's initial interpretation that section 1008 not only prohibited Title X projects from performing or providing abortions, but also prohibited actions by Title X projects that "promoted or encouraged" abortion as a method of family planning. Over time, questions were raised, and answered in a series of legal opinions, as to whether particular actions would violate the statute by promoting or encouraging abortion as a method of family planning. As summarized in the proposed rules, the answers that were developed were generally as follows:

> Title X projects [are] required, in the event of an unplanned pregnancy and where the patient requests such action, to provide nondirective counseling to the patient on all options relating to her pregnancy, including abortion, and to refer her for abortion, if that is the option she selects. However, consistent with the long-standing Departmental interpretation of the statute, Title X projects [are] not * * * permitted to promote or encourage abortion as a method of family planning, such as by engaging in pro-choice litigation or lobbying activities. Title X projects [are] also * * * required to maintain a separation (that is more than a mere exercise in bookkeeping) of their project activities from any activities that promote or encourage abortion as a method of family planning.

Id. By notice dated June 23, 1993 (58 FR 34024), the Secretary made available for public comment a detailed exposition of the prior policies and interpretations.

In the public comment periods, the Secretary received 146 comments,

virtually all of which concerned the proposed policies and interpretations rather than the proposed regulations themselves. Approximately one-third of these opposed the proposed policies and interpretations on various grounds; most of these comments were from individuals who, in general, were opposed to any change to the Gag Rule. The remainder of the public comments, most of which were from providers and other health organizations, generally supported the reinstatement of the prior policies and interpretations, although a number of these comments suggested that they be modified in various respects. The public comments and the Secretary's response thereto are summarized below.

II. Public Comment and Departmental Response

The public comment generally focused on a few issues raised by the rulemaking. As noted above, these comments generally pertained to the proposed policies and interpretations rather than to the proposed regulatory language itself. Accordingly, the comments on the issues raised in the rulemaking are summarized below, and the Secretary's response thereto is provided.

A. Lack of a Rational Basis To Revoke the Gag Rule; Necessity for Continuation of the Gag Rule

Most of the comments in opposition to the proposed rules came from individuals, and most objected to the proposed revocation of the Gag Rule on the ground that abortion is wrong or that tax dollars should not be used to provide abortion services of any kind. Several comments also objected that the Secretary had not rational basis for revoking the Gag Rule, as it had never gone into operation. For example, a comment signed by fifteen members of Congress argued that—

> HHS intends to discard the February 2, 1988 regulations in their entirety * * * regardless of whether any particular portion was the subject of court challenge or legislative action. * * * We believe the rejection of the 1988 rule is precipitous and that each portion of the 1988 regulations must be reviewed on its merits and justification provided in any final regulations as to why the 1988 clarifications were or were not maintained in a new rule.

With respect to the comments objecting to the revocation of the Gag Rule or the use of tax dollars for abortion on moral grounds, the Secretary notes that, under the interpretations adopted in conjunction with the regulations below, the funding of abortion or activities that promote or encourage abortion with Title X funds has been and will continue to be prohibited. Rather, what changes under the interpretations reinstated in conjunction with the regulations below is which activities are considered to "promote or encourage" abortion. In contrast to the position taken under the Gag Rule, under the present view (which was also the Department's view of the statute prior to 1988), the provision of neutral and factual information about abortion is not considered to promote or encourage abortion as a method of family planning. Indeed, the rule itself, now requires the provision to pregnant women, on request, of neutral, factual information and non-directive counseling on each of three options. The basic statutory interpretation underlying both the Gag Rule and the specific policies that governed the Title X program prior to 1988—that section 1008 prohibits activities that promote or encourage abortion as a method of family planning—remains unchanged.

With respect to the contentions that the Secretary lacks a rational basis for revoking the Gag Rule and that she must justify each separate part of the Gag Rule being discarded, we do not agree. The pre-1988 interpretation of the statute represents a permissible exercise of administrative discretion. The crucial difference between this approach and the Gag Rule is one of experience. Because of ongoing litigation, the Gag Rule was never implemented on a nationwide basis, so that its proponents can point to no evidence that it can and will work operationally on a national basis in the Title X program. The policies reflected in, and interpretations reinstituted in conjunction with, the regulations below, on the other hand, have been used by the program for virtually its entire history; indeed, they have been in effect during the pendency of this rulemaking. Both the program managers and the Title X grantee community are well-versed in these policies and interpretations, and the grantees have in the past generally been able to operate in compliance with them. Further, as evidenced by the public comment received, the reinstituted policies and interpretations are generally acceptable to the grantee community, in contrast to the compliance standards in the Gag Rule, which were generally unacceptable to the grantee community. This factor likewise favors their adoption, as it suggests a far greater likelihood of voluntary compliance by grantees. Finally, the suggestion that the Gag Rule provisions should be accepted or rejected separately is rejected as unsound. The provisions of the Gag Rule were an interrelated set of requirements that depended on several underlying assumptions about how the Title X program should work; moreover, they depended in part on several definitions that applied to all the major provisions of the Gag Rule. *See,* in this regard, 53 FR 2923, 2925; *see also,* the discussion of definitions at 53 FR 2926–2927.

B. Failure To Comply With the Administrative Procedure Act; Vagueness of Standards

A number of comments, from both proponents of and opponents to the proposed rules, objected to the failure to publish the actual policies and interpretations as part of the proposed rule on the ground that this violated the public comment requirements of the Administrative Procedure Act (APA); several comments argued that it was impossible to comment on policies that had never been published. A related criticism was that several of the interpretations described in the preamble to the notice of proposed rulemaking, particularly the interpretation relating to physical separation, were too vague.

The Secretary agreed that the provision of further information on the specific details of the pre-1988 policies and interpretations would promote more helpful public comment. Accordingly, by notice dated June 23, 1993 (58 FR 34024), the Department made available on request a summary of the policies and interpretations in existence prior to 1988. The June notice also extended the public comment period for 45 days, to permit further substantive comment on the prior policies and interpretations. Over a third of the public comments, including the majority of the comments from individuals, were received during the re-opened and comment period. The Secretary has thus addressed the concern about notice of the content of the policies and interpretations expressed by these comments.

As is further discussed below, the Secretary has incorporated in the regulatory text the policies relating to nondirective counseling and referral of the 1981 Program Guidelines for Project Grants for Family Planning Services (1981 Guidelines). The comments urging that these Guidelines requirements be reflected in the regulations have thus been accepted. With respect to the longstanding program interpretations, however, the Secretary does not agree that the Department is required to set out those

interpretations in the regulations promulgated below and accordingly, has not accepted the comments suggesting that it do so. As noted above, the interpretations themselves were developed in the classic way in which statutory interpretations are done: That is, they have generally been developed in legal opinions written to answer questions about how the statutory prohibition, as initially interpreted by the Department, applied to particular situations. This is not an unusual approach within the program as a whole: Interpretive guidance has been provided on a number of issues (*e.g.*, fee schedules, use of certain methods) over the years, as particular questions have arisen in the course of the program. While the program could incorporate those interpretations in the legislative rules below, the Secretary has decided not to do so. With respect to the areas that continue to be covered by guidance, the Secretary believes that incorporating the guidance into the regulations below would be inadvisable and unnecessary. The Secretary has thus chosen to preserve the program's flexibility to address new issues that may arise in this area.

Moreover, the Title X program grantees have operated on the basis of the policies of the 1981 Guidelines and the interpretations summarized in the notice published elsewhere in this issue of the **Federal Register** for virtually the entire history of the program and in general compliance with them. As the comment of one State agency grantee stated with regard to this issue:

> The [State] Family Planning Program has been a participant in the nation's Title X program since the early 1970's. The rules and *1981 Family Planning Guidelines* in place prior to the "Gag Rule" were adequate guidance to the state for program operation and for compliance with the statutory prohibition related to abortions. These guidelines and directives have been used successfully for many years in providing quality medical care, education and counseling to clients in the program.

The audits of 14 Title X grantees conducted by the GAO and of 31 Title X grantees conducted by the Department's Office of the Inspector General in the 1980's showed only minor compliance problems. Indeed, the principal recommendation of both audit reports was that the Department provide more specific guidance to its grantees than that previously available in the program guidelines and prior legal opinions, not that the Department undertake major disallowances, require major corrective actions, or develop new interpretations of the law such as that embodied in the Gag Rule. *See, e.g.*, Comp. Gen. Rep. No GAO/HARD–HRD–82–106 (1982), at 14–15. The Secretary is addressing this recommendation through the specific guidance in the notice published elsewhere in this edition of the **Federal Register** and believe that the notice will provide grantees with sufficient guidance to reduce or eliminate potential variations in grantee practice.

The Secretary views this final rule, the principal purposes of which are to revoke the Gag Rule and adopt the counseling and referral requirements noted, as separate and severable from the Notice. The interpretations set out in the Notice are being set out in order to clarify the Department's view of the statute and its operation in practical terms, and because so much of the public comment received was directed at the interpretations reflected in the Notice rather than at the revision of the regulation itself. Were the policies set forth in the Notice to be challenged or invalidated, it is our view that the Title X program could still be administered under the rules below in compliance with the statute, in that grantees would be prohibited by § 59.5(a)(5) below from providing abortions as part of the Title X family project and from engaging in counseling and referral practices inconsistent with the regulatory requirements adopted in that section. Such an outcome would be consistent with a permissible interpretation of the statute.

C. Amend, or Adopt a More Restrictive Reading of, the Statute

Fifteen of the comments that stated support for the proposed policies and interpretations suggested, however, that the prior limitations in the policies and interpretations with respect to what abortion-related activities a Title X project could engage in be eliminated. A few of these comments suggested that the statutory prohibition of section 1008 be repealed outright. Most of the comments suggested in essence that the statute be read strictly to prohibit only the use of funds for abortions, thereby permitting Title X projects to engage in a number of abortion-related activities that would not be permitted under the pre-1988 interpretations.

With respect to the suggestion that section 1008 be repealed, such an action is obviously outside the scope of what can be accomplished through rulemaking and thus cannot be accepted in this context. With respect to the remaining comments, while the Secretary agrees that the statute could on its face be read only to proscribe the use of Title X funds for the provisions of abortion, this is not considered to be the better reading of the statutory language. Rather, the legislative history of section 1008 indicates that that section was intended to restrict the permissible scope of abortion-related services provided under Title X. Conf. Rep. No. 1667, 97th Cong., 2d Sess. 8–9 (1970). The floor statements by the section's principal sponsor, Rep. Dingell, indicated that the section's restrictions on the "use" of Title X funds should be read as having a broader scope that is urged by these comments:

> Mr. Speaker, I support the legislation before this body. I set forth in my extended remarks the reasons why I offered to the amendment which prohibited abortion as a method of family planning * * *. With the "prohibition of abortion" the committee members clearly intended that abortion is not to be encouraged or promoted in any way through this legislation. Programs which include abortion as a method of family planning are not eligible for funds allocated through this Act.

116 Cong. Rec. 37375 (1970). The Department has consistently, since 1972, read section 1008 as incorporating this legislation on activities that "promote or encourage" abortion as a method of family planning. This interpretation is well-known to Congress, which has not, to date amended section 1008. Thus, there is legal support for this longstanding interpretation of the statute. Moreover, there is nothing in the rulemaking record that suggests that this fundamental reading of the statute, as it was administered before the Gag Rule, presented major operational problems for Title X projects. Accordingly, the Secretary has not accepted the suggestions made by this group of comments that section 1008 be read only to prohibit the provision of, or payment for, abortions.

D. Abortion Information and Counseling

The Gag Rule prohibited the provision of information other than information directed at protecting maternal and fetal health to women determined to be pregnant; thus, it prohibited what is generally known as "options counseling", *i.e.*, the provision to pregnant women in a nondirective fashion of neutral, factual information about all options for the management of a pregnancy, including abortion. *See*, 42 CFR 59.8 (1989 ed.). The pre-1988 policies, in contrast, required options counseling, if requested. As stated in the 1981 "Title X Guidelines":

> Pregnant women should be offered information and counseling regarding their pregnancies. Those requesting information on options for the management of an

unintended pregnancy are to be given non-directive counseling on the following alternative courses of action, and referral upon requests:

- Prenatal care and delivery
- Infant care, foster care, or adoption
- Pregnancy termination.

The June, 1993 summary of the pre-1988 interpretations also stated that Title X projects were not permitted to provide options counseling that promoted abortion or encouraged patients to obtain abortion, but could advise patients of all medical options and accompanying risks.

Most of those comments supporting adoption of the proposed rules appeared to agree with the pre-1988 policies and interpretations. However, there appeared to be some confusion among those who agreed with the pre-1988 requirement for options counseling as to how much information and counseling could be provided. Several of these comments also suggested that the "on request" limitation be deleted, particularly where State law requires the provision of information about abortion to women considering that option.

Several comments opposing adoption of the proposed rules and revocation of the Gag Rule also specifically addressed the issue of counseling. Several of these comments suggested that counseling on "all options" include the option of keeping the baby, and two comments suggested that the rules should contain an exception for grantees or individuals who object to providing such information and counseling on moral grounds.

A number of comments argued that the regulatory text should reflect the requirement for nondirective counseling and referral. These comments recommended that the final regulations include specific language providing for options counseling as a necessary component of quality reproductive health care services. Some cited medical ethics and good medical care as requiring that patients receive full and complete information to enable them to make informed decisions. For example, a leading medical organization commented that all women, regardless of their income level, have a right to full and accurate information about all options for managing an unwanted pregnancy. The organization pointed out that it is essential that the program regulations contain specific language about the counseling and referral requirements, and recommended the incorporation of sections of the 1981 Title X program guidelines into the regulations so as to be absolutely clear that pregnancy counseling and referral must be provided to patients facing an unwanted pregnancy upon request. Congress has also repeatedly indicated that it considers this requirement to be an important one: the program's four most recent appropriations, Pub. L. 104–208 (110 Stat. 300–243), Pub. L. 105–78 (111 Stat. 1478), Pub. L. 105–277 (112 Stat. 2681), and Pub. L. 106–113 (113 Stat. 1501–225), required that pregnancy counseling in the Title X program be "nondirective." Consequently, the Secretary has decided to reflect this fundamental program policy in the regulatory text. *See,* § 59.5(a)(5) below. The interpretive summary has also been revised to reflect this change to the regulation. However, in response to the apparent confusion as to the amount of counseling permitted to be provided under the pre-1988 interpretations, the interpretive summary clarifies that Title X grantees are not restricted as to the completeness of the factual information they may provide relating to all options, including the option of pregnancy termination. It should be noted, though, that the previous restriction as to the "type" of information that may be provided about abortion continues: Information and counseling provided by Title X projects on all options for pregnancy management, including pregnancy termination, must be nondirective. Thus, grantees may provide as much factual, neutral information about any option, including abortion, as they consider warranted by the circumstances, but may not steer or direct clients toward selecting any option, including abortion, in providing options counseling.

The Secretary is retaining the "on request" policy in the regulatory language adopted below, on the ground that it properly implements the requirement for nondirective counseling. If projects were to counsel on an option even where a client indicated that she did not want to consider that option, there would be a real question as to whether the counseling was truly nondirective or whether the client was being steered to choose a particular option. We note that under the "on request" policy a Title X grantee is not prohibited from offering to a pregnant client information and counseling on all options for pregnancy management, including pregnancy termination; indeed, such an offer is required under § 59.5(a)(5) below. However, if the client indicates that she does not want information and counseling on any particular option, that decision must be respected. The regulatory language below reflects this policy. Also, consistent with longstanding program practice and sound public health policy (see the discussion in the following paragraphs) and to avoid ambiguity in when the offer of pregnancy options counseling must be made, the rule has been clarified to require the offer of pregnancy options counseling to be made whenever a pregnant client presents, not just when the pregnancy is "unintended."

With respect to the suggestion that counseling on "keeping the baby" be provided, the Secretary views that suggestion as co-extensive with the requirement for the provision of counseling on prenatal care and delivery, as the remaining counseling option set out in the 1981 "Title X Guidelines" and the regulatory language adopted below relates to foster care and adoption. If a more directive form of counseling is meant by this suggestion, it is rejected as inconsistent with the underlying interpretation, recently reinforced by Congress, that counseling on pregnancy options should be nondirective.

Finally, the Secretary rejects the suggestion that an exception to the requirement for options counseling be carved out for those organizations that object to providing such counseling on religious or moral grounds. First, totally omitting information on a legal option or removing an option from the client's consideration necessarily steers her toward the options presented and is a directive form of counseling. Second, the Secretary is unaware of any current grantees that object to the requirement for nondirective options counseling, so this suggestion appears to be based on more of a hypothetical than an actual concern. Third, the requirement for nondirective options counseling has existed in the Title X program for many years, and, with the exception of the period 1988–1992, it has always been considered to be a necessary and basic health service of Title X projects. Indeed, pregnancy testing is a common and frequent reason for women coming to visit a Title X clinic: in 1995, an estimated 1.1 million women obtained pregnancy tests in Title X clinics. (National Survey of Family Growth, 1995 cycle, special table.) Clearly, a significant number of Title X clients have a need for information and counseling relating to pregnancy. Fourth, this policy is also consistent with the prevailing medical standards recommended by national medical groups such as the American College of Obstetricians and Gynecologists and the American Medical Association. "Guidelines for Women's Health Care," American College of Obstetricians and

Gynecologists, 1996 ed., at 65; "Pregnancy Choices: Raising the Baby, Adoption, and Abortion," American College of Obstetricians and Gynecologists, September, 1993, reviewed December, 1995; "Code of Medical Ethics: Current Opinions with Annotations," American Medical Association, 199–1997 ed. Accordingly, the Secretary has not accepted this suggestion.

The corollary suggestion, that the requirement to provide options counseling should not apply to employees of a grantee who object to providing such counseling on moral or religious grounds, is likewise rejected. In addition to the foregoing considerations, such a requirement is not necessary: under 42 U.S.C. 300a–7(d), grantees may not require individual employees who have such objections to provide such counseling. However, in such cases the grantees must make other arrangements to ensure that the service is available to Title X clients who desire it.

E. Referral for abortion

The Gag Rule specifically prohibited referral for abortion as a method of family planning and required grantees to give women determined to be pregnant a list of providers of prenatal care, which list could not include providers "whose principal business is the provision of abortion." 42 CFR 59.8(a) (1989 ed.). The Gag Rule permitted referral to an abortion provider only where there was a medical emergency. 42 CFR 59.8(a)(2) (1989 ed.). By contrast, the 1981 Guidelines required appropriate referral on request, while the pre-1988 interpretations permitted Title X projects to make what was known as a "mere referral" for abortion; a "mere referral" was considered to be the provision to the client of the name and address and/or telephone number of an abortion provider. Affirmative actions, such as obtaining a consent for the abortion, arranging for transportation, negotiating a reduction in the fee for an abortion or arranging for or scheduling the procedure, were considered to be prohibited by section 1008. The pre-1988 rules (§ 59.5(b)(1)) were interpreted by the agency to require referral for abortion where medically indicated. *See, Valley Family Planning v. State of North Dakota,* 489 F.Supp. 238 (D.N.D. 1980), *aff'd.,* 661 F.2d 99 (8th Cir. 1981).

A number of comments, mostly from individuals and organizations supporting revocation of the Gag Rule, suggested modifications of the proposed referral policies and interpretations. Most of these comments suggested that the content limitations on referrals be broadened, with Title X grantees being permitted to provide other relevant information, such as comparative charges, stage of pregnancy up to which referral providers may under State law or will provide abortion, the number of weeks of estimated gestation, etc. These comments argued that the provision of such factual information does not "promote or encourage" abortion any more than does the provision of the abortion providers' names and addresses and/or telephone numbers. One comment also suggested that the restriction on negotiating fees for clients referred for abortion conflicts with the requirement to refer for abortion where medically indicated.

Several comments opposing revocation of the Gag Rule also expressed problems with the proposed referral policies and interpretations. A few comments urged that referrals to agencies that can assist clients who choose the "keeping the baby" or adoption options should be required. Another comment criticized the requirement for referral where "medically indicated" as confusing. Revisions suggested were that "self-referrals" for abortion be specifically prohibited, to reduce commercialization and profiteering by Title X grantees who are also abortion providers and that grantees who objected to abortion on moral or religious grounds be permitted not to make abortion referrals.

The Secretary agrees with the comments advocating expanding the content of what information may be provided in the course of an abortion referral. The content (as opposed to action) restrictions of the "mere referral" policy proceeded from an assumption that the provision of information other than the name and address and/or telephone number of an abortion provider might encourage or promote abortion as a method of family planning. The Secretary now agrees, based on experience and the comments of several providers on this point, that the provision of the types of additional neutral, factual information about particular providers described above is likely to do little, if anything, to encourage or promote the selection of abortion as a method of family planning over and above the provision of the information previously considered permissible; at most, such information would seem likely to assist clients in making a rational selection among abortion providers, if abortion is being considered. Moreover, it does not seem rational to restrict the provision of factual information in the referral context, when no similar restriction applies in the counseling context. Accordingly, the Secretary has revised the interpretations summarized in the notice section to clarify that grantees are not restricted from providing neutral, factual information about abortion providers in the course of providing an abortion referral, when one is requested by a pregnant Title X client.

Consistent with the incorporation of the requirement for nondirective counseling in the regulations, the regulations below also include the remaining requirement from the 1981 Guidelines, the requirement to provide a referral, if requested by the client. As referenced previously, a number of comments argued that the regulatory text should reflect the requirement for nondirective counseling and referral. One comment described the provision of factual information and referral as requested as both a necessary and significant component of the Title X program for many years. Another comment pointed out that the program guideline requirements regarding pregnancy options counseling and referral have been used for many years, are well understood and accepted in the Title X provider community, and should be required services in Title X family planning clinics. Since the services about which pregnancy options counseling is provided are not ones which a Title X project typically provides, the provision of a referral is the logical and appropriate outcome of the counseling process.

The Secretary is not accepting the remainder of the comments on this issue, as they either proceed from a misunderstanding of, or do not raise valid objections to, the regulations and the proposed policies and interpretations. The comment arguing that the restriction on negotiating fees conflicts with the requirement to refer for abortion where medically indicated is based on a misunderstanding of that requirement: in such circumstances, the referral is not for abortion "as a method of family planning" (*i.e.*, to determine the number and/or space of one's children) but is rather for the treatment of a medical condition; thus, the statutory prohibition does not apply, so there is no restriction on negotiating fees and similar actions. The suggestion that referrals to agencies that can assist clients who choose the options of "keeping the baby" or adoption be required is likewise rejected as unnecessary. Under the regulatory language adopted below, the options of prenatal care and delivery and adoption are options that are required to be part of the options counseling process, so an

appropriate referral for one or the other option would be required, if the client chose one of those options and requested a referral. However, requiring a referral for prenatal care and delivery or adoption where the client rejected those options would seem coercive and inconsistent with the concerns underlying the "nondirective" counseling requirement. The Secretary also rejects the criticism that the provision requiring referral for abortion where medically indicated is undefined and confusing. The meaning of the regulatory requirement for referrals where medically indicated (which applies to all medical services not provided by the project, not just abortion services) has not in the past been a source of confusion for providers, and the Secretary believes that Title X medical personnel are able to make the medical judgments this requirement calls for.

The Secretary likewise rejects the suggestion that "self-referrals" for abortion be banned. Very few current Title X providers are also abortion providers: it is estimated that, over the past decade, the percentage of Title X providers located with or near abortion providers has been at or below five percent, with approximately half of these providers consisting of hospitals. Thus, the issue this comment raises is irrelevant to the vast majority of Title X grantees and the program as a whole. Moreover, with respect to those few grantees that are also abortion providers, some may be the only or one of only a few abortion providers in their service area, making "self-referrals" a necessity in such situations. The Department has no evidence that commercialization and profiteering are occurring in these circumstances; absent such evidence, the Secretary sees no reason to limit or cut off a legal service option for those Title X clients who freely select it. However, the Department will continue to monitor the issue of self-referrals in the Title X program, to forestall the type of problem suggested by these commenters.

Finally, the Secretary rejects the suggestion that the referral requirement not apply to providers that object to it on moral or religious grounds for the same reasons it objected to the same suggestion with respect to counseling.

F. Physical and Financial Separation

The Gag Rule required Title X projects to be organized so as to have a physical and financial separation from prohibited abortion activities, determined by whether there was "objective integrity and independence [of the Title X project] from prohibited activities." 42 CFR 59.9 (1989 ed.). This determination was to be based on a case-by-case review of facts and circumstances. Factors relevant to this determination included, but were not limited to, the existence of separate accounting records, the degree of separation from facilities (such as treatment, consultation, examination, and waiting room) in which prohibited activities occurred and the extent of such prohibited activities, the existence of separate personnel, and the extent of the presence of evidence of identification of the Title X project and the absence of identification of material promoting abortion. *Id.*

The pre-1988 interpretations required Title X grantees to maintain physical and financial separation between the Title X project and any abortion-related activities they conducted, in that a Title X grantee was required to ensure that the Title X-supported project was separate and distinguishable from those activities. This requirement was held to go beyond a requirement for the technical allocation of funds between Title X project activities and impermissible abortion activities. However, it was considered permissible for a hospital grantee to provide abortions, as long as "sufficient separation" was maintained, and common waiting rooms were also permissible, as long as no impermissible materials were present. Common staff and unitary filing systems were also permissible, so long as costs were properly allocated and, with respect to staff members, their abortion-relation activities were performed in a program that was itself separate from the Title X project. The test, as articulated in the summary made available for comment by the June 23, 1993 notice, was "whether the abortion element in a program of family planning services bulks so large and is so intimately related to all aspects of the program as to make it difficult or impossible to separate the eligible and non-eligible items of cost."

These interpretations received by far the most specific and extensive public comment. The vast majority of this public comment was from providers and provider organizations and was negative. Although it was generally agreed that the financial separation of Title X project activities from abortion-related activities was required by statute and, in the words of one comment, "absolutely necessary," many of these comments objected that requiring additional types of separation would be unnecessary, costly, and medically unwise. The argument was made that the requirement for physical separation is unnecessary, as it is not required by the statute which, on its face, requires financial separation only. Further, it was argued that since Title X grantees are subject to rigorous financial audits, it can be determined whether program funds have been spent on permissible family planning services, without additional requirements being necessary. With respect to the issue of cost, it was generally objected that requiring separation of staff and facilities would be inefficient and cost ineffective. For example, one comment argued that—

> The wastefulness and inefficiency of the separation requirements is * * * illustrated by the policy which allows common waiting rooms, but disallows "impermissible materials" in them. This puts grantees in the position of having to continuously monitor health information for undefined "permissibility" or to build a separate waiting room just to be able to utilize those materials * * *.

It was argued that these concerns were particularly important for small and rural clinics "that may be the only accessible Title X family planning and/or abortion providers for a large population of low-income women." Of particular concern for such clinics was the duplication of costs inherent in the separation requirements, as they—

> cannot afford to operate separate facilities or to employ separate staff for these services without substantially increasing the prices of * * * services. Nor can they offer different services on different days of the week because so many of their patients * * * are only able to travel to the clinic on one day.

Many providers also pointed out that requiring complete physical separation of services would be inconsistent with public health principles, which recommend integrated health care, and would impact negatively on continuity of care. As one comment stated, "women's reproductive health needs are not artificially separated between services: a woman who needs an abortion may also need contraceptive services, and may at another time require parental care." Several providers objected in particular that such a separation would, in the words of one comment, "remove * * * one of the most opportune time[s] to facilitate the entry of the abortion patent into family planning counseling, which is at the post-abortion check-up." it was also pointed out that separation of services would burden women, by making them "make multiple appointments or trips to visit different staff or facilities." Finally, the separation policy was objected to by several of the comments that otherwise generally supported the proposed rule

as unnecessarily broad, ambiguous, and vague.

Several of the comments opposing the revocation of the Gag Rule and the adoption of the proposed rules likewise objected specifically to the separation requirements, generally on the ground that the pre-1988 policies were vague and unenforceable. Two comments also argued that, if the pre-1988 requirement of physical separation was to be reinstituted, it made no sense to revoke § 59.9 of the Gag Rule in its entirety, as that section of the Gag Rule contained specific standards to implement this requirement; alternatively, it was argued that if the Secretary is going to use different standards to determine whether the requisite physical separation existed, those should be published for public comment.

The Secretary agrees that the comments on both sides of this issue have identified substantial concerns with the pre-1988 interpretations with respect to the issue of how much physical separation should be required between a grantee's Title X project activities and abortion-related activities. The Secretary agrees with the comments that the pre-1988 interpretation that some physical separation was required was unenforceable. Indeed, since the pre-1988 interpretations had held that it was permissible to provide abortions on a Title X clinic site and to have common waiting areas, records, and staff (subject largely to proper allocation of costs), it was difficult to tell just what degree and kind of physical separation were prohibited. As a consequence, the agency attempted to enforce this requirement on only a few occasions prior to 1988. The Secretary does not agree with opponents of the proposed rules, however, who argued that the "physical separation" requirements in § 59.9 of the Gag Rule should be retained on the ground that they provide a necessary clarification of this issue. Although § 59.9 provided ostensibly more specific standards, the fundamental measure of compliance under that section remained ambiguous: "the degree of separation from facilities [in which prohibited activities occurred] and the extent of such prohibited activities," and "[t]he extent to which" certain materials were present or absent. Furthermore, since under § 59.9 compliance was to be determined on a "facts and circumstances" basis, this section of the Gag Rule provided grantees with less specific advance notice of the compliance standards than did the pre-1988 policies and interpretations. Moreover, the change in policy from the more concrete policies proposed during the Gag Rule rulemaking to the less concrete "facts and circumstances" standard ultimately adopted in the final Gag Rule as a result of the public comment suggests the practical difficulties of line-drawing in this area. In fact, since the Gag Rule was never implemented on a national basis, the precise contours of the compliance standards of § 59.9 were never determined. The Secretary has accordingly not accepted the suggestion from several opponents of the proposed rule that the policies of § 59.9 be retained.

As noted by many of the comments from groups that generally supported the revocation of the Gag Rule, the statute does not on its face require physical separation; rather, by its terms it is addressed to the use of "funds." While the interpretation of the statute by agency counsel on which the requirement for physical separation is based was reasonable, it is not the only possible reading of the statute. Rather, the fundamental question under the statute is, as the agency sees it, whether Title X funds are used by Title X grantees to promote or encourage abortions as a method of family planning in the Title X-assisted project. The Department has traditionally viewed a grant project as consisting of an identified set of activities supported in whole or in part by grant funds. If a Title X grantee can demonstrate by its financial records, counseling and service protocols, administrative procedures, and other means that—within the identified set of Title X-supported activities—promotion or encouragement of abortion as a method of family planning does not occur, then it is hard to see what additional statutory protection is afforded by the imposition of a requirement for "physical" separation. Indeed, in the light of the enforcement history noted above, it is not unreasonable to say that the standard of "physical" separation has, as a practical matter, had little relevance or applicability in the Title X program to date. Moreover, the practical difficulty of drawing lines in this area, both as experienced prior to 1988 and as evident in the history of the Gag Rule itself, suggests that this legal interpretation is not likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services. Accordingly, the Secretary has accepted the suggestion of a number of the comments that the requirement for physical separation be dropped; the interpretations summarized in the notice published in the notices section of this edition of the **Federal Register** are revised accordingly. This decision makes it unnecessary to respond to the remaining comments on the issue.

G. Advocacy Restrictions

The Gag Rule, at 42 CFR 59.10 (1989 ed.), prohibited Title X projects from encouraging, promoting, or advocating abortion as a method of family planning. This section prohibited Title X projects from engaging in actions to "assist women to obtain abortions or increase the availability or accessibility of abortion for family planning purposes," including actions such as lobbying for the passage of legislation to increase the availability of abortion as a method of family planning, providing speakers to promote the use of abortion as a method of family planning, paying dues to any group that as a significant part of its activities advocated abortion as a method of family planning, using legal action to make abortion available as a method of family planning, and developing or disseminating materials advocating abortion as a method of family planning. The pre-1988 interpretations likewise prohibited the promotion or encouragement of abortion as a method of family planning through advocacy activities such as providing speakers, bringing legal action to liberalize statutes relating to abortion, and producing and/or showing films that tend to encourage or promote abortion as a method of family planning. However, under those prior interpretations, it was considered permissible for Title X grantees to be dues-paying members of abortion advocacy groups, so long as there were other legitimate program-related reasons for the affiliation.

Very few comments were received concerning these proposed interpretations. Those received from persons and entities that generally supported the proposed rules generally argued against the restriction on showing films advocating abortion, on the ground that it was possible to violate this restriction by showing a film that was purely factual and detailed relative risks. The few comments on this part of the policies and interpretations received from those who generally opposed revoking the Gag Rule pointed out the similarity between the advocacy policies articulated in the proposed interpretations and § 59.10 of the Gag Rule and argued that § 59.10 should accordingly be reinstated.

As set out above, the Secretary is of the view the Gag Rule cannot and should not be adopted piecemeal, as recommended by these comments. Moreover, the Secretary is of the view

that the prohibition against dues paying contained in § 59.10 is not required by the statute and does not represent sound public policy. Accordingly, the suggestion that § 59.10 be reinstated has not been adopted. With respect to the criticism of the prohibition against Title X grantees showing films advocating abortion as a method of family planning, it is recognized that the prohibition should not encompass the kind of neutral, factual information that grantees are permitted to provide in the counseling context; the interpretations have been clarified accordingly. To the extent that these comments seek to further liberalize the advocacy restrictions, however, they are rejected as inconsistent with the Secretary's basic interpretation of section 1008.

H. Miscellaneous

A number of comments were received on miscellaneous issues. Those comments, and the Secretary's responses thereto, are summarized below.

1. Changes outside the scope of the rulemaking

Several comments were received advocating changes to other sections of the regulations on issues other than the issue of compliance with section 1008. These comments included the following suggestions: that the regulations be revised to permit natural family planning providers to be Title X grantees; that the regulations be revised to prohibit single method providers from participating in Title X projects; that the footnote in the regulation addressing Pub. L. 94–63 be revised to state that the law also forbids coercion to carry a pregnancy to term; that the regulations be revised to deal with recent medical developments, such as HIV or Norplant. All of these suggestions are rejected on the ground that they exceed the scope of the rulemaking because these issues were not the subject of the Notice of Proposed Rulemaking.

2. Audit standards

Several providers urged that the OMB audit standards for Title X projects be revised to reflect the change in the regulations. While this comment is likewise outside the scope of the rulemaking, the Department intends to work with the Office of Management and Budget to revise the program audit standards to reflect the regulations below and the policies and interpretations also being reinstituted.

3. Separation of Powers

Two comments, including one from four members of Congress, argued that the suspension of the Gag Rule violated the separation of powers insofar as it misspent federal tax dollars without amendment to the statute or compliance with the APA. The Secretary disagrees that suspension of the Gag Rule violated either the statute or the APA. The Gag Rule was, in the Secretary's view, a permissible interpretation of the statute, but not the only permissible interpretation of the statute; thus, suspension of those rules (and reinstitution of the Department's longstanding policies and interpretations of the statute) is not inconsistent with the statute. Nor was the suspension action inconsistent with the APA, as the findings which the APA requires be made in such circumstances were made. Finally, the Secretary notes that this issues is now moot, with the publication of the regulations below.

I. Technical Amendments

Because the proposed rules proposed the reissuance of the program regulations that were issued in 1980, it was recognized that—

> some of the other regulations cross-referenced in the rules below may no longer be operative or citations may need to be updated. However, such housekeeping details will be addressed in the final rules.

58 FR 7464. Further review of the proposed regulations has established that this is indeed the case. Accordingly, a number of technical amendments have been made to the regulations, to delete obsolete statutory or regulatory references or to clarify the existing provisions or incorporate new regulatory or other references made relevant by subsequent changes in the law. A summary of the technical amendments, and the reasons therefor, follows:

1. *§ 59.2 (definition of "low income family"):* The reference to "Community Services Administration Income Poverty Guidelines (45 CFR 1060.2)" is changed to "Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2)." This change reflects a change in the law, effected by Pub. L. 97–35, § 673.

2. *§ 59.2 (definition of "State"):* The definition of this term is changed to reflect statutory changes regarding the Trust Territories of the Pacific Islands effected by Pub. L. 99–239 (relating to the Federated States of Micronesia, the Marshall Islands, and the Republic of Palau).

3. *§ 59.5(a)(8):* The reference to the "CSA Income Poverty Guidelines" is changed, consistent with and for the reason set out above with respect to § 59.2 (definition of "low income family").

4. *§ 59.9:* The reference to "Subpart Q" of 45 CFR Part 74 has been deleted, as that subpart has been revoked. A reference to 45 CFR Part 92 has been added, to reflect the requirements at that part that apply by their terms of State and local governments.

5. *§ 59.10:* The references to 42 CFR Part 122 and 45 CFR Part 19 have been deleted, as those parts have been revoked. A reference to 37 CFR Part 401, which applies by its terms, has been added, reflecting a change in the law. The description of 45 CFR Part 74 has been changed, to reflect accurately the current title of that part. A reference to 45 CFR Part 92 has been added, to reflect the requirements at that part that apply by their terms to State and local governments.

6. *§ 59.11*: The word "documented" has been inserted before the word "consent" in this section to clarify what was implicit in this section, that the consent for disclosure must be documented by the project.

7. *§ 59.12 (proposed):* The proposed section (which was the prior section relating to inventions and discoveries) has been deleted, as it has been superseded by the government-wide regulations at 37 CFR Part 401, a reference to which has been added to § 59.10. This change has also occasioned the renumbering of the proposed § 59.13.

The above changes are all technical in nature and simply bring the regulations issued below into conformity with current law. They are thus essentially housekeeping in nature, as noted in the proposed rules. Accordingly, and for the reasons set out above, the Secretary finds that public comment on these changes would be impracticable, unnecessary, and contrary to the public interest and that good cause therefore exists for omitting public comment thereon.

III. Effective Date

These regulations are adopted effective upon publication, as they meet the conditions for exception from the requirement for a 30-day delay in effective date under 5 U.S.C. 553(d). First, by revoking the Gag Rule, the regulations below relieve the restrictions imposed on grantees' conduct of their Title X projects by the Gag Rule. Second, the policies adopted in the regulations below and the interpretations adopted in conjunction with them are already largely in effect, by virtue of the suspension of the Gag Rule and the reinstitution of the pre-

1988 policies and interpretations effected by the interim rules of February 5, 1993. To the extent this *status quo* is changed by the revision of the policies and interpretations in question, the effect of those revisions is to clarify and simplify certain of the present restrictions, which should make complying with the policies and interpretations easier for grantees than is presently the case. Thus, no useful purpose would be served by delaying the effective date of these regulations, and the Secretary accordingly finds that good cause exists for making them effective upon publication.

IV. Analysis of Impacts

The Secretary has examined the impacts of the final rule under the Regulatory Flexibility Act (5 U.S.C. 601–612), and certifies that this final rule will not have a significant impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act (the Act) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted for inflation) in any year. This rule will not result in such an expenditure; consequently, it is not covered by Section 202 of the Act.

Executive Order 13132 requires that a Federalism Assessment be prepared in any cases in which policies have significant federalism implications as defined in the Executive Order. The Department does not intend or interpret this final rule as imposing additional costs or burdens on the States. The Department has evaluated the public comments. Public comments from State and local health departments indicate support for the Title X policies contained in the final rule and the interpretations to ensure the provision of quality medical care and patients' rights to comprehensive services. In the interest of consistent program operation and uniform understanding of the policy, the final rule codifies what has been longstanding program policy and is consistent with current program practice.

The Office of Management and Budget has reviewed this rule pursuant to Executive Order 12866.

List of Subjects in 42 CFR Part 59.

Family planning—birth control; Grant programs—health; Health facilities.

Dated: June 28, 2000.

David Satcher,

Assistant Secretary for Health and Surgeon General.

Approved: June 28, 2000.

Donna E. Shalala,

Secretary.

PART 59—GRANTS FOR FAMILY PLANNING

For the reasons set out in the preamble, subpart A of part 59 of title 42, Code of Federal Regulations, is hereby revised to read as follows:

Subpart A—Project Grants for Family Planning Services

Sec.

Subpart A—Project Grants for Family Planning Services

Authority: 42 U.S.C. 300a–4.

§ 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 3200) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

§ 59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Family means a social unit composed of one person, or two or more persons living together, as a household.

Low income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). "Low-income family" also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

Nonprofit, as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

State includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlaying Islands (Midway, Wage, *et al.*), the Marshall Islands, the Federated State of Micronesia and the Republic of Palau.

§ 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

§ 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain—

(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) A budget and justification of the amount of grant funds requested;

(3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) Such other pertinent information as the Secretary may require.

§ 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods

(including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, it may participated as part of a project as long as the entire project offers a broad range of family planning services.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the applicant.[1]

(3) Provide services in a manner which protects the dignity of the individual.

(4) Provide services without regard of religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or martial status.

(5) Not provide abortion a method of family planning. A project must:

(i) Offer pregnant women the opportunity to provided information and counseling regarding each of the following options:

(A) Prenatal care and delivery;

(B) Infant care, foster care, or adoption; and

(C) Pregnancy termination.

(ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.

(6) Provide that priority in the provision of services will be given to persons from low-income families.

(7) Provide that no charge will be made for services provided to any persons from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to persons other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

(9) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX or XXI agency is required.

(10)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subgrantees in the ongoing policy decisionmaking of the project.

(11) Provide for an Advisory Committee as required by § 59.6.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including physician's consultation, examination prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for informational and educational programs designed to—

(i) Achieve community understanding of the objectives of the program;

(ii) Inform the community of the availability of services; and

(iii) Promote continued participation in the project by persons to whom family planning services may be beneficial.

(4) Provide for orientation and in-service training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.

(8) Provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate, that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

§ 59.6 What procedures apply to assure the suitability of informational and educational material?

(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population

[1] Section 205 of Pub. L. 94–63 states: "Any (1) officer or employee of the United States, (2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than $1,000 or imprisoned for not more than one year, or both."

or community to which they are to be made available and the purposes of title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) *Size.* The Committee shall consist of no fewer than five but not more than nine members, except that this provision may be waived by the Secretary for good cause shown.

(2) *Composition.* The Committee shall include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of the population or community for which the materials are intended.

(3) *Function.* In reviewing materials, the Advisory Committee shall:

(i) Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct;

(iv) Determine whether the material is suitable for the population or community to which is to be made available; and

(v) Establish a written record of its determinations.

§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of patients, and, in particular, the number of low-income patients to be served;

(2) The extent to which family planning services are needed locally;

(3) The relative need of the applicant;

(4) The capacity of the applicant to make rapid and effective use of the federal assistance;

(5) The adequacy of the applicant's facilities and staff;

(6) The relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project; and

(7) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

§ 59.8 How is a grant awarded?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for three to five years.

(b) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR Part 74 or Part 92, as applicable.

§ 59.10 What other HHS regulations apply to grants under this subpart?

Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include:

37 CFR Part 401—Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements

42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure

45 CFR Part 16—Procedures of the Departmental Grant Appeals Board

45 CFR Part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80 of this Title

45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefitting from Federal financial assistance

45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

45 CFR Part 92—Uniform administrative requirements for grants and cooperative agreements to state and local governments

§ 59.11 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 59.12 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to or at the time of any award, when in the Department's judgment these conditions are necessary to assure orb protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

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COMPLETED
ORIGINAL

PROGRAM GUIDELINES FOR PROJECT GRANTS FOR FAMILY PLANNING SERVICES

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Public Health Service
Health Services Administration
Bureau of Community Health Services

BCHS

PROGRAM GUIDELINES FOR PROJECT GRANTS FOR FAMILY PLANNING SERVICES

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Public Health Service
Health Services Administration
Bureau of Community Health Services
Office for Family Planning
5600 Fishers Lane
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PART I

1.0 Introduction to the Program Guidelines

This document, *Program Guidelines for Project Grants for Family Planning Services*, has been developed by a task force under the direction of The American College of Obstetricians and Gynecologists (ACOG) for the Bureau of Community Health Services, U.S. Department of Health and Human Services (DHHS), to assist current and prospective grantees in understanding and utilizing the Title X family planning services grants program. The document is organized into two parts. Part I (sections 1-6) covers project management and administration, including the grant application and award process. Part II (sections 7-11) covers required, recommended, and related client services and clinic management.

Reference is made throughout the document to specific sections of the Title X law and regulations, which are contained in their entirety in *Attachments A* and *B*. (Reference to specific sections of the regulations will appear in brackets, e.g., [45, CFR 74, Subpart H].) Federal sterilization regulations are contained in *Attachment C*. Reference is made throughout the document to selected other materials that provide additional guidance in specific areas. These materials are classified as *Appendices* or *Related Documents*. The *Appendices* contain program requirements relating to the operation of Title X projects and facilities. *Related Documents* contain relevant standards and protocols that represent current accepted medical practice. A current listing of these materials is attached to the document. Projects may contact the appropriate DHHS Regional Office listed in *Attachment D* for information on how to obtain them.

1.1 DEFINITIONS

Throughout this document, the words "shall" and "must" indicate *mandatory* program policy. "Should" indicates *recommended* program policy relating to components of family planning and project management that the service provider is urged to utilize in order to fulfill the intent of Title X. The words "can" and "may" indicate options, suggestions, and alternatives for consideration by individual projects.

The "grantee" is the entity that receives a federal grant and assumes legal and financial responsibility and accountability for the awarded funds and for the performance of the activities approved for funding. The "project" consists of those activities described in the grant application and supported under the approved budget. "Delegate agencies" are those entities that provide family planning services with Title X funds under a negotiated, written agreement with a grantee. "Service sites" are those entities actually providing services *on-site* for the grantee or delegate agency. The word "provide" is used to mean the provision of services on-site and/or by referral, unless otherwise stipulated.

2.0 The Law, Regulations, and Guidelines

To enable persons who desire to obtain family planning care to have access to the requisite services, Congress enacted the Family Planning Services and Population Research Act of 1970 (Public Law 91-572), which added Title X, "Population Research and Voluntary Family Planning Programs," to the Public Health Service Act. Section 1001 of the Act (as amended by Public Laws 94-63 and 95-613) "authorizes grants to assist in the establishment and operation of family planning projects which offer a broad range of acceptable and effective family planning methods, including natural family planning methods, infertility services, and services to adolescents" *(see Attachment A)*. The mission of Title X is to provide individuals the information and means to exercise personal choice in determining the number and spacing of their children.

The regulations governing Title X [42 CFR, Subpart A, Part 59], published in the Federal Register on June 3, 1980, are the requirements of the Secretary, Department of Health and Human Services, in the provision of family planning services funded under Title X and implement the statute as authorized under Section 1001 of the Public Health Service Act. Prospective applicants and grantees should refer to the regulations in their entirety *(Attachment B)*.

This document, *Program Guidelines for Project Grants for Family Planning Services*, interprets the law and regulations in operational terms and provides a general orientation to the Federal perspective on family planning.

3.0 The Application Process

3.1 ELIGIBILITY

Any public or nonprofit private entity located in a State (which, by definition, includes the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, Northern Marianas, and the Trust Territory of the Pacific Islands) is eligible to apply for a Title X family planning services project grant [59.2, 59.3]. A nonprofit private agency, institution, or organization must furnish evidence of its nonprofit status in accordance with instructions accompanying the project grant application form. Under the law, grants cannot be made to entities that propose to offer only a single method or a limited number of family planning methods. A facility or entity offering a single method can receive assistance under Title X by participating as a special service provider in an approvable

project that offers a broad range of services [59.5(a)1].

If an application proposes to consolidate service areas or health resources or to otherwise affect the operations of other local or regional entities, the applicant must document that these entities have been given the maximum opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees that have previously provided or propose to provide family planning services to the area to be served by the applicant [59.5(a)10(i)].

3.2 NEEDS ASSESSMENT

An assessment of the need for family planning services must be conducted prior to applying for a new grant award. This needs assessment documents the need for family planning services in the service area and should include:

- *Demographic description of the service area;*
- *Description of existing services (e.g., Title V, Community Health Center projects providing family planning services);*
- *Identification of community resources and networks related to reproductive health (e.g., health centers, hospitals);*
- *Identification of high priority services, populations, or target areas (e.g., adolescent services, a low income community).*

Grantees should perform periodic reassessment of service needs. New grant applications should include the initial needs assessment statement. Continuation and renewal grant applications need only provide an update of the previous needs assessment.

3.3 THE APPLICATION

The application form, PHS 5161, with instructions, is available from the appropriate Regional Office of the Department of Health and Human Services *(see Attachment D)*. Assistance in the preparation of an application may be sought from the Regional Office.

An application must contain: (1) a narrative description of the project and the manner in which the applicant intends to conduct it in order to carry out the requirements of the law and the regulations; (2) a budget that includes an estimate of project income and costs, with justification for the amount of grant funds requested; (3) a description of the standards and qualifications that will be required for all personnel and facilities to be used by the project; and (4) such other pertinent information as may be required [59.4(c)]. The application must address all points contained in section 59.7(a) of the regulations, which are the criteria DHHS will use to decide which family planning projects to fund and in what amount.

An application must also define project objectives that are specific, realistic, and measurable. The application shall not include activities that cannot be funded under Title X, such as abortion, fund raising, or lobbying activities.

3.4 PROJECT REQUIREMENTS

Projects must adhere to:

- Section 59.5 of the regulations, which lists the requirements to be met by each project supported by Title X and which prohibits the provision by the project of abortion services.
- These *Program Guidelines for Project Grants for Family Planning Services.*
- Bureau of Community Health Service (BCHS) requirements applicable to the Title X program *(see Appendices).*
- Other federal and DHHS regulations which apply to grants made under Title X. These include regulations on sterilization *(see Attachment C)*, the Privacy Act (P.L. 93-579), the Freedom of Information Act [45 CFR, 5 and 5b], Human Subjects Clearance, A-95, and those Code of Federal Regulations parts listed in section 59.10 of the regulations. *For assistance in identifying other relevant regulations, contact the Regional Office.*

3.5 NOTICE OF THE GRANT AWARD

The notice of the grant award will inform the grantee how long DHHS intends to support the project without requiring it to recompete for funds [59.6]. This period of funding is called the "project period." Under the project period system, projects that continue for more than one year may have the program approved for support in its entirety, or for a portion thereof, but the project will be funded in increments called "budget periods." The budget period is normally twelve months, although shorter or longer budget periods may be established for compelling administrative or programmatic reasons.

4.0 Grant Administration

All projects must comply with grants administration requirements as described in the *DHHS Grants Administration Manual* and the PHS Supplements. The *DHHS Grants Administration Manual* is for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402; the PHS Supplements and the *Public Health Service Grants Policy Statement* may be obtained from the PHS Regional Offices or the Division of Grants and

Contracts, ORM/OAM/PHS, 5600 Fishers Lane, Rockville, MD 20857.

5.0 Legal Issues

5.1 NONDISCRIMINATION

Projects must provide services without regard to religion, race, color, national origin, creed, handicap, sex, number of pregnancies, marital status, age, and contraceptive preference. Services must be provided in a manner that protects the dignity of the individual [59 5(a)3, 4].

5.2 VOLUNTARY PARTICIPATION

Use by any individual of project services must be solely on a voluntary basis. Individuals must not be subjected to coercion to receive services or to use any particular method of family planning. Acceptance of family planning services must not be a prerequisite to eligibility for or receipt of any other service or assistance from or participation in any other programs of the applicant [59.5(a)2].

Project personnel should be informed that they will be subject to legal action if they coerce or endeavor to coerce any person to undergo an abortion or sterilization procedure, as detailed in P.L. 94-63, Section 205 *(see Attachment A)*.

5.3 CONFIDENTIALITY

Every project must assure client confidentiality and provide safeguards for individuals against the invasion of personal privacy, as required by the Privacy Act. No information obtained by the project staff about individuals receiving services may be disclosed without the individual's consent, except as required by law or as necessary to provide services. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual [59.11].

5.4 CONFLICT OF INTEREST

Grantees must establish safeguards to prevent employees, consultants, or members of governing or advisory bodies from using their positions for purposes of private gain for themselves or for others.

5.5 LIABILITY COVERAGE

Programs and projects must ensure the existence of adequate liability coverage for all segments of the program funded under the grant, including personnel providing services. Projects should consider obtaining liability coverage for members of their governing boards.

5.6 HUMAN SUBJECTS CLEARANCE (RESEARCH)

Grantees considering clinical or sociological research must adhere to the legal requirements governing human subjects research, specifically with regard to informed consent. Grantees must advise the Regional Office in writing of research projects involving Title X clients or resources. In order to provide for the adequate discharge of this institutional responsibility, grantees must provide written assurances of (1) compliance with DHHS policy regarding the protection of human subjects, and (2) approval of the research by a properly constituted committee of the grantee institution. *The Office for the Protection from Research, NIH, Bethesda, MD 20014, is responsible for the implementation and enforcement of this policy for DHHS.*

6.0 Program Management

6.1 STRUCTURE OF THE GRANTEE

Family planning services under Title X grant authority may be offered by grantees directly or by delegate agencies operating under the umbrella of the grantee. However, the grantee will be held responsible for the quality, cost, accessibility, acceptability, reporting, and performance of its delegate agencies. Grantees must therefore have a negotiated, written agreement with each delegate agency and establish written standards and guidelines consistent with the appropriate section(s) of the *Program Guidelines for Project Grants for Family Planning Services* for all delegated services. If service sites are funded by delegate agencies or if special service providers are utilized, e.g., providers of fertility awareness methods including natural family planning, a written, negotiated agreement approved by the grantee must be maintained by the delegate. All service providers should be invited to participate in the establishment of grantee standards and guidelines.

6.2 PLANNING AND EVALUATION

All projects receiving Title X funds must provide services of high quality and be competently and efficiently administered. To assist in meeting these requirements, each project must prepare a health care plan which identifies overall goals and specific measurable objectives for the coming year. The objectives may be directed to all clients or to specific groups of clients and should be consistent with Bureau of Community Health Services objectives. The health care plan must include an evaluation component that addresses and defines indicators by which the project intends to evaluate itself. The health care plans for all delegate agencies and special service providers (e.g., infertility services) must be in-

corporated into the grantee's health care plan. These plans should be reviewed regularly by the grantee and be updated periodically to assure project effectiveness. *For further information, see Related Documents—Planning and Evaluation.*

6.3 FINANCIAL MANAGEMENT

Grantees must maintain a financial management system that meets the standards specified in Subpart H of 45 CFR 74, Administration of Grants, and complies with federal standards to safeguard the use of funds. Documentation and records of all income and expenditures must be maintained.

- Charges, Billing, and Collections

A grantee is responsible for the implementation of policies and procedures for charging, billing, and collecting funds for the services provided by the project. The policies and procedures are approved by the governing board or advisory board and the Regional Office [59.5(a)8]. Billing and collection procedures must have the following characteristics:

(1) Charges are based on a cost analysis of all services provided by the project. Bills are given directly to the client or to another payment source such as Title XIX, Title XX, or private insurance.

(2) A schedule of discounts is required for individuals with family incomes between 100% and 250% of poverty based on family size, income, and other specified economic considerations [59.5(a)8]. The upper limit for the schedule of discounts must be based on local circumstances. Substantial justification is expected for a schedule of discounts for which the limit is above 200% of poverty.

(3) Clients whose documented income is at or below 100% of poverty are not billed, although projects must bill all third parties legally obligated to pay for services [59.5(a)7].

(4) Individual eligibility for a discount must be documented in the client's record.

(5) Bills to third parties show total charges without applying any discount [59.5(a)9].

(6) Where reimbursement is available from Title XIX or Title XX of the Social Security Act, a written agreement is required [59.5(a)9].

(7) Bills to clients show total charges less any allowable discounts.

(8) Bills for minors obtaining confidential services shall be based on the resources of the minor.

(9) Reasonable efforts to collect bills include mailing of bills when client confidentiality is not jeopardized.

(10) A method for the "aging" of outstanding accounts is to be established.

(11) Clients must not be denied services because of the inability to pay.

Effective financial management will assure the short and long term viability of the project, including the efficient use of grant funds. Technical assistance in achieving this objective is available from the Regional Office.

- Financial Audit

Annual grantee audits must be conducted in accordance with the provision of 45 CFR 74, Subpart H. The audits shall be conducted by auditors meeting established criteria for qualifications and independence. Additional guidance on the performance of audits can be found in the *Guide for Adults of Financial and Business Systems and Federal Assistance Recipients Funded by the Public Health Service*, which is available from the DHHS Office of the Inspector General audit agency.

6.4 FACILITIES AND ACCESSIBILITY OF SERVICES

Family planning facilities and services should be geographically accessible to the population served and should be available at times convenient to those seeking services, i.e., evening and/or weekend hours in addition to daytime hours. The facilities should be adequate to provide the necessary services and should be designed to ensure comfort and privacy for clients and to expedite the work of the staff. Facilities must meet standards established within each State or community (e.g., local fire and building codes) and comply with the *Ambulatory Health Care Standards*. Projects should conform to standards for out-of-hospital facilities when their facilities are used for surgical procedures such as female and male sterilizations.

Projects should be in compliance with 45 CFR, Part 84, regarding discrimination against handicapped persons and requiring that program facilities be made accessible to the handicapped.

6.5 PERSONNEL

Grantees and delegate agencies must establish and maintain written personnel policies that comply with Federal and State requirements and Title VI of the Civil Rights Act. These policies shall include but need not be limited to staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, and grievance procedures.

Grantees shall also ensure:

- *That the medical care component of the project operates under the supervision and responsibility of a medical director who is a licensed and qualified physician*

with special training or experience in family planning [59.5(b)6];

- *That when health professionals other than physicians (e.g., nurse practitioners) perform delegated medical functions they do so under protocols and/or standing orders approved by the medical director;*
- *That personnel records be kept confidential;*
- *That an organizational chart and personnel policies be available to all personnel;*
- *That job descriptions be available for all positions, and that these be reviewed annually and updated when necessary to reflect changes in duties;*
- *That an evaluation and review of the job performance of all project personnel be conducted annually.*

6.6 TRAINING AND TECHNICAL ASSISTANCE

Projects must provide for the orientation and in-service training of all project personnel, including the staffs of delegate agencies and service sites [59.5(b)4]. Projects should develop an in-service training capability and prepare a training plan for skills development and/or continuing education based on an assessment of training needs. All project personnel should participate in continuing education related to their activities, including on-the-job training, workshops, institutes, and courses. Documentation of attendance should be kept in the project's records to be used in evaluating the scope and effectiveness of the staff training program.

Training and technical assistance through regional training centers and resources available through other grantees or projects are available to all projects under the Title X program. Information on obtaining these services is available from the Regional Offices. Training and/or travel allowances for training not funded under Title X may be included in the grantee budget with documented justification.

6.7 REPORTING REQUIREMENTS

Projects must comply with the *BCHS Common Reporting Requirements* (BCRR). In addition, the grantee must file an annual grant report and report of expenditures, and must report user, encounter, revenue, and cost data on the BCRR at intervals specified by the Regional Office. Projects must also comply with other reporting requirements, such as sterilization, State, and local reporting requirements.

6.8 INDICATORS FOR FUNDING

Indicators calculated from the BCRR are among the criteria used to evaluate the productivity and effectiveness of ambulatory health care centers supported by BCHS. These program indicators consist of administrative indicators (e.g., provider productivity, cost per medical encounter) and clinical indicators (e.g., immunization, family planning counseling for adolescents, pap smear follow-up, hypertension screening, and anemia screening). Performance on these indicators, in addition to other project activities and plans described in the grant application, are evaluated for funding purposes. For more details, see the *Instruction Manual for BCHS Common Reporting Requirements* and the current *Funding Criteria for BCHS Programs*.

6.9 REVIEW AND APPROVAL OF INFORMATIONAL AND EDUCATIONAL MATERIALS

An advisory committee of five to nine members who are broadly representative of the community must review and approve all informational and educational (I and E) materials developed or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X.

This committee shall (1) consider the educational and cultural backgrounds of the individuals to whom the materials are addressed, (2) consider the standards of the population or community to be served with respect to such materials, (3) review the content of the material to assure that the information is factually correct, (4) determine whether the material is suitable for the population or community to which it is to be made available, and (5) establish a written record of its determinations [59.6].

The committee may delegate responsibility for the review of technical materials (e.g., medical) to appropriate persons or groups, but final responsibility and authority for the approval of I and E materials rests with the committee.

6.10 COMMUNITY PARTICIPATION

Grantees must provide, to the maximum extent feasible, an opportunity for participation in the development, implementation, and evaluation of the project (1) by persons broadly representative of all significant elements of the population to be served, and (2) by persons in the community knowledgeable about the community's needs for family planning services [59.5(b)10].

The I and E advisory committee may be utilized to serve the community participation function or a separate group may be identi-

fied. In either case, the grantee's health care plan must include a plan for community participation, and by-laws or guidelines for these activities should be prepared. The community participation committee shall meet at least annually or more often if appropriate.

6.11 PROGRAM PROMOTION

To facilitate community acceptance of and access to family planning services, projects must establish and implement planned activities whereby their services are made known to the community [59.5(b)3]. In planning for program promotion, projects should review a range of strategies and assess the availability of existing resources and materials. The participation of elected, civic, health, and education leaders, youth agency representatives, as well as users of services, should be solicited. Program promotion activities should be updated periodically and be responsive to the changing needs of the community. *For more information, contact the Regional Offices, the Office for Family Planning, and the National Clearinghouse for Family Planning Information, as listed in Attachment D.*

6.12 COMMUNITY EDUCATION

Each family planning project must plan to provide for community education [59.5(b)3]. This should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy. Community education can be directed toward identifying local agencies and institutions which are likely to serve significant numbers of individuals in need of family planning care, such as schools, postpartum clinics, abortion services, mental health facilities, and clinics for the management of sexually transmitted diseases. Projects should offer orientation sessions for the staffs of these related health and social services in order to help them better counsel and refer potential family planning clients.

Efforts can also be directed toward more general community education about family planning, such as values clarification with regard to family planning, family life, and human sexuality. A variety of approaches should be used, depending on the objectives of the program and the intended audiences. Some examples of techniques are individual contacts by outreach workers, more formal programs or discussions for larger groups or classes, and the use of public service announcements and posters.

Community education can serve to enhance community understanding of the objectives of the program, make known the availability of services to potential clients, and encourage continued participation by persons to whom family planning may be beneficial.

6.13 PUBLICATIONS AND COPYRIGHT

Unless otherwise stipulated, publications resulting from activities conducted under the grant need not be submitted to DHHS for prior approval. It is recommended, however, than an informational copy of any such publication be sent to the National Clearinghouse for Family Planning Information. Projects should assure that publications developed under Title X do not contain information which is contrary to program requirements (45 CFR, 74.145) or to accepted medical practice. Federal grant support must be acknowledged in any publication. Except as otherwise provided in the conditions of the grant award, the author is free to arrange for copyright without DHHS approval of publications, films, or similar materials developed from work supported by DHHS. Restrictions on motion picture film production are outlined in the *Public Health Service Grants Policy Statement*. Any such copyrighted materials shall be subject to a royalty-free, non-exclusive, and irrevocable license or right to the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

6.14 INVENTIONS OR DISCOVERIES

Family planning project grant awards are subject to the regulations of DHHS as set forth in 45 CFR, Parts 6 and 8, as amended [59.12]. These regulations shall apply to any activity of the project for which grant funds are used, whether the activity is part of an approved project or is a by-product of the project. The grantee shall take appropriate measures to assure that no contracts, assignments, or other arrangements inconsistent with the grant obligation are entered into or continued and that all personnel involved in the grant activity are aware of and comply with such obligations.

PART II

7.0 Client Services

Projects funded under Title X must provide medical, social, and referral services relating to family planning to all eligible clients who desire such services [59.5(b)1, 2, 8]. Part II of this document has been developed to provide guidance to grantees as to those services which are *required*, *recommended*, or *related* to fulfill the mission and intent of Title X. The *required* services are those services which are stipulated either in the law or the regulations, or which are otherwise considered essential to the provision of family planning services of high quality. The *recommended* services are those services intended to promote the reproductive and general health care of the family planning client population. The *related* services are those services which are not authorized under Title X but which may be provided by projects in order to meet the specific reproduction-related health needs of the family planning client.

7.1 SERVICE PLANS AND PROTOCOLS

The service plan is the component of the grantee's health care plan which is developed by the medical director and clinical staff and which identifies those services to be provided to clients under Title X by the project. As part of the service plan, all delegates and/or service sites must have written protocols, approved by the grantee, which detail specific procedures for the provision of each service offered. Plans must be written in accordance with Title X program guidelines and current medical practice and must cover the services provided at initial visits, annual revisits, and other revisits, including supply and problem revisits (see chart 7.1).

Under exceptional circumstances, a waiver from a particular requirement in the guidelines may be obtained from the Regional Office upon written request from an individual project. For example, the hemoglobin or hemotocrit requirement may be waived if a project's medical director determines that routine anemia screening is unwarranted in the client population served. In submitting a request for such an exception, the project must provide epidemiologic, clinical, and other supportive data to justify the request and the duration of the waiver.

7.2 PROCEDURAL OUTLINE

The services provided to family planning clients, and the sequence in which they are provided, will depend upon the type of visit and the nature of the service requested. However, the following components should be offered to all clients at the initial visit: Presentation of relevant educational materials; initial counseling; explanation of all procedures and signing of an informed consent covering examination and treatment; obtaining of a personal and family history; performance of a physical examination; performance of routine and other laboratory tests; individual counseling; performance of any necessary medical procedures; provision of medications and/or supplies; exit counseling. Return visits should include an assessment of the client's health status and an opportunity to change methods.

For clients electing nonprescription methods of contraception or fertility awareness methods including natural family planning, the initial required medical work-up may be deferred at their request, with appropriate documentation in the medical record. Such clients should be encouraged to have health screening at return visits.

7.3 EMERGENCIES

Emergency situations involving clients and/or staff may occur at any time. All projects should therefore have written plans and procedures for the management of on-site medical emergencies (e.g., cardiac arrest, shock, hemorrhage, and respiratory difficulties) with which project staff are familiar. Written plans and procedures should also be available for emergencies requiring ambulance services and/or hospital treatment. Information and instructions on dealing with fire, natural disaster, robbery, power failure, harrassment, and other emergency situations should also be available, and appropriate training in these areas should be provided to staff.

7.4 REFERRALS AND FOLLOW-UP

Grantees must provide all family planning services listed under "Required Services" either on-site or by referral. When required services are to be provided by referral, the grantee must establish formal arrangements with a referral agency for the provision of services and reimbursement of costs, as appropriate. Title X funds may be used to cover the cost of these referred services only if no other sources of funds are available.

For other than required services, that is services which are determined to be necessary but which are beyond the scope of the program, clients should be referred to other providers for care. Examples of such referrals are: treatment for gynecologic dysplasia or malignancy, pregnancy management, family or general medical practice, general surgery, genetic testing, dentistry, mental health services, marriage/sexual counseling, services related to

Chart 7.1

MINIMUM REQUIREMENTS FOR ROUTINE CONTRACEPTIVE MANAGEMENT

Legend X = Routine
(X) = If Indicated

		ORAL CONTRACEPTIVES			IUD		DIAPHRAGM			
	FIRST COMPLETE VISIT ALL METHODS	3 mos. after initial Rx	every 6 mos. for high risk	every 12 mos.	within 3 mos. of insertion	every 12 mos.	Preferably within 1 month of fitting	every 12 mos.	NON-PRESCRIPTIVE METHODS every 12 mos.	EVERY 24 MOS. ALL METHODS
A. HISTORY										
1. General	X			(Update)		(Update)		(Update)	(Update)	UPDATE
2. Method Specific		X	X	X	X	X	X	(X)	(X)	X
B. PHYSICAL EXAM										
1. General	X		(X)	(X)		(X)		(X)	(X)	X
2. Method Specific	X		(X)	X	X	X	check fit	(X)	(X)	X
3. Weight	X	X	X	X		(X)		(X)	(X)	X
4. Blood pressure	X	X	X	X		X		(X)	(X)	X
C. LABORATORY										
1. Hct &/or Hgb	X			(X)	(X)	X		(X)	(X)	(X)
2. Urinalysis	(X)		(X)	(X)		(X)		(X)	(X)	(X)
3. Pap smear	X			X		X		(X)	(X)	X
4. GC culture	(X)*			(X)		(X)		(X)	(X)	(X)
5. Serology	(X)									
6. Rubella titer	(X)									
D. EDUCATION	X	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)
E. COUNSELING	X	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)

* Gonorrhea cultures must be provided to clients requesting IUD insertion.
Note: This schedule provides guidance for the management of asymptomatic contraceptive users only.

abortion, and other social services. Grantees should maintain a list of health care providers, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other Federal programs [59.5(b)2] to use for referral purposes. Projects must select referral providers according to procedures which assure fairness in the referral practice and which identify providers of acceptable quality. Whenever possible, clients should be given a choice of providers from which to select.

Projects should have written referral and follow up procedures. The timing and manner of referral and follow-up depend upon the nature of the problem for which the referral was made. For example:

- *Emergency referrals (e.g., possible ectopic pregnancy) should be made immediately with the provider.*
- *Urgent referrals (e.g., solitary breast nodule) should be followed up within two weeks with the client.*
- *Essential referrals (e.g., hypertension) should be followed up with the client, the timing to depend on professional judgment.*
- *Discretionary referrals (made at the request of the client) should be followed up with the client at the next clinic visit. Further follow-up may not be necessary but should be based on professional judgment.*

Projects should make arrangements for the transfer (with client consent) of pertinent client information to the referral provider. In addition, internal systems should be developed to document (1) that recommended referral appointments are made within an appropriate period of time, (2) that these appointments are kept, (3) that providers return complete pertinent client information to the referring center, (4) action taken in response to recommendations received from the referral provider, and (5) any comments the client makes about the referral provider. Efforts may be made to aid the client in identifying potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of this care.

When family planning services are provided by the project to clients referred from other agencies, the project has a responsibility to share client information with the referring agency. Such information may only be given with the written permission of the client.

When family planning clients are referred for services, projects have a responsibility to assure that clients obtain the appropriate services, and referred clients should be contacted to assure that the services are obtained. However, follow-up of family planning clients must be sensitive to the client's concerns for confidentiality and privacy. Therefore, mechanisms for follow-up must be negotiated with the client on the first visit, and the negotiated method of follow-up should be noted on the follow-up card and the client's medical record.

8.0 Required Services

The services contained in this section *must* be provided by all projects funded under Title X.

8.1 CLIENT EDUCATION

Education services should provide clients with the information they need to make informed decisions about family planning, to use specific methods of contraception, and to understand the procedures involved in the family planning clinic visit. On an initial visit clients should be offered information about basic female and male reproductive anatomy and physiology and the value of fertility regulation in maintaining individual and family health. The range of available services and the purpose and sequence of clinic procedures should also be explained. Clients must be given information about all contraceptive methods in order to make an informed choice. This instruction should be documented in the client record. Additional education, particularly at subsequent visits, should include information on reproductive health and health promotion/disease prevention, as appropriate.

The project's education component should include written goals, content outlines and procedures, and an evaluation strategy. The educational approach used should be appropriate to the patient's age, situation, and previously acquired information on the various methods. Providers of education should have a mechanism to determine that information given has been understood.

- Informed Consent

  For ethical, medical, and legal reasons, an informed consent documenting the client's voluntary consent to receive the project's services must be signed by the client prior to his or her receiving any medical services. The form should be written in the primary language of the client or witnessed by an interpreter. It should cover all procedures and medications to be provided. To give informed consent for contraception, the client must receive education on the benefits and risks of the various contraceptive alternatives and details on the safety, effectiveness, potential side effects, complications, and danger signs of the contraceptive method(s) of choice. Forms for each contraceptive method, including sterilization, should be part of the project's service plan.

All forms should contain a statement that the client has been counseled, has read the appropriate informational material, and has understood the content of both. The signed informed consent should be part of the client's record. It should be renewed and updated when there is a major change in the client's health status or a change to a different prescriptive contraceptive method.

When sterilization services are provided or arranged for with Government funding, Federal sterilization consent guidelines must be followed *(see Attachment C)*.

8.2 COUNSELING

The primary purpose of counseling in the family planning setting is to assist clients in reaching an informed decision regarding the choice and continued use of family planning methods and services. The counseling process is designed to help clients resolve uncertainty, ambivalence, and anxiety in relation to reproductive health and to enhance their capacity to arrive at a decision that reflects their considered self-interest.

The counseling process involves mutual sharing of information. Persons who provide counseling should be knowledgeable, objective, non-judgmental, sensitive to the rights and differences of clients as individuals, and able to create an environment in which the client feels comfortable discussing personal information. The counselor's knowledge should be sufficient to provide ample information regarding the risks, benefits, contraindications, and effective use of any method, procedure, treatment, or option being considered by the client. Documentation of counseling must be included in the client's record.

- Method Counseling
  Post-examination counseling should be provided to assure that the client knows results of the history, physical examination, and laboratory studies that may have a bearing on the choice of method(s); knows how to use and is comfortable with the contraceptive method selected and prescribed; knows the common side effects and possible complications of the method selected and what to do in case they occur; knows the planned return schedule and has a next appointment at an appropriate interval; knows an emergency 24-hour telephone number and a location where emergency services can be obtained; and receives appropriate referral for additional services as needed.

- Special Counseling
  Clients should receive special counseling regarding future planned pregnancies, management of a current pregnancy, sterilization, and other individual problems (e.g., genetic, nutritional, sexual) as indicated.

8.3 HISTORY, PHYSICAL ASSESSMENT, AND LABORATORY TESTING

- History
  A comprehensive personal history and pertinent history of immediate family members must be obtained on all female clients. This should be done at the initial medical visit. The history should be updated at subsequent visits. Histories are recommended for all male clients and are required for those requesting medical services. The initial history should address the following areas:
  —Allergies; immunizations, especially rubella; current use of prescription and over-the-counter medications; significant illnesses; hospitalizations; surgery; review of systems; extent of use of tobacco, alcohol, and drugs.
  Histories of reproductive function in female patients should include:
  —Menstrual history; sexual activity; sexually transmitted diseases; contraceptive use; pregnancies; in utero exposure to DES.
  On medical revisits, oral contraceptive users must be asked about symptoms of embolic disease and other major complications and side effects. IUD users must be asked, in particular, about symptoms of pelvic infection.
  The male reproductive history should include:
  —Sexual activity; sexually transmitted diseases; fertility; in utero exposure to DES.

- Physical Assessment
  Female clients requesting prescriptive methods of contraception (e.g., oral contraceptives, IUDs, diaphragms) must have a general physical examination at the initial medical visit. The initial examination should include at least the following:
  —Height; weight; blood pressure; thyroid; heart; lungs; extremities; breasts, including instruction in self-exam; abdomen; pelvic examination, including visualization of the cervix and bimanual exam; rectal exam, as indicated.
  For oral contraceptive users, initial and annual physical examinations must include evaluation of weight, blood pressure, extremities, breasts, and pelvic organs. For IUD users, initial and annual physical exam, blood pressure, and pelvic exam are required, and a more complete exam is recommended.
  Female clients using nonprescriptive methods or diaphragms should have a general physical examination at least every two years. This exam is particularly important for clients who are not receiving general health care elsewhere.

Male clients requesting temporary methods of contraception are not required to undergo physical examination, but should be offered this service, to include:

—Height; weight; blood pressure; thyroid; heart; lungs; abdomen; examination of the genitals and rectum, including palpation of the prostate and instruction in self-exam of the testes.

- Laboratory Testing

The following laboratory procedures should be done on-site for all female clients at the initial visit and must be done for those receiving prescription methods. They may be waived if written results of these tests done within six months at another facility are available.

—Hemoglobin (Hgb) or hematocrit (Hct)
—Pap smear
—Gonorrhea culture for clients requesting IUD insertion

In addition, pregnancy testing and gonorrhea screening must be available and provided upon request.

Initial laboratory procedures should be repeated annually or as indicated. Oral contraceptive users must have annual pap smears, and IUD users must have annual hemoglobins or hematocrits and pap smears.

Gram stains and cultures for gonorrhea, and other laboratory tests as indicated, should be available for male clients.

Every effort should be made to assure that laboratory tests performed by or for the clinic are of high quality. This means that the grantee should assess the credentials of laboratories with which it contracts. If laboratory testing is performed on-site, written protocols for quality control and proficiency testing are necessary.

- Notification of Abnormal Lab Results

A procedure must be established to allow for client notification and adequate follow-up of significantly abnormal laboratory results. This procedure must respect the client's request to maintain confidentiality. When initial contact is not successful, a reasonable further effort should be made, consistent with the severity of the abnormality.

- Other Laboratory Services or Procedures

The following procedures and lab tests should be provided by the project when medically indicated:

—Screening for non-gonococcal sexually transmitted diseases, e.g., syphilis
—Microscopic examination of vaginal smears and wet mounts for diagnosis of vaginitis
—Microscopic examination and/or culture and sensitivity of urine
—Selected laboratory tests, e.g., blood sugar or cholesterol test for women who are potentially at high risk for oral contraceptive use
—Hemagglutination test for rubella

Other procedures and lab tests may be indicated for some clients and may be provided on-site or by referral.

- Revisits

Revisit schedules should be individualized, based upon the client's need for education, counseling, and medical care beyond that provided at the initial visit. Younger clients and clients initiating a new contraceptive method may need special opportunities for reassurance and clarification. On the other hand, projects should avoid antagonizing well-informed clients who are comfortable with the method being used; such clients should not be required to return for unwanted counseling or frequent supply visits.

Clients selecting oral contraceptives, IUDs, or diaphragms should be scheduled for a revisit within three months after initiation of the method to reinforce its proper use, to check for possible side effects, and to provide additional information as needed. A new client who chooses to continue a method in use upon entry to the program need not return for this early revisit unless a need for reevaluation is determined on the basis of the findings at the initial visit.

Annual revisits are mandatory for clients using oral contraceptives or intrauterine devices and must include at a minimum the components of the history, physical examination, and laboratory procedures as specified for such clients. Annual history updates, exams, and laboratory tests are recommended for all clients. The frequency with which specific procedures are to be routinely repeated should be determined by the medical director and documented in the health care plan.

8.4 FERTILITY REGULATION

Projects must make available, either directly or through referral, all of the DHHS approved methods of contraception. *For recommendations on the management of each method, see Related Documents—Fertility Regulation.*

- Temporary Contraception

Currently, the temporary methods of contraception include barrier methods (female and male), IUDs, fertility awareness methods including natural family planning, and hormonal contraceptives. More than one method of contraception can be used simultaneously by a client and should be offered if the client requests it, e.g., the use of two barrier methods, the use of a

barrier method with an IUD, or the combination of a barrier method with techniques of ovulation detection. Current FDA guidelines as to relative and absolute contraindications, e.g., package inserts, should be followed.

- Permanent Contraception
Projects must ascertain that the counseling and consent process assures voluntarism and full knowledge of the permanence, risks, and benefits associated with female and male sterilization procedures. Federal regulations must be met if the sterilization procedure is performed or arranged for by the project (see *Attachment C*). For further guidance, see also *Appendices—Permanent Contraception.*

- Emergency Contraception
Projects must comply with FDA recommendations for the administration of drugs or devices for postcoital contraception.

The use of diethylstilbestrol (DES) within 72 hours of unprotected sexual intercourse around the time of presumed ovulation has been found to be highly effective in preventing pregnancy. However, this drug has been implicated in the development of reproductive abnormalities and fertility-related risks in the offspring of women who took DES during pregnancy. Although the doses and duration of DES use for postcoital contraception are less than those commonly used when DES was prescribed for pregnancy complications, health risks may be similar. It also is possible that women may take the drug as a postcoital contraceptive when already pregnant from a previous intercourse. In such cases, the potential offspring of such pregnancies would be exposed to the risks previously described. In light of these considerations, the following recommendations are made:

—*Postcoital contraception with DES in any woman should be restricted to situations where no alternative is judged acceptable by a fully informed patient and her physician.*

—*Thorough birth control counseling should accompany or follow any prescription of DES for postcoital purposes. A principal objective of such counseling should be to discourage women from considering it as a routine method of contraception.*

8.5 INFERTILITY SERVICES

Grantees are required by law to make basic infertility services available to clients desiring such services. Infertility services which may be supported by Federal funds are categorized as follows:

—*Level I* Includes initial infertility interview, education, examination, appropriate laboratory testing (hemoglobin or hematocrit, pap smear, and culture for gonorrhea), counseling, and appropriate referral.

—*Level II* Includes semen analysis, assessment of ovulatory function through basal body temperature and/or endometrial biopsy, and postcoital testing.

—*Level III* More sophisticated and complex than Level I and Level II services.

Grantees must provide Level I infertility services as a minimum. Those with infertility programs supervised by physicians with special training in infertility can offer Level II services. However, when considering the scope of the infertility services to be offered to clients, grantees must be aware that such services are expensive, not necessarily successful, and may be high risk from medical and legal points of view. It is therefore important that the proportion of the grantee's budget which is to be used for infertility services be determined very carefully.

The grantee's health care plan must have an infertility service component that identifies those services to be provided by each delegate at individual service sites or by referral. The infertility plan must address how services will be provided, including the criteria for diagnosis of infertility, the scope of services, identification of referral sites, follow-up, fee schedules, and payment mechanisms. When referring for Level II or Level III infertility services, efforts should be made to help the client identify sources of funding for these services.

Since infertility may be due to male factors, female factors, or a combination of the two, both partners need to be involved in the infertility evaluation. Adequate education should be provided so that clients understand human reproduction and sexuality as it relates to their particular problem. The benefits and risks of proposed diagnostic and therapeutic measures to be provided on-site must be clearly explained and informed consent obtained.

For further guidance, see Appendices—Infertility Services.

8.6 PREGNANCY DIAGNOSIS AND COUNSELING

Grantees must provide pregnancy diagnosis and counseling to all clients in need of this service. Pregnancy testing is one of the most frequent reasons for an initial visit to the family planning facility, particularly by adolescents. It is therefore important to use this occasion as an entry point for providing education and counseling about family planning.

Pregnancy cannot be accurately diagnosed

and staged through laboratory testing alone. Pregnancy diagnosis consists of a history, pregnancy test, and physical assessment, including pelvic examination. Projects providing pregnancy testing on-site should have available at least one test of high specificity and one of high sensitivity. If the medical examination cannot be performed in conjunction with laboratory testing, the client must be counseled as to the importance of receiving a physical assessment as soon as possible, preferably within 15 days. This can be done on-site, by a provider selected by the client, or by a provider to which the client has been referred by the project. For those clients with positive pregnancy test results who elect to continue the pregnancy, the examination may be deferred, but should be performed within 30 days. For clients with a negative pregnancy diagnosis, the cause of delayed menses should be investigated. If ectopic pregnancy is suspected, the client must be referred for immediate diagnosis and therapy.

Pregnant women should be offered information and counseling regarding their pregnancies. Those requesting information on options for the management of an unintended pregnancy are to be given non-directive counseling on the following alternative courses of action, and referral upon request:

- *Prenatal care and delivery*
- *Infant care, foster care, or adoption*
- *Pregnancy termination*

Clients planning to carry their pregnancies to term should be given information about good health practices during early pregnancy, especially those which serve to protect the fetus during the first three months (e.g., good nutrition, avoidance of smoking, drugs, and exposure to x-rays) and referral for prenatal care.

Clients who are found not to be pregnant should be given information about the availability of contraceptive and infertility services.

For further information, contact the National Clearinghouse for Family Planning Information, as listed in Attachment D.

8.7 ADOLESCENT SERVICES

Adolescent clients require skilled counseling and detailed information. Appointments should be available to them for counseling and medical services on short notice.

It is important not to assume that adolescents are sexually active simply because they have come for family planning services. Many teenagers are seeking assistance in reaching this decision. Abstinence is a valid and responsible option and should be discussed. Adolescents must be assured that the sessions are confidential and that any necessary follow-up will assure the privacy of the individual. However, counselors should encourage young clients to discuss their needs with parents or other family members.

Adolescents seeking contraceptive services should be informed about all methods of contraception. As their needs frequently change, counseling should prepare them to use a variety of methods effectively. In addition, teenagers and their partners should be encouraged to participate fully in project medical services, including physical examination and laboratory studies. However, as some teenagers may fear the medical procedures usually performed at the first clinic visit, projects may defer them for those teenagers who request deferral and elect nonprescription methods.

Because there is a high incidence of sexually transmitted diseases (STD) among teenagers, it is appropriate to ask them about symptoms or possible exposure to these infections. Teens at particularly high risk of STD should be urged to undergo examination and treatment as indicated, either directly or by referral.

For further recommendations, see Appendices—Adolescent Services.

8.8 SEXUALLY TRANSMITTED DISEASES (STD)

Projects must provide an initial gonorrhea culture for women requesting IUD insertion. Gonorrhea cultures should also be provided for clients with probable or definite exposure to gonorrhea and those with symptoms and signs suggesting gonococcal infection. Projects must comply with State and local STD reporting requirements.

Treatment of a client and partner(s) for gonorrhea should be provided through the project. When treatment is provided on-site, appropriate follow-up measures must be undertaken to ensure cure of all persons treated. If parenteral antibiotics are administered, personnel capable of handling an anaphylactic reaction must be in attendance, and appropriate resuscitation drugs and equipment must be available.

For further information, see Appendices—Sexually Transmitted Diseases.

8.9 IDENTIFICATION OF ESTROGEN-EXPOSED OFFSPRING

The daughters and sons of women who received DES or similar hormones during pregnancy may have abnormalities of their reproductive systems or other fertility-related risks. As part of the history, clients born between 1940 and 1970 should be asked to find out whether or not their mothers took estrogens during pregnancy. Clients prenatally exposed to estrogens should receive special screening

either on-site or by referral. Female clients should be made aware that they are at risk for developing a rare cervico-vaginal tumor and for a number of complications of pregnancy. Male clients should be made aware that they are at risk of certain lesions of the genital tract and for decreased fertility.

For further recommendations, see Appendices—Estrogen-Exposed Offspring.

9.0 Recommended Services

Since the services contained in this section are important to reproductive health care, it is recommended that they be provided at individual service sites.

9.1 GONORRHEA SCREENING

In community or client populations with a high incidence of gonorrhea, endocervical cultures for gonorrhea should be performed on each female client at the time of the initial pelvic examination and repeated as indicated. A yield of equal to or greater than 4 percent positive cultures merits universal screening.

For additional guidance, see Appendices—Sexually Transmitted Diseases.

9.2 MINOR GYNECOLOGIC PROBLEMS

Family planning programs should provide for the diagnosis and treatment of minor gynecologic problems so as to avoid fragmentation or lack of medical care for clients with these conditions. Problems such as vaginitis or urinary tract infection may be amenable to on-the-spot diagnosis and treatment, following microscopic examination of vaginal secretions or urine.

9.3 GENETIC SCREENING AND REFERRAL

For clients at risk for transmission of genetic abnormalities, some basic effort to define this risk is a logical component of family planning services. Initial genetic screening and referral services should be offered to clients who are in need of such services.

Initial screening consists of a careful family history of the client and the client's partner. More complete genetic screening and counseling may be offered *directly* (by a genetic counselor who functions in association with a clinical genetics team capable of providing comprehensive services for a broad range of genetic disorders) or *indirectly* (through referral to a comprehensive genetic service program or programs which may be federally, State, or privately funded). In either case, linkages with a comprehensive genetic service program should be established, specifically with clinical genetic services centers.

Where feasible, in-service training in genetics should be arranged for project staff to enable them to provide simple genetic screening. Training may be appropriately provided by a genetic service program to which the project is linked. The purpose of training is to familiarize staff with the indications for genetic services, referral mechanisms, and resources. Literature and informational materials regarding the availability of genetic services, including but not limited to prenatal diagnosis, should be available in the appropriate language to all clients on request.

When genetic screening services are offered by a project, they must (1) be supported by a program of public information and education which is sensitive to the concerns of local ethnic and religious groups and upholds the dignity of individuals with congenital physical or mental limitations, (2) include education and counseling to all clients on a voluntary basis, and (3) include referral for testing or further screening if indicated.

For additional guidance, see Appendices—Genetic Screening.

9.4 HEALTH PROMOTION/DISEASE PREVENTION

For many clients, family planning programs are their only continuing source of health information and medical care. Therefore, while most of the client services will necessarily relate to fertility regulation, family planning programs should, whenever possible, provide health maintenance services such as screening, immunization, and general health education and counseling directed toward health promotion and disease prevention. These additional services should promote the clients' general state of health and, in turn, the health of their infants and children. Programs are therefore encouraged to assess the health problems prevalent among the populations they serve and to develop services to address them.

Nutrition services are an example of an important activity directed toward promoting health and preventing disease which can be integrated into the existing family planning services. Projects should provide nutritional problem identification, basic nutrition information, screening, and medical care to clients at high risk of nutrition problems or those requiring nutritional management of disease. These services can be provided without the resources of a full-time nutritionist. Project staff can deliver such services with nutrition training and consultation with a qualified nutritionist.

For further information, see Appendices—Health Promotion/Disease Prevention.

10.0 Related Services

There are some reproduction-related health services that projects may offer if skilled personnel and

equipment are available, since to send clients elsewhere for diagnosis and treatment could contribute to fragmentation of medical care or result in no care. If such services are to be offered, however, projects should seek funds from appropriate agencies (e.g., a Title V agency for prenatal care) or arrange to cover the cost for care through third-party payments (including government agencies) or patient fees.

If a project plans to provide any related services, the following conditions must be met:

- *The project must assure that skilled personnel, equipment, and medical back-up services are available, and*
- *The project must receive approval from the Regional Office.*

10.1 PRENATAL CARE

Clients with confirmed pregnancies who wish to continue them to term must receive counseling and continuing care. Projects must therefore refer pregnant clients for adequate prenatal care. However, projects may provide prenatal care if the following conditions are met:

- *Documentation shows an unmet need and lack of other adequate sources of prenatal care;*
- *The project has the capability to provide prenatal care for non-high risk clients in accordance with standards developed by The American College of Obstetricians and Gynecologists;*
- *Sources for newborn care are identified prior to delivery;*
- *The institutions to which clients will be referred for delivery and management of complications have been involved in the establishment of the prenatal care service and assure continuity of care;*
- *The project has appropriate linkages for referral of high risk clients or those who become high risk during the course of pregnancy;*
- *Specific prior approval has been obtained from the Regional Office.*

Projects offering prenatal care must utilize all other sources of funding for such services before applying Title X funds for this activity.

For further information, see Appendices and Related Documents—Maternity Services.

10.2 POSTPARTUM CARE

Family planning programs may provide postpartum care for uncomplicated cases in collaboration with local agencies or institutions which provide prenatal and/or intrapartum care. If a family planning program undertakes responsibility for postpartum care, such care should be directed toward assessment of the woman's physical health, initiation of contraception if desired, and counseling and education related to parenting, breast feeding, infant care, and family adjustment.

For further information, see Appendices and Related Documents—Maternity Services.

10.3 SPECIAL GYNECOLOGIC PROCEDURES

Procedures such as colposcopy, biopsy, and cryosurgery are useful in the diagnosis and management of gynecologic abnormalities. Since such procedures and management require specialized training, they may be provided only under the supervision of a specially qualified physician who has had appropriate training and experience in the colposcopic diagnosis and management of cervical disease. Provision of this service must be limited to the treatment of benign cervical disease. Care must be taken to assure that provision of these procedures does not direct either professional or financial resources from the provision of basic family planning services.

11.0 Clinic Management

11.1 EQUIPMENT AND SUPPLIES

Equipment and supplies shall be safe, adequate, and appropriate to the type of care offered by the project. It is the responsibility of the medical director to assure proper selection and maintenance of equipment and supplies.

11.2 PHARMACEUTICALS

Projects must be operated in accordance with State and Federal laws relating to security and record keeping for drugs and devices. The prescription of pharmaceuticals must be done under the direction of a physician. However, inventory, supply, and provision of pharmaceuticals may be delegated by the medical director to appropriately qualified health professionals in accordance with State laws regarding such delegation.

It is essential that each facility maintain an adequate supply and variety of drugs and devices to meet the contraceptive needs of its clients. If special services are offered that require the dispensing of additional medications, these should also be part of the inventory. Each facility must maintain emergency resuscitative drugs, supplies, and equipment appropriate to the complexity of the program. These should be in a location readily accessible to the examination and treatment rooms. Facilities providing medical services shall, as a

minimum, have readily available those elements needed for the treatment of vasovagal shock.

Contraceptive and therapeutic pharmaceuticals must be kept in a secure place, either under direct and continuous observation or locked. Clinics which stock narcotics and tranquilizing drugs must keep records proving count of the medications at the beginning and end of each day during which drugs are used. State laws with regard to accountability must be followed. If Federal or State statutes pertaining to record keeping, inventory, and dispensing cannot be met by the program, or if community standards of good medical care in the performance of the above activities cannot be met, projects should contract for such services.

11.3 MEDICAL RECORDS

Projects must establish a medical record for every client who obtains medical services. These records must be maintained in accordance with accepted medical standards. Records must be:

—*Complete and accurate, including documentation of telephone encounters of a medical nature;*

—*Signed by the physician or other appropriately trained health professional making the entry, including name and title;*

—*Readily accessible;*

—*Systematically organized to facilitate retrieval and compilation of information;*

—*Confidential;*

—*Safeguarded against loss or use by unauthorized persons;*

—*Secured by lock when not in use;*

—*Available upon request to client.*

- Content of the Client Record

The client's medical record must contain sufficient information to identify the client, indicate where and how the client can be contacted, justify the clinical impression or diagnosis, and warrant the treatment and end results. The required content of the medical record includes:

—*Personal data*

—*Medical history, physical exam, laboratory test orders, results, and follow-up*

—*Treatment and special instructions*

—*Scheduled revisits*

The record must also contain reports of clinical findings, diagnostic and therapeutic orders, and documentation of continuing care, referral, and follow-up. The record must allow for entries by the counseling and social service staff. Projects should maintain a problem list at the front of each chart listing identified problems to facilitate continuing evaluation and follow-up.

- Confidentiality and Release of Records

A confidentiality assurance statement must appear on the client's record. The written consent of the client is required for the release of personally identifiable information, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality [59.11]. When information is requested, projects should release only the specific information requested. Information collected for reporting purposes may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Clients transferring to other providers should be provided with a copy of their record to exepdite continuity of care.

For more information, see Appendices—Medical Records.

11.4 QUALITY ASSURANCE AND AUDIT

Projects must develop a quality assurance system that provides for the continued development and evaluation of their services. The quality assurance system should include:

- *A health care plan based on community needs assessment which specifies all services to be provided routinely by the project and which may also include additional services for specific population groups;*
- *A tracking system to identify clients in need of follow-up and/or continuing care;*
- *Quality review procedures to evaluate project performance, to provide feedback to providers and clients, and to initiate corrective action when deficiencies are noted.*

Medical audits to determine conformity with standards must be an ongoing activity. Monthly review of a reasonable number of client records is an essential part of quality assurance.

For further information, see Appendices—Quality Assurance/Audit.

ATTACHMENT A

TITLE X—POPULATION RESEARCH AND VOLUNTARY FAMILY PLANNING PROGRAMS

PROJECT GRANTS AND CONTRACTS FOR FAMILY PLANNING SERVICES

SEC. 1001. [300] (a) The Secretary is authorized 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 (including natural family planning methods, infertility services, and services for adolescents).

(b) In making grants and contracts under this section the Secretary shall take into account the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance. Local and regional entities shall be assured the right to apply for direct grants and contracts under this section, and the Secretary shall by regulation fully provide for and protect such right.

(c) For the purpose of making grants and contracts under this section, there are authorized to be appropriated $30,000,000 for the fiscal year ending June 30, 1971; $60,000,000 for the fiscal year ending June 30, 1972; $111,500,000 for the fiscal year ending June 30, 1973; $111,500,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $115,000,000 for fiscal year 1976; $115,000,000 for the fiscal year ending September 30, 1977; $136,400,000 for the fiscal year ending September 30, 1978; $200,000,000 for the fiscal year ending September 30, 1979; $230,000,000 for the fiscal year ending September 30, 1980; and $264,500,000 for the fiscal year ending September 30, 1981.

FORMULA GRANTS TO STATES FOR FAMILY PLANNING SERVICES

SEC. 1002. [300a] (a) The Secretary is authorized to make grants, from allotments made under subsection (b), to State health authorities to assist in planning, establishing, maintaining, coordinating, and evaluating family planning services. No grant may be made to a State health authority under this section unless such authority has submitted, and had approved by the Secretary, a State plan for a coordinated and comprehensive program of family planning services.

(b) The sums appropriated to carry out the provisions of this section shall be allotted to the States by the Secretary on the basis of the population and the financial need of the respective States.

(c) For the purposes of this section, the term "State" includes the Commonwealth of Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, the District of Columbia, and the Trust Territory of the Pacific Islands.

(d) For the purpose of making grants under this section, there are authorized to be appropriated $10,000,000 for the fiscal year ending June 30, 1971; $15,000,000 for the fiscal year ending June 30, 1972; and $20,000,000 for the fiscal year ending June 30, 1973.

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TRAINING GRANTS AND CONTRACTS

SEC. 1003 [300a-1] (a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to provide the training for personnel to carry out family planning service programs described in section 1001 or 1002.

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $2,000,000 for the fiscal year ending June 30, 1971; $3,000,000 for the fiscal year ending June 30, 1972; $4,000,000 for the fiscal year ending June 30, 1973; and $3,000,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $4,000,000 for fiscal year 1976; $5,000,000 for the fiscal year ending September 30, 1977; $3,000,000 for the fiscal year ending September 30, 1978; $3,100,000 for the fiscal year ending September 30, 1979; $3,600,000 for the fiscal year ending September 30, 1980; and $4,100,000 for the fiscal year ending September 30, 1981.

RESEARCH

SEC. 1004. [300a-2] (a) The Secretary may—

(1) conduct, and

(2) make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for,

research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.

(b)(1) To carry out subsection (a) there are authorized to be appropriated $55,000,000 for fiscal year 1976, $60,000,000 for the fiscal year ending September 30, 1977, $68,500,000 for the fiscal year ending September 30, 1978, $105,000,000 for the fiscal year ending September 30, 1979[; $3,600,000 for the fiscal year ending September 30, 1980;] [1] 1980, and $138,900,000 for the fiscal year ending September 30, 1981.

(2) No funds appropriated under any provision of this Act (other than this subsection) may be used to conduct or support the research described in subsection (a) or for the administration of this section.

INFORMATIONAL AND EDUCATIONAL MATERIALS

SEC. 1005. [300a-3] (a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to assist in developing and making available family planning and population growth information (including educational materials) to all persons desiring such information (or materials).

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $750,000 for the fiscal year ending June 30, 1971; $1,000,000 for the fiscal year ending June 30, 1972; $1,250,000 for the fiscal

[1] Error in law. Bracketed material should read ", $120,800,000 for the fiscal year ending September 30,"

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year ending June 30, 1973; $909,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $2,000,000 for fiscal year 1976; $2,500,000 for the fiscal year ending September 30, 1977; $600,000 for the fiscal year ending September 30, 1978; $700,000 for the fiscal year ending September 30, 1979; $805,000 for the fiscal year ending September 30, 1980; and $926,000 for the fiscal year ending September 30, 1981.

REGULATIONS AND PAYMENTS

SEC. 1006. [300a–4] (a) Grants and contracts made under this title shall be made in accordance with such regulations as the Secretary may promulgate. The amount of any grant under any section of this title shall be determined by the Secretary; except that no grant under any such section for any program or project for a fiscal year beginning after June 30, 1975, may be made for less than 90 per centum of its costs (as determined under regulations of the Secretary) unless the grant is to be made for a program or project for which a grant was made (under the same section) for the fiscal year ending June 30, 1975, for less than 90 per centum of its costs (as so determined), in which case a grant under such section for that program or project for a fiscal year beginning after that date may be made for a percentage which shall not be less than the percentage of its costs for which the fiscal year 1975 grant was made.

(b) Grants under this title shall be payable in such installments and subject to such conditions as the Secretary may determine to be appropriate to assure that such grants will be effectively utilized for the purposes for which made.

(c) A grant may be made or contract entered into under section 1001 or 1002 for a family planning service project or program only upon assurances satisfactory to the Secretary that—

(1) priority will be given in such project or program to the furnishing of such services to persons from low-income families; and

(2) no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge.

For purposes of this subsection, the term "low-income family" shall be defined by the Secretary in accordance with such criteria as he may prescribe so as to insure that economic status shall not be a deterrent to participation in the programs assisted under this title.

(d)(1) A grant may be made or a contract entered into under section 1001 or 1005 only upon assurances satisfactory to the Secretary that informational or educational materials developed or made available under the grant or contract will be suitable for the purposes of this title and for the population or community to which they are to be made available, taking into account the educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials.

(2) In the case of any grant or contract under section 1001, such assurances shall provide for the review and approval of the suit-

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ability of such materials, prior to their distribution, by an advisory committee established by the grantee or contractor in accordance with the Secretary's regulations. Such a committee shall include individuals broadly representative of the population or community to which the materials are to be made available.

VOLUNTARY PARTICIPATION

SEC. 1007. [300a-5] The acceptance by any individual of family planning services or family planning or population growth information (including educational materials) provided through financial assistance under this title (whether by grant or contract) shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information.

PROHIBITION OF ABORTION

SEC. 1008. [300a-6] None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.

PLANS AND REPORTS

SEC. 1009. (a) Not later than seven months after the close of each fiscal year, the Secretary shall make a report to the Congress setting forth a plan to be carried out over the next five fiscal years for—

(1) extension of family planning services to all persons desiring such services,

(2) family planning and population research programs,

(3) training of necessary manpower for the programs authorized by this title and other Federal laws for which the Secretary has responsibility and which pertain to family planning, and

(4) carrying out the other purposes set forth in this title and the Family Planning Services and Population Research Act of 1970.

(b) Such a plan shall, at a minimum, indicate on a phased basis—

(1) the number of individuals to be served by family planning programs under this title and other Federal laws for which the Secretary has responsibility, the types of family planning and population growth information and educational materials to be developed under such laws and how they will be made available, the research goals to be reached under such laws, and the manpower to be trained under such laws;

(2) an estimate of the costs and personnel requirements needed to meet the purposes of this title and other Federal laws for which the Secretary has responsibility and which pertain to family planning programs; and

(3) the steps to be taken to maintain a systematic reporting system capable to yielding comprehensive data on which service figures and program evaluations for the Department of Health, Education, and Welfare shall be based.

(c) Each report submitted under subsection (a) shall—

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(1) compare results achieved during the preceding fiscal year with the objectives established for such year under the plan contained in the previous such report;

(2) indicate steps being taken to achieve the objectives during the fiscal years covered by the plan contained in such report and any revisions to plans in previous reports necessary to meet these objectives; and

(3) make recommendations with respect to any additional legislative or administrative action necessary or desirable in carrying out the plan contained in such report.

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ATTACHMENT B

PART 59—GRANTS FOR FAMILY PLANNING SERVICES

Subpart A—Project Grants for Family Planning Services

Sec.

Authority: The provisions of this Subpart A are issued under sec. 5(c), 84 Stat. 1507, 42 U.S.C. 300a-4; sec. 6(c), 84 Stat. 1508, 42 U.S.C. 300.

Subpart A—Project Grants for Family Planning Services

§ 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

§ 59.2 Definitions.

As used in this subpart:

"Act" means the Public Health Service Act, as amended.

"Family" means a social unit composed of one person, or two or more persons living together, as a household.

"Low income family" means a family whose total annual income does not exceed 100 percent of the most recent Community Services Administration Income Poverty Guidelines (45 CFR 1060.2). "Low-income family" also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

"Nonprofit," as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"State" means one of the 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, Northern Marianas, or the Trust Territory of the Pacific Islands.

§ 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

§ 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain—

(1) a description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) a budget and justification of the amount of grant funds requested;

(3) a description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) such other pertinent information as the Secretary may require.

§ 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, such as natural family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other service, assistance from or participation in any other program of the applicant.[1]

(3) Provide services in a manner which protects the dignity of the individual.

(4) Provide services without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status.

(5) Not provide abortions as a method of family planning.

(6) Provide that priority in the provision of services will be given to persons from low-income families.

(7) Provide that no charge will be made for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a Government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to persons other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent CSA Income Poverty Guidelines (45 CFR 1060.2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

[1] Section 205 of Pub. L. 94-63 states: "Any (1) officer or employee of the United States, (2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than $1,000 or imprisoned for not more than one year, or both."

(9) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without

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application of any discounts. Where the cost of services is to be reimbursed under title XIX or title XX of the Social Security Act, a written agreement with the title XIX or title XX agency is required.

(10)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subgrantees in the ongoing policy decisionmaking of the project.

(11) Provide for an Advisory Committee as required by § 59.8.

(b) In addition to the requirements of subsection (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including physician's consultation, examination prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical service agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for informational and educational programs designed to (i) achieve community understanding of the objectives of the program, (ii) inform the community of the availability of services, and (iii) promote continued participation in the project by persons to whom family planning services may be beneficial.

(4) Provide for orientation and inservice training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.

(8) Provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other Federal programs.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and methods of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

§ 59.6 What procedures apply to assure the suitability of informational and educational material?

(a) A grant under this section may be made only upon assurances satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in subsection (a) of this section shall be established as follows:

(1) *Size.* The Committee shall consist of no fewer than five but not more than nine members, except that this provision may be waived by the Secretary for good cause shown.

(2) *Composition.* The Committee shall include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of population or community for which the materials are intended.

(3) *Function.* In reviewing materials, the Advisory Committee shall:

(i) Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct;

(iv) Determine whether the material is suitable for the population or community to which it is to be made available; and

(v) Establish a written record of its determinations.

§ 59.7 What criteria will Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of patients and, in particular, the number of low-income patients to be served;

(2) The extent to which family planning services are needed locally;

(3) The relative need of the applicant;

(4) The capacity of the applicant to make rapid and effective use of the Federal assistance;

(5) The adequacy of the applicant's facilities and staff;

(6) The relative availability of non-Federal resources within the community to be served and the degree to which those resources are committed to the project; and

(7) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a

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project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent of the project's estimated costs.

§ 59.8 How is a grant awarded?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 3 to 5 years.

(b) Generally the grant will initially be for 1 year and subsequent continuation awards will also be for 1 year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74.

§ 59.10 What other HHS regulations apply to grants under this subpart?

Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include:

42 CFR Part 50—PHS Informal Grant Appeals Procedure
45 CFR Part 16—Department Grant Appeals Process
45 CFR Part 19—Limitation on Payments or Reimbursements for Drugs
45 CFR Part 74—Administration of Grants
45 CFR Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services' Implementation of Title VI of the Civil Rights Act of 1964
45 CFR Part 81—Practice and Procedures for Hearings Under Part 80
45 CFR Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance.
45 CFR Part 90—Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance.
42 CFR Part 122, Subpart E—Health System Agency Reviews of Certain Proposed Uses of Federal Health Funds.

§ 59.11 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 59.12 Inventions or discoveries.

(a) A project grant award is subject to the regulations of HHS as set forth in 45 CFR Parts 6 and 8, as amended. These regulations shall apply to any activity of the project for which grant funds are used, whether the activity is part of an approved project or is an unexpected byproduct of that project.

(b) The grantee and the Secretary shall take appropriate measures to assure that no contracts, assignments, or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the grant activity are aware of and comply with such obligations.

§ 59.13 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to or at the time of any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

[FR Doc. 80-16733 Filed 6-2-80; 8:45 am]

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ATTACHMENT C

Subpart B—Sterilization of Persons in Federally Assisted Family Planning Projects

SOURCE: 43 FR 52165, Nov. 8, 1978, unless otherwise noted.

§ 50.201 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service.

§ 50.202 Definitions.

As used in this subpart:

"Arrange for" means to make arrangements (other than mere referral of an individual to, or the mere making of an appointment for him or her with, another health care provider) for the performance of a medical procedure on an individual by a health care provider other than the program or project.

"Hysterectomy" means a medical procedure or operation for the purpose of removing the uterus.

"Institutionalized individual" means an individual who is (1) involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness, or (2) confined, under a voluntary commitment, in a mental hospital or other facility for the care and treatment of mental illness.

"Mentally incompetent individual" means an individual who has been declared mentally incompetent by a Federal, State, or local court of competent jurisdiction for any purpose unless he or she has been declared competent for purposes which include the ability to consent to sterilization.

"Public Health Service" means the Health Services Administration, Health Resources Administration, National Institutes of Health, Center for Disease Control, Alcohol, Drug Abuse and Mental Health Administration and all of their constituent agencies.

The "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"Sterilization" means any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing.

§ 50.203 Sterilization of a mentally competent individual aged 21 or older.

Programs or projects to which this subpart applies shall perform or arrange for the performance of sterilization of an individual only if the following requirements have been met:

(a) The individual is at least 21 years old at the time consent is obtained.

(b) The individual is not a mentally incompetent individual.

(c) The individual has voluntarily given his or her informed consent in accordance with the procedures of § 50.204 of this subpart.

(d) At least 30 days but not more than 180 days have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of premature delivery or emergency abdominal surgery, if at least 72 hours have passed after he or she gave informed consent to sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

§ 50.204 Informed consent requirement.

Informed consent does not exist unless a consent form is completed voluntarily and in accordance with all the requirements of this section and § 50.205 of this subpart.

(a) A person who obtains informed consent for a sterilization procedure

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must offer to answer any questions the individual to be sterilized may have concerning the procedure, provide a copy of the consent form, and provide orally all of the following information or advice to the individual who is to be sterilized:

(1) Advice that the individual is free to withhold or withdraw consent to the procedure any time before the sterilization without affecting his or her right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled;

(2) A description of available alternative methods of family planning and birth control;

(3) Advice that the sterilization procedure is considered to be irreversible;

(4) A thorough explanation of the specific sterilization procedure to be performed;

(5) A full description of the discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

(6) A full description of the benefits or advantages that may be expected as a result of the sterilization; and

(7) Advice that the sterilization will not be performed for at least 30 days except under the circumstances specified in § 50.203(d) of this subpart.

(b) An interpreter must be provided to assist the individual to be sterilized if he or she does not understand the language used on the consent form or the language used by the person obtaining the consent.

(c) Suitable arrangements must be made to insure that the information specified in paragraph (a) of this section is effectively communicated to any individual to be sterilized who is blind, deaf or otherwise handicapped.

(d) A witness chosen by the individual to be sterilized may be present when consent is obtained.

(e) Informed consent may not be obtained while the individual to be sterilized is:

(1) In labor or childbirth;

(2) Seeking to obtain or obtaining an abortion; or

(3) Under the influence of alcohol or other substances that affect the individual's state of awareness.

(f) Any requirement of State and local law for obtaining consent, except one of spousal consent, must be followed.

§ 50.205 Consent form requirements.

(a) *Required consent form.* The consent form appended to this subpart or another consent form approved by the Secretary must be used.

(b) *Required signatures.* The consent form must be signed and dated by:

(1) The individual to be sterilized; and

(2) The interpreter, if one is provided; and

(3) The person who obtains the consent; and

(4) The physician who will perform the sterilization procedure.

(c) *Required certifications.* (1) The person obtaining the consent must certify by signing the consent form that:

(i) Before the individual to be sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized;

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form; and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(2) The physician performing the sterilization must certify by signing the consent form, that:

(i) Shortly before the performance of the sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized;

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form; and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized. Except in the case of premature delivery or emergency abdominal surgery, the

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physician must further certify that at least 30 days have passed between the date of the individual's signature on the consent form and the date upon which the sterilization was performed. If premature delivery occurs or emergency abdominal surgery is required within the 30-day period, the physician must certify that the sterilization was performed less than 30 days but not less than 72 hours after the date of the individual's signature on the consent form because of premature delivery or emergency abdominal surgery, as applicable. In the case of premature delivery, the physician must also state the expected date of delivery. In the case of emergency abdominal surgery, the physician must describe the emergency.

(3) If an interpreter is provided, the interpreter must certify that he or she translated the information and advice presented orally, read the consent form and explained its contents and to the best of the interpreter's knowledge and belief, the individual to be sterilized understood what the interpreter told him or her.

§ 50.206 Sterilization of a mentally incompetent individual or of an institutionalized individual.

Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any mentally incompetent individual or institutionalized individual.

§ 50.207 Sterilization by hysterectomy.

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of any hysterectomy solely for the purpose of rendering an individual permanently incapable of reproducing or where, if there is more than one purpose to the procedure, the hysterectomy would not be performed but for the purpose of rendering the individual permanently incapable of reproducing.

(b) Programs or projects to which this subpart applies may perform or arrange for the performance of a hysterectomy not covered by paragraph (a) of this section only if:

(1) The person who secures the authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing, that the hysterectomy will render her permanently incapable of reproducing; and

(2) The individual or her representative, if any, has signed a written acknowledgment of receipt of that information.

§ 50.208 Program or project requirements.

(a) A program or project must, with respect to any sterilization procedure or hysterectomy it performs or arranges, meet all requirements of this subpart.

(b) The program or project shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The program or project shall submit other reports as required and when requested by the Secretary.

§ 50.209 Use of Federal financial assistance.

(a) Federal financial assistance administered by the Public Health Service may not be used for expenditures for sterilization procedures unless the consent form appended to this section or another form approved by the Secretary is used.

(b) A program or project shall not use Federal financial assistance for any sterilization or hysterectomy without first receiving documentation showing that the requirements of this subpart have been met. Documentation includes consent forms, and acknowledgments of receipt of hysterectomy information.

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Attachment D

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OFFICES OF REGIONAL PROGRAM CONSULTANTS (RPC's) FOR FAMILY PLANNING

DHHS Region	Address	Telephone	States
I	DHHS Region I, JFK Federal Building, Boston, MA 02203	(617) 223-1673	Conn., Me., Mass., N.H., R.I., Vt.
II	DHHS Region II, 26 Federal Plaza, Room 3300, New York, NY 10007	(212) 264-4622	N.J., N.Y., Puerto Rico, Virgin Is.
III	DHHS Region III, 3535 Market St., Rm. 4103, P.O. Box 13716, Philadelphia, PA 19101	(215) 596-1804 596-1565	Del., Dist. of Columbia, Md., Pa., Va., W.Va.
IV	DHHS Region IV, 101 Marietta Street, Suite 1202, Atlanta, GA 30323	(404) 221-5297 8-242-5297	Ala., Fla., Ga., Ky., Miss., N.C., S.C., Tenn.
V	DHHS Region V, 300 S. Wacker Dr., 34th Fl., Chicago, IL 60606	(312) 353-1700	Ill., Ind., Mich., Minn., Ohio, Wisc.
VI	DHHS Region VI, 1200 Main Tower, Dallas, TX 75202	(214) 767-6530 8-729-6530	Ark., La., N.M., Okla., Tex.
VII	DHHS Region VII, Federal Office Building, 601 E. 12th St., Kansas City, MO 64106	(816) 374-5777 8-758-5777	Iowa, Kans., Mo., Nebr.
VIII	DHHS Region VIII, 11037 Federal Building, 1961 Stout St., Rm. 11-04, Denver, CO 80294	(303) 837-3356 8-327-3356	Colo., Mont., N.D., S.D., Utah, Wyo.
IX	DHHS Region IX, 50 United Nations Plaza, San Francisco, CA 94102	(415) 556-5581	Ariz., Calif., Hawaii, Nev., Guam, Pacific Is., Samoa
X	DHHS Region X, Arcade Plaza Building, MS 833, 1321 Second Ave., Seattle, WA 98101	(206) 442-1020 8-399-1020	Alas., Ida., Ore., Wash.

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FAMILY PLANNING GENERAL TRAINING GRANTEES (1980-1981)

DHHS Region	Address	Telephone	States
I	JSI Research and Training Institute, Inc., 210 Lincoln St., 6th Fl., Boston, MA 02111	(617) 482-9485	Conn., Me., Mass., N.H., R.I., Vt.
II	Cicatelli Associates, Inc., 505 8th Ave., Suite 1801, New York, NY 10018	(212) 594-7741	N.J., N.Y., Puerto Rico, Virgin Is.
III	Family Planning Council of Southeastern Pennsylvania, 2 Penna. Center, Ste. 616, Philadelphia, PA 19102	(215) 563-7700	Del., Dist. of Columbia, Md., Pa., Va., W.Va.
IV	Emory University, United Way Building, Rm. 802, 100 Edgewood Ave., N.E., Atlanta, GA 30303	(404) 523-1996	Ala., Fla., Ga., Ky., Miss., N.C., S.C., Tenn.
V	Indiana Family Health Council, Inc., 21 Beachway Dr., Suite B, Indianapolis, IN 46224	(317) 247-9158	Ill., Ind., Mich., Minn., Ohio, Wisc.
VI	The Center for Health Training, 411 W. 13th St., Austin, TX 78701	(512) 476-8342	Ark., La., N.M., Okla., Tex.
VII	Development Centers, Inc., 4049 Pennsylvania Ave., Kansas City, MO 64111	(816) 931-4828	Iowa, Kans., Mo., Nebr.
VIII	Rocky Mountain Planned Parenthood, 1525 Josephine St., Denver, CO 80206	(303) 321-2471	Colo., Mont., N.D., S.D., Utah, Wyo.
IX	Center for Health Training, 2229 Lombard St., San Francisco, CA 94123	(415) 929-9100	Ariz., Calif., Hawaii, Nev., Guam, Pacific Is., Samoa
X	Center for Health Training, 157 Yesler Way, Seattle, WA 98101	(206) 447-9538	Alas., Ida., Ore., Wash.

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DHHS CENTRAL OFFICE

U.S. Department of Health and Human Services
Public Health Service
Health Services Administration
Bureau of Community Health Services
Office for Family Planning
5600 Fishers Lane
Rockville, Maryland 20857

OTHER SOURCES OF
FAMILY PLANNING INFORMATION

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

National Clearinghouse for
Family Planning Information
P.O. Box 2225
Rockville, Maryland 20852

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Attachment E

APPENDICES

Part I

6.4 Facilities and Accessibility of Services

- Ambulatory Health Care Standards (BCHS, 1977)

  Available from the Regional Offices or BCHS

6.7 Reporting Requirements

- Instruction Manual for the BCHS Common Reporting Requirements (BCHS, 1980; Revised periodically)

  Available from the Regional Offices or BCHS

6.8 Indicators for Funding

- Funding Criteria for BCHS Programs (BCHS; Revised periodically)

  Available from the Regional Offices or BCHS

Part II

8.4 Fertility Regulation

Temporary Contraception

- Natural Family Planning Services (BCHS Regional Memorandum, 79-12)

  Available from the Regional Offices or BCHS

Permanent Contraception

- Understanding Female Sterilization (DHHS, 1976)
- A Male Sterilization Procedure (DHHS, 1976)
- Your Sterilization Operation: Information for Women (DHHS, 1978); also available in Spanish
- Your Sterilization Operation: Information for Men (DHHS, 1978); also available in Spanish

  Available from the National Clearinghouse for Family Planning Information

8.5 Infertility Services

- Handbook on Infertility Services (BCHS, 1981)*

8.7 Adolescent Services

- Adolescent Health Care: A Guide for BCHS-Supported Programs and Projects (BCHS, 1979)
- Counseling Adolescents in Reproductive Health Care Settings (BCHS, 1980)

Available from the Regional Offices or BCHS

8.8 Sexually Transmitted Diseases

- Diagnosis and Treatment of Sexually Transmitted Diseases in Family Planning Projects (BCHS, 1981)*

8.9 Estrogen-Exposed Offspring

- Physician Advisory: Health Effects of the Pregnancy Use of Diethylstilbestrol (October 4, 1978)

Available from the Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Washington, D.C. 20201

9.3 Genetic Screening

- Clinical Genetic Service Centers: A National Listing (DHHS, 1980)

Available from the National Clearinghouse for Family Planning Information

9.4 Health Promotion/Disease Prevention

- Health Promotion: An Assessment for BCHS Projects (BCHS, 1981)
- Health Promotion and Disease Prevention in a Reproductive Health Care Setting (BCHS, 1981)*
- Nutrition Service Guide for Family Planning Projects (BCHS, 1981)*

10.1 Prenatal Care

Maternity Services

- Guidance for Maternity Services in BCHS Programs and Projects (BCHS, 1981)*

10.2 Postpartum Care

Maternity Services

- Guidance for Maternity Services in BCHS Programs and Projects (BCHS, 1981)*

11.3 Medical Records

- Problem-Oriented Medical Record System and Medical Record Management Guidance (BCHS, 1978)

  Available from the Regional Offices or BCHS

11.4 Quality Assurance

- Primary Care Effectiveness: An Approach to Quality Assurance in BCHS Programs and Projects (BCHS, 1980)

  Available from the Regional Offices or BCHS

* Publications not yet available.

Attachment F

RELATED DOCUMENTS

Part I

6.2 Planning and Evaluation

- Family Planning Project Evaluation Protocol (BCHS, 1978)

  Available from the Regional Offices or BCHS

Part II

8.4 Fertility Regulation

Temporary Contraception

- Hatcher RA, et al: Contraceptive Technology. New York, Irvington Publishers, 1980
- Porter CW Jr., et al: Oral Contraceptives: A Guide for Programs and Clinics. Third edition. Chestnut Hill, MA, Pathfinder, 1979
- Oral Contraceptives. Population Reports, Series A, No. 5, January, 1979
- Second Report on Intrauterine Contraceptive Devices. Food and Drug Administration, December, 1978
- Intrauterine Devices. Population Reports, Series B, No. 3, May, 1979

Permanent Contraception

- Penfield AJ: Female Sterilization by Minilaparotomy or Open Laparoscopy. Baltimore, Urban & Schwarzenburg, 1980
- Sciarra JJ, et al: Control of Male Fertility. New York, Harper & Row, 1975

10.1 Prenatal Care

Maternity Services

- Standards for Obstetric-Gynecologic Services. Chicago, The American College of Obstetricians and Gynecologists, 1974, 1981*

10.2 Postpartum Care

Maternity Services

- Standards for Obstetric-Gynecologic Services. Chicago, The American College of Obstetricians and Gynecologists, 1974, 1981*

  Available from The American College of Obstetricians and Gynecologists, 600 Maryland Avenue, S.W., Suite 300, Washington, D.C. 20024

11.4 Quality Assurance

- Patient Care Audit Manual (PPFA, 1980)

  Available from Planned Parenthood Federation of America, 810 Seventh Avenue, New York, NY 10019

*U.S. GOVERNMENT PRINTING OFFICE: 1981-0-341-166/6346

12/10/2002 17:41 FAX 202 293 4349 PPFA GOVT RELATIONS 002
Dec-10-02 09:44am From-COMMERCE COMMITTEE DEMOCRATIC STAFF 2022255244 T-362 P.02 F-195

(3)

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

NOV 29 2002

Honorable John Dingell
House of Representatives
Washington, DC 20515

Dear Mr. Dingell:

In accordance with Section 330F (a)(6)(C) of the Public Health Service Act, as amended by Public Law 106-310, as required by the Infant Adoption Awareness Act (IAAA), Title XIII of the Children's Health Act of 2000, I am submitting an initial assessment report evaluating the extent to which adoption information and referral, upon request, are provided by eligible health centers (i.e., federally funded health centers and family planning clinics).

The purpose of the IAAA is to promote training for presenting the option of infant adoption as part of a course of non-directive counseling to pregnant women. The Act requires that two reports be submitted to Congress: this initial assessment and, at a later date, a post-training evaluation to determine the effectiveness of the training.

This report details an assessment of the current practices related to adoption counseling in federally funded health centers and family planning clinics. The professional standard of care in the case of pregnant women, particularly with respect to women who experience an unplanned pregnancy, was examined. Professional practice guidelines that set forth recommended standards of care related to pregnancy management, including pregnancy related counseling, were collected and reviewed. A Clinical Guidelines Matrix describing the relevant professional guidelines is also attached as Appendix 1.

The Department is confident that this initial assessment will serve as a baseline study for the post-training evaluation determining the effectiveness of the training of eligible health centers' designated staff in presenting the option of infant adoption as part of a course of non-directive counseling to pregnant women.

Sincerely,

Tommy G. Thompson

Enclosure

U.S. Department of Health and Human Services

HRSA

Health Resources and Services Administration

Report to Congress

The Infant Adoption Awareness Training Program

Title XII of the Children's Health Act of 2000 (Public Law 106-310)

Elizabeth James Duke, Ph.D.,
Administrator, HRSA

Overview

This report presents an initial analysis relevant to the implementation of Title XII of the Children's Health Act of 2000 (Public Law 106-310). Title XII, which pertains to adoption awareness, amended the Public Health Service (PHS) Act to establish a program of training grants regarding infant adoption awareness. The Act requires the Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration (HRSA), to submit to Congress "a report evaluating the extent to which adoption information and referral, upon request, are provided by eligible health centers." PHS Act § 330F(a)(6)(C). The following report is the result of such an evaluation.

II. Infant Adoption Awareness Provisions in the Children's Health Act

The Infant Adoption Awareness Act (IAAA) was signed into law on October 17, 2000, as Title XII of the Children's Health Act (Public Law 106-310). The goal of the IAAA, as reflected in the provisions of the Act, is to promote training regarding the option of infant adoption as part of a course of "non-directive counseling to pregnant women." In order to further this goal, the IAAA instructs the Secretary to make grants to national, regional, or local adoption organizations for the purpose of "developing and implementing programs to train the designated staff of eligible health centers in providing adoption information and referrals to pregnant women." PHS Act § 330F (a)(1). "Eligible health centers," as the term is defined under the Act, include both federally funded community health centers and family planning clinics. PHS Act § 330F (a)(5)(A)-(C). The Act requires that two reports be submitted to Congress: this initial assessment and a post-training evaluation to determine the effectiveness of the training. PHS Act § 330F (a)(6)(C).

III. Methods

In order to assess current practices related to adoption counseling in federally funded health centers and family planning clinics, the professional standard of care in the case of pregnant women, particularly with respect to women who experience an unplanned pregnancy, was examined.

The following three processes were used to determine the relevant standard of care: ascertainment of established professional standards of practice to the extent that they exist; consultation with experts in the field; and measurement of actual practice patterns with clinicians attempting to furnish care in real-life situations.

A. Review of Professional Guidelines in the Area of Pregnancy Management and Counseling

Professional practice guidelines that recommend standards of care related to pregnancy management, including pregnancy related counseling, were collected and reviewed. The Clinical Guidelines Matrix describing the relevant professional guidelines may be found in Appendix 1. The Matrix identifies the professional society and type of guideline and sets

forth the key relevant language contained in the guideline. Included in this review were guidelines issued by the federal government and relevant to pregnancy management at health centers and family planning clinics.

B. Consultation with Clinical Experts

A series of unstructured interviews and/or focus group discussions with nine clinical experts in the field were conducted. Several of the experts are nationally recognized for their expertise in pregnancy management, family planning, and women's health. Others have expertise related to their extensive familiarity with practice conditions in public and private nonprofit clinics serving medically underserved populations. The experts represented a variety of geographic and professional backgrounds. All of the participants were assured of the confidentiality of their answers.

C. Interviews with Key Clinical Informants Working in Health Centers and Title X Clinics

Clinicians who practice in health centers and family planning clinics and who engage in significant levels of care for pregnant patients were also interviewed. The 14 clinicians interviewed included nurse practitioners, family planning directors, registered nurses, social workers, trained counselors, and physicians. Clinicians were assured that their answers would remain confidential and that any information reported would be disclosed as aggregate information.

In order to maximize the practice settings in which the interviews occurred, the following types of sites were selected: three clinical providers funded under § 330 (health center grantees); three clinical providers funded under Title X of the Act (family planning grantees); and three providers funded under both §330 and Title X (it is not uncommon for a single nonprofit or public provider to receive grant support under numerous sources of comprehensive primary care funding). In total, nine expert clinicians and fourteen key informants were interviewed for this study.

The sites were chosen to achieve as much variation as possible in terms of (1) race/ethnicity of patient population, (2) urban/rural location of the clinic, (3) ratio of pregnant women to births, (4) clinical staffing arrangements, and (5) State policy emphasis on adoption as a public policy priority. The last factor was included because the standard of care can be highly influenced by the community in which a health professional actually works. The Child Welfare League of America was consulted to identify states where the Governor has made adoption a major public policy issue.

IV. Findings from the Review of Professional Practice Guidelines

As noted, the first step taken to determine the professional standard of care in pregnancy counseling was an analysis of existing professional practice standards. These standards apply not only to the public and nonprofit clinics who are encouraged to participate in the statutorily created adoption awareness training program but also to private health professionals as well.

The review of these guidelines revealed that every professional practice standard, as well as guidelines issued by the HRSA's Bureau of Primary Health Care (BPHC) and regulations issued by the Office of Population Affairs, specified non-directive counseling as part of the professional standard of care. Furthermore, every organization instructs its providers to explain all available options to pregnant women - maintaining a pregnancy and keeping their babies, placing their babies up for adoption, or terminating the pregnancy.

In the case of health centers funded under §330 of the PHS Act, the Federal government has specifically required the use of professional society standards providing for comprehensive non-directive counseling. The BPHC issued a "Health Center Program Expectations" Policy Information Notice (PIN) 98-23 that instructs health centers on counseling pregnant women. This PIN directs health centers to establish clinical protocols that:

> "reflect the current guidelines established by health agencies or professional organizations such as...the American College of Obstetrics and Gynecology (ACOG)"[1]

Consistent with nationally recognized standards, Federal regulations governing family planning clinics funded under Title X of the PHS Act require that projects offer pregnant women the opportunity to be provided information and counseling regarding each of the following options: prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination. If requested to provide such information and counseling, clinics must provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.[2]

ACOG's guidelines state:

> In the event of an unwanted pregnancy, the patient should be counseled about her options: 1) continuing the pregnancy to term and keeping the infant, 2) continuing the pregnancy to term and offering the infant for legal adoption, or 3) terminating the pregnancy.[3]

The ACOG guidelines and other educational materials indicate that non-directive counseling is appropriate when the pregnancy is considered to be a crisis or the patient otherwise indicates that she is unsure of her plans regarding the pregnancy. No guidelines appear to recommend comprehensive non-directive counseling in those cases in which women have affirmatively decided to continue with their pregnancies and keep their babies.

Thus, under professional society guidelines, including those specifically adhered to by the Federal government in its oversight of health center pregnancy management services, there

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[1] PIN 98-23 at 25.
[2] 42 CFR 59.5(a)(5)
[3] American College of Obstetricians and Gynecologists, "Guidelines for Women's Health Care," at 65.

appears to be a consensus among the relevant professional societies that in cases other than those in which women have definitively decided to maintain a pregnancy and keep their babies, pregnancy counseling should take place. Furthermore, such pregnancy counseling should be non-directive and should explore all three options relating to pregnancy – keeping the infant, putting the infant up for adoption, and terminating the pregnancy - in a neutral manner. Such non-directive counseling is particularly appropriate when the pregnant woman indicates that she is ambivalent about her plans regarding the pregnancy but also appears to be recommended by the leading set of guidelines (i.e., ACOG) even in the case of women who indicate that the pregnancy is unwanted. Health centers, through the BPHC Health Center Program Expectations, as well as the Office of Population Affairs' family planning clinics, are required to conform to these generally accepted principles by basing their clinical protocols on the guidelines published by ACOG or other established professional organizations. Family planning clinics are expected to conform to those standards as set forth in the program regulations.

V. Expert Consultation Results

A. Understanding of Non-Directive Counseling

The expert leaders had a clear and consistent understanding of the term "non-directive counseling" and its use in practice. Non-directive counseling was described as providing women with all of their options (taking the pregnancy to term and keeping the baby, taking the pregnancy to term and giving the baby up for adoption, and terminating the pregnancy) without any coercion regarding which option to choose. Providing women with options includes assuring that women understand each option and, when requested, assisting women in their decision-making process. As one provider explained it, "My job is to make sure they are aware of all three options and have the information they need to make decisions." Another said, "The professional obstetric standards speak to an affirmative obligation to do three-pronged counseling."

All of the experts were aware that non-directive counseling for pregnancy options is required in health centers under Federal guidelines that require adherence to professional standards such as those issued by the American College of Obstetricians and Gynecologists (ACOG), the Association of Nurse Practitioners in Women's Health, and the American College of Nurse Midwives. "BPHC could not be clearer – you provide care at the ACOG standards." The requirement to present pregnant women with all options is long-standing and has become an integrated part of the clinic's care for pregnant women. "This issue is not new; it has been front and center and being dealt with for many years. In communication in publicly funded clinics, there is more attention to the pregnancy counseling issues because it has been drummed into people. People are serious about meeting the letter of the law."

Some experts mentioned that their States also have laws requiring non-directive counseling. One expert noted, "We have regulations related to non-directive counseling. . . non-directive counseling is a contract requirement for all local agencies that provide family planning services." Another commented that there are "family planning and reproductive health manuals that give guidance to contractors. There is a section in the manual about non-

directive counseling. Any agency that has a contract from our State is obligated by the manual, which uses the same wording as the Title X Federal guidance."

In fact, several experts suggested that use of non-directive counseling was more prevalent in federally-funded clinics than in the private sector. Several experts emphasized that patient education is a core part of the public health system that is not necessarily found in private settings. Also, publicly-funded clinics are more likely to conduct non-directive counseling because they have extensive documentation requirements, quality assurance programs, and auditing of their charts.

Overall, it appeared that experts were quite familiar with the concept of non-directive counseling and believed it occurred as a usual course of business within federally funded clinics.

B. Variations in Non-Directive Counseling by Practice Setting and Patient Needs

The experts' personal experience with non-directive counseling varied by practice type and clinic setting. For example, the obstetrician/gynecologists often found that they became involved in a woman's pregnancy after she had already decided to carry the baby to term. In contrast, the family practitioners usually met women when they were still in the process of deciding what action to take regarding their pregnancy. Regardless, the experts emphasized that they would always conduct non-directive counseling (or set up an appointment for the woman with a counselor) if the woman was unsure about her decision.

Experts recognized there might be situations when counseling is not appropriate. Many women come to the clinic with their decision already made regarding their pregnancy. If the woman has decided to take the pregnancy to term, experts felt that terminating the pregnancy should not be discussed. As one expert said, "If 'We are so thrilled' is the response [to a positive pregnancy test], it would not be appropriate to recite all three options." Another commented that "if she clearly wants prenatal care and has no ambivalence about the pregnancy, there is no point in raising the issues of abortion or adoption."

However, experts also stressed that they try to make sure women are aware of all of their options regarding their pregnancy. One explained, "Even when a woman is married and appears to be fine, there is an opportunity to discuss choices and situations. A provider has to explore the situation." Another said, "Even when someone comes in sure in her choice, as her provider, I try to make sure all three options are presented."

The concern about whether all three options should always be discussed may stem from the universal feeling among the providers that the counseling process must be tailored to each woman's needs. Even experts who hesitated in saying that they would always present all three options agreed that they have an obligation to make sure women understand how the pregnancy fits into her life.

Experts also felt that providing individualized non-directive counseling included being sensitive to geographical and cultural considerations that may impact a woman's decision

regarding her pregnancy. Women in extremely rural areas may feel pressure to keep the baby because of lack of access to other services. In addition, significant distances between a woman's home and clinic may produce trust and confidence barriers between the counselor and the patient. Cultural and religious sentiments against abortion and adoption also make counseling a sensitive issue. "Cultural factors affect how different segments of the community see these options."

The experts felt that training models existed throughout the country, particularly in Title X funded clinics. "Everybody in Title X gets pretty extensive training. In nurse practitioner and other health professions training, this topic would be covered in instruction multiple times." Another commented, "structurally, a publicly funded health clinic may be better able to do this [non-directive counseling] because they hire and train staff who have expertise and skills in counseling and communicating." However, several experts emphasized the need for more funding so clinics could employ more providers and provide more space and written materials for counseling services. "The public health infrastructure needs money. . . . there is also always a challenge in finding the best staff for low salaries."

C. Adoption Agencies' Amenability to Public Health Clinics

One issue that was raised by experts was the amenability of adoption programs themselves to patients served in public clinics. A shared sentiment was that local adoption agencies have been perceived by clinicians as sending a message to clinics treating poor women – in particular women of color with high health risks – that their infants are not desirable and that an adoption referral is not warranted. This finding may be a matter for particular attention as adoption training unfolds in communities in which local adoption agencies have been less than enthusiastic about the referrals that come from public clinics.

VI. Key Informant Interview Results

A. Understanding and Use of Non-Directive Counseling

Non-directive counseling or options counseling was described as a method of counseling that provides all three options to pregnant women (taking the pregnancy to term and keeping the baby, taking the pregnancy to term and placing the baby for adoption, and terminating the pregnancy) in a non-judgmental fashion. Every provider indicated their counselors were well-trained in non-directive counseling for pregnant women, and indicated that they were required to provide such counseling.

The providers reported that counseling began when women came in for a pregnancy test in almost every case. A majority of the time women have taken home pregnancy tests and were coming into the clinic to confirm their pregnancy. For that reason, providers in all of the clinics found that most women usually knew what they wanted to do regarding their pregnancy before coming to the clinic.

The clinics used a variety of methods to initiate counseling. Some clinics provided every woman with a form that they completed during the pregnancy test. The forms ask the woman

to check-off whether or not they look forward to a positive pregnancy test and if they would like information on adoption, abortion, prenatal care, and counseling. Based on the response to the form, the clinic provides the appropriate type of counseling. Other clinics take their cues from the woman after she is given the results of the pregnancy test. Some cues include: whether the woman is happy that she is pregnant, whether she is upset that she is pregnant, whether the woman appears or indicates that she is unsure about what she wants to do regarding her pregnancy, how she responds when the three options are initially mentioned. The length of the counseling session or whether follow-up counseling sessions are scheduled varies based on the individual's needs.

Counselors at all of the clinics stressed that they would not encourage a client to choose one option over another, even when there are barriers to a good outcome or other social factors that may make it difficult for the woman to raise a child.

B. Training Programs for Counselors

All sites provided comprehensive reproductive counseling training to their staff before allowing them to counsel pregnant women. Training program formats included two-week counseling training sessions, one-day and several day workshops, and as-needed training sessions. All of the training programs cover all three pregnancy related options, including facts and referral sources. In addition, all programs reviewed how to present information in an unbiased, non-judgmental manner.

C. Experiences with Adoption

All of the providers found that adoption was not a popular choice among their patient population. They believed this occurred for a variety of cultural, religious, and social reasons. Some providers felt that adoption was not accepted in the culture of many of their patients. If the woman could not keep the child, the child would be "informally adopted" by a grandparent or other relative. One provider specifically mentioned that the local adoption agency needed to become more culturally sensitive to the clinic's patient population. Another reason that adoption was not often chosen was because women felt that they could not carry the pregnancy to term and then give up the baby. Therefore, the only realistic options were keeping the child or terminating the pregnancy. Also, because there is less of a stigma associated with being a single mother now than in the past, more women have been electing to keep their child even if they did not plan on marrying the father.

While all of the providers felt that their counselors had sufficient information to present the adoption option to patients, the amount and quality of information relating to adoption varied by clinic. While some clinics noted that they had a very close working relationship with the local adoption agency, other clinics indicated they would be interested in receiving further information on adoption to help explain the complicated legal, confidentiality, and family issues related to the adoption process.

VII. Conclusions

The purpose of this report is to evaluate "the extent to which adoption information and referral, upon request, are provided by eligible health centers." PHS Act § 330F(a)(6)(C). The findings from this initial assessment suggest several conclusions. First, counseling about adoption and assisting in the referral process already is a basic part of written guidelines setting forth the professional standard of practice in the area of obstetrical care and management. Guidelines issued by Federal health service agencies suggest that federally-assisted clinical providers furnishing family planning and obstetrical services to pregnant women are expected to adhere to the general professional standard, not only as a condition of grant award but as a basic matter of clinical and professional ethics.

Second, the experts interviewed were quite familiar with the concept of non-directive counseling and believe it occurs as a usual course of business within federally funded clinics. All key informants interviewed for this analysis indicated that the sites where they work provide comprehensive reproductive counseling training, including training on all three pregnancy related options, to their staff before allowing them to counsel pregnant women.

This analysis indicates that the option of infant adoption as part of a course of non-directive counseling to pregnant women is an accepted and adhered-to standard among clinicians at federally funded heath clinics, and the interviews with experts and key informants shed light on important issues that arise when counseling standards are put into practice in the area of pregnancy. For example, clinicians and experts were concerned about any form of counseling that would be viewed as heavy handed or intrusive or less than respectful of the patient, her family, and the community in which she identifies herself as a member.

It is clear that adoption as an option carries its own adverse images in the minds of some clinicians, just as other pregnancy options might. This may be particularly true in the case of practices serving communities in which the thought of removing a child from an extended caregiving situation and informal adoptions would be culturally anathema. Where the adoption agency in a community is inadequately sensitive (or perceived as such), the tendency may be to avoid bringing up the subject.

Several interviewees indicated that there are some agencies that actively discourage referrals from public clinics. Whether this is true or merely perceived, it is an issue that must be addressed in regional training regarding adoption. Further research is needed to study clinical settings in which the relationship between health provider and adoption agency is a strong and positive one. Methods to replicate these positive relationships should be explored.

APPENDIX 1: Clinical Guidelines for Non-Directive Counseling of Pregnant Women

Organization	Guideline Type	Non-Directive	Language	Cite	Mention Adoption
Bureau of Primary Health Care	Policy Information Notice: 98-23	Y	"...Health center clinic protocols should reflect the current guidelines established by health agencies or professional organizations such as the Agency for Health Care Policy and Research, the American College of Obstetrics and Gynecology..."	Part II.7.a	N/A
Office of Population Affairs	Program Regulations	Y	A project must: (i) Offer pregnant women the opportunity to be provided information and counseling regarding each of the following options: (A) Prenatal care and delivery; (B) Infant care, foster care, or adoption; and (C) Pregnancy termination. (ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.	42 CFR 59.5 (a)(5)	Y
American College of Obstetricians and Gynecologists	Guideline for Women's Health Care	Y	"In the event of an unwanted pregnancy, the patient should be counseled about her options: 1) continuing the pregnancy to term and keeping the infant 2) continuing the pregnancy to term and offering the infant for legal adoption, or 3) terminating the pregnancy."	Routine Assessments ; Under 18 Years of Age	Y
Child Welfare League of America	Standard of Excellence: Services for Adolescent Pregnancy Prevention, Pregnant Adolescents, and Young Parents	Y	"The pregnant adolescent should be provided with individual and group counseling: (1) to help her cope with the ramifications of the pregnancy and to become aware of the options in relation to pregnancy resolution... (2) to help her recognize her options if she decides to carry to term, including parenting the child..., planning for the adoption of the child..."	Standard 4.10	Y
Council on Accreditation for Children and Families	Standard: Pregnancy Counseling and Supportive Services	Y	"The organization offers counseling to help expectant parents decide if they want to parent the child, plan for adoption, transfer custody of the child, or terminate the pregnancy."	Standard S13.2.01	Y

Clinical Guidelines for Non-Directive Counseling of Pregnant Women, continued

Organization	Guideline Type	Non-Directive	Language	Cite	Mention Adoption
American College of Nurse-Midwives[4]	Code of Ethics for Certified Nurse-Midwives	Y	"Nurse-midwives share professional information with their clients that leads to informed participation and consent. This sharing is done without coercion, or deception."	Code Four	N
National Association of Social Workers	Policy Statement: Family Planning and Reproductive Choice	Y	"The nature of the reproductive health services that a client receives should be a matter of client self-determination in consultation with the qualified health care provider furnishing them."	"Social Work Speaks": Page 113, Policy Four	N
American Medical Association	House of Delegates: Adoption Policy	Y	"It is the policy of the AMA to (1) support the provision of adoption information as an option to unintended pregnancies; and (2) support and encourage the counseling of women with unintended pregnancies as to the option of adoption."	H-420.973	Y

[4] American College of Nurse Midwives Position Statement of Reproductive Choices states: "every woman has the right to access to factual, unbiased information about reproductive choices, in order to make an informed decision. . . ." (Position 2).

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Office of the President
Lisa M. Hollier, MD, MPH, FACOG

July 31, 2018

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

Re: HHS-OS-2018-0008; Compliance with Statutory Program Integrity Requirements

Dear Secretary Azar:

The American College of Obstetricians and Gynecologists (ACOG) appreciates the opportunity to submit comments in response to the proposed rule, "Compliance with Statutory Program Integrity Requirements" (Proposed Rule), published in the Federal Register on June 1, 2018 by the Department of Health and Human Services (HHS). The Proposed Rule would fundamentally undermine Title X of the Public Health Service Act ("Title X"). It puts at risk the patient-physician relationship and the high-quality evidence-based care that millions of women, men, and adolescents receive each year. The Proposed Rule constitutes an improper restriction on the practice of medicine that, if implemented, would threaten access to reproductive health options and effective family planning methods for the patients who receive care through Title X. It would also place physicians in ethically compromised situations. It contains arbitrary standards and medically inaccurate terminology and, thus, represents a political attempt to interfere with the health care access available to low-income women, and to improperly restrict care that physicians and other medical professionals serving these populations are able to provide.

ACOG is the nation's leading organization of physicians who provide health services unique to women. As the only national medical specialty society of women's health physicians, ACOG has more than 58,000 members representing more than 90 percent of all board-certified obstetrician-gynecologists (ob-gyns) in the United States. ACOG advocates for policies that ensure access to health care for women throughout their lives and believes that a full array of clinical services should be available to women without costly delays or the imposition of cultural, geographic, financial, or legal barriers. Few federal programs are as important to women's health care access as the Title X program. The services presently available through Title X health care providers include Food and Drug Administration (FDA)-approved contraceptive methods and counseling services, well-woman exams, breast and cervical cancer screenings, screening and treatment for sexually transmitted infections (STIs), testing for HIV, pregnancy testing and counseling, and other patient education and/or health referrals. Title X funds are not used for abortions. ACOG affirms the efforts of its members and other medical providers who practice at Title X-funded facilities to provide access to high-quality reproductive health care to all people regardless of their financial circumstances.

Contrary to the preamble of the Proposed Rule, which states that "the new regulations would contribute to more clients being served, gaps in service being closed, and improved client care that better focuses on the family planning mission of the Title X program,"[i] the proposed changes to the Title X program would jeopardize access to family planning and preventive health care for more than four million low-income women, men, and adolescents, and is antithetical to physicians' codes of ethics and commitment to high-quality patient care. The Proposed Rule is laden with medically inaccurate terminology, prioritizing ideology over scientific evidence, exposing the arbitrary nature of the proposed regulation. For these reasons and those explained in full below, we call for the Proposed Rule's immediate and complete withdrawal.

I. The Title X program plays a critical role in our nation's public health safety net.

As the only federal grant program dedicated exclusively to providing low-income patients with essential family planning and preventive health services and information, Title X plays a vital role in ensuring that safe, timely, and evidence-based care is available to every woman regardless of her financial circumstances. Rates of adverse reproductive health outcomes are higher among low-income and minority women, and unintended pregnancy rates are highest among those least able to afford contraception.[ii] According to the HHS Office of Population Affairs website, "Access to quality family planning and reproductive health services is integral to overall good health for both men and women. Few health services are used as universally. In fact, more than 99 percent of women aged 15–44 who have ever had sexual intercourse have used at least one contraceptive method."[iii]

The care made available to women through the Title X program has contributed to the dramatic decline in the unintended pregnancy rate in the United States, now at a 30-year low.[iv] Improved access to contraception and information for adolescents, including those provided by Title X projects, has contributed to a record low teen pregnancy rate.[v] The services provided by Title X projects help prevent nearly one million unintended pregnancies each year.[vi]

In addition to pregnancy prevention, Title X projects meet other reproductive health needs for women, men, and adolescents. In 2016, Title X projects provided nearly five million STI tests, and provided more than 700,000 Pap tests and 900,000 clinical breast exams.[vii] Further, it is estimated that in 2010 alone, services provided by Title X projects helped avert 53,450 chlamydia infections, 8,810 gonorrhea infections, 250 HIV infections, and 6,920 cases of pelvic inflammatory disease.[viii]

The Title X program has improved the lives of women and their families, enabling many women to achieve greater educational, financial, and employment success and stability. These public health strides help American society in many ways, including by saving taxpayer dollars. Because of the high-quality health care that individuals have received through the Title X program, there is an estimated taxpayer savings of $7.09 for every dollar invested in the Title X program.[ix]

The Proposed Rule would undermine the Title X program and detrimentally restrict the ability of patients to access care. If implemented, the Proposed Rule would limit access to vital preventive and often life-saving services for the more than four million patients seeking care annually at Title X-funded facilities. In addition, it would reverse our nation's historic achievements in reducing unplanned and teen pregnancy rates, and make evidence-based contraception methods

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inaccessible to women who otherwise cannot afford them, turning back the clock on women's health.

II. The Proposed Rule would interfere with the patient-physician relationship, restrict the information available to patients, and hinder the ability of physicians to practice medicine in accordance with their ethical obligations.

ACOG's Code of Professional Ethics for ob-gyns unequivocally states that "the patient-physician relationship is the central focus of all ethical concerns, and the welfare of the patient must form the basis of all medical judgments."[x] The patient-physician relationship is essential to the provision of safe and quality medical care, and political efforts to regulate elements of patient care and counseling can drive a wedge between a patient and her medical provider.[xi] HHS acknowledges in the preamble of the Proposed Rule that:

> "…[O]pen communication in the doctor-patient relationship would foster better over-all care for patients. While the benefit of open and honest communication between a patient and her doctor is difficult to quantify, one study showed that even "the quality of communication [between the physician and patient] affects outcomes . . . [and] influences how often, and if at all, a patient would return to that same physician." Facilitating open communication between providers and their patients helps to eliminate barriers to care, particularly for minorities."[xii]

However, if implemented, the Proposed Rule would put the patient-physician relationship in jeopardy by placing restrictions on the ability of physicians to make available important medical information, permitting physicians to withhold information from pregnant women about the full range of their options, and erecting greater barriers to care, especially for minority populations.

1. *The Proposed Rule includes vague restrictions on counseling and removes the requirement that providers offer nondirective pregnancy options counseling, limiting information available to women.*

ACOG supports a woman's right to decide whether to have children, to determine the number and spacing of her children, and to have the information, education, and access to health services to make those decisions.[xiii] ACOG's Code of Professional Ethics states that physician respect for the right of patients to make their own choices about their health care is fundamental.[xiv] Physicians have an "ethical obligation to provide accurate information that is required for the patient to make a fully informed decision."[xv] Yet, the Proposed Rule removes the requirement that providers receiving Title X funds offer the opportunity for pregnant women to receive nondirective counseling and information about their full range of pregnancy options, including prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination. This concerning deletion also removes the exception that counseling of pregnant women exclude those "option(s) about which the pregnant woman indicates she does not wish to receive."[xvi] If implemented, the Proposed Rule would permit providers to withhold information from patients, and would permit, and in some cases require, the provision of counseling, information, and referral for services that the patient has clearly stated she does not wish to receive. In the case where a patient seeks counseling once pregnant, under the Proposed Rule a provider would not be permitted to offer such counseling, and instead would be required to provide the patient with a list of prenatal and/or social services, and would require that the patient "be provided with

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information necessary to protect her health and the health of her unborn child."[xvii] ACOG opposes efforts to restrict the medical information that Title X providers can make available to their patients, especially where, as here, the restriction would prevent Title X providers from sharing complete and accurate medical information necessary to ensure that their patients are able to make fully informed medical decisions and obtain timely care.[xviii] Moreover, it is imperative that HHS, the nation's foremost health policy agency, understand and orient all of its activities on a foundation firmly based on scientifically valid and appropriate terms and evidence. The term "unborn child" used in §59.14(b) of the Proposed Rule is not a medical term and should not be used in regulations governing a federal public health program. The agency's use of terms such as this only further emphasizes the fact that the Proposed Rule is ideologically driven and does not align with evidence-based medicine.

In addition to improperly restricting a physician's ability to provide complete and accurate information to his or her patients, the requirements in the Proposed Rule surrounding what information a physician is permitted to share during nondirective counseling are vague and confusing. Specifically, the Proposed Rule contains a new requirement that grantees are not permitted to "promote, refer for, support, or present" abortion as a method of family planning.[xix] It is unclear to what extent counseling that references abortion would be permissible. For instance, would sharing ACOG's patient education document, Frequently Asked Questions #168 "Pregnancy Choices: Raising the Baby, Adoption, and Abortion" be considered a violation?[xx] Without additional guidance, grantees may interpret this language as a complete prohibition on any conversation with their patients that references abortion. At a minimum, these changes would have a chilling effect on providers, who could fear even mentioning the word abortion while counseling a patient on their options would violate the Title X regulations. Merely stating in the preamble of the Proposed Rule that "a doctor would be permitted to provide nondirective counseling on abortion," while subjecting that counseling to vague and confusing restrictions, is not sufficient to describe the requirements the Proposed Rule is seeking to impose.

2. *The Proposed Rule dictates how physicians treat their patients, denies the ability of physicians to refer for abortion care, and discriminates among providers.*

Safe, legal abortion is a necessary component of women's health care. In the United States, where nearly half of all pregnancies are unintended, almost one third of women will seek an abortion by age 45.[xxi] Despite reductions in the unintended pregnancy and abortion rates in recent years, rates remain higher among low-income and minority populations.[xxii] Many factors influence or necessitate a woman's decision to seek abortion care. They include, but are not limited to, contraceptive failure, barriers to contraceptive use and access, rape, incest, intimate partner violence, fetal anomalies, and exposure to teratogenic medications. Additionally, pregnancy complications may be so severe that an abortion is the only measure to preserve a woman's health or save her life.[xxiii] As is acknowledged in the preamble of the Proposed Rule, Title X funds have never been used for abortion. However, the Proposed Rule goes beyond the statute in an effort to further restrict access to abortion care outside of the Title X program.

Like all medical matters, decisions regarding abortion should be made by patients in consultation with their health care providers and without undue interference by outside parties. Like all patients, women obtaining abortion are entitled to privacy, dignity, respect, and support.[xxiv] The Proposed Rule inappropriately regulates provider interactions with patients, going so far as to

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detail restrictions governing when a provider may offer certain referral information, and dictate how that information may be shared.

ACOG's Code of Professional Ethics states that ob-gyns should "serve as the patient's advocate and exercise all reasonable means to ensure that appropriate care is provided to the patient."[xxv] Yet, under the Proposed Rule, only when a patient who is currently pregnant "clearly states that she has already decided to have an abortion," is a physician permitted to share a list of "licensed, qualified, comprehensive health service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care)."[xxvi] This provision could be read to arbitrarily deny the ability of a physician to provide a referral to a woman who decides after presenting to a Title X facility for care to have an abortion. In addition, the Proposed Rule states that "The list shall not identify the providers who perform abortion as such."[xxvii] This proposed regulation restricts the ability of physicians to provide clear, direct information to patients, and it even goes so far as to actively require physicians to withhold full and accurate information and provide referrals to providers that do not offer the service requested by the patient.

The Proposed Rule further clarifies in the examples provided in proposed §59.14(e) that projects do not have to provide any referrals to abortion providers, even if directly requested by the patient, meaning that these changes would also lead to inconsistency in the information offered to patients at different Title X facilities. These provisions represent an improper intrusion into the patient-physician relationship, the importance of which is underscored in the preamble of the Proposed Rule. HHS has provided no justification for this complex and incredibly prescriptive requirement, nor is it supported by the statute. The result of such a regulation would be to mislead patients and delay their access to abortion care, placing providers in ethically compromised positions.

As written, the Proposed Rule requires that a list of referrals for abortion defined by proposed §59.14(a) be provided by a medical doctor, and the preamble of the Proposed Rule suggests that counseling is also confined to a physician. This restriction will unnecessarily further limit access to information that can be – and often is today – provided by a qualified non-physician provider, and delay care for patients. ACOG recognizes that advanced practice clinicians, such as nurse-midwives, physician assistants, and nurse practitioners, possess the clinical skills necessary to provide first-trimester medical abortion.[xxviii] There is no question that these non-physician providers are qualified to provide counseling and referrals to patients. In addition, roughly half of counties in the United States lack an ob-gyn, and those shortages are exacerbated in rural and underserved communities.[xxix] Ob-gyn workforce shortages are expected to increase – not decrease – in the coming years, with a projected shortage of 18 percent by 2030.[xxx] Through arbitrarily limiting the providers who can provide referrals to physicians, the Proposed Rule erects an unnecessary and unsupported barrier to care.

The requirement that the list of referral providers be restricted only to those physicians who provide comprehensive prenatal care (as opposed to providers who only offer gynecological services) would further limit the care options offered to patients, and is not consistent with evidence-based medicine. The Proposed Rule would exclude physicians and medical providers who specialize in the provision of abortion and contraception. In addition, the Proposed Rule's restrictions on referred providers would exclude older ob-gyns who have retired their obstetric practice but continue to provide gynecologic care, including abortion. According to ACOG's 2015 Survey on Professional Liability, the average age at which surveyed physicians stopped

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practicing obstetrics was 48 years, which is considered the near-midpoint of a physician's career.[xxxi]

In cases where a patient is pregnant and does not "clearly state" her decision to have an abortion, the Proposed Rule requires that the patient be "referred for appropriate prenatal and/or social services (such as prenatal care and delivery, infant care, foster care, or adoption), and shall be given assistance with setting up a referral appointment to optimize the health of the mother and unborn child."[xxxii] In addition to the inappropriate use of nonmedical language, as already addressed, proposed §59.14(b) undermines the patient-physician relationship, and is not reflective of the realities of that relationship, where a patient regularly seeks the counsel of their provider. It is also counter to the ethical obligations that physicians have to provide a pregnant woman who may be ambivalent about her pregnancy full information about all options in a balanced manner, including raising the child herself, placing the child for adoption, and abortion. ACOG has long recognized the physician's "ethical obligation to provide accurate information that is required for the patient to make a fully informed decision."[xxxiii]

The restrictions on counseling and referral information that can be shared by Title X providers may put them at increased risk of medical liability. As one example, the decision in *Wickline v. State of California* found that "it is no defense in a medical liability case to argue that physicians simply have followed a payer's instructions."[xxxiv] Ob-gyns already face greater liability risks than many of their physician colleagues, and many ob-gyns report changing their practice due to liability risks. Of those ob-gyns surveyed by ACOG in 2015, "delay in or failure to diagnose" was cited as one of the top three gynecologic liability allegations.[xxxv] By restricting the provision of clear, direct referrals to patients, based on the politically motivated requirements in proposed §59.14(a), the patient is faced with unnecessary barriers and delayed access to care, placing Title X providers at elevated risk of liability.

Restrictions on counseling and referrals undercut a woman's access to safe, legal abortion and jeopardize quality of care. The Institute of Medicine (now National Academy of Medicine) study titled "Crossing the Quality Chasm: A New Health System for the 21st Century" defines high quality care as health care that is safe, effective, patient-centered, timely, efficient, and equitable.[xxxvi] Any changes to the regulations governing the Title X program should aim to advance the quality of care received, in order to best meet patient needs and improve the safety, reliability, responsiveness, integration and availability of care. ACOG has long recognized that "[l]aws [or regulations] should not interfere with the ability of physicians to determine appropriate treatment options and have open, honest, and confidential communications with their patients. Nor should laws [or regulations] interfere with the patient's right to be counseled by a physician according to the best currently available medical evidence and the physician's professional medical judgment."[xxxvii] The Proposed Rule's restrictions on counseling and referral for abortion are a violation of the patient-physician relationship, undermine the quality of care provided to patients, place physicians in ethically compromising situations, and, accordingly, should not be implemented.

III. The Proposed Rule's onerous new reporting requirements for grantees raise safety concerns and are not required to ensure statutory compliance.

The Title X program, as currently regulated, has considerable oversight and reporting requirements. Yet, the Proposed Rule seeks unprecedented additional oversight of Title X

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grantees' subrecipients, referral agencies and individuals, and other partners. The stated purpose of the newly proposed §59.5(a)(13) is to "ensure transparency in the delivery of services" by requiring that all grant applications and required reports include (1) name, location, expertise, and services provided or to be provided by subrecipients, referral individuals and agencies; (2) detailed description of collaboration with those entities, as well as less formal community partners; and (3) a clear explanation of how a grantee will "ensure adequate oversight and accountability for the quality and effectiveness of outcomes" for patients seen by subrecipients or referrals.[xxxviii] The preamble appears to call into question the "governmental accountability for [Title X] funds" if HHS does not have this information, but does not offer any evidence to support this claim and fails to adequately justify these new requirements, nor account for the added costs to grantees.[xxxix] These requirements are burdensome at best and dangerous at worst; they do not improve patient care and are contradictory to other initiatives currently being undertaken at HHS.

1. *The Proposed Rule is inconsistent with other administrative efforts to reduce regulatory burden.*

President Donald Trump's Executive Order to "lower regulatory burdens on the American people," and the Centers for Medicare and Medicaid Services' (CMS) initiative titled "Patients Over Paperwork" are representative of an Administration-wide effort to reduce unnecessary regulatory burdens in federal programs, in particular those that impact health care providers.[xl] The stated goals of the Patients Over Paperwork initiative are to streamline regulations in order to "reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience."[xli] Despite this trend elsewhere within the Administration and HHS, the Proposed Rule seeks to add to the regulatory burden of the Title X program, by implementing new costly and time-consuming reporting requirements.

2. *The Proposed Rule's requirement that grantees report on all referral agencies and individuals, including services provided, is burdensome and raises safety concerns.*

It is not standard practice for providers to keep a dedicated and exhaustive list of all of the providers they interact with, whether through referral or consultation, nor to keep a comprehensive list of the services provided by those colleagues. The Proposed Rule would require Title X-funded entities to track services among referral networks that they are not funded to provide, and appears to suggest that Title X-funded entities would be held accountable for outcomes of patients who receive services at other facilities. This is outside the scope and purpose of the Title X program, and holds Title X providers to an unreasonable standard that is inconsistent with other federally-funded programs.

The collection and reporting to HHS of the names, locations, expertise, and services provided by referral agencies and individuals, as required by proposed §59.5(a)(13)(i), raises several serious questions and concerns. For instance, what happens if a referral agency or individual is inadvertently left off of an application or report to HHS? Is a patient then unable to be referred to or receive care from that agency or individual? Alternatively, how would HHS manage a request by an agency or individual that wishes to be removed from a reported list? In addition, because the Proposed Rule only permits referral for abortion to providers who also offer comprehensive prenatal care, proposed §59.5(a)(13)(i) would require grantees to provide the names and locations of those providers who may not otherwise advertise their abortion services to the

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public. It is unclear what purpose collecting this information would serve aside from establishing an inventory or registry at HHS of the names and locations of abortion providers. Abortion providers face violence and threats to themselves, their staff, and their families.[xlii] The Proposed Rule provides no assurance of confidentiality for those referral providers listed, nor does it provide a guarantee that the information would not be used for other purposes.

HHS seeks comment on whether HHS should impose additional policies or requirements on referral agencies, specifically "expanding the requirement that referral agencies that do not receive Title X funds but nevertheless provide information, counseling, or services to Title X clients be subject to the same reporting and compliance requirements as do grantees and subrecipients."[xliii] Such an expansion of reporting requirements is well beyond the scope of the Title X program and should not be pursued. Requiring providers that do not receive federal Title X funding to comply with onerous reporting requirements is inappropriate and would serve as a disincentive for those providers to serve as referrals for Title X patients. This would exacerbate barriers to specialty care already faced by low-income patients, particularly those living in rural or other underserved communities.[xliv]

IV. The Proposed Rule undermines access to evidence-based family planning methods.

All people seeking care in Title X programs should have access to the contraceptive method that works best for their individual circumstances. We are concerned that the Proposed Rule lowers the threshold on the contraceptive services available at Title X-funded organizations, limiting access to a woman's contraceptive method of choice, and negatively impacting the quality of care provided to patients. The Proposed Rule also appears to prioritize new Title X projects that do not offer a broad range of the most effective contraceptive methods. Collectively, if implemented, these changes will result in reduced access to the most effective contraception methods, threatening to reverse decades of progress, including our nation's historic achievements in reducing unplanned and teen pregnancy rates.

1. *The Proposed Rule lowers the standards for what family planning services must be offered.*

As stated above, ACOG supports a woman's right to decide whether to have children, and to determine the number and spacing of her children. ACOG believes a woman must have unhindered access to information, education, and health services, including the full range of contraceptive methods, in order to make the best decision for herself and her family.[xlv] Currently, Title X projects must provide a "broad range of acceptable and effective medically approved family planning methods (including natural family planning) and services."[xlvi] Access to "the full range of FDA-approved contraceptive methods" has likewise been deemed an essential feature of quality family planning by the U.S. Office of Population Affairs, which administers Title X, and the Centers for Disease Control and Prevention in their authoritative clinical guidelines for quality care, the Quality Family Planning (QFP) recommendations.[xlvii] Despite this body of evidence, the Proposed Rule removes the requirement that methods of family planning be "medically approved," instead placing increased emphasis on the provision of natural family planning (NFP) and "other fertility-awareness based methods."[xlviii] In contrast, the QFP recommendations emphasize that family planning care should be "medically accurate, balanced, and provided in a nonjudgmental manner."[xlix] This modification to the requirements that must be met by family planning projects, together with the newly proposed definition of "family

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planning" appears to be diluting long-standing Title X program requirements, lowering the standards governing the services that must be offered. These changes threaten the quality of family planning available to Title X patients. In addition, the Proposed Rule inserts "adoption" as a service to be offered by a family planning project.[l] Such an expansion of services is puzzling and appears outside the intended scope of the Title X program.

2. *The Proposed Rule's permissive language may result in fewer Title X-funded sites providing the broad range of contraceptive methods that have been a core part of the program since its inception.*

The current regulations allow, though do not encourage, organizations receiving Title X funds to offer only a single method of family planning "as long as the entire project offers a broad range of family planning services."[li] The Proposed Rule is much more permissive, appearing to encourage the inclusion of more providers within a Title X project that only offer a single contraceptive method or very limited methods, putting at risk access to the most effective – and often most desired and expensive – forms of contraception, such as long-acting reversible contraception (LARC).[lii]

The Proposed Rule appears to justify this new emphasis by stating in the preamble that "it has become increasingly difficult and expensive for a Title X project to offer all acceptable and effective forms of family planning."[liii] However, the Proposed Rule does not provide evidence to support this statement. In fact, a recent study by the Kaiser Family Foundation and George Washington University found that Title X-funded health centers are far more likely than non-Title X-funded health centers to provide a larger range of effective family planning methods onsite and to offer services associated with high quality care.[liv] This study found that health centers that receive Title X funds were nearly twice as likely to offer onsite dispensing of oral contraceptives (78 percent versus 41 percent) and more than 1.5 times more likely to offer LARCs, including the contraceptive implant and intrauterine devices (IUDs).[lv] In fact, the availability of onsite oral contraceptive pills has significantly decreased among clinics that do not receive Title X funding, from 53 percent in 2011 to 41 percent in 2017.[lvi] While the Proposed Rule suggests the proposed changes would improve access to and quality of care provided at Title X-funded sites, evidence indicates that Title X-funded sites are more likely than non-Title X-funded sites to follow recommendations of the U.S. Preventive Services Task Force and QFP recommendations, such as screening sexually active women age 25 or younger for chlamydia that can result in infertility if untreated. [lvii,lviii]

Additionally, while Title X does not currently require each service site to offer the full range of contraceptive methods, Title X service sites are required to consult with existing local and regional projects that serve the same population. The Proposed Rule removes the requirement that new Title X applicants communicate with existing health resources serving the same area. By removing this requirement for open communication and coordination between service sites for a shared population, there is no assurance that the population in a particular area has sufficient access to a broad range of the most effective methods of contraception. The Proposed Rule erroneously argues that "loosening the status quo" will allow sites a broader reach, but there is no evidence to support this assumption.[lix]

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3. *The Proposed Rule appears to give preference to Title X projects that provide only limited contraception options, risking access to comprehensive contraceptive care for large parts of the traditional Title X population.*

By lowering the threshold for participation in the Title X program, we are concerned that HHS will prioritize organizations with little or no experience providing sexual and reproductive health care. While NFP and fertility awareness-based methods of family planning have always been included in the full range of contraceptive options offered to women seeking family planning care, the new emphasis on NFP in the Proposed Rule is a major departure from the previous focus on counseling women on the most effective methods. When fertility awareness is used to prevent pregnancy, in the first year of typical use, as many as one in four women will have an unintended pregnancy.[lx] Underserved women, including those who are low-income, already experience the highest rates of unintended pregnancy and abortion, and the Proposed Rule could further exacerbate those disparities.[lxi]

HHS's apparent preference for organizations utilizing fertility awareness-based methods could leave large populations without access to the most effective methods of family planning. Medically underserved populations, including racial and ethnic minorities, LGBTQ individuals, and adolescents will be most harmed by this reduction in access. ACOG's recommendations for adolescent contraceptive care specifically advise that discussions about contraception begin with the most effective methods first.[lxii] Deviating from this recommendation is of significant concern as there is a knowledge gap among this population. Data on unmarried young adults aged 18-29 years in the U.S. suggests misperceptions are common regarding contraception use, and there is a gap between intent and behavior in preventing unintended pregnancy.[lxiii] Encouraging more single-method or limited method service providers within a Title X project will threaten access to comprehensive information about the full range of contraception methods, and is at odds with evidence-based recommendations.

Moreover, the suggested preference for providers offering only NFP methods over medical providers who offer a larger range of FDA-approved contraceptive methods is out of proportion with the known preferences of many Americans. The Proposed Rule contends many people would prefer "single-method NFP service sites," however, utilization of NFP methods in the U.S. is in fact low, with only approximately 2 percent of sexually active women aged 15-44 choosing NFP in 2014.[lxiv,lxv] By contrast, 67 percent of women who use contraception choose more effective methods of contraception (the pill, patch, implant, injectable, vaginal ring, and condom).[lxvi] Clinical recommendations including both the QFP recommendations and the Health Resources and Services Administration-supported Women's Preventive Services Initiative (WPSI) assert that offering the full range of FDA-approved methods is a core component of quality family planning care.[lxvii] The proposed changes would put at risk women's access to their preferred method of contraception. How does HHS plan to ensure that quality care is safeguarded for all Title X patients, including the QFP and ACOG recommendations that women have access to their preferred method of contraception?[lxviii,lxix]

Of note, the preamble of the Proposed Rule references ACOG and WPSI's inclusion of "fertility awareness-based methods" in its clinical recommendations of contraception as a women's preventive service. However, HHS selectively excludes the substance of WPSI's clinical recommendations for contraception, incorrectly suggesting that ACOG either supports fertility awareness-based methods over other methods, or views fertility awareness-based methods as

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equally effective as FDA-approved methods.[lxx] Indeed, the WPSI recommendations were clear that fertility awareness-based methods are "less effective" than FDA approved methods of contraception but should be provided for women desiring an alternative method. To ensure there is no confusion as to ACOG and WPSI recommendations, read in full, the WPSI clinical recommendation for contraception states:

> "The Women's Preventive Services Initiative recommends that adolescent and adult women have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes. Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (eg, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method). The Women's Preventive Services Initiative recommends that the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures be available as part of contraceptive care.
>
> The full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration include: (1) sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives (combined pill), 8) oral contraceptives (progestin only, and), (9) oral contraceptives (extended or continuous use), (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms, (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, and (17) emergency contraception (levonorgestrel), and (18) emergency contraception (ulipristal acetate), and additional methods as identified by the FDA. Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method."[lxxi]

It is ACOG's unequivocal position that all women and adolescents should have unhindered and affordable access to comprehensive contraceptive care and contraceptive methods as an integral component of women's health care. The Proposed Rule threatens that access.

V. The Proposed Rule creates substantial burdens on qualified providers and puts at risk access to quality family planning services for low-income women and adolescents.

The Proposed Rule is designed to make it impossible for specialized reproductive health providers, like Planned Parenthood health centers, to continue to participate in the program, by requiring more than mere programmatic separation between Title X project activities and abortion-related activities, including referrals and counseling. These requirements threaten patient access to comprehensive reproductive health care, ignore the significant role specialized providers play in the Title X program, and further marginalize comprehensive reproductive health-focused providers from mainstream medical care.

Requiring complete financial and physical separation is a clear effort to force out reproductive health-focused providers and prioritize providers that do not specialize in reproductive health care. Planned Parenthood plays an outsized role in the Title X program, and the loss of these

service sites would disproportionately affect medically underserved patients including women of color, who make up more than half of all Title X patients, and women living in rural areas.[lxxii] The Proposed Rule provides HHS broad discretion to evaluate individual Title X funding recipients' compliance with the new physical and financial separation standard, considering at least four factors: (1) separate accounting records; (2) degree of separation of facilities; (3) the existence of separate personnel, electronic or paper-based health care records and work stations; and (4) the extent to which signs and other forms of identification of the Title X program are present, and signs and material referencing or promoting abortion are absent.[lxxiii] These factors reverse HHS's longstanding interpretation that if a Title X grantee can demonstrate separation of financial records, counseling and service protocols, and administrative procedures, "then it is hard to see what additional statutory protection is afforded by the imposition of a requirement for 'physical' separation."[lxxiv] HHS does not adequately justify this reversal.

The preamble of the Proposed Rule states that the "optics and practical operation of two distinct services within a single collocated space are difficult, if not impossible to overcome." However, this statement is not supported by evidence, as can be seen by the emergence of multi-specialty practices (MSPs). MSPs are defined as practices offering various types of medical specialty care within one organization. There is some evidence to suggest these practices may provide higher quality care at a lower cost, when compared to small group practices, including one analysis published in *Health Affairs* that found that patients of MSP providers received more evidence-based care than patients of non-MSP providers.[lxxv]

HHS requests comment on whether additional regulatory provisions are necessary, yet offers no justification for why even this proposed separation is warranted. The proposed reorganization of Title X provider sites will already have significant repercussions on patient access, and should be revoked. No further regulatory modifications should be pursued.

1. *Eliminating specialized reproductive health-focused providers will result in a significant gap in access that the health care system is not equipped to handle.*

Planned Parenthood sites represent only 13 percent of Title X service sites yet serve 41 percent of all Title X patients.[lxxvi] While Planned Parenthood is not explicitly named in the Proposed Rule, the dramatic changes to Title X compliance requirements would have an immense effect on Planned Parenthood service sites. Evidence demonstrates that other providers, including Federally Qualified Health Centers (FQHCs), would not have the capacity to absorb the nearly 2 million contraceptive patients who would lose access to care.[lxxvii] Not all FQHC sites offer contraceptive care services, and among those who do, the average site serves 320 contraceptive clients in a year. By contrast, the average Planned Parenthood health center serves 2,950 contraceptive clients annually.[lxxviii] Moreover, FQHC sites often score lower on critical indicators of quality contraceptive care than Planned Parenthood health centers. For example, Planned Parenthood sites are more likely to offer the full range of contraceptive methods, and specific services such as same-day insertion of LARC methods and on-site dispensing of oral contraceptives.[lxxix]

There is also strong evidence of adverse changes in contraception provision and serious public health consequences in states that have eliminated Planned Parenthood from their family planning programs. When Texas excluded Planned Parenthood from a state program serving low-income patients, the number of women using the most effective methods of birth control

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decreased by 35 percent, and the number of births covered by Medicaid increased by 27 percent.[lxxx] In addition to losing access to family planning services, communities also lose access to STI testing and treatment. When public health funding cuts in Indiana forced many clinics, including Planned Parenthood health centers, to close, rural areas of the state experienced a dramatic HIV outbreak. Access to STI testing at Planned Parenthood clinics could have minimized or even prevented the outbreak.[lxxxi] Targeting comprehensive reproductive health care providers, like Planned Parenthood, puts a larger range of health care services at risk for medically underserved communities.

We are also concerned by the requirement that grantees provide comprehensive primary care on site. Not only is that not a statutorily permissible use of Title X funds, it will further limit eligible entities, cutting otherwise qualified women's health providers from the program. The existing primary care workforce is poorly distributed, with fewer physicians, advanced practice nurses, and physician assistants located in underserved communities, particularly in rural areas. More than half of Planned Parenthood health centers are located in rural and medically underserved areas, helping to minimize the gap in both preventive and reproductive health services for populations in those communities.[lxxxii] If the Proposed Rule were implemented, the U.S. health system would not be prepared to meet this need; both ob-gyns and primary care physicians face workforce shortages. As stated above, ACOG projects an ob-gyn shortage of 18 percent by 2030, and the Association of American Medical Colleges has projected a shortfall of as many as 49,300 primary care physicians and as many as 72,700 nonprimary care physicians by 2030.[lxxxiii,lxxxiv] Limiting the eligibility of current Title X providers would exacerbate this women's health workforce shortage.

The Proposed Rule does suggest applicants can meet this requirement via a robust referral linkage with primary care providers who are "in close physical proximity," but HHS neglects to define this term.[lxxxv] For Title X clinics located in rural areas facing severe primary care provider shortages, how does HHS suggest they meet these new requirements to provide 'holistic' primary care? How will this requirement be measured in health professional shortage areas where there are few primary care providers?

If implemented, the Proposed Rule would exacerbate racial and socioeconomic disparities in access to care by leaving Title X patients, who are disproportionately black and Latinx, without alternate sources of care. Restricting access to qualified providers will increase rates of unplanned pregnancy, pregnancy complications, and undiagnosed medical conditions, leaving patients worse off than they are today.

VI. The Proposed Rule undermines critical confidentiality protections for minors, erecting additional barriers to care.

Family planning services are particularly important for adolescents. The United States has the highest adolescent pregnancy rate in the industrialized world.[lxxxvi] In addition, adolescents and young adults are more likely to acquire sexually transmitted infections than older individuals.[lxxxvii] Projects funded through Title X are expressly required by law to provide care to adolescent patients. The current Title X regulations fulfill this mandate through requiring that Title X facilities provide services to adolescents on a confidential basis. Existing law requires that Title X grantees certify that they encourage minors to include their family in their decisions to seek family planning services.

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The Proposed Rule threatens access to care for adolescents particularly through its weakening of confidentiality protections for adolescents seeking family planning care. Without these protections, adolescents, especially those without adult support systems, may be more likely to delay or not receive needed, sometimes lifesaving care.[lxxxviii] ACOG and other major medical associations support efforts to reasonably encourage adolescents to involve their parents in their decision to seek reproductive healthcare. However, when taking a health history, clinicians sometimes learn of circumstances (short of abuse) in a minor's family that make it not "practicable," or unrealistic or even harmful, to encourage the minor to involve their parents or guardians.[lxxxix] In these situations, clinicians should not be mandated to take "specific actions" to encourage the minor to do so (and then document those specific actions) as the Proposed Rule requires.[xc] ACOG and other major medical associations recommend that adolescents receive confidential, comprehensive reproductive health care without mandated parental notification or consent.[xci] According to the American Academy of Pediatrics, "…policies supporting adolescent consent and protecting adolescent confidentiality are in the best interests of adolescents. Accordingly, best practice guidelines recommend confidentiality around sexuality and sexually transmitted infections (STIs) and minor consent for contraception."[xcii] Ensuring adolescent confidentiality is not only consistent with medical ethics, but also with the importance of ensuring a strong patient-physician relationship.

The Proposed Rule creates barriers to adolescents receiving confidential care. The Title X program should continue to ensure that adolescents are able to access confidential care, while maintaining compliance with all state and federal laws. Failure to do so will erect additional barriers to adolescents seeking preventive and lifesaving reproductive health care and will also undermine the patient-physician relationship.

VII. The Proposed Rule redefines "low-income family" in a way that is contrary to Title X and puts low-income patients presently relying on Title X services at risk of losing access.

The current Title X regulations require that "no charge will be made for services provided to any person from a low-income family" except to the extent that payment can be made by a third-party payer, such as commercial insurance or Medicaid.[xciii] The preamble of the Proposed Rule highlights the increased need for publicly funded family planning services, "as the number of Americans at or below the poverty level has increased," yet at the same time redefines "low-income family" to include women whose employer-based health insurance coverage does not cover contraception due to the employer's religious or moral objections.[xciv,xcv] This expanded definition would potentially require Title X providers to provide free contraceptive services to any woman whose employer objects to insurance coverage of contraception, regardless of her income. HHS has recently expanded the availability of exceptions to the contraceptive coverage requirements of the Affordable Care Act to a broad range of employers. By proposing to expand the definition of "low-income family," the Proposed Rule would greatly increase the number of women who qualify for Title X-funded services, without providing any additional funding or support to ensure the program can sustain this patient increase. The Title X program was not designed to absorb the unmet needs of all individuals above 250 percent of the federal poverty level. Additionally, Title X is designed to subsidize a program of care, not pay the full cost of any service or activity. Title X regulations encourage Title X projects to work with third-party payers to reduce the cost of the program. The Title X program is already underfunded, and

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without additional funding from Congress, the Proposed Rule would result in even fewer resources to serve low-income patients, in direct contrast to the Proposed Rule's stated intent. The Title X network does not have the capacity to serve a flurry of new middle-income patients who have insurance coverage through their employer, nor the resources to serve those patients at low- or no-cost.

***

Policy decisions about public health must be firmly rooted in science, and increase access to safe, effective and timely care. Policies and regulations that improperly restrict the practice of medicine, place political preferences over medical necessities, and restrict the ability of millions of women, men, and adolescents to access high quality care should not be implemented. The Proposed Rule would interfere with the patient-physician relationship, exacerbate disparities for low-income and minority women, men, and adolescents, and harm patient health. We urge HHS to immediately withdraw the Proposed Rule. Thank you for your full consideration of our comments.

Sincerely,

Lisa M. Hollier, MD, MPH, FACOG
President

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July 30, 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
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: Comments on Proposed Rule: Compliance With Statutory Program Integrity, 83 Fed. Reg. 25502 (June 1, 2018), RIN 0937-ZA00

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

We, the Attorneys General of California, Connecticut, Delaware, Hawai'i, Illinois, Iowa, Maine, Maryland, Minnesota, New Jersey, New Mexico, North Carolina, and the District of Columbia write today to urge the U.S. Department of Health and Human Services (HHS) to withdraw the Proposed Rule: *Compliance With Statutory Program Integrity*, 83 Fed. Reg. 25502 (June 1, 2018), RIN 0937-ZA00 (Proposed Rule). The regulation severely undermines the Title X family planning program, restricting access to affordable, life-saving reproductive healthcare. In our States alone, this Proposed Rule will impact over 1.6 million patients.

Title X has successfully provided critical care in our States for decades. As State Attorneys General, we have a duty to protect our residents, safeguard their health and safety, and defend state laws. If implemented, this Proposed Rule will have significant negative impacts on states; their residents, including women, LGBTQ individuals, and other marginalized

populations; doctors and other women's healthcare providers; and numerous entities in the states that receive federal healthcare funding.

Title X is the only national family planning program that serves low-income women and families and otherwise underserved communities. Title X provides patients with basic primary and preventive healthcare services, including well-woman exams, lifesaving cervical and breast cancer screenings, birth control, contraception education, and testing and treatment for sexually transmitted infections (STIs), including HIV. Our States collectively and uniquely are served by this program:

- California benefits from the largest Title X program in the nation, which funds providers throughout the State to support the delivery of quality preventive and reproductive healthcare. California's Title X family planning program collectively serves more than one million patients annually—over 25% of all Title X patients nationwide—through 59 healthcare organizations, operating nearly 350 health centers in 37 of California's 58 counties.

- In Connecticut, Title X clinics served over 43,000 individuals at 17 different sites in 2017. About 85% of all those served had incomes below 250% of the federal poverty level.

- In Delaware, the Delaware Health and Social Services is the Title X grantee. In 2017, the US Department of Health and Human Services' Office of Population Affairs (OPA) granted $1,135,000 to Delaware. In 2017, Delaware's 55 Title X clinics served 19,132 patients.

- In the District of Columbia, Title X funding supports access to high-quality family planning and sexual health care at 35 service sites across the District. Nine of the service sites are Federally Qualified Health Centers, and the remaining 26 service sites throughout the District include school-based health centers and mobile clinics for individuals experiencing homelessness. Title X funding enabled these service sites to serve more than 51,000 individuals in Fiscal Year 2016.

- In Hawai'i, the Hawai'i State Department of Health and Planned Parenthood of the Great Northwest and the Hawaiian Islands are the Title X grantees. In 2017, the OPA granted $2,987,300 to support 37 service sites across the island state. In 2016, Title X served 13,335 patients.

- In Illinois, Title X clinics served over 110,000 individuals in 2016. As of April 2018, more than 98 facilities receive Title X funding in Illinois. Illinois's Department of Public Health Family Planning Program is a Title X grantee and

funds more than 65 clinic sites that include health departments, hospital-based clinics, single service not-for-profit agencies, federally qualified health centers, and community-based organizations.

- In Iowa, Family Planning Council of Iowa and the Iowa Department of Public Health are the Title X grantees. In 2017, the OPA provided $4,077,000 to support access to high-quality family planning and sexual health care at 40 service sites across the state. In 2016, Iowa's Title X clinics served 37,607 patients.

- In Maine, Maine Family Planning is the sole Title X grantee. In 2017, it received $1,965,000 from the OPA to support access to high-quality family planning and sexual healthcare at 42 service sites across the state. In 2016, Title X served 21,911 patients in Maine.

- In Maryland, the Title X Family Planning Program serves approximately 71,000 Maryland women at more than 75 clinical sites. Maryland's Department of Health is a Title X grantee. Title X grantees in Maryland include local health departments, community health centers, Planned Parenthood clinics, and other providers.

- In Minnesota, Planned Parenthood Minnesota, North Dakota, South Dakota and St. Paul-Ramsey County Department of Public Health are the Title X grantees. In 2017, the OPA provided $3,187,000 to support access to high-quality family planning and sexual health care at 38 service sites across the state. In 2016, Title X clinics served 56,400 patients.

- New Jersey has 9 Title X sub-grantees, which operate a total of 48 clinics. New Jersey has six counties with only 1 Title X provider site: Atlantic, Burlington, Cape May, Hunterdon, Salem, and Sussex. Of those, the single county site provides abortion outside of the Title X program in 4 counties: Atlantic, Burlington, Hunterdon, and Sussex. If that one single site closed, all 4 counties would be without a Title X provider. In 2017, 72% of Title X-eligible women who received Title X services at providers in New Jersey received those services at clinics that provide abortions outside the Title X program (64,890 women out of 89,845 women). In 2017, the Title X program in New Jersey prevented 13,190 unplanned pregnancies, 6,210 unplanned births, and 4,460 abortions.

- In New Mexico, the New Mexico Department of Health is the Title X grantee. In 2017, the OPA provided $3,325,000 to support 67 service sites across the state. In 2016, Title X served 17,252 patients in New Mexico.

- In North Carolina, in 2015, there were 120 Title X-funded sites. Collectively, these Title X-funded sites delivered contraceptive care to 111,010 women in North Carolina. If all Title X funds were redirected only to federally qualified health center sites, those sites would have to increase their contraceptive client caseloads by a factor of five or more to maintain the current range of service provided by Title X.

The Proposed Rule seeks to create barriers to access to women's healthcare, including abortion. Among other things, it requires a physical and financial separation between any Title X program and any facility that provides abortion: the provider must have at a minimum separate examination and waiting rooms, office entrances and exits, phone numbers, email addresses, educational services, websites, personnel, electronic or paper-based health care records, and workstations. Providers will effectively have to open a second clinic in order to continue to provide abortions and continue to obtain Title X funding. It also undermines the standard of care by allowing Title X providers to refuse to provide medically-approved contraceptive methods, in favor of less effective methods such as abstinence only. Importantly, it eliminates nondirective options counseling and instead steers all pregnant women to be referred for prenatal care and social services, regardless of a patient's choice. It undermines the provider-patient relationship trust, instead allowing the federal government to interfere in longstanding practices aimed to advance confidence and trust. It also gags healthcare providers. The Proposed Regulation takes several steps to create barriers to women seeking abortion and the healthcare providers that provide them care, from prohibiting activities like advocacy related to abortion, making abortion counseling impossible, and gagging doctors from discussing healthcare options, including abortion, with patients.

Alarmingly, this Proposed Rule, if finalized, will force Title X recipients into an untenable position of deciding whether to accept program funds with mandates that restrict access to care and force a gag on clinics, or forfeit Title X funding altogether, leaving gaps in access to family planning care that the Title X program was first established to fill. The former scenario will result in the invasion of the physician-patient relationship, the trampling of the constitutional rights of patients and providers, the transmission of incomplete, misleading, and medically dangerous information to women, and the frustration of the right to make an informed, independent decision as to whether to terminate a pregnancy. The latter scenario will reduce funding available to crucial family planning providers, thereby reducing critical healthcare services available to vulnerable populations. Either decision will lead to serious public health threats, increased risk of unintended pregnancies, and gaps in care. Our States will be left to pick up the pieces. Thus, we urge that the Proposed Rule be withdrawn immediately.

HHS Secretary Azar appears to largely agree with our position that ensuring patient access to accurate information is of vital public interest. He recently stated that HHS was "[e]nding gag clauses" "to bring more transparency" to healthcare and to ensure that patients obtain necessary healthcare information. Consequently, he proposed eliminating the current gag

order on pharmacists that prevents them from educating patients about drug pricing.[1] To act to the contrary with respect to reproductive health would seem arbitrary. Like Secretary Azar, we agree that HHS should end gag clauses to ensure that patients have all necessary healthcare information to make an informed decision and to ensure transparency and honesty in the provider-patient relationship.

I. The Proposed Rule's Mandates Will Harm the States' Residents

The Proposed Rule imposes a gag on healthcare providers. It expressly prohibits a healthcare provider from providing a patient with full information, to make an informed decision, regarding her healthcare decisions. *See, e.g.*, 83 Fed. Reg. at 25531. Specifically, the Proposed Rule prohibits a Title X clinic, including all of its healthcare providers and staff, from referring, supporting, or promoting abortion even with separate, non-Title X funds unless there is both financial *and* physical separation. This gag further prohibits the healthcare provider from providing a patient with nondirective options counseling and mandates that healthcare providers give a pregnant woman a misleading referral list that does not clearly identify abortion providers.

This gag will have far-reaching consequences. It will create a barrier to the provider-patient relationship, as women will not be able to make an informed decision about their healthcare condition and options. In healthcare, information can "save lives," *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 566 (2011), permit "alleviation of physical pain," *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 763-64 (1976), and enable people to act in "'their own best interest,'" *Sorell*, 564 U.S. at 578 (quoting *Va. State Bd. of Pharmacy*, 425 U.S. at 770). Such medical information allows women to take control of their most "intimate and personal choices . . . central to personal dignity and autonomy." *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 851 (1992) (plurality op.). In the context of women's health decisions, and in particular with respect to a woman's decision about whether to carry to full term or terminate a pregnancy, obtaining complete and honest healthcare information is critical *and* time-sensitive.

a. HHS's Proposed Rule Interferes with the Provider-Patient Relationship

The provider-patient relationship inherently requires complete confidence and trust. The American Medical Association's (AMA) Counsel on Ethical and Judicial Affairs has stated that "[t]he relationship between a patient and a physician is based on trust, which gives rise to

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[1] *See* HHS: Remarks on Drug Pricing Blueprint, *available* at https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html (May 14, 2018) (visited June 12, 2018); *See also* 83 Fed. Reg. at 22695, 22699 (May 16, 2018) (discussing eliminating gag clauses to ensure that patients receive full information from their healthcare providers to make informed decisions).

physicians' ethical responsibility to place patients' welfare above the physician's . . . obligations to others."[2] The AMA's Code of Medical Ethics further states that, "[t]ruthful and open communication between physician and patient is essential for trust in the relationship and for respect for autonomy. Withholding pertinent medical information from patients . . . creates a conflict between the physician's obligations to promote patient welfare and to respect patient autonomy."[3] Indeed, "withholding information without the patient's knowledge or consent is *ethically unacceptable*."[4] This honesty is crucial because the role of a physician is not only to treat a patient's medical condition and ailments, but also to educate patients so that they can be proactive in their healthcare decisions.[5] The Proposed Rule requires physicians to disregard their Code of Medical Ethics and to tailor their speech to not provide full and accurate healthcare information. As a consequence, patients will not know whether their doctors are speaking frankly and candidly, and the quality of medical care may erode, with potentially dire consequences, such as patients forgoing care altogether. These government-imposed barriers to the physician-patient relationship interfere with the provision of medical care and will impede public health.

These same concerns extend to nurses, physician assistants, and nurses' aides. For instance, the American Nurses Association Code of Ethics states that, "[t]he nurses's primary commitment is to the patient, whether an individual, family, group, community, or population."[6] The patient-provider relationship remains the foundational responsibility of healthcare. This

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[2] Code of Medical Ethics, Current Opinions (2017); Opinion 1.1.1-Patient-Physician Relationships, available at https://goo.gl/qKXwA6.

[3] Opinion 2.1.3-Withholding Information from Patients, available at https://goo.gl/q1bpt8.

[4] Opinion 2.1.3-Withholding Information from Patients, available at https://goo.gl/q1bpt8 (emphasis added).

[5] *See* HHS: Remarks on Drug Pricing Blueprint, available at https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html (May 14, 2018) (visited June 12, 2018); *See also* 83 Fed. Reg. at 22695, 22699 (May 16, 2018) (discussing eliminating gag clauses to ensure that patients receive full information from their healthcare providers to make informed decisions).

[6] American Nurses Association, Code of Ethics for Nurses (2015); *id.* ("[t]he nurse practices with compassion and respect for the inherent dignity, worth, and unique attributes of every person."); *See also, e.g.*, Cal. Code Regs. tit. 16, § 1443.5 (outlining the standards of competent performance for nurses as including "[a]ct[ing] as the client's advocate . . . by giving the client the opportunity to make informed decisions about health care before it is provided" and "[f]ormulat[ing] a care plan, in collaboration with the client").

Proposed Rule undermines that responsibility by inhibiting all healthcare providers from providing comprehensive medical information to patients.

b. The Proposed Rule Presents Women Seeking or Considering an Abortion with Illusory Healthcare Options

The Proposed Rule provides that a "referral" for an abortion may only occur when a woman "clearly states that she has already decided to have an abortion." There are no exceptions. Even when a woman makes such a "clear" statement to her healthcare provider in order to obtain care guidance, the provider is prohibited from arranging for her appointment (83 Fed. Reg. at 25532) or providing her with a specific list of healthcare entities that perform abortions (83 Fed. Reg. at 25531-25532). Instead, the healthcare provider may only provide a referral list of "comprehensive health services providers (*some* of which also provide abortion in addition to comprehensive prenatal care)." 83 Fed. Reg. at 25531 (emphasis added). This proviso has several flaws that make it a barrier to care and forces the woman to navigate the misleading, incomplete, and unreliable information regarding her "options" alone.

1. Doesn't Meet the Federal Quality Family Planning Guidelines on Referrals. The Proposed Rule is contradictory to the Centers for Disease Control and Prevention's (CDC) Quality Family Planning Guidelines—the quality standard of recommendations for providers on what to offer during a family planning visit and how to provide such services.[7] Among other things, the Guidelines provide that pregnancy testing and counseling services are a "core part of family planning services, in accordance with recommendations of major professional medical organizations, such as the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP)."[8] To that end, the CDC specifically instructs that after a Title X provider administers a pregnancy test, the "test results should be presented to the client, followed by a discussion of **options and appropriate referrals**." *Id.* at 14 (emphasis added). The CDC Guidelines continue that "[r]eferral to appropriate providers of follow-up care should be made at the request of the client, as needed," and "[e]very effort should be made to expedite and follow through on all referrals." *Id.* In terms of providing a referral list, the CDC Guidelines instruct that Title X providers "provide a resource listing or directory of providers to help the client identify options for [pregnancy] care." *Id.* This instruction is not limited to only those women who choose to continue with their pregnancy. *Id.* Rather, the CDC instruction is

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[7] HHS continues to refer Title X providers to the Quality Family Planning Guidelines. *See* HHS Office of Population Affairs, https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html (last visited June 19, 2018).

[8] Providing Quality Family Planning Services, Recommendations of CDC and the U.S. Office of Population Affairs, Centers for Disease Control and Prevention, at 14 (Apr. 25, 2014), https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf.

broad and instructs that providers give referrals, "at the request of the client," including for termination of pregnancy.

2. Limits Which Healthcare Providers Can Be on "Referral List." The Proposed Rule inexplicably mandates that the referral list only contain abortion providers that also provide "comprehensive prenatal care." 83 Fed. Reg. at 25531. This means that a stand-alone healthcare provider who provides abortions and other healthcare services, but not "comprehensive prenatal care" would be ineligible to be placed on the referral list. HHS fails to provide any justification for this additional requirement. This is likely to leave out many qualified abortion providers, providing women with even less information and fewer choices.

3. Compels Medical Providers to Give Incomplete Healthcare Information. The Proposed Rule not only mandates that Title X doctors give a misleading referral list, but it does not permit the doctor to inform the patient—who has requested a referral for an abortion—that the referral list includes healthcare facilities that do not provide abortions. Thus, in some circumstances, the patient will not even know that her healthcare provider—whom she has turned to for honest healthcare information—has knowingly provided her with an intentionally deceptive referral list. Because the patient has been given a misleading list, and because her physician is prohibited from providing her the necessary referral, she will be forced to investigate on her own, without her physician's guidance, which providers in the referral list provide the necessary and time-sensitive medical care she requires. This inserts a cruel and useless obstacle that is specifically targeted to women who have sought medical advice for the purpose terminating a pregnancy.

4. Limits Who Can Provide "Referral List," Excluding Advanced Practice Providers. Without any justification, this limited permission to provide a referral list, if asked, is only available to "doctors." 83 Fed. Reg. at 25531 (providing that "a *doctor*, may, if asked, provide" a referral list to a pregnant woman). In practice, this doctor-only limitation unnecessarily restricts who may provide this information. Counselling regarding medical options can be, and is, safely and effectively provided by clinicians with a variety of credentials, with no evidence of complications. Thus, the doctor-only requirement means that several qualified, licensed medical providers could not provide a referral list. In practice, if an Advanced Practice Provider is present in a medical clinic, but a doctor is not, the patient would not be able to receive any referral list.

5. Directs Counseling Against Abortion. This misleading referral list mandated by the Proposed Rule runs contrary to Congress's express instruction—an instruction that HHS relies upon (83 Fed. Reg. at 25502)—that Title X providers give "nondirective" counseling.[9] The current Title X regulation requires nondirective counseling to offer "pregnant women the

[9] *See* Omnibus Consolidated Rescissions and Appropriations Act, 1996, Public Law 104-134, Title II, 110 Stat. 1321, 1321-221 (1996).

opportunity to be provided information and counseling regarding…prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination." 42 C.F.R. § 59.5(a)(5)(i). The current regulation further requires that such information and counseling "provide neutral, factual information and nondirective options counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling." 42 C.F.R. § 59.5(a)(5)(ii). The Proposed Rule deletes all references to nondirective options counseling. It instead mandates that Title X healthcare providers give a woman who has "clearly state[d]" that she wants an abortion a referral list with both abortion providers and non-abortion providers, forcing her to call each entity. By doing so, the Title X provider has given her "directive" counseling, steering her away from abortion despite her stated decision. Indeed, in contrast to the limited exception for a woman who has "clearly state[d]" that she intends to terminate her pregnancy, the regulation mandates that Title X clinics give "assistance with setting up a referral appointment" for prenatal care for *all* women who have been "medically verified as pregnant," including those who express a desire to terminate. 83 Fed. Reg. at 25531. Thus, when a woman comes to a Title X clinic and learns that she is pregnant, the clinic is mandated to steer a woman towards a prenatal care appointment, *even if* the woman "clearly state[d]" her intention to terminate her pregnancy. This is "directive" counselling. It gags a healthcare provider from informing a woman as to all of her healthcare options and instead directs her towards a single option: prenatal care. It pushes women away from pregnancy termination in favor of carrying a pregnancy to full-term. Under the regime of this Proposed Rule, if a woman in fact exercises her constitutional right to safe, legal abortion, the Title X clinic is forced to abandon her, providing zero guidance or worse, misdirecting her away from her decision to terminate a pregnancy.

6. Does Not Require that Providers on Referral List Be Publicly Funded or Accessible to Low-Income Patients. Last, there is no requirement that the providers on the referral list be publicly-funded or make available no- or low-cost healthcare, or even identify such providers. Title X clinics serve low-income patients that are underinsured or uninsured. Providing a referral list to patients without designating which options will provide no- or low-cost healthcare services will result in women paying an exorbitant amount of out-of-pocket fees, wasting precious time trying to find a provider to perform the time-sensitive service at no- or low-cost, or having to forego the healthcare services altogether.[10] This is in direct conflict with

[10] In 2011-2012, the median cost of an abortion was $495. The Cost of Abortion, When Providers Offer Services and Harassment of Abortion Providers All Remained Stable Between 2008 and 2012, Guttmacher Institute (July 2, 2014), available at https://www.guttmacher.org/news-release/2014/cost-abortion-when-providers-offer-services-and-harassment-abortion-providers-all.

the Title X statute, which directs program funds for "services to persons from low-income families."[11]

c. The Proposed Rule Creates Barriers for Young People to Obtain Care

The Proposed Rule imposes several new—yet ironically antiquated—requirements on providing care to minors. The Proposed Rule mandates that Title X clinics conduct a "screening" of any adolescent who has an STD or is pregnant. 83 Fed. Reg. at 25533. It further mandates that Title X clinics "[e]ncourage family participation in the decision of minors to seek family planning services and ensure that the record maintained with respect to each minor document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged)." 83 Fed. Reg. at 25530. The Proposed Rule will cause confusion for providers about their obligations, is not in line with the CDC Quality Guidelines, and runs afoul of the Title X regulation which requires a patient-centered approach in providing services in a manner that protects patient dignity and ensures patient choices are entirely voluntary. 42 C.F.R. § 59.5. It also conflicts with state and local regulations that allow minors to consent to confidential health services for the prevention, diagnosis, or treatment of pregnancy, its lawful termination, or sexually transmitted diseases. *See, e.g.*, D.C. Mun. Reg. 22-B600.7. These new requirements impede the ability of providers to care for their patients and would have a deleterious effect on public health in states as young people forgo care to avoid the pressure of refusing requests to involve unwanted family involvement in decisionmaking.

II. If Implemented, the Proposed Rule Would Decrease Access to Care Throughout the Country

The Proposed Rule puts current Title X clinics in an untenable predicament: either give up their crucial Title X funds or incur devastating costs by complying with the physical separation mandate, violating their ethical obligations by imposing gags on all their doctors, nurses, and staff, and surrendering their constitutional First Amendment rights to associate with other entities and organizations that provide or advocate for abortion. Given the Proposed Rule's unnecessary and dangerous mandates, several Title X clinics will likely forgo Title X funding or will apply, but will be denied. The consequences will be devastating to the providers and patients alike.

For providers, Title X is "literally keeping the lights on" at several clinics in rural parts of the country. For example, without Title X funds, "six or seven health centers, including four rural sites" will close in Wisconsin "within three to six months, as they already operate at a loss and cannot be sustained with Medicaid and private reimbursement alone." Decl. Atkinson (ECF

[11] 42 U.S.C. § 300, Section 1006 (c)(1).

No. 18-1) at ¶ 48, *Planned Parenthood of Wisconsin, et al. v. Azar*, No. 18-cv-01035-TNM (05/08/2018). In addition, "two or three additional sites throughout Milwaukee" will close. *Id.* If these health centers close, employees will be laid off. *Id.* at ¶ 49. This will also have a devastating impact in our States. For example, numerous clinics in California will be forced to decide whether to embrace the Proposed Rule's mandates and requirements that are contrary to the most effective family planning practices, diverting resources from their core mission of patient care, or face major losses of funding that will dramatically impair their ability to provide family planning services. Connecticut's Title X providers will face the same decision for their 17 sites. In the District of Columbia, 36 healthcare facilities and clinics will have to decide whether to accept the unconstitutional conditions on Title X funding, or lose a major source of funding that helps prevent thousands of unintended pregnancies and helps educate tens of thousands of people about their reproductive health. In North Carolina, more than 110 healthcare providers will have to make a substantially similar choice. Furthermore, other Title X clinics will also have to shut their doors to patients as a result of the Proposed Rule's gag or colocation of services ban.

For patients, without clinics providing life-saving care, many will go without needed medical services. As HHS's 2016 Title X Family Planning Annual Report notes, "[f]or many clients, Title X providers are their only ongoing source of health care and health education."[12] For example, 47% of Title X patients go to a Title X clinic for general health information and 49% of patients go to a Title X clinic for a physical exam.[13]

a. The Proposed Rule Will Have a Disparate Impact on Low-Income Families, Women, Women of Color, and Rural Communities

1. Disparate Impact on Women and Low-Income Families. Title X clinics are crucial for low-income families and women. They provide no-cost family planning services to people with very low incomes, and services on a sliding fee scale for others. For example, in California, 91% of Title X patients had incomes at or below 250% of the federal poverty level, and nearly

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[12] Title X Family Planning Annual Report: 2016 National Summary, HHS-Office of Population Affairs, at 1 (Aug. 2017), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf (citing Jennifer J. Frost, U.S. Women's Use of Sexual and Reproductive Health Services: Trends, Sources of Care and Factors Associated with Use, 1995-2010, New York: Guttmacher Institute (May 2013) https://www.guttmacher.org/report/us-womens-use-sexual-and-reproductive-health-services-trends-sources-care-and-factors).

[13] Oglesby, Willie, Perceptions of and preferences for Federally-Funded Family Planning Clinics, Reprod. Health (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4086278/pdf/1742-4755-11-50.pdf.

60% were uninsured in 2016.[14] Title X clinics act as a "one stop shop" where a patient can seamlessly see medical providers, get screened and tested as necessary for disease, and access any needed prescription or medical supplies, without having to travel offsite to a pharmacy, additional medical facility, or lab testing facility. Women comprise 89% (3.6 million out of 4 million) of Title X family planning users.[15] A U.S. woman spends more than 30 years trying to avoid becoming pregnant, but still, approximately "2.8 million women have an unintended pregnancy" each year with approximately 42% resulting in abortions.[16] Because the Proposed Rule will effectively force some Title X clinics to shut down, and deprive others of crucial resources, the consequences will be disproportionately felt by low-income families and women. A recent report from the United Nations highlighted that placing barriers for low-income women to access healthcare "traps many women in cycles of poverty."[17] This Proposed Rule accentuates this consequence as it will decimate our nation's family planning network, which is why it is opposed by a majority of Americans.[18]

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[14] Similarly, in Vermont, 47% of patients had incomes at or below 100% of the federal poverty level, while 77% of patients had incomes at or below 250% of the federal poverty level. In Connecticut, 37% of patients had incomes at or below 100% of the federal poverty level, 28% more are below 150% of the federal poverty level, 13% more had incomes below 200% of the federal poverty level, and 7% more had incomes below 250% of the federal poverty level. In the District of Columbia, 60% of Title X patients had incomes 100% of the federal poverty level, while 85% of patients had incomes at or below 250% of the federal poverty level. In North Carolina, 66% of patients had incomes at or below 100% of the poverty line and 87% of patients earned less than 250% of the federal poverty line.

[15] Title X Family Planning Annual Report: 2016 National Summary, HHS-Office of Population Affairs, at 9 (Aug. 2017), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.

[16] Susan Moskosky, U.S. Department of Health and Human Services, Office of Population Affairs, Public Health Reports (2016), http://journals.sagepub.com/doi/full/10.1177/0033354916662638.

[17] Report of the Special Rapporteur on Extreme Poverty and Human Rights on his Mission to the United States of America, United Nations General Assembly, at 15 (May 4, 2018), https://documents-dds-ny.un.org/doc/UNDOC/GEN/G18/125/30/PDF/G1812530.pdf.

[18] Ashley Kirzinger, et al., Further Findings from Kaiser's June Health Tracking Poll: Women's Issues, Kaiser Family Foundation, at 14 (June 29, 2018), http://files.kff.org/attachment/Topline-Kaiser-Health-Tracking-Poll–June-2018-9212. The same poll also found that eight in 10 (80%) of the public say federal funding for family planning and other reproductive health services to low-income women is "very important" or "somewhat important" to them, including most Republicans and the overwhelming majority (94%) of women 18-44. *Id.* And, one-third of

2. Disparate Impact on Communities of Color. This Proposed Rule also fails to account for the harm that will come to the disproportionately high number of minority patients who rely on these Title X clinics as their primary source of healthcare. Nationwide, 21% of Title X patients self-identify as black or African-American and 32% as Hispanic or Latino/a.[19] For women of color, access to these services is crucial. Women of color already face disparities in healthcare. For example, black women with cervical cancer—a disease that can easily be prevented or cured—have lower survival rates than white women, due to later diagnosis and treatment differences, owing to a lack of health insurance and regular access to healthcare.[20] The United States also has the highest rate of maternal mortality among wealthy countries and black women are three to four times more likely to die during childbirth than white women.[21] HHS's mandates will only further harm minority communities by reducing access to essential health care.

3. Disparate Impact on Rural, Non-Urban Communities. Title X family planning clinics are especially critical in rural areas, where reproductive health access is often limited by healthcare provider shortages, lack of transportation, and other factors. In seven rural California counties, a Title X clinic is the only publicly funded clinic offering a full range of contraceptive methods. Likewise, in New Jersey, eight of its Title X clinics are sole providers in rural areas.

In the event that clinics decide to comply with the Proposed Rule's unlawful and harmful mandates, including the gag rule, the impacted patients who will receive partial, misleading information are from the same disadvantaged communities: women and low-income families, communities of color, and rural, non-urban communities. The Proposed Rule's mandate of

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women of reproductive age, who are more likely to have direct experience, say it is "too difficult" to access reproductive healthcare services. *Id.*

[19] *See* Title X Family Planning Annual Report: 2016 National Summary, HHS-Office of Population Affairs, at 12 (Aug. 2017), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf. These statistics are consistent with States' Title X patient populations. For example, in the District of Columbia, more than 60% of Title X patients identified as black or African-American and 32% identified as Hispanic or Latino/a.

[20] Wonsuk Yoo, et al., "Recent trends in racial and regional disparities in cervical cancer incidence and mortality in United States", *PLOS ONE*, vol. 12, No. 2 (Feb. 2017).

[21] *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; Pregnancy Mortality Surveillance System, CDC, https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pmss.html.

providing slanted and misleading information will undermine rather than promote a woman's right and ability to make an informed reproductive healthcare decision, and that impact will be felt by these patient populations.

b. Current Title X Clinics Cannot Be Replaced

Title X clinics that will be forced to shut their doors due to this Proposed Rule cannot easily be replaced. A recent report by the Guttmacher Institute concluded that although federally qualified health centers are vital sources for healthcare, they cannot fill the shoes of safety-net Title X clinics.[22] Specifically, the report found that Title X family planning sites, like Planned Parenthood locations, each serve 2,950 contraceptive patients per year, whereas federally qualified health centers (community health centers) serve only 320 contraceptive patients per year. If Title X's mandates take effect and force safety net clinics like Planned Parenthood to close, community health centers would be severely impacted. *Id.* In 27 states, they would have to double their caseloads and in nine states, they would have to triple them. *Id.* Even if current community health centers could handle the massive influx of new patients, there would still be huge gaps in service. For example, 13% of the 415 U.S. counties with Planned Parenthood health centers, do not have a community health center site that provides contraceptive care. In addition, while there are over 2,000 U.S. counties with Title X sites, in 33% of these counties no community health centers provide contraceptive services, meaning that women in these areas could simply lose access to this coverage. This will impact will be felt most acutely by poor women, rural communities, and communities of color that rely on these services. In many instances, the women, men, and adolescents served by the program will have no alternative source of care. In many cases, women will go without preventive care such as family planning care or sexually transmitted infection screenings, leading to increased unintended pregnancies as well as increased risks for public health outbreaks of diseases. Further, if women are not able to get their full range of care through Title X-funded clinics, they are more likely to seek care at other state-funded providers that are not gagged and will provide them with complete and truthful medical information, increasing the burden on state resources. However, because many state programs will be unable to fill this gap, inevitably, fewer women will receive family planning services, and as a result, unintended pregnancies will increase and government costs for medical treatment and social services will rise.

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[22] Kinsey Hasstedt, Federally Qualified Health Canters: Vital Sources of Care, No Substitute for the Family Planning Safety Net, Guttmacher Institute (May 17, 2017), https://www.guttmacher.org/gpr/2017/05/federally-qualified-health-centers-vital-sources-care-no-substitute-family-planning.

c. The Loss of Title X Funding and Closure of Clinics Will Harm the States' Public Health and Public Fisc

The availability of publicly funded family planning services will be sacrificed as a result of this Proposed Rule. Title X clinics play an indispensable role in improving a State's public health and ensuring access to care for the State's most vulnerable residents. States know from experience that restricting access to reproductive healthcare also burdens the public at large. For instance, Title X clinics play a major role in preventive healthcare, such as providing screenings and early treatment to prevent the spread of communicable, preventable diseases. Indeed, between 2006 and 2010, 18% of all women who were tested, treated, or received counseling for an STD did so at a Title X clinic, as did 14% of women tested for HIV and 10% of those receiving a Pap test or pelvic exam.[23]

During public health crises, such as the Zika outbreak, Title X providers play an important role in providing contraceptive methods to prevent the transmission of the disease and collaborating with the CDC.[24] The Proposed Rule could not come at a worse time: the CDC recently reported that in 2016, there were more than 2 million cases of chlamydia, gonorrhea, and syphilis reported—the highest number of reported cases ever.[25] The states and their residents need reliable and comprehensive Title X programs now more than ever to help address this public health crisis.

Finally, Title X providers and the comprehensive care they provide have a huge fiscal impact on the states. In helping women avoid unplanned pregnancies and investing in early detection and treatment of disease, Title X providers play a role in protecting the public fisc. For example, the United States has the highest maternal mortality rate in the developed world—17 to 28 per 100,000 live births—which is more than double the rate three decades ago. In the District of Columbia, the rate is 39 women per 100,000 live births—the highest in the Nation. For black

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[23] Kinsey Hasstedt, *Title X: An Essential Investment, Now More than Ever*, 16 GUTTMACHER POLICY REVIEW 14, 15 (Summer 2013), https://www.guttmacher.org/sites/default/files/article_files/gpr160314.pdf.

[24] Ctrs. for Disease Control & Prevention, *The Importance of Pregnancy Planning in Areas with Active Zika Transmission*, (June 2, 2016), at 23, https://www.cdc.gov/zika/pdfs/postzap-familyplanning.pdf; *see also* Office of Population Affairs, U.S. Health & Human Servs. Dep't: Providing Family Planning Care for Non-Pregnant Women and Men of Reproductive Age in the Context of Zika (Nov. 2016), https://www.hhs.gov/opa/reproductive-health/zika/toolkit/index.html (providing a toolkit, based on CDC guidance, for Title X clinics).

[25] STDs at Record High, Indicating Urgent Need for Prevention, Centers for Disease Control and Prevent (Sep. 26, 2017), https://www.cdc.gov/media/releases/2017/p0926-std-prevention.html.

women, this rate is three times that of white women.[26] The Proposed Rule will result in less access to critical preventive care, leading to increased unintended pregnancies, and in some cases, lead women to providers that are not medical providers, delaying access to prenatal care and increased maternal mortality outcomes. Yet the Proposed Rule makes no exceptions when necessary to protect the life of the mother. In addition, the loss of Title X funding will result in increased costs to states due to unintended pregnancies. Nationally, 68% of unplanned births are paid for with public funds. The average cost of an unintended pregnancy is $15,364 and of a miscarriage is $4,249. Further, many states will see increased usage of state-funded family planning and public health programs, which will face increased patient load and financial burdens if patients are not able to seek care at their trusted provider under Title X.

III. The Proposed Rule Is Not Supported by Evidence

HHS's gag rule and additional mandates in the Proposed Rule are arbitrary and capricious. Although HHS may change its policies within limits set by the Title X statute, the agency must "provide a reasoned explanation for the change." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). Here, the Proposed Rule fails to provide the necessary "satisfactory explanation" for its proposed changes to the Title X regulations. *See Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

The Proposed Rule rejects scientific, evidence-based policies, favoring unscientific ideologies. The Proposed Rule is opposed by all leading healthcare experts, including the American Medical Association, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Nurse-Midwives, the American College of Physicians, the Association for Physician Assistance 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. Women and children's health providers warn that the Proposed Rule puts "more than 40 percent of Title X patients [] at risk of losing access to critical primary and preventive care services."[27] Moreover, "[r]estricting access to care and information will increase rates of unplanned pregnancy, pregnancy complications, and undiagnosed medical conditions," reversing decades of progress that have brought our nation to a 30-year low for unplanned pregnancy and teen pregnancy. *Id.*

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[26] https://www.nejm.org/doi/full/10.1056/NEJMp1709473.

[27] America's Women's Health Providers Oppose Efforts to Exclude Qualified Providers from Federally-Funded Programs (May 23, 2018), available at https://www.acog.org/About-ACOG/News-Room/Statements/2018/Health-Providers-Oppose-Efforts-to-Exclude-Qualified-Providers-from-Federally-Funded-Programs.

The Proposed Regulation alters and eliminates longstanding standards for reproductive healthcare without evidentiary support. These changes are not rooted in law or based on medical-evidence and drastically undermine the Title X program and access to care:

1. **Disregards Medically-Approved Definition**: The Proposed Rule eliminates the requirement that a Title X family planning project offer "medically approved" family planning methods. 83 Fed. Reg. at 25515; 83 Fed. Reg. at 25530. Rather than deferring to the federal agency charged with determining what is medically appropriate (the Food and Drug Administration (FDA)), HHS instead opens the door to non-experts to decide what is acceptable and effective reproductive healthcare. This new position is entirely unsupported by evidence, and is inconsistent with the position that HHS has taken in several other healthcare areas. For instance, HHS's Health Resources and Services Administration (HRSA) commissioned the Institute of Medicine (IOM) to study what should be considered women's preventive services and to make evidence-based recommendations. 42 U.S.C. § 300gg-13(a)(4).[28] The IOM responded by assembling a panel of independent experts to survey the relevant literature and peer reviewed research, and produced a report that ultimately recommended that preventive services for women include all FDA-approved "contraceptive methods, sterilization procedures, and patient education and counseling." IOM, Clinical Prevention Services for Women: Closing the Gaps 110 (2011) (IOM Report).[29] HRSA adopted the IOM Report's recommendation, and the three federal agencies responsible for implementing the Affordable Care Act (ACA) (Treasury, HHS, and Labor) promulgated regulations that gave them legal effect. *See* 76 Fed. Reg. 46,621 (Aug. 3, 2011); 77 Fed. Reg. 8,725 (Feb. 15, 2012). Although the Proposed Rule acknowledges its own FDA as the entity with "regulatory jurisdiction over drugs, biologics, and medical devices," including contraceptives, it disregards the FDA's role in setting standards for reproductive healthcare because the FDA does not recognize "non-drug and non-device fertility awareness-based methods of family planning" such as the rhythm method or abstinence only. Thus, the Proposed Rule changes the definition of "medically approved," despite FDA's guidance and expertise. HHS's new position that it need not defer to experts, including its own regulators such as the FDA or HRSA, is entirely inconsistent with HHS's prior position, and HHS provides no reasonable explanation for disregarding medical science when it comes to

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[28] "The IOM is an arm of the National Academy of Sciences, an organization Congress established 'for the explicit purpose of furnishing advice to the Government.'" *Hobby Lobby*, 134 S. at, 2789 n.3 (Ginsburg, J., dissenting).

[29] *available at* https://www.nap.edu/read/13181/chapter/1.

reproductive health. It is also inconsistent with Secretary Azar's own public statements emphasizing the important of "evidence-based guidance on public health issues."[30]

2. **Undermines Family Planning to Allow Abstinence Only and Non-Approved Methods**: The Proposed Rule seeks to change the definition of "family planning" to "the voluntary process of identifying goals and developing a plan for the number and spacing of children and the means by which those goals may be achieved." 83 Fed. Reg. at 25529. Such "means" include "choosing not to have sex" and "natural family planning." *Id.* This definition conflicts with the CDC's own definition of family planning services as well as the World Health Organization and United Nation's definitions.[31] The Proposed Rule concedes that its definition does not meet these other longstanding definitions, but gives little by way of justification or support for the change. 83 Fed. Reg. at 25513 n.44.

3. **Provides Women Refused Birth Control Under the ACA an Illusory and Inadequate Accommodation**: The Proposed Rule changes the definition of "low income family" to include "women who are unable to obtain certain family planning services under their employer-sponsored health insurance policies due to their employer's religious beliefs or moral convictions." 83 Fed. Reg. at 25514. This change is premised on the Administration's Interim Final Regulations, "Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act"[32] and "Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act"[33] (Birth Control Refusal Regulations), both of which are currently enjoined by two U.S. District Courts.[34] But, the Proposed Rule provides women and families with an illusory option. First, because the Title X family planning program is a discretionary government program funded by Congress, there is no guarantee the annually appropriated Title X funding will cover this

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[30] *See* https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/hhs-secretary-alex-azar-world-health-assembly-plenary-remarks.html.

[31] *See* World Health Organization: Family planning/contraception, available at http://www.who.int/news-room/fact-sheets/detail/family-planning-contraception; United Nations: Guidelines on Reproductive Health, available at http://www.un.org/popin/unfpa/taskforce/guide/iatfreph.gdl.html.

[32] *See* 82 Fed. Reg. 47838 (Oct. 13, 2017).

[33] *See* 82 Fed. Reg. 47792 (Oct. 13, 2017).

[34] *Pennsylvania v. Trump*, 281 F. Supp. 3d 553 (E.D. Pa. 2017); *California v. Health & Human Services*, 281 F. Supp. 3d 806 (N.D. Cal. 2017).

> potentially massive increase in patients who will need contraceptives. Second, the Proposed Rule requires Title X providers to provide women—but not their families—with care. This is problematic because the Administration's harmful Birth Control Refusal Regulations affect not just the employed woman, but her covered dependents and family, as well. But, even modifying the Proposed Rule to encompass the impacted women and their families will result in an untenable situation because Title X providers are already at capacity with their ability to serve low-income patients, and this definition change does not come with increased annual funding (while simultaneously leaving the program with fewer providers as a result of the gag). Third, because this Proposed Rule and the accompanying Title X Funding Opportunity Announcement favor entities that do not provide comprehensive family planning, including all 18-FDA approved methods of contraceptives, the Rule is directing women who are harmed by the Administration's Birth Control Refusal Regulations to healthcare providers that cannot provide them with the Affordable Care Act required coverage, creating further barriers to care for these women. Finally, this aspect of the Proposed Rule is clearly contrary to law, as defining "low income family" to include people who are not necessarily "low income," and based on characteristics independent of their income, is nowhere contemplated, or permitted, by the statute.

These definitional changes, in addition to the numerous other changes outlined *infra*, do not result from any new developments in the healthcare field, nor are they supported by any new report. In contrast to the Reagan-Era regulatory changes, no congressional reports support these new changes. Indeed, the Proposed Rule relies largely on a 1988 rule and its subsequent litigation history. As HHS acknowledges, however, the 1988 rule was preceded by a 1982 report by HHS's Office of Inspector General (OIG) finding instances of non-compliance with existing rules. 83 Fed. Reg. at 25503. There is no such report here. In fact, several audits of Title X providers have been conducted by several different HHS agencies (and other federal agencies) and *none* have concluded that there is malfeasance or non-compliance by Title X providers in terms of federal dollars being used for abortion. The Proposed Rule cites a handful of examples, but those examples rely exclusively on *Medicaid* overbilling. As such, the "evidence" upon which the Proposed Rule relies utterly fails to actually justify the new mandates on Title X grantees. Furthermore, the Proposed Rule relies primarily on evidence from an anti-abortion group, the Lozier Institute, as a reason for the Proposed Rule, in place of an actual government Report or neutral scientific or medical evidence.

The Proposed Rule also ignores the numerous safeguards already in place to monitor Title X funds and activities. For example, HHS carefully reviews grant applications to ensure applicants have the capacity to comply with requirements, including the financial separation requirement; there are independent financial audits to analyze and account for program funded activities and prohibited activities, yearly comprehensive reviews of grantees financial status and budget reports, and periodic and comprehensive program reviews and site visits by Office of

Population Affairs regional offices. These oversight and monitoring measures ensure that there is no misuse of Title X funds. HHS provides no evidence otherwise.

IV. The Proposed Rule is Unconstitutional

The Proposed Rule is itself unconstitutional and undermines constitutional rights in several ways. The gag rule prevents healthcare providers from giving patients comprehensive information regarding medical options. The Proposed Rule requires dissemination of information about prenatal services and even requires Title X providers to arrange for a prenatal follow-up visit, but censors speech about the option of legally terminating a pregnancy. Thus, on its face, the Proposed Rule is a content-based restriction on speech related to a controversial topic of public importance. It also prohibits Title X grantees from using other funds to pay dues to any organization that advocates on behalf of abortion rights unless the dues are paid by an entity that is both financially *and* physically separate from the Title X project. 83 Fed. Reg. at 25519, 25532. Because it is viewpoint motivated, it is the purest example of a law abridging the freedom of speech.[35]

The Proposed Rule also violates a woman's constitutional right to procreative choice. American women possess a constitutional right to be free of impermissible government interference when they seek to make choices about their own bodies. This applies when they seek reproductive healthcare services, including healthcare information, contraceptives, and/or referrals for abortion.[36] This also applies to adolescents of child-bearing age.[37] The Proposed Rule

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[35] *See FCC v. League of Women Voters of Cal.*, 468 U.S. 364, 383-384 (1984) ("A regulation of speech that is motivated by nothing more than a desire to curtail expression of a particular point of view on controversial issues of general interest is the purest example of a law abridging the free of speech."); *NIFLA v. Becerra*, No. 16-1140, Slip Op. at 6-7 (2018) (reiterating the "fundamental principle that governments have 'no power to restrict expression because of its message, its ideas, its subject matter, or its content'").

[36] *See, e.g. Akron v. Akron Center for Reproductive Health, Inc.*, 462 U.S. 416 (1983) (invalidating city ordinance requiring all physicians to make specific statement to the patient prior to performing abortion); *Thornburgh v. American College of Obstetricians and Gynecologists*, 476 U.S. 747 (1986) (invalidating a governmental intrusion into the patient-doctor dialogue where statute mandated that a list of agencies offering alternative to abortion be provided to every woman).

[37] Twenty-six states and the District of Columbia allow minors to consent to contraceptive services, and all states and the District of Columbia permit minors to consent to services for sexually transmitted infections. *See* Guttmacher Inst., *An Overview of Minors' Consent Law*, https://www.guttmacher.org/state-policy/explore/overview-minors-consent-law.

impermissibly interferes with a woman's ability to choose abortion, in violation of the federal constitution.

The Proposed Rule forces Title X healthcare providers and family planning clinics to abandon their constitutional rights in order to obtain federal funding. Such a regulation squarely violates the unconstitutional conditions doctrine.[38] The doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Id.* Here, the regulation impermissibly and unlawfully penalizes those who choose to exercise a constitutionally-protected right by denying them benefits. Both the Title X healthcare physician and the Title X facility must abandon their speech as it relates to providing full and complete medical care and information to women patients to obtain federal benefits, and the entity must abandon its membership in outside organizations unless the Title X grantee is both financially and physically separate. In contrast to the Reagan-era regulation, this regulation is not limited to the Title X project—to which the Title X funding is attached—but extends to the personnel and staff at the Title X project and the activities and statements they make outside of the Title X project.

V. HHS Has Not Conducted an Adequate Analysis of Federalism Impacts

As the Proposed Rule acknowledges, Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on state and local governments or has federalism implications. 83 Fed. Reg. at 25521-25523. HHS concludes that the Proposed Rule "does not contain policies that have federalism implications, as defined in Executive Order 13132 and, consequently, a federalism summary impact statement is not required." *Id.* This conclusion is erroneous.

The Proposed Rule, if implemented, will impose substantial costs on state and local governments. As a threshold matter, several states and local entities are either direct Title X grantees or are sub-recipients that will be affected by the rule.[39] Indeed, HHS recognized this fact in its 2016 Regulation, when it included a federalism impact statement and invited states not

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[38] *See Koontz v. St. Johns River Water Mgmt. Dist.*, 133 S. Ct. 2586, 2594 (2013) (government ordinarily "may not deny a benefit to a person because he exercises a constitutional right" (quoting *Regan v. Taxation with Representation of Wash.*, 461 U.S. 540, 545 (1983)).

[39] *See, e.g.* HHS Title X Planning Directory (April 2018), https://www.hhs.gov/opa/sites/default/files/OPA_Title_X_Family_Planning_Directory_April2018_508.pdf (Title X directory including several state and local government entities).

only to comment but to "consult with them" in promulgating the final rule. 81 Fed. Reg. 61646 (Sep. 7, 2016).[40] There is no justification for this deviation in HHS's practice.

Notably, states engage in several federal partnerships, which are not subject to as broad restrictions as this Proposed Rule. For instance, the Temporary Assistance to Needy Families Block Grant Program (Title IV), the Maternal and Child Health Services Block Grant Program (Title V), and the Social Services Block Grant Program (Title XX) permit states to administer these grants in a manner that reflect state policy, provided that the implementation is congruent with federal requirements. Nothing in the statutes and implementing regulations for these other programs prohibits State partners from directing grants to particular providers to maximize the effective delivery of preventive healthcare services.[41] In fact, the comment letter from the "chief legal officers and/or governors from nine States," relied upon by HHS in its Proposed Rule, made this same argument with respect to the 2016 Regulation. 83 Fed. Reg. at 25504. And, HHS in this 2018 Proposed Rule, citing that comment letter, laments that the 2016 Regulation would have "denied States and other grantees the freedom to choose subrecipients as they saw fit." 83 Fed. Reg. at 25504. Yet, this Proposed Rule does exactly that. It prevents states and other grantees from freely selecting subrecipients—as has been done since the Title X program came into existence. We are extremely concerned about the overreach reflected in this Proposed Rule and the clear intent to override state laws and policy choices that are legal, supported by Congress, and overwhelmingly supported by the citizens of the states in which such legislative priorities are in place.

VI. HHS's Economic Impact Analysis is Wholly Inadequate

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. at 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 will (1) have an annual effect on the economy of $100 million or more and will also "adversely and materially affect" a sector of the economy and public health; (2) create a serious inconsistency and interfere with an action taken or planned by another agency; (3) materially alter budgetary impacts of

[40] We note that California attempted to schedule a meeting with the Office of Management and Budget, writing a letter on May 29, 2018, but never received a response and the agency never scheduled a meeting.

[41] *See* generally 42 U.S.C. §§ 401, 403, 404 (purpose of and limitations on TANF grants); 42 U.S.C. § 704 (purpose of and limitation on Maternal and Child Health service grants); and 42 U.S.C. §§ 1397, 1397d (purpose of and limitations of Social Services grant).

entitlement grants or the right and obligations of recipients thereof; and (4) raise novel legal or policy issues arising out of legal mandates.

While the Proposed Rule outlines the "Benefits and Protections" to providers and patients, it totally neglects an economic analysis of the burdens and harms to patients and providers. This one-sided economic analysis entirely ignores the steep costs to the patients trying to obtain healthcare and to the providers trying to comply with the new mandates. For patients, if a woman obtains a "referral list" from her Title X provider, she must then call each provider on the list to determine whether the provider actually provides abortion and at what cost, then make an appointment and then once again seek out necessary medical care, taking time off work or school, and finding childcare. Many women will be unable to weave their way through this intricate set of government barriers to obtain lawful healthcare, resulting in an unintended birth, which of course carries severe physical, emotional, and financial consequences for the patient. For providers, the Proposed Rule fails to account for the cost of complying with the physical separation requirement, and ensuring compliance by sub-grantees, while ensuring providers can exercise their First Amendment right to provide patients with complete medical information. To comply with the separation requirement, the provider must have at a minimum separate examination and waiting rooms, office entrances and exits, phone numbers, email addresses, educational services, websites, separate personnel, electronic or paper-based health care records, and workstations. The Proposed Rule claims that abiding with the physical separation requirements will only cost $10,000-$30,000; however, such an assertion is wholly unsupported. Many providers will effectively have to open a second clinic for every site to obtain Title X funding. Many Title X grantees, including federally qualified health centers, will not be able to separate both financially and physically their Title X projects from the "prohibited activities," including membership in advocacy organizations. Additionally, to comply with the new mandate that Title X providers maintain records to demonstrate compliance with the new requirements for minor patients, Title X clinics will need to make massive changes to their electronic health records. Conservative estimates provide that this will cost $10,000 for development and installation, depending on the number of sites across which the updates needs to be installed and the extent of the changes, and this amount does not include staff time to implement changes.[42]

Additionally, the Proposed Rule does not provide an economic analysis for 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 the Administration's Birth Control Refusal Regulations. This will inevitably increase costs for Title X providers as they shoulder

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[42] 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.

the patients that should be receiving seamless coverage through their employer-sponsored health insurance. The burden on these patients is also unaccounted for.

We have significant concerns with this regulation, its impact in our States, and consequence to our States' residents constitutionally protected rights, and for the reasons set forth above, the States strongly oppose the Proposed Rule and urge that it be withdrawn.

Sincerely,

Xavier Becerra
California Attorney General

George Jepsen
Connecticut Attorney General

Matthew P. Denn
Delaware Attorney General

Karl A. Racine
Attorney General for the District of Columbia

Russell A. Suzuki
Hawai'i Attorney General

Lisa Madigan
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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
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.[1] DOH and PHS in turn provide funding to a total of 50 sub-recipients at 178 service sites across the state.[2] 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.[3] 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.[4] 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 12th grade or below and approximately 61% were at or below the federal poverty level (with approximately 83% of patients at or below 250% FPL).[5] Title X services are estimated to have prevented 59,200 unintended pregnancies in New York State in 2015 alone.[6]

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

[2] 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.

[3] 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).

[4] *Id.*

[5] 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.

[6] *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.[7] 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.[8] OPA administers this

[7] 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.

[8] 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."[9]

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."[10] 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.[11]

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[9] *Id.*

[10] 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.

[11] *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.[12]

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

[12] *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.[13] 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*."[14] 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."[15] 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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[13] 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.

[14] 83 Fed. Reg. at 25507 (emphasis added).

[15] *Id.*

anecdotal example of such confusion (which would still be insufficient to justify the regulations).[16]

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."[17] 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.[18] It is unlikely providers will undertake such dramatic changes to their operations when there is the very real risk that HHS would still

[16] *Id.*

[17] 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.

[18] *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.[19]

- 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.[20] 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."[21] 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."[22] Moreover,

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[19] *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).

[20] 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.").

[21] 42 C.F.R. § 59.5.

[22] Jami S. Leichliter, 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.[23]

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,[24] and it can be harder to find a health care provider who will provide a woman with an abortion after the 12th week of pregnancy.[25] Moreover, it is widely recognized that while abortion is safe, there is nevertheless an increased mortality risk after the 8th week of pregnancy with the risk of complications increasing each week thereafter.[26] 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-

[23] *See, e.g.* Jeffrey F. Piepert, et al., *Preventing unintended pregnancy by providing no-cost contraception*, 120(6) OBSTET GYNECOL1291-1297 (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.").

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

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

[26] *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 (last updated Jan. 2015).

conception care: "Every effort should be made to expedite and follow through on all referrals."[27] 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."[28] 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.[29]

- 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).[30] As there is increased knowledge within a community about these

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[27] 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.

[28] *Doe v. Bolton*, 410 U.S. 179, 198 (1973).

[29] 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.

[30] 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. [31]

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.[32] 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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[31] 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. Leichliter, 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).

[32] 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.[33] 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."[34] 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 multi-faceted. 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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[33] 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.

[34] 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."[35] 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.*"[36] 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."[37] 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.*"[38] 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.[39] 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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[35] 83 Fed. Reg. at 25525.

[36] 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.*

[37] 83 Fed. Reg. 25519.

[38] *Id.* (emphasis added).

[39] 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."[40] 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."[41] 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

[40] 83 Fed. Reg. at 25506.

[41] 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.[42] HHS defends this shell game as consistent with HHS's apparent "recogni[tion] of . . . the duty of a physician to promote patient safety."[43] 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."[44]

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.[45] 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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[42] 83 Fed. Reg. at 25531.

[43] *Id.*

[44] *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).

[45] 42 C.F.R. § 59.5.

permits nondirective counseling on abortion,[46] 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.[47]

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.[48] 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."[49] 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."[50]

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[46] 83 Fed. Reg. at 25507.

[47] 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.

[48] 83 Fed. Reg. at 25531 (proposed § 59.14(b)).

[49] *Id.*

[50] *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."[51]

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.[52] 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*

[51] 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.

[52] *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 . . . [53]

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."[54] 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."[55] 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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[53] *NIFLA v. Becerra*, No. 16-1140, Slip Op. at 12 (2018).

[54] *Agency for International Development v. Alliance for Open Society International*, 570 U.S. 205, 214-15 (2013).

[55] 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."[56] 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.[57] 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 –

[56] 83 Fed. Reg. at 25521.

[57] 83 Fed. Reg. at 25525.

which is not accounted for at all in this analysis.[58] 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

[58] 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.

CALIFORNIA MEDICAL ASSOCIATION

July 31, 2018

VIA ELECTRONIC SUBMISSION

The Honorable Alex Azar, Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: Notice of Proposed Rulemaking: Compliance With Statutory Program Integrity Requirements, Docket ID No. HHS-OS-2018-0008 (RIN: 0937-ZA00)

Dear Secretary Azar:

On behalf of more than 43,000 physician members and medical students of the California Medical Association (CMA), we appreciate the opportunity to provide comments on the Department of Health and Human Services' (the "Department") proposed changes ("Proposed Rule") to the regulations governing the Title X program, published in the Federal Register on June 1, 2018.[1] Through a comprehensive program of legislative, legal, regulatory, economic and social advocacy, CMA promotes the science and art of medicine, the care and well-being of patients, the protection of the public health, and the betterment of the medical profession.

The Proposed Rule would withhold federal funds to qualified family planning providers that also offer abortion services; prohibit in most cases referrals for abortion and restrict counseling about abortion services; eliminate current requirements that Title X sites offer a broad range of medically approved family planning methods and nondirective pregnancy options counseling; and direct new funds to faith-based and other organizations that promote fertility awareness and abstinence as methods of family planning rather than the full range of evidence-based family planning methods.

Established in 1970, Title X is the sole federal program dedicated to funding family planning services for low-income individuals. Title X supports the delivery of family planning and related services including contraception, STD prevention and treatment, pregnancy tests, and life-saving cancer screenings. According to the Guttmacher Institute, more than $7 billion in taxpayer dollars are saved every year by preventing unintended pregnancies and by early treatment of breast and cervical cancer through Title X health centers nationwide. California's Title X provider network is the largest in the nation and serves over 1,000,000 low-income individuals

[1] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. 25502 (June 1, 2018) (to be codified at 42 CFR Part 59).

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throughout the state – over 25% of Title X patients nationwide. In California, $1.3 billion is saved annually thanks to public investment in family planning and related services provided at Title X-funded health centers.

The proposed changes would severely undermine the effectiveness of the Title X program.[2] By reconfiguring who receives Title X funding, as well as the scope of family planning methods and services that those providers offer, the proposed regulations would make it more difficult for low-income individuals to obtain the quality family planning services that they need and have historically received. The rule would interfere with the physician-patient relationship, undermine established medical access, and prevent low-income people from accessing the full range of reproductive health care. For these reasons, and those outlined below, CMA strongly opposes the Proposed Rule changes and requests that HHS maintain Title X program regulations in their current form.

I. The Notice of Proposed Rulemaking ("NPRM") would interfere with the physician-patient relationship and prevent physicians from providing medically-accurate information

The NPRM would ban Title X providers from giving women full information about their health care options. Specifically, the proposed rule would eliminate the existing requirement that patients be provided with referrals upon request for the full range of pregnancy options, including prenatal care and delivery; infant care, foster care, or adoption; and abortion.[3] That requirement would be replaced with a complete ban on health care providers giving abortion referrals.[4] This provision would restrict providers from speaking freely with their patients, violates core ethical standards, and undermines the physician-patient relationship.

Referral and counseling restrictions

Consistent with ethical and medical standards described below, the current Title X regulations require projects to give pregnant patients the opportunity to receive information and counseling about: prenatal care and delivery; infant care, foster care, or adoption; and abortion. If a patient requests such information and counseling, projects must provide neutral, factual information and nondirective counseling on each of the options, as well as referrals upon request.[5]

HHS proposes several changes, all of which would undermine the provider-patient relationship and cause significant harm to pregnant individuals. First, HHS proposes to eliminate the requirement that Title X projects provide neutral, factual information and nondirective options counseling to pregnant individuals.[6] Title X regulations currently direct Title X projects to

[2] *See* Dep't of Health & Human Servs., *Announcement of Anticipated Availability of Funds for Family Planning Services Grants* (2018), https://www.hhs.gov/opa/sites/default/files/FY18-Title-X-Services-FOA-Final-Signed.pdf.
[3] 42 C.F.R. § 59.5(a)(5).
[4] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25,531.
[5] 42 C.F.R. § 59.5(a)(5).
[6] 83 Fed. Reg. at 25530 (§ 59.5(a)).

"[o]ffer pregnant women the opportunity to be provided information and counseling" on all pregnancy options.[7] All such counseling must be neutral, factual, and nondirective.[8] The Title X statute states that no federal funds appropriated under the program shall be used in programs where abortion is a method of family planning. This provision has generally been interpreted throughout the program's history as meaning that Title X funds cannot be used to pay for or support abortion, which is reflected in the current regulations. While HHS states in the preamble that a doctor would be permitted to provide nondirective counseling on abortion, the proposed regulations themselves would prohibit projects from "encouraging," "promoting," or "presenting" abortion.[9] At a minimum, these changes would have a chilling effect on physicians, who could fear even mentioning the word abortion while counseling a pregnant patient on their options would violate the Title X regulations.

Second, HHS seeks to prohibit Title X projects from providing abortion referrals.[10] The proposed rule would eliminate the options counseling requirement in its entirety. In addition to eliminating the requirement for nondirective pregnancy options counseling, the NPRM seeks to ban Title X projects from providing abortion referrals. The Proposed Rule would allow a limited exception if a pregnant patient has already decided to have an abortion and explicitly requests a referral. In this situation, a physician—and no other clinical staff—would be permitted, but not required, to provide the patient with a list of licensed, qualified, and comprehensive health care providers, some of which may or may not provide abortion services, in addition to prenatal care. However, the list cannot identify the providers that perform abortions and the physician may not indicate which providers on the list offer abortion services, thus requiring the patient to vet the listed providers themselves to receive the care they seek. If a pregnant patient does not explicitly state that she has decided to have an abortion, but requests a referral for one, the patient can only be given list of providers which do not provide abortion but do provide prenatal care.

Furthermore, the proposed changes seem to encourage projects to provide confusing and even misleading referral information to pregnant individuals. When a pregnant patient clearly states that she has already decided to have an abortion and explicitly requests a referral, a physician (and only a physician) may – but is not required to – provide "a list of licensed, qualified, comprehensive health service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care)."[11] However, neither the physician nor the list may indicate which providers on this list offer abortion services.[12] In essence, the doctor may or may not choose to provide the list, the list may include a long list of providers, which may or may not offer abortion services, and the patient would have to identify on her own which providers – if any – in fact offer abortion services. Moreover, when a pregnant patient does not clearly state

[7] 42 C.F.R. § 59.5(a)(5).
[8] *Id.*
[9] 83 Fed. Reg. at 22506; 25531 (§ 59.14).
[10] 83 Fed. Reg. at 25530 (§ 59.14).
[11] *Id.*
[12] *Id.*

that she has already decided to have an abortion, but explicitly requests a referral for an abortion, the patient must be given "a list of licensed, qualified, comprehensive health service providers (including providers of prenatal care) who do not provide abortion as part of their services."[13]

These proposed changes to the regulations would force Title X providers to violate their ethical obligations to their patients. Providers must provide patients with complete, accurate, and unbiased information about their health care options so that they can make voluntary decisions about their care.[14] This proposal directly conflicts with the requirements of medical professional associations, including the American College of Obstetricians and Gynecologists and the American College of Physicians, which assert that patients should receive complete and accurate information to inform their health care decisions.[15] ACOG recommends that a "pregnant woman who may be ambivalent about her pregnancy should be fully informed in a balanced manner about all options, including raising the child herself, placing the child for adoption, and abortion. . . There is an ethical obligation to provide accurate information that is required for the patient to make a fully informed decision."[16] Similarly, the American Medical Association states in its Code of Medical Ethics that providers "present relevant information accurately and sensitively, in keeping with the patient's preferences"[17] and that "withholding information without the patient's knowledge or consent is ethically unacceptable."[18] That is why both the American Medical Association[19] and the American Nurses Association,[20] among others, have publicly announced their strong objection to the NPRM.

Physicians' inability to comply with their ethical obligations could not only harm the patient-physician relationship, but also could result in harm to their pregnant patients at Title X projects, especially if such patients are delayed in finding abortion providers. Moreover, any restriction on the right of patients and physicians to communicate freely would require assertion of a

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[13] *Id.*
[14] *See* AMA, Informed Consent, Code of Medical Ethics Opinion 2.1.1, https://www.ama-assn.org/delivering-care/informed-consent; ACOG, *Committee Opinion Number 439: Informed Consent* (reaffirmed 2015), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Ethics/co439.pdf?dmc=1&ts=20180710T1746338624
[15] Kinsey Hasstedt, *Unbiased Information on and Referral for All Pregnancy Options Are Essential to Informed Consent in Reproductive Health Care*, Guttmacher Institute (Jan. 2018), available at https://www.guttmacher.org/gpr/2018/01/unbiased-information-and-referral-all-pregnancy-options-are-essential-informed-consent.
[16] ACOG, *College Statement of Policy: Abortion Policy* (revised 2014), https://www.acog.org/-/media/Statements-of-Policy/Public/sop069.pdf?dmc=1&ts=20180710T1333046794.
[17] American Medical Association, Code of Medical Ethics Opinion 2.1.1, Informed Consent, available at https://www.ama-assn.org/delivering-care/informed-consent.
[18] 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.
[19] American Medical Association, AMA Response to Administration's Attack on Family Planning Services (May 23, 2018), available at https://www.ama-assn.org/ama-response-administrations-attack-family-planning-services.
[20] American Nurses Association, ANA Condemns Title X Funding Cuts Proposed by the Trump Administration (May 22, 2018), available at https://www.nursingworld.org/news/news-releases/2018/ANA-condemns-title-x-funding-cuts--proposed-by-the-trump-administration/.

compelling government interest. While HHS has suggested some general rationales for its proposed amendments, it has not indicated such a compelling interest for the proposed restrictions. In fact, CMA believes there is no such compelling interest.

The purpose of these clinical guidelines is to protect patients and help ensure that they receive high quality, evidence-based care. If Title X providers are no longer able to follow the established standards of care due to the federal regulations, patients would suffer serious consequences. Some pregnant patients might not know that abortion is an option for them. Even pregnant individuals who are aware of the option could experience a delay in receiving care because they have trouble locating an abortion provider. Notably, time is of the essence for pregnant patients – the longer it takes to access abortion services, the more complicated and costly the procedure would be.[21]

Forced referral for prenatal care

In contrast to the prohibition on referring for abortion, the proposed rule would mandate that all pregnant patients be referred for prenatal and social services, such as infant or foster care, and "be given assistance with setting up a referral" – regardless of their wishes or health status.[22] Again, this requirement conflicts with medical ethics and the established standards of care described above and is harmful to patients. In the long term, patients would no longer trust their providers to provide full and accurate information about their health care. The implications are worse for the population that Title X most serves – low-income women and women of color – who have experienced coercive and other damaging treatment in the context of reproductive health care.

CMA strongly opposes any government interference in the exam room, especially legislation or regulations that attempt to dictate the content of physicians' conversations with their patients. Protecting the sanctity of the patient-physician relationship, including defending the freedom of communication between patients and their physicians, is a core priority for CMA. The ability of physicians to have open, frank, and confidential communications with their patients has always been a fundamental tenet of high quality medical care.

II. The proposed rule would reduce low-income individuals' access to the full range of contraceptive methods and services

To have true control over their bodies and their health, individuals need access to the full range of contraceptive methods and services. In addition, evidence indicates that access to all available

[21] Kinsey Hasstedt, *Unbiased Information on and Referral for All Pregnancy Options Are Essential to Informed Consent in Reproductive Health Care*, 21 Guttmacher Policy Review 1 (2018), https://www.guttmacher.org/sites/default/files/article_files/gpr2100118.pdf.
[22] 83 Fed. Reg. 25531.

contraceptive methods leads to better health outcomes.[23] Women who are able to use the method of their choice are more likely to use contraception consistently and effectively.[24] When women use contraception consistently and correctly, their risk of unintended pregnancy drops significantly.[25]

Consistent with this evidence, the Department of Health and Human Services (HHS) has taken steps to ensure that individuals have access to all FDA-approved contraceptive methods. For example, the Affordable Care Act requires most private plans to cover women's preventive health services with no cost sharing and directs the Health Resources & Services Administration (HRSA) to define those services.[26] Upon the recommendation of the independent Institute of Medicine, in 2011 HRSA defined women's preventive health services to include all female-controlled FDA-approved contraceptive methods. HRSA reaffirmed its position in 2016.[27] In addition, as part of its Healthy People 2020 campaign, the Office of Disease Prevention and Health Promotion established a goal of increasing the proportion of publicly funded family planning clinics that offer the full range of FDA-approved contraceptive methods onsite.[28] Similarly, in 2014 the Office of Population Affairs and the Centers for Disease Control and Prevention (CDC) issued joint recommendations for providing quality family planning services.[29] The evidence-based recommendations support offering a full range of FDA-approved contraceptive methods.[30] California law requires health plans to cover as well as all FDA-approved methods of contraception without cost-sharing.[31]

The current Title X regulations require funded projects to provide medical services related to family planning and to offer a broad range of acceptable and effective medically approved family

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[23] *See* Adam Sonfield, *Why Family Planning Policy and Practice Must Guarantee a True Choice of Contraceptive Methods*, 20 GUTTMACHER POLICY REVIEW 103 (2017), https://www.guttmacher.org/sites/default/files/article_files/gpr2010317.pdf.

[24] *See* Caroline Moreau et al., *Social, Demographic and Situational Characteristics Associated with Inconsistent Use of Oral Contraceptives: Evidence from France*, 38(4) PERSPECTIVES ON SEXUAL & REPRODUCTIVE HEALTH 190 (2006), https://www.guttmacher.org/sites/default/files/article_files/3819006.pdf; Joanne Noone, *Finding the Best Fit: A Grounded Theory of Contraceptive Decision Making in Women*, 39(4) NURSING FORUM 13 (2004); Loretta Gavin et al., Ctrs. for Disease Control and Prevention & U.S. Off. of Population Affairs, Providing Qualify Family Planning Services: Recommendations of CDC and the U.S. Off. of Population Affairs, MORBIDITY & MORTALITY WEEKLY REP. at 37 (April 25, 2014), http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf [hereinafter "QFP"].

[25] *See* Adam Sonfield et al., Guttmacher Inst., *Moving Forward: Family Planning in the Era of Health Reform* at 8, 9 (2014), https://www.guttmacher.org/sites/default/files/report_pdf/family-planning-and-health-reform.pdf.

[26] 42 U.S.C. § 300gg-13(a)(4).

[27] Health Resources & Servs. Admin., *Women's Preventive Services Guidelines* (last updated Oct. 2017), https://www.hrsa.gov/womens-guidelines-2016/index.html.

[28] Off. of Disease Prevention and Health Promotion, Healthy People 2020 Topics & Objectives, Family Planning https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning/objectives.

[29] QFP, *supra* note 24.

[30] QFP, *supra* note 24, at 2, 7. In addition, prior administrations have required applicants who do not intend to offer all FDA-approved contraceptive methods within their project to provide a justification for excluding a particular method. *See* OPA, *Announcement of Anticipated Availability of Funds for Family Planning Services Grants* (FY 2017), https://www.hhs.gov/opa/sites/default/files/FY-17-Title-X-FOA-New-Competitions.pdf.

[31] CAL. WELF. AND INST. CODE §14132; CAL. INS. CODE §10123.196; CAL HEALTH AND SAFETY CODE § 1367.25

planning methods. The NPRM eliminates the requirement that projects offer the full range of family planning methods, and further eliminates "medically approved" from the current regulatory requirement. The Proposed Rule would no longer require that sites follow the Quality Family Planning guidelines of the Centers for Disease Control and Prevention and the OPA. Instead, HHS emphasizes non-medical services, such as abstinence, natural family planning, and adoption as a way to manage infertility. HHS' emphasis on non-medical services is contradicted by data showing that fertility awareness methods are among the least effective methods of family planning, and the Food and Drug Administration has warned that these are not reliable forms of contraception.

Changes to Title X Services (§§ 59.2, 59.5)

First, HHS seeks to transform the meaning of family planning, proposing a definition of the term that emphasizes non-medical services, such as abstinence, natural family planning, and adoption as a way to manage infertility.[32] HHS's emphasis on non-medical services is misplaced, as Congress designed Title X to provide health care services to people who did not have the means to access the most effective methods to prevent pregnancy.[33] Significantly, data shows that fertility awareness methods are among the least effective family planning methods.[34] In fact, the FDA has warned that these methods are not reliable forms of contraception.[35] This is likely one of the reasons why very few women choose to use natural family planning to prevent pregnancy.[36]

Second, in keeping with its emphasis on abstinence, fertility awareness methods, and adoption, HHS proposes several changes to section 59.5(a), which sets forth the basic requirements for Title X projects. The current provision requires each Title X project to "[p]rovide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents)."[37] HHS seeks to delete the term "medically approved" and instead add fertility awareness methods of family planning. In the preamble, HHS emphasizes that fertility awareness methods, many of which do not require FDA approval because they do not involve drugs or medical devices, qualify as acceptable and effective family planning methods. The agency cites the fact that HRSA added fertility awareness methods to the women's preventive health services

[32] 83 Fed Reg. at 25529 (§ 59.2).
[33] S. Rep. No. 91-1004, at 9 (1970).
[34] QFP, *supra* note 24, at 47.
[35] *See* FDA, iPledge Program FAQs 9 (2006), https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm094313.pdf.
[36] Megan L. Kavanaugh & Jenna Herman, *Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014*, 97 CONTRACEPTION 14 (2018), https://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf (finding that 2 percent of women who use a contraceptive method use natural family planning).
[37] 42 C.F.R. § 59.5(a)(1).

guidelines in 2016.[38] Notably, HHS refrains from directly quoting the guidelines, which indicate that fertility awareness methods are "less effective," but "should be provided for women desiring an alternative method."[39]

Even more strikingly, proposed section 59.5(a)(1) would explicitly state that Title X projects need not provide every acceptable and effective family planning method or service, as long as they offer a "broad range" of family planning methods and services. However, the preamble indicates that a "broad range" does not mean all FDA-approved methods.[40] This represents a marked shift in position, as HHS has required Title X sites to follow the Quality Family Planning guidelines, which since 2014 have recommended providing all FDA-approved contraceptive methods.[41] In explaining its rationale for the shift, HHS claims that it is difficult and expensive for projects to offer all acceptable and effective family planning methods. However, HHS cites no evidence indicating that entire projects have been unable to offer the full range of contraceptive methods or services, or that HHS has denied Title X funding to such projects in the past. Instead, HHS highlights providers who object to some or all forms of contraception and focuses on the need for more Title X sites that only offer natural family planning services.[42] It is clear that HHS designed the proposed rules to cater to providers who refuse to provide the full range of family planning services that Title X patients need.

Taken together, these changes could reduce low-income individuals' access to the full range of contraceptive methods and services. If finalized, the proposed rule would likely reverse the progress Title X providers have made in offering comprehensive family planning services, making it more difficult for Title X patients to access their preferred contraceptive method. With fewer Title X sites offering the full range of contraceptive services and methods, low-income individuals could be forced to settle for a method that is not right for them or to forgo contraception altogether.

Contrary to HHS' assertion that its proposed changes will improve access to and the quality of care at Title X projects, CMA believes that the proposed revisions discussed above will undermine the quality and standard of care upon which millions of women depend for their reproductive health care. Moreover, the Proposed Rule threatens to reverse decades of progress in reducing unintended and teen pregnancy: the United States currently has a 30-year low in unplanned pregnancy and an all-time low in teen pregnancy. Access to affordable contraception, including through programs funded by Title X, has helped make these results possible.

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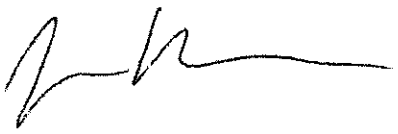
[38] 83 Fed Reg. at 25515.
[39] *Women's Preventive Services Guidelines*, *supra* note 27.
[40] 83 Fed. Reg. at 25516.
[41] *See, e.g.*, OPA, *Announcement of Anticipated Availability of Funds for Family Planning Services Grants* (FY 2017), https://www.hhs.gov/opa/sites/default/files/FY-17-Title-X-FOA-New-Competitions.pdf.
[42] 83 Fed. Reg. at 25516.

Conclusion

In conclusion, Title X is the only federal program dedicated specifically to providing low-income patients with essential family planning and preventive health services and information. As such, it plays a vital role in the nation's public health safety net by ensuring that timely, safe, and evidence-based care is available to women, men, and adolescents, regardless of their financial circumstances. In addition to pregnancy prevention, Title X projects provide other important health services, including sexually transmitted infection testing and treatment, Pap tests, and clinical breast exams. CMA believes that this Proposed Rule, if finalized, would limit access to critically needed care and services for millions of individuals who depend upon the Title X program for their care and would result in harm to patients and the public' health. We urge HHS to withdraw this proposal.

We appreciate your consideration of our comments. We have included numerous citations to supporting research, including direct links to the research. We direct HHS to each of the studies we have cited and made available to through active links, and we request that the full text of each of the studies cited, along with the full text of our comment, be considered part of the formal administrative record on this proposed rule for purposes of the Administrative Procedures Act. If you have questions about these comments, please contact me at jrubenstein@cmadocs.org or (916) 551-2554.

Sincerely,



Jessica Rubenstein
Associate Director
Center for Health Policy
California Medical Association

Planned Parenthood® Care. No matter what.
Planned Parenthood Federation of America

Planned Parenthood® Act. No matter what.
Planned Parenthood Action Fund

July 31, 2018

VIA ELECTRONIC TRANSMISSION

Alex Azar, Secretary of Health and Human Services
Attention: Family Planning
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 716G
200 Independence Avenue SW
Washington, DC 20201

Valerie Huber, Senior Policy Advisor, Assistant Secretary for Health
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: RIN 0937-ZA00 Compliance With Statutory Program Integrity Requirements

Dear Secretary Azar and Ms. Huber:

Planned Parenthood Federation of America (Planned Parenthood) and Planned Parenthood Action Fund (Action Fund) submit these comments in response to the notice of proposed rulemaking (Proposed Rule) issued by the U.S. Department of Health and Human Services (Department) entitled, "Compliance With Statutory Program Integrity Requirements" and published in the Federal Register at 83 Fed. Reg. 25,502 on June 1, 2018. As a trusted women's health care provider and advocate, Planned Parenthood takes every opportunity to weigh in on policy proposals that impact the communities we serve across the country.

Planned Parenthood is the nation's leading women's health care provider and advocate and a trusted, nonprofit source of primary and preventive care for women, men, and young people in communities across the United States. Each year, Planned Parenthood's more than 600 health centers provide affordable birth control, lifesaving cancer screenings, testing and treatment for sexually transmitted diseases (STDs), and other essential care to 2.4 million patients. We also

provide abortion services and ensure that women have accurate information about all of their reproductive health care options. One in five women in the U.S. has visited a Planned Parenthood health center. The majority of Planned Parenthood patients have incomes at or below 150 percent of the Federal Poverty Level (FPL).

Since the program's inception almost half a century ago, Planned Parenthood has played a central role in fulfilling Title X's mission. Planned Parenthood health centers serve more than 40 percent of the program's patients annually. Given our extensive experience with Title X, we are well-suited to evaluate and provide input on proposals to modify the Title X program. Based on our review of the Proposed Rule, we urge the Department to:

- **Withdraw the Proposed Rule in its entirety**. The Proposed Rule lacks a reasoned justification, exceeds the Department's legal authority, raises serious constitutional concerns, and is otherwise riddled with errors, inconsistencies, and unresolved questions. And, as we explain in these Comments, Planned Parenthood would have no choice but to discontinue its participation in Title X should the Proposed Rule take effect. The Department should therefore abandon it completely.

- **Extend the Department's public comment period for the Proposed Rule by at least 60 days**. Because of the Proposed Rule's complexity, its wide-ranging consequences on health, and its rushed pre-publication process, meaningful public input cannot be provided within the current 60-day public comment period.

- **Assess all the costs of the Proposed Rule and its regulatory alternatives**. Contrary to the faulty estimate provided by the Department, the consequences of the Proposed Rule would clearly elevate it to the status of a "significant regulatory action" under Executive Order 12866, therefore warranting the development and publication of a comprehensive regulatory impact analysis.

- **Conduct a complete assessment of the Proposed Rule's effect on family well-being**. The Department may not ignore the Proposed Rule's probable consequences on Title X patients and their families. We believe these consequences necessarily lead to the determination the Proposed Rule would, in fact, negatively affect family well-being.

I. The Department Should Withdraw its Proposed Rule.

For nearly all of its 50-year history, the Department has administered the Title X program under common-sense regulations that promote the purpose and goals of the statute. These regulations have allowed an exceptionally effective network of Title X providers to flourish across the country, permitting women and men to obtain "a broad range of acceptable and

effective family planning methods and services," as the statute requires.[1] Any departure from this immensely successful regime would require a very compelling justification.

Yet the Department's Proposed Rule falls wide of the mark. Throughout the Proposed Rule, the Department presents scant evidence to support its policy decisions, rests its proposals on shaky legal and constitutional grounds, and completely ignores the Proposed Rule's enormous negative consequences on the health and well-being of Title X patients. The worst of these consequences, moreover, will fall on people with low incomes, women, young people, communities of color, and LGBTQ populations, who already face inequalities in health care. In fact, the confusions and falsehoods contained within the boundaries of Proposed Rule are so numerous and egregious that it is difficult to imagine any public health or health care service organization offering even qualified support to any of its component parts. We strongly urge the Department to withdraw the Proposed Rule in its entirety.

A. Prohibition on Referral for Abortion and Removal of Nondirective Options Counseling Requirement (§§ 59.5, 59.14).

The Department proposes to bar Title X projects from referring pregnant patients for abortion. It also proposes to remove the current requirement that Title X projects offer pregnant patients "neutral, factual information and nondirective counseling" on a range of pregnancy options, including abortion.[2] We find a number of problems with the Department's proposal. First, its asserted legal basis is flawed. Second, the Department ignores ample evidence against its proposed changes while offering few real reasons to recommend them. Third, the regulatory text proposed by the Department to make these changes is unclear. Finally, these changes would raise serious constitutional questions. For these reasons, we conclude that the Department's referral ban and its proposal to remove Title X's counseling requirements should be withdrawn.

1. The Department's proposals to ban referrals for abortion and to remove the counseling requirement rest on a flawed interpretation of federal law.

The Department lacks the legal authority to make the changes it proposes for at least three reasons. First, section 1008 of the Public Health Service Act does not preclude either referral for abortion or nondirective options counseling. Next, Title X and its appropriations mandates require "comprehensive" and "nondirective" family planning services and counseling, which necessarily includes the presentation of abortion as an option and referral on the same terms as other options. And finally, federal "conscience" laws do not require or justify removing the abortion counseling requirement or banning referrals for abortion.

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[1] 42 U.S.C. § 300(a).
[2] 42 C.F.R. § 59.5(a)(5).

a. The text and legislative history of section 1008 of Title X demonstrate that it does not preclude referral for or nondirective options counseling on abortion.

The Proposed Rule is fundamentally inconsistent with long-held agency and congressional construction of Title X and its purpose. Section 1008, which prohibits the use of Title X funding for "programs where abortion is a method of family planning,"[3] was added late in the legislative process, after the legislation had passed the Senate. During consideration of the bill by the Subcommittee on Public Health and Welfare of the House Committee on Interstate and Foreign Commerce, several witnesses noted concern that Title X's effect would be to fund abortions and, furthermore, that Title X projects would coerce women into obtaining abortions.[4]

Due to these concerns, and because the criminal laws of many states at the time prohibited abortion, Representative John D. Dingell offered an amendment adding section 1008. Representative Dingell provided the only in-depth explanation for the late addition, stating, "For the Congress of the United State to appropriate funds for a *procedure* that would violate the criminal law of a vast majority of American jurisdictions would be to raise constitutional questions of a most serious nature."[5] Title X was passed before the Supreme Court decided *Roe v. Wade,*[6] and Congress was concerned that federal money might be used to support what was then criminal conduct.

Representative Dingell never intimated that the purpose of section 1008 was to prevent funding for abortion referral or counseling. In fact, in a comment to the Department opposing the 1988 Rule, which the Proposed Rule is modeled after, Representative Dingell explicitly disclaimed any misreading of his statements to prohibit counseling or referral for abortion services. Representative Dingell emphasized, "My remarks did not suggest—either expressly or implicitly—that the legislation being considered intended or required prohibition on non-directive counseling or referral of pregnant women to abortion facilities."[7]

Title X itself only limits funding "where abortion is a *method* of family planning."[8] The legislative history shows that Congress did not understand referral and counseling to be a method of family planning. The House Report states that "[i]n all projects, information would be provided on the

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[3] 42 U.S.C. § 300a-6.
[4] *See, e.g.*, *Family Planning Services: Hearings Before the Subcomm. On Public Health and Welfare of the House Comm. On Interstate and Foreign Commerce*, 91st Cong., 2d Sess. 240-41 (1970) (testimony of Mrs. D.R. Mogilka, Chairman, Reverence for Life of America); *id.* at 359 (testimony of Rev. James T. McHugh, Director, Family Life Division, U.S. Catholic Conference).
[5] 116 Cong. Rec. S10276-302 (1970) (statement of Rep. Dingell) (emphasis added).
[6] 410 U.S. 113 (1973).
[7] *Comments of Chairman John D. Dingell, Committee on Energy & Commerce, on Proposed Rules 42 CFR Part 59—Fed Reg. Notice*, Sept. 1, 2981 (Oct. 14, 1987) at 2.
[8] 42 U.S.C. § 300a-6 (emphasis added).

full range of family planning methods."[9] The House Report thus viewed family planning *methods* as separate from *providing information* on those methods.

While the Department has, on occasion, interpreted section 1008 to bar funding for abortion procedures and anything that could be construed as promoting or advocating for abortion, this interpretation has never included nondirective referrals or counseling. Until the promulgation of the 1988 Rule, the Department never advocated or even suggested such a broad construction of section 1008. In a 1978 Office of General Counsel opinion, the Department stated, "The provision of information concerning abortion services, [or] mere referral of an individual to another provider of services . . . are not considered to be proscribed by § 1008."[10] In 1981, the Department also issued guidelines to Title X grant recipients requiring them to provide nondirective counseling and referrals for all family planning methods and pregnancy alternatives, including "pregnancy termination."[11] In 2000, the Department promulgated a rule clarifying that section 1008 does not preclude full options counseling, indicating that "[a] Title X project may not provide pregnancy options counseling which promotes abortion or encourages persons to obtain abortion, although the project may provide patients with complete factual information about all medical options and the accompanying risks and benefits."[12] Consistent with the 1981 guidelines and the longstanding interpretation of section 1008, this same rule also required nondirective counseling for all pregnancy options, including abortion.

Congressional response in the decades following the enactment of Title X confirms the Department's narrow construction of section 1008. Congress has continued to reauthorize Title X knowing that the Department has not interpreted section 1008 to prohibit the provision of information or referrals for abortion.[13] Through these reenactments, Congress is presumed to adopt the Department's interpretation.[14] Indeed, since Congress enacted Title X, multiple members of Congress have sought to amend section 1008 to explicitly bar counseling and referral, but all these attempts have failed.[15]

Additionally, although Congress has consistently required that the funds allocated for Title X programs not "be expended *for abortions*," Congress has never prohibited the use of Title X

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[9] H. Rep. 91-1472, at *10.
[10] Letter from Carol C. Conrad, Office of General Counsel, Department of Health, Education, and Welfare, to Elsie Sullivan, Office of Family Planning (Apr. 14, 1978).
[11] Department of Health and Human Services, Program Guidelines for Project Grants for Family Planning Services, §§ 7.4, 8.0, 8.1 and 8.6 (1981).
[12] 65 Fed. Reg. 41,281, 41,281 (July 3, 2000).
[13] *See, e.g.*, H.R. Rep. No. 1161, 93d Cong., 2d Sess. 18-19 (1974); S. Rep. No. 822, 9th Cong., 2d Sess. 39; H.R. No. 403, 99th Cong., 1st Sess. 6 (1985).
[14] *See Lindahl v. OPM*, 470 U.S. 768, 782 n.15 (1985) ("'Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it reenacts a statute without change ....'" (citations omitted)).
[15] *See* 120 Cong. Rec. 21,687-95 (1974); *id.* at 31,452-58; 121 Cong. Rec. 20,863-64 (1975); 131 Cong. Rec. 25, 16 (1985) (statement of Sen. Hatch); *Congressional Quarterly Weekly Report* 2,589-90 (Dec. 7, 1985) (reporting on H.J. Res. 465).

funds to provide counseling or referrals for abortion.[16] Congress knows how to prohibit such activities when it wants to. Recent appropriations bills have explicitly prohibited the use of Title X funds for "any activity (*including the publication or distribution of literature*)" promoting legislation or candidates for public office.[17] But Congress has not prohibited the use of Title X funds for "the publication or distribution of literature" regarding abortions. Congress has also not used language restricting the use of Title X funds for referrals or counseling on abortion.

b. Title X was intended to provide "comprehensive" and family planning services and all counseling must be "nondirective," which necessarily includes the presentation of all options, including abortion.

Congress enacted Title X to make "comprehensive voluntary family planning services readily available to all persons desiring such services" and "to develop and make readily available information (including educational materials) on family planning . . . to all persons desiring such information."[18] As the congressional reports explained, "[c]omprehensive family planning services" is not "merely a euphemism for birth control. It is properly a part of comprehensive health care and should consist of much more than the dispensation of contraceptive devices."[19] A Title X program should include "preventive family planning services, population research, infertility services and other related medical, information, and educational activities."[20] This legislative history makes clear that Congress did not intend for Title X funds to cover only the performance of a medical service itself, but that Congress instead intended to fund medical services that include "consultation, examination, prescription, and continuing supervision, supplies, instruction, and referral to other medical services as needed."[21]

Congress has repeatedly declared that the purpose of Title X was not only to provide "voluntary family planning *services*," but also to make "*information* relating thereto[] readily available to all persons in the United States."[22] The House Report echoed this statement: "The purpose of this legislation is to improve and expand the availability of family planning services *and information to all persons desiring such*."[23] Congress thus saw counseling and referrals as integral components of the services to be provided by Title X grantees.

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[16] Consolidated Appropriations Act of 2018, Pub. L. No. 115-141, 132 Stat. 348, 716-717 (2018) (emphasis added); *see also* Pub. L. No. 103-112 § 509, 107 Stat. 1082 (1993).
[17] Consolidated Appropriations Act of 2018, Pub. L. No. 115-141, 132 Stat. 348, 716-717 (2018) (emphasis added).
[18] Family Planning Services and Population Research Act of 1970, Pub. L. No. 91-572, sec. 2, 84 Stat. 1504 (1970).
[19] S. Rep. No. 91-1004, at *10.
[20] H. Rep. No. 91-1667, at *8 (1970) (Conf. Rep.).
[21] S. Rep. No. 91-1004, at *10.
[22] S. Rep. No. 91-1004, at *3.
[23] H. Rep. No. 91-1472, at *4 (emphasis added).

At the same time, Congress has also repeatedly emphasized that family planning is to be voluntary and individualized, subject to limited governmental constraints.[24] In subsequent appropriations, Congress has emphasized that "all pregnancy counseling" provided with Title X funds is to be "nondirective."[25] To fulfill Congress's intent that family planning services and consultations be "comprehensive" and "nondirective," Title X projects must be not only permitted but required to provide patients with their full range of medically appropriate options, including information about and referrals for abortion where appropriate. Indeed, a 1985 House Report on continuing appropriations for Title X stated: "[T]hose requesting information on options for the management of an unintended pregnancy are to be given non-directive counseling on the following alternative courses of action, and referral upon request: a. prenatal care and delivery; b. infant care, foster care or adoption; *c. pregnancy termination.*"[26]

By requiring that Title X projects refer for "prenatal and/or social services" but barring them for referring for abortions, the proposal runs afoul of the requirement that all counseling be "nondirective." The Proposal acknowledges as much when the Department states, of abortion, that "[r]eferrals . . . are, by definition, directive." Existing regulation, not the Proposed Rule, complies with Congress' mandate. In fact, to the extent that Title X projects provide any post-conception care at all, including any counseling or referral services, that care must be "nondirective" under current appropriations law, which means counseling on and referrals for the full range of pregnancy options must not be limited in any way.

By prohibiting Title X projects from providing educational materials about or referrals for abortion, the Proposed Rule violates statutory requirements that Title X projects provide "comprehensive" family planning services and information and that all counseling be "nondirective." Projects that are restricted in the information or referrals they can provide are necessarily not "comprehensive." Similarly, when projects are required to provide patients with information or referrals for certain procedures but not others, the projects are necessarily directing the patients to noncomprehensive options.

c. Federal "conscience" laws do not require or justify removing the abortion counseling requirement or banning referrals for abortion.

The Department incorrectly suggests that federal "conscience laws" require or justify the Proposed Rule prohibiting Title X programs from providing abortion referrals and eliminating the requirement for abortion counseling.[27] But by their terms these laws do not require or authorize these prohibitions. The Church, Coats-Snowe, and Weldon Amendments allow certain

[24] *See, e.g.*, 116 Cong. Rec. 24092 (1970) (statement of Sen. Eagleton) (stating that the central purpose of Title X is to enable "all individuals ... within the dictates of their conscience, to exert control over their own life destinies"); *id.* at 37,388 (statement of Rep. Burke) (noting that the purpose of Title X is to "enable people to do what their conscience dictates is proper or advisable in their own situation").
[25] *See, e.g.*, Consolidated Appropriations Act of 2018, Pub. L. No. 115-141, 132 Stat. 348, 716-717 (2018).
[26] Further Continuing Appropriations, H.R. Rep. No. 99-403, 99th Cong., 1st Sess., at *6 (1985).
[27] *See, e.g.*, 83 Fed. Reg. at 25506, 25512.

individuals and entities to refuse to participate in the training and provision of abortion.[28] The Church Amendment, which applies to funding under specific laws not implicated here, and the Coats Amendment, which applies to medical education, do not have any application to Title X grant funding. The Weldon Amendment prohibits funds from going to a federal agency or program, or to a state or local government, if such agency, program, or government requires any institutional or individual health care entity to provide, pay for, provide coverage of, or refer for abortions.[29] The Department of Justice has taken the formal position that the receipt of federal funds does not mean that an organization, such as an individual Title X clinic, is a federal agency or program under the Weldon Amendment, and "no agency responsible for the implementation or enforcement of the statute has adopted a reading to that effect."[30] Even if that were not the case, as noted above, the Title X appropriations language requires nondirective options counseling and referrals, and Weldon provides no authority to override these requirements in order to accommodate the religious beliefs of some unknown minority of providers. The Department is exceeding its statutory authority by interpreting these amendments far beyond what Congress intended.

Moreover, these laws provide absolutely no authority for the contention that they can be used as a sword to be wielded against all *other* providers. Rather than simply authorize conscience-based refusals, which by itself would undermine the goals of the Title X program, the Proposed Rule would mandate the silence of providers who have no objection to speaking. The federal refusal laws do not permit, let alone require this. Indeed, they do not concern nonobjecting providers at all. And, by adopting this interpretation, the Proposed Rule would impede the conscience rights and moral convictions of these providers, many of whom understand their ethical obligations to include discussing abortion with their patients, as patients rightly expect honest and accurate information about all of their medical options. Doing so, the Department fails to fulfill its core mandate to protect public health. The interests of a small minority of health care providers, whom the Department shows no evidence even exist, do not justify the potentially devastating effect the Proposed Rule would have on the country's most vulnerable populations.

And while the Department's clear public-health mandate rests on one side of the scale, a largely hypothetical concern rests on the other. The Proposed Rule cites the Department's 2008 opinion that the counseling and referral requirements are inconsistent with the federal conscience protections of the Church, Coats-Snowe, and Weldon Amendments.[31] But to the extent there is such a conflict, and we do not agree that there is, this concern is resolved in the very next sentence of the Proposed Rule: "'The Office of Population Affairs, which administers

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[28] *See* 42 U.S.C. § 300a-7; PHS Act sec. 245, 42 U.S.C. § 238n; Consolidated Appropriations Act, 2018, Public Law 115-141, Div. H, sec. 507(d), 132 Stat. 348, 764 (2018); Consolidated Appropriations Act, 2017, Public Law 115-31, Div. 507(d), 131 Stat. 135, 562 (2017).
[29] Weldon Amendment, Consolidated Appropriations Act 2017, Pub. L. 115-31, Div. H, Tit. V, Sec. 507(d).
[30] Brief of Respondent, *NFPRHA v. Gonzales*, 391 F.Supp.2d 200 (D.D.C. 2004) (No. 04-2148).
[31] 83 Fed. Reg. at 25506. *See* 73 Fed. Reg. at 78,087.

the Title X program, is aware of this conflict with the statutory requirements and, as such, would not enforce this Title X regulatory requirement on objecting grantees or applicants."[32] Further, the Department presents no evidence that "the abortion referral and counseling requirements in the current Title X regulations" are, in fact, "be[ing] enforced against objecting grantees or applicants" or "be[ing] used to deny participation in the Title X program or a Title X project of objecting family planning providers."[33] As such, at the outset, the federal conscience laws cannot justify the prohibition on referrals for abortion now proposed.

2. *The Department's public policy justification for imposing the referral ban and removing the counseling requirement is inadequate.*

In proposing to ban referrals for abortion and remove Title X's nondirective options counseling requirement, the Department appears to rest its entire policy rationale on a need to enhance "grantee diversity."[34] According to the Department, current regulations requiring that Title X projects offer nondirective options counseling and referrals have deterred potential program participants from seeking funding because they have a religious or moral objection to abortion. The Proposed Rule provides that banning abortion referrals and removing the counseling requirement would "promote grantee diversity by expanding the number of qualified entities that would be willing and able to apply to provide Title X services."[35]

Planned Parenthood has a number of significant concerns with the Department's reasoning. First, it is mere speculation that there are, in fact, any entities that would participate in Title X but for its counseling and referral requirements. Though the Department seems to suggest that many entities would apply for funding if only they could skirt these patient protections, it can only provide a single example, and even this turns out to be a poor fit. Specifically, the Department points to a letter sent by the Texas Attorney General which, far from contesting Title X's counseling and referral requirements, claims that, "because Texas is unwilling to function as a conduit of federal monies to abortion providers, Texas has been denied the ability to participate in [Title X]."[36] The Texas Attorney General goes on to ask the Department to "assure that Texas law forbidding the extension of taxpayer funds to entities that perform or promote elective abortions, or otherwise affiliate with abortion-promoting or abortion-performing entities, will not summarily disqualify Texas from otherwise participating in the Title X program."[37] It is hard to see how the Proposed Rule's ban on abortion referrals or its removal of Title X's counseling requirement would resolve Texas's complaint that it was penalized for refusing to include abortion-affiliated providers in its Title X project. Indeed, far from an entity that is "diverse" under the Department's reasoning, Texas has participated in the past in the Title X program under the

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[32] *Id.* (quoting 73 Fed. Reg. at 78,087).
[33] *Id.*
[34] 83 Fed. Reg. at 25518.
[35] *Id.*
[36] Attorney General of Texas, Letter re: Discrimination Against Texas Regarding Title X Grants (Mar. 22, 2018), available at https://www.texasattorneygeneral.gov/files/epress/Texas_AG_letter_to_HHS_regarding_Title_X.pdf.
[37] *Id.*

very rules the Department now seeks to change. Providing no other evidence, the Department fails to show in the first instance that any actual problem is created by the current counseling and referral requirements.

Second, the Department fails to connect its purported value of "grantee diversity" to any legitimate health-related end. We remind the Department that Title X was enacted not to distribute federal funding across diverse organizations, but to solve the problem of limited access to family planning for those with low incomes. Given this purpose, it is striking that the Department makes no attempt to explain not only the type of "grantee diversity" its proposed referral ban is intended to promote, but also how that diversity would ultimately benefit Title X patients or the public health. We see no reason why redirecting Title X funds to grantees that refuse to give patients information about abortion would permit more patients to obtain a broad range of quality family planning methods and services. In fact, we are concerned that blindly pursuing grantee diversity in the Title X program would have serious negative consequences. For example, if the type of grantee diversity the Department envisions can only be achieved at the expense of access to a broad range of family planning methods and services for Title X patients (*e.g.*, by withdrawing funds from reproductive health-focused providers and redirecting them to lower performing entities), this would interfere with Title X's overall aim and therefore could not be justified in the context of the program.

Third, even if the Department's "diversity" justification made sense, it would not warrant the regulatory changes that have been proposed. The most that the Department's diversity interest could conceivably be claimed to justify would be a narrow exception to existing counseling and referral requirements for certain objecting entities while maintaining the current regulation's general applicability to the remainder of Title X recipients. The Department cannot draw a rational line between its stated goal of incentivizing the participation of new entities and banning *all other Title X providers* from providing abortion referrals to patients. Nor could this goal justify allowing non-objecting entities to withhold nondirective options counseling from these patients.

3. The Department ignores a number of problems with its proposals to ban referrals for abortion and remove the counseling requirement.

On top of its inadequate rationale, the Department ignores several major problems with its proposals. First, the referral ban would contravene the ethical and professional commitments of health care providers. Second, the Department's own evidence-based guidelines contradict the referral ban and removal of the nondirective options counseling requirement. Third, the Department's proposed narrow "exception" for physicians is arbitrary. Fourth, the referral ban and absence of a requirement for nondirective options counseling will have significant negative consequences on health. And finally, the Department fails to address how the ban on abortion referrals will interact with other requirements in federal law.

a. The Department's ban on referrals for abortion would contravene the basic ethical and professional duties of health care providers.

The Department fails to acknowledge or address that its proposed ban on referrals for abortion would contravene the ethical duties of physicians, nurses, and other health care professionals that provide information and services at Title X service sites. A provider's responsibility to convey complete, accurate, and unbiased information to patients is a widely-accepted ethical imperative. The Proposed Rule directly conflicts with the recommendations of major medical professional associations, including the American College of Obstetricians and Gynecologists and the American College of Physicians, which assert that patients should receive complete and accurate information to inform their health care decisions.[38] Similarly, the American Medical Association states in its Code of Medical Ethics that providers must "present relevant information accurately and sensitively, in keeping with the patient's preferences"[39] and that "withholding information without the patient's knowledge or consent is ethically unacceptable."[40] The Code of Ethics for Nursing stipulates that "[p]atients have the moral and legal right to determine what will be done with and to their own person; to be given accurate, complete, and understandable information in a manner that facilitates an informed decision."[41] Referral for medical care is fundamental to this duty. The Department's proposal, in both prohibiting Title X projects from referring for abortion and creating the possibility that patients would be denied nondirective counseling on abortion, is clearly inconsistent with these principles. In fact, because the Proposed Rule would so profoundly breach the trust between patients and health care professionals and violate bedrock ethical commitments, a number of major medical associations and health care provider groups have already warned of its harms and have announced their opposition to it.[42]

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[38] Kinsey Hasstedt, *Unbiased Information on and Referral for All Pregnancy Options Are Essential to Informed Consent in Reproductive Health Care*, Guttmacher Institute (Jan. 2018), *available at* https://www.guttmacher.org/gpr/2018/01/unbiased-information-and-referral-all-pregnancy-options-are-essential-informed-consent.

[39] American Medical Association, Code of Medical Ethics Opinion 2.1.1, Informed Consent, available at https://www.ama-assn.org/delivering-care/informed-consent.

[40] 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.

[41] American Nurses Association. Code of Ethics for Nurses. Provision 1.4.

[42] *See, e.g.*, American Medical Association, AMA Response to Administration's Attack on Family Planning Services (May 23, 2018), available at https://www.ama-assn.org/ama-response-administrations-attack-family-planning-services; American Nurses Association, ANA Condemns Title X Funding Cuts Proposed by the Trump Administration (May 22, 2018), available at https://www.nursingworld.org/news/news-releases/2018/ANA-condemns-title-x-funding-cuts--proposed-by-the-trump-administration/; America's Women's Health Providers Oppose Efforts to Exclude Qualified Providers from Federally-Funded Programs, Joint statement from The American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), the American College of Nurse-Midwives (ACNM), the American College of Physicians (ACP), the Association for Physician Assistants in Obstetrics and Gynecology (APAOG), the National Association of Nurse Practitioners in Women's Health (NPWH), Nurses for Sexual and Reproductive Health (NSRH), and the Society for Adolescent Health and Medicine (SAHM) (May 23, 2018), available at https://www.acog.org/About-ACOG/News-Room/Statements/2018/Health-Providers-Oppose-Efforts-to-Exclude-Qualified-Providers-from-Federally-Funded-Programs.

In the face of these serious ethical issues, the Department cannot merely assert that a health care provider's hypothetical objection is the agency's most important priority. Even if the Department's decision to ignore the position of the entire medical community[43] were defensible —and it very clearly is not—that could only plausibly support allowing providers with religious objections to deny Title X patients full information about their health care options, an untenable policy itself. It would provide absolutely no support to the Department's chosen regulatory option: barring all Title X projects from offering referrals for abortion and allowing all Title X projects to withhold counseling on abortion.

Moreover, the Department's proposed ban on referrals for abortion interferes with the fiduciary duty owed by health care providers to their patients. The trust and reliance between patient and provider gives rise to a fiduciary relationship under common law.[44] That duty requires providers to avoid "the withholding or distortion of information in order to affect the patient's beliefs and decisions."[45] In other words, common-law fiduciaries must disclose all material facts.[46] By mandating health care providers' silence on abortion except in the narrowest of circumstances, the Proposed Rule overlooks—and would require providers to routinely violate—these other duties.

In addition to the ethical and professional consequences of violating these duties, health care providers risk incurring tort liability. The American tort law doctrine of informed consent requires providers to disclose "any material information important to choosing a course of treatment."[47] Under informed consent laws, a woman who is not informed about or properly referred for abortion can sue the provider who was barred by Title X from providing her that information or

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[43] *See* William A. Galston and Melissa Rogers, *Health Care Providers' Consciences and Patients' Needs: The Quest for Balance*, Brookings Institution (Feb. 2012), available at https://www.brookings.edu/wp-content/uploads/2016/06/0223_health_care_galston_rogers.pdf ("Most agree that conscientious objectors have a duty to notify patients about their concerns and that these patients should be provided with prompt and complete information about service alternatives."); Nancy Berlinger, "Conscience Clauses, Health Care Providers, and Parents," *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns*, (2008), available at https://www.thehastingscenter.org/briefingbook/conscience-clauses-health-care-providers-and-parents/ ("Health care providers with moral objections to providing specific services have an obligation to minimize disruption in delivery of care and burdens on other providers.")

[44] *See, e.g., Chiarella v. United States*, 445 U.S. 222, 227-228 (1980) (at common law, a duty to disclose arises when one party has information 'that the other [party] is entitled to know because of a fiduciary or other similar relation of trust and confidence between them'" (quoting Restatement (Second) of Torts § 551(2)(a) (1976))).

[45] 1 President's Commission for the Study of Ethical Programs in Medicine and Biomedical and Behavioral Research, Making Health Care Decisions 68, 67 (1982).

[46] Chiarella, 445 U.S. at 228.

[47] *Unthank v. United States*, 732 F.2d 1517, 1521 (10th Cir. 1984); *see also, e.g.,* Cruzan by Cruzan v. Dir., Missouri Dep't of Health, 497 U.S. 261, 269 (1990); Lori B. Andrews, *Informed Consent Statutes and the Decisionmaking Process*, 5 J. of Legal Medicine 163 (1984).

referral.[48] Title X providers who fail to discuss and refer for abortion, alongside all her options, with a woman whose pregnancy risks severe cognitive or physical impairment at birth could also face tort liability.[49]

b. The Proposed Rule is at odds with the Department's own evidence-based guidelines.

On top of flouting medical ethics, the Department's proposed changes in this area conflict with its own clinical recommendations. Issued by the Department in 2014, the evidence-based *Providing Quality Family Planning Services* (QFP) recommendations constitute the current national standard for quality clinical family planning care. The QFP recommends that providers of family planning care, including Title X providers, "offer pregnancy testing and counseling services as part of core family planning services, in accordance with recommendations of major professional medical organizations, such as the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP)."[50] On the subject of referrals, the QFP also provides:

> Referral to appropriate providers of follow-up care should be made at the request of the client, as needed. Every effort should be made to expedite and follow through on all referrals. For example, providers might provide a resource listing or directory of providers to help the client identify options for care. Depending upon a client's needs, the provider may make an appointment for the client, or call the referral site to let them know the client was referred. Providers also should assess the client's social support and refer her to appropriate counseling or other supportive services, as needed.[51]

Because the process of developing the QFP recommendations was rigorous and based on the effectiveness of services, it constitutes a body of objective, research-based practices that the

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[48] *See, e.g.*, *Steele v. United States*, 463 F. Supp. 321, 330 (D. Alaska 1978) (failure to refer patient to qualified medical practitioner that results in delay in treatment is breach of standard of care); *Lindquist v. Dengel*, 92 Wash. 2d 257, 263, 595 P.2d 934, 937 (Wash. 1979) ("To delay a referral [to a specialist when diagnosis indicates such expert treatment is required] could itself be a breach of the general practitioner's duty."); *Manion v. Tweedy*, 257 Minn. 59, 65, 100 N.W.2d 124, 128 (Minn. 1959) (if physician knows or should know that a patient's condition is beyond his knowledge, ability or capacity to treat, he must advise the patient of necessity of other treatment).

[49] *See, e.g.*, *Robak v. United States*, 658 F.2d 471 (7th Cir. 1981) (failure to diagnose rubella and inform parents of risk to fetus); ; *Goldberg v. Ruskin*, 471 N.E.2d 530 (Ill. App. Ct. 1984), aff'd, 499 N.E.2d 406 (Ill. 1986) (failure to advise parents of tests designed to detect Tay Sachs disease); *Smith v. Cote*, 513 A.2d 341 (N.H. 1986) (failure to timely diagnose rubella and inform parents of consequences); . *See generally* S. Elias & G.J. Annas, *Reproductive Genetics and the Law* 109-10 (1977).

[50] Centers for Disease Control and Prevention, "Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs," Morbidity and Mortality Weekly Report (Apr. 2014), *available at* https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf.

[51] *Id.*

Department cannot reasonably ignore. Yet nowhere in the Proposed Rule is the QFP discussed, certainly not in the context of nondirective counseling on and referral for abortion.

c. The Department's proposed "exception" for physicians is unreasonable.

The Proposed Rule would provide, in section 59.14(c), that a Title X project may not use referrals as an indirect means of promoting abortion as a family planning method. That prohibition includes only one narrow exception: if and only if "a woman who is currently pregnant clearly states that she has already decided to have an abortion" and "ask[s]" for a referral, "a doctor may ... provide a list of licensed, qualified, comprehensive health service providers (some of which also provide abortion, in addition to comprehensive prenatal care)." This exception purports to "[r]ecogniz[e] . . . the duty of a physician to promote patient safety." Similarly, according to the preamble to the Proposed Rule, "a doctor would be permitted to provide nondirective options counseling on abortion."[52] Setting the substance of the prohibition itself aside, this exception is unreasonably narrow for a number of reasons.

As outlined above, physicians have duties other than "to promote patient safety" that section 59.14(c) would require them to breach. But section 59.14(c) also fails to properly accommodate even the duty to promote patient safety, on at least two fronts. First, the exception only applies after a woman "clearly states that she has already decided to have an abortion," but many patients will need information from their doctor in order to make that decision. For example, the duty to promote patient safety requires a doctor to advise a patient with cancer that it may not be safe for her to carry a pregnancy to term and provide her with information about how to access necessary care—but the provider cannot do so under the Proposed Rule since that uninformed patient has not already clearly stated her intent to have an abortion. Second, even after the patient has clearly stated that she has decided to have an abortion, the doctor cannot refer her to an abortion provider. Instead, the physician can only provide a potentially confusing and misleading list of providers that includes *some* providers of abortions *in addition* to other prenatal care. The delay faced by the patient deciphering this list and locating a provider for the services she has already decided to use will increase her risk of complications. The misdirection mandated by this list therefore inevitably obstructs the duty to promote patient safety. And it may not even be possible to compile such a list since providers tend to specialize and may not provide all of the required services.

Moreover, proposed section 59.14(c) does not make any exceptions for the ethical, legal, and professional obligations of other health care professionals. The preamble's discussion of nondirective options counseling leaves them out, too. The proposed rule refers only to "the duty of a physician" and "a doctor," but nurses, counselors, and other health care professionals owe similar duties to their patients. And, in fact, most care at Title X health centers, including Planned Parenthood health centers, is provided by nonphysician providers. According to the

[52] 83 Fed. Reg. at 25,507.

Department's own analysis, in 2016, Title X services were provided by the full-time equivalents of only 780 physicians and 2,770 combined registered nurses, physician's assistants, nurse practitioners, and certified nurse midwives.[53] Nurses are bound by nearly identical ethical obligations to physicians.[54] And a fiduciary duty to disclose arises because of the nature of the relationship, not because of the title of the professional.[55] The Proposed Rule would categorically bar these nonphysician professionals from fulfilling their ethical and professional duties, and, as discussed above, would expose them to significant tort liability.

d. The Department's proposals would have serious unacknowledged consequences on health.

The Department, moreover, fails to predict the effect of its proposed referral ban on the continued participation of providers of family planning care in the Title X program. By conditioning funds on restrictions that are fundamentally at odds with the professional and ethical obligations of health care professionals, the Department will give many grantees, subrecipients, and health care professionals no choice but to withdraw from Title X. In fact, a number of state grantees, including Washington,[56] New York,[57] Hawaii,[58] and Oregon[59] have already put the Department on notice that they would be forced to exit the program if the proposed regulations are finalized, along with other direct grantees. Together these states serve 427,000 Title X patients. Similarly, Planned Parenthood affiliates and their health centers would be forced to discontinue their participation in Title X if the Proposed Rule takes effect.

Although the Department fails to mention this, it is obvious that the resulting exodus of program participants would cause gaps in access to care, harm population health, and produce significant, unnecessary costs. The proposed ban on abortion referrals would restrict the ability

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[53] *Id.* at 25,523.
[54] *See, e.g.,* American Nurses Association, "Code of Ethics for Nurses with Interpretive Statements" (2015).
[55] *See, e.g., Chiarella*, 445 U.S. at 228 ("[T]he duty to disclose arises when one party has information 'that the other [party] is entitled to know because of a fiduciary or other similar relation of trust and confidence between them.'").
[56] Press Release, Washington Governor Jay Inslee, Inslee Statement on Protecting Washington Women from Trump Gag Rule (July 30, 2018), available at https://www.governor.wa.gov/news-media/inslee-statement-protecting-washington-women-trump-gag-rule
[57] Press Release, New York Governor Andrew M. Cuomo, Governor Cuomo Issues Letter to HHS Secretary Threatening Legal Action if Title X Rule Changes are Adopted (July 30, 2018), available at https://www.governor.ny.gov/news/governor-cuomo-issues-letter-hhs-secretary-threatening-legal-action-if-title-x-rule-changes-are
[58] Press Release, Hawaii Governor David Ige, Governor Ige Opposes Trump Administration's Attempt to Limit Women's Health Care Services (July 30, 2018), available at https://governor.hawaii.gov/newsroom/latest-news/office-of-the-governor-news-release-governor-ige-opposes-trump-administrations-attempt-to-limit-womens-health-care-services/.
[59] Press Release, Oregon Governor Kate Brown, Governor Brown on Federal Title X Rollbacks on Access to Reproductive Health (July 30, 2018), available at https://mailchi.mp/oregon/news-release-governor-brown-on-federal-title-x-rollbacks-on-access-toreproductive-health?e=351baaef1c.

of reproductive health-focused providers, including Planned Parenthood, to serve Title X patients, thereby reducing patients' access to a broad range of quality family planning methods and services. Planned Parenthood health centers serve more family planning patients than other safety-net providers. Of the 6.2 million female contraceptive patients at publicly funded family planning clinics in 2015, 32 percent received care at Planned Parenthood health centers.[60] On average, each Planned Parenthood health center serves more family planning patients than other individual sites; for instance, Planned Parenthood health centers had an average annual contraceptive caseload of 2,950 patients per site, compared to 320 per site at Federally Qualified Health Centers (FQHCs).[61] Although Planned Parenthood health centers represent only 13 percent of Title X service sites, they serve over 40 percent of the program's patients.[62]

Other safety-net providers would face an enormous strain in attempting to absorb the patients that would lose access to services. In order to serve all the women who currently obtain contraceptive care at Title X–supported Planned Parenthood health centers in the 50 states and the District of Columbia, other types of Title X sites would need to increase their client caseloads by 70 percent, on average.[63] In 13 states, other Title X providers would have to at least double their capacity—and in many, to an even greater degree—to maintain the current reach of their states' Title X networks.[64] Also, many Planned Parenthood health centers serve communities that lack alternative providers of Title X services. Fifty-six percent of Planned Parenthood health centers are in health provider deserts, where residents live in areas that are medically underserved and may have nowhere else to go to access essential health services without Planned Parenthood. Even in communities where alternate entities could be identified, they would incur unnecessary costs on the front-end in readying systems, revising protocols and policies, entering into contracts and other agreements, and training staff, all while the existing capabilities of former participants would be wastefully sidelined.

Even for those patients that are able to shift from Planned Parenthood to other safety-net providers, in addition to being a costly and harmful disruption in access to services, patients would likely receive inferior care. First, the disruption caused by having to switch providers itself would impose costs on patients who would have to engage in the time-intensive process of locating, evaluating, and selecting a suitable alternative provider. And second, once a provider is selected, this new provider may not offer the same range of services at the same level of quality as a patient's previous Title X-funded provider. Planned Parenthood and other providers that specialize in reproductive health typically offer a broader range of reproductive health

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[60] Guttmacher Institute, "Publicly Funded Contraceptive Services At U.S. Clinics, 2015" (2016), *available at* https://www.guttmacher.org/sites/default/files/report_pdf/publicly_funded_contraceptive_services_2015_3.pdf.
[61] *Id.*
[62] *Id.*
[63] Kinsey Hasstedt, *Beyond the Rhetoric: The Real-World Impact of Attacks on Planned Parenthood and Title X*, Guttmacher Policy Review, (Aug. 2017), *available at* https://www.guttmacher.org/gpr/2017/08/beyond-rhetoric-real-world-impact-attacks-planned-parenthood-and-title-x.
[64] *Id.*

services than other safety-net providers. In a study by the administrators of Title X evaluating service delivery characteristics of Title X providers, being a Planned Parenthood health center was associated with a higher quality and scope of family planning services when controlling for other health center characteristics, including the onsite availability of each contraceptive method, comprehensive counseling, and adolescent-friendly services.[65] In general, 99 percent of Planned Parenthood health centers provide at least 10 reversible contraceptive methods on site, compared with 71 to 81 percent of other provider types.[66] Planned Parenthood health centers are more likely than all other types of clinics to provide a Long Acting Reversible Contraceptive (LARC) method (98 percent versus 69 percent to 77 percent); are more likely than FQHCs and "other" clinics to provide pill supplies on-site (83 percent versus 34 to 56 percent); and are more likely than any other types of clinics to provide same-day IUD insertions (81 percent versus 30 to 48 percent). Eighty-three percent of Planned Parenthood health centers provide initial oral contraceptive supplies and refills on-site, compared with only 34 percent of FQHCs.[67] Planned Parenthood health centers also typically have shorter waiting periods—an average of 1.2 days for an initial contraceptive visit—and appointments can often be made the same day.[68] By contrast, one study found that the average wait time for an FQHC appointment was nine days.[69]

Additionally, Title X patients may prefer to see a provider that specializes in reproductive health. Research has shown that patients prefer to receive care at specialized clinics, like Planned Parenthood health centers, because such clinics can offer better or faster services such as having oral contraceptives available on site or same day IUD insertion.[70] Also, women trust OB/GYN specialists and are generally more likely to talk with them about health concerns both within and outside the scope of sexual and reproductive health care.[71] For instance, women are twice as likely to talk with OB/GYNs about birth control and HIV than internal or family medicine providers, and they are more likely to talk to OB/GYNs about substance abuse.[72] Thirty-five percent of women report their OB/GYN as being their primary health care provider.[73]

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[65] Carter, et al., *Four aspects of the scope and quality of family planning services in US publicly funded health centers: Results from a survey of health center administrators*, 94 J. Contraception 340 (2016), http://dx.doi.org/10.1016/j.contraception.2016.04.009.
[66] Zolna, M. R., & Frost, J. J., *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols* (2016), *available at* https://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.
[67] *Id.*
[68] *Id.*
[69] Rhodes, K. V., Kenney, G. M., Friedman, A. B., Saloner, B., Lawson, C. C., Chearo, D., &; Polsky, D., *Primary Care Access for New Patients on the Eve of Health Care Reform*, JAMA Internal Medicine, 174(6), 861-69 (2014).
[70] Frost, J.J., Gold, R.B., 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, 22(6) (2012), e519-e525.
[71] PerryUndem, "Research Findings: Women + OB/GYN Providers," (Nov. 2013), *available at* https://www.plannedparenthood.org/files/4914/0656/5723/PPFA_OBGYN_Report.FINAL.pdf.
[72] *Id.*
[73] *Id.*

Reduced access to a broad range of quality family planning care resulting from the Department's proposed ban on abortion referrals would translate to worse health outcomes for Title X patients. These adverse consequences are likely to include, among others, more unintended pregnancies. In 2015, the Guttmacher Institute estimated that Planned Parenthood's provision of contraceptive services averted 430,000 unintended pregnancies.[74] If 10 percent fewer pregnancies were averted as a result of the Proposed Rule, this would create considerable cost to patients and the health care system. In Medicaid, the average total maternal and newborn charges for care with vaginal or cesarean births are $29,800 and $50,373, respectively.[75] So, at minimum, even a 10 percent increase in births resulting from the Proposed Rule would impose $128.1 million in costs (4,300 x $29,800). Similarly, a study in California found that removing free or low-cost access to family planning services would result in patients using less effective methods of contraception with correspondingly higher rates of failure.[76] Unintended pregnancy can put the health of women and children at risk.[77] It is also likely that a decrease in contraceptive use would result in a rise in the rate of abortions.[78]

Furthermore, reduced access to family planning care also means STDs will go undetected or be detected later, leading to higher rates of STDs and more severe consequences for patients experiencing them. STDs among women can result in pelvic inflammatory disease, which is a major cause of infertility; ectopic pregnancy; and chronic pelvic pain.[79] Certain STDs, including syphilis and gonococcal infections, also facilitate the transmission of HIV.[80] In 2010, publicly funded family planning sites, including Planned Parenthood health centers, averted 99,100

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[74] Guttmacher Institute, *Unintended Pregnancies and Abortions Averted by Planned Parenthood*, (Jun. 2017), *available at* https://www.guttmacher.org/infographic/2017/unintended-pregnancies-and-abortions-averted-planned-parenthood-2015.

[75] Truven Health Analytics, The Cost of Having a Baby in The United States: Executive Summary (Jan. 2013), available at https://transform.childbirthconnection.org/wp-content/uploads/2013/01/Cost-of-Having-a-Baby-Executive-Summary.pdf.

[76] M. Antonia Biggs et al., *California Family Planning Health Care Providers' Challenges to Same-Day Long-Acting Reversible Contraception Provision*, 126 Obstetrics & Gynecology 338, 338 (2015).

[77] ACOG, *Committee Opinion No. 654, Reproductive Life Planning to Reduce Unintended Pregnancy* (2016), https://journals.lww.com/greenjournal/Fulltext/2016/02000/Committee_Opinion_No__654___Reproductive_Life.53.aspx; ACOG, *Frequently Asked Questions No. 182, Obesity and Pregnancy* (2016), https://www.acog.org/Patients/FAQs/Obesity-and-Pregnancy; ACOG, *Frequently Asked Questions No. 142, Diabetes and Women* (2016), https://www.acog.org/-/media/For-Patients/faq142.pdf?dmc=1&ts=20180724T1744238808.

[78] Lawrence B. Finer & Mia R. Zolna, *Declines in Unintended Pregnancy in the United States, 2008-2011*, 374 N. Engl. J. Med. 843, 846-47 (2016) (finding that approximately 40 percent of unintended pregnancies end in abortion).

[79] Centers for Disease Control and Prevention, *Pelvic Inflammatory Disease (PID) – CDC Fact Sheet* (2014), available at https://www.cdc.gov/std/pid/pid-fact-sheet-july-2014-press.pdf; Kristen Kreisel et al., *Prevalence of Pelvic Inflammatory Disease in Sexually Experienced Women of Reproductive Age—United States 2013-2014*, 66 Morbidity & Mortality Wkly Rpt. 80, 80 (2017).

[80] CDC, Sexually Transmitted Disease Surveillance 2015, at 6, 43, 54, 55 (2016), available at https://www.cdc.gov/std/stats15/std-surveillance-2015-print.pdf.

cases of chlamydia; 16,240 cases of gonorrhea; 410 cases of HIV; 13,170 cases of pelvic inflammatory disease (PID), which would have led to 1,130 ectopic pregnancies; and 2,210 cases of infertility.[81] These preventable infections are costly to patients and the health care system. For example, the Guttmacher Institute estimates that the total burden of the nine million new cases of STDs that occurred among 15-24-year-olds in 2000 was $6.5 billion, with HIV and the human papillomavirus (HPV) the most costly STDs by far in terms of total estimated direct medical costs, accounting for 90% of the total burden ($5.9 billion).[82] In addition to a rise in unintended pregnancies and STDs, reduced access to Planned Parenthood's Title X services would likely have other negative effects on health.

These negative consequences will fall most heavily on certain populations that, due to systemic racism, sexism and other forms of oppression, already face health disparities—disparities that the Department has an obligation to address, not exacerbate. These include women, who comprise the vast majority of Title X patients, including women impacted by the opioid epidemic, who are in critical need of affordable family planning services. It also includes people of color, LGBTQ people, and young people. Of the four million family planning patients served by Title X in 2016, 21 percent identified as Black or African American and 32 percent identified as Hispanic or Latino.[83] Women of color in underserved areas, such as those served by many Title X clinics, including Planned Parenthood health centers, are at high risk for negative sexual and reproductive health outcomes, due to poverty, geographic and social isolation, and limited access to care.[84] Similarly, people who identify as LGBTQ often have few options for LGBTQ-friendly care, such as that provided at Title X centers—including cancer screenings, contraception, and STI and HIV services. Title X is also a vital source of confidential care for young people across the country, playing an important role in the plummeting teen pregnancy rates, as well as providing prevention, testing and treatment for STDs. Without comprehensive contraceptive services at Title X centers, the teen unintended pregnancy rate would be 44 percent higher.[85]

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[81] Jennifer J. Frost et al., *Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program*, 92 Milbank Q. 667, 668 (2014).
[82] Guttmacher Institute, The Estimated Direct Medical Cost of Sexually Transmitted Diseases Among American Youth, 2000, (2004), available at https://www.guttmacher.org/journals/psrh/2004/estimated-direct-medical-cost-sexually-transmitted-diseases-among-american.
[83] *See* Dep't of Health & Human Servs., Off. of Population Affairs, Title X Family Planning Annual Report: 2016 National Summary (2017), available at https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.
[84] *See* American College of Obstetricians and Gynecologists, Health Care Systems for Underserved Women (2012), available at https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-Systems-for-Underserved-Women.
[85] Kinsey Hasstedt, *Why We Cannot Afford to Undercut the Title X National Family Planning Program* (2017), available at https://www.guttmacher.org/gpr/2017/01/why-we-cannot-afford-undercut-title-x-national-family-planning-program.

Unfortunately, we already have seen the negative health consequences of laws and policies that restrict the ability of providers like Planned Parenthood to serve patients with low incomes. For example, one study found that the exclusion of Planned Parenthood from a state-funded family planning program in Texas was associated with adverse changes in the provision of contraception, including a 35 percent decline in the use of the most effective methods of contraception and an increase in unintended pregnancy leading to a 27 percent increase in childbirth covered by Medicaid.[86]

In addition to the effects of reduced access to family planning care due to exodus of qualified, long-standing providers, the Department fails to consider the likely negative effects on the quality of patient care at Title X-funded sites that attempt to adhere to the terms of the referral ban or are allowed to withhold counseling, including interference with care coordination and the other burdens placed on patients. Full information is critical to positive health outcomes. In a meta-analysis of studies examining care management plans, the authors concluded that "patient health outcomes can be improved with good physician-patient communication," which includes the need for patients to feel "that they are active participants in care and that their problem has been discussed fully."[87] Suppressing a provider's discussion with a patient about where and how to access abortion, as per the Department's proposal, interferes with such "full discussion." Referrals are also an important part of care coordination. For example, a survey on care coordination from the Department's Agency for Healthcare Research and Quality asks patients whether they were able to obtain a needed referral from their primary care provider to see another health care professional in the past year.[88]

On top of implicating these aspects of quality and care coordination, the Proposed Rule would harm patients seeking abortions by introducing extraordinary difficulties into the already arduous process of obtaining one. It would do this not only by forcing providers to decline to offer any guidance to patients seeking abortion, but also by coercing or confusing patients into unwanted appointments for prenatal care. Under proposed section 59.14, only in the narrow circumstance where a pregnant patient "clearly states that she has already decided to have an abortion" would the rule allow a doctor to give that patient a list of "comprehensive health service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care)" without identifying which providers on that list actually offer abortion. All other pregnant patients could only be given a list of "comprehensive health service providers (including providers of prenatal care) who do not provide abortion as a part of their services"

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[86] Stevenson, A. J., Flores-Vazquez, I. M., Allgeyer, R. L., Schenkkan, P., & Potter, J. E., *Effect of Removal of Planned Parenthood from the Texas Women's Health Program*, New England Journal of Medicine, 374(9) (2016), 853-60.
[87] Moira Stewart, PhD, *Effective Physician-Patient Communication and Health Outcomes: A Review*, Canadian Medical Association Journal, (May 1995), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1337906/pdf/cmaj00069-0061.pdf.
[88] Agency for Healthcare Research and Quality, "Care Coordination Measure for Primary Care Survey" (Jul. 2016), *available at* https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/prevention-chronic-care/improve/coordination/ccqmpc/ccqm-pc-survey-instructions.pdf.

under the Proposed Rule. In addition to banning abortion referrals, the Proposed Rule would appear to require Title X projects to not only refer any pregnant patient for "appropriate prenatal and/or social services," but to also give the patient "assistance with setting up a referral appointment to optimize the health of the mother and unborn child."[89] This appears to require Title X projects to set up an appointment for a patient for "prenatal care and delivery, infant care, foster care, or adoption" even if the patient has declined to be connected to those services, or worse, even if the patient had already clearly expressed their intent to have an abortion.[90]

Whether because patients are coerced into making an appointment with a provider that they never asked to see, or simply because of the deliberately confusing nature of the Department's approved "referral list," the Proposed Rule virtually guarantees that many patients interested in seeking an abortion will be pressured or misled into scheduling one or more unnecessary in-person office visits for unwanted services. The Department fails to account for the costs this would impose on Title X patients (many of whom have low incomes and lack health insurance) who would be forced to pay for an unnecessary visit with another health care provider, arrange for transportation, and take time off from work or school—only to find out that they must do so at least once more to actually obtain an abortion. Studies of mandatory waiting periods for abortion confirm that imposing delays on access to abortion burdens patients and results in later-term abortions.[91] These extra visits would also impose unwarranted costs on health care providers, and would unnecessarily burden other publicly funded programs and or health plans. Moreover, the Department fails to consider that the proposed referral ban would shift the burden of gathering and evaluating information about where and how to obtain an abortion to the patient. Being much less likely than the provider to have a complete understanding of the available options and to be able to weigh the comparative advantages of each, the patient would have to engage in this process without guidance and at great personal expense. From a public policy perspective, there is no conceivable benefit to requiring additional, unnecessary visits, but there are considerable costs to the patients and to the health care system. The Department must at a minimum address these costs in its rationale and provide some justification for these features of its proposed ban on abortion referrals.

Additionally, the Department's proposed "physical and financial" separation requirement would likely reduce access to abortion referrals even for non-Title X patients. Discussed below, the "physical and financial" separation requirement expressly requires referrals for abortion to be

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[89] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25,531.
[90] *Id.*
[91] *See, e.g.*, Michael Lupfer and Bohne Goldfarb Silber, "How Patients View Mandatory Waiting Periods for Abortion," Family Planning Perspectives, (Mar. 1981), *available at* https://www.jstor.org/stable/2134696?seq=1#page_scan_tab_contents; Frances A. Althaus and Stanely K. Henshaw, "The Effects of Mandatory Delay Laws On Abortion Patients and Providers," Family Planning Perspectives, (Sept. 1994), *available at* https://www.jstor.org/stable/2135944; Joyce, Henshaw et al., "The Impact of State Mandatory Counseling and Waiting Period Laws on Abortion: A Literature Review," Guttmacher Institute (Apr. 2009), *available at* https://www.guttmacher.org/report/impact-state-mandatory-counseling-and-waiting-period-laws-abortion-literature-review.

provided separately from Title X services, necessitating separate facilities. We show below that the costs of avoiding noncompliance with the proposed separation standard would be financially impractical for many entities. Faced with the prospect of having to make costly investments to establish separate facilities, some recipients may instead forfeit their the provision of abortion referrals entirely in order to continue to participate in Title X. This would effectively withhold referrals from patients who seek non-Title X care from recipients, imposing harms and costs on these patients similar to those assessed for Title X patients above.

e. The Department fails to address how its proposed ban on abortion referrals would interact with other federal requirements.

Finally, the Department makes no attempt to clarify the interaction between its proposed ban on referrals for abortion and its removal of the counseling requirement and applicable federal requirements to the contrary. For example, the Department's Proposed Rule prohibiting Title X projects from referring women for abortion creates a conflict with the requirements of section 330 of the Public Health Service Act.[92] Health centers receiving funding under that Act as well as FQHC look-alikes are required to provide "primary health services,"[93] which include "referrals to providers of medical services (including specialty referral when medically indicated) and other health-related services."[94] These health centers are therefore required by federal law and regulation to refer patients to providers of abortions as medically indicated.

Under the Proposed Rule, FQHCs that operate Title X projects would face conflicting federal obligations. Congress did not intend for Title X grantees to have to choose between receiving funding under Title X or under other federal programs, such as section 330 of the Public Health Service Act. Indeed, Title X providers *must* secure other sources of revenue even to be eligible to receive Title X grants.[95] As of 2010, FQHCs administered 38% of Title X clinics.[96] Thus, the Proposed Rule is contrary to law, and it is arbitrary and capricious insofar as it conflicts with the statutory requirements of other federal programs in which Title X grantees might participate.

4. The regulatory text the Department provides is unclear and confusing.

While we urge the Department to withdraw the rule in its entirety, the Department must at a minimum address a number of unclear or confusing features of its proposals to ban referrals for abortion and to remove Title X's nondirective options counseling requirement. As these proposals stand, they provide insufficient notice to Title X recipients about their obligations under the Proposed Rule. In resolving these issues, a reasoned justification should also be

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[92] 42 U.S.C. § 254b.
[93] *Id.* § 254b(a)(1).
[94] *Id.* § 254b(b)(1)(A). *See also* 42 C.F.R. § 51c.102(c), (h).
[95] See 42 C.F.R. § 59.7(c) (Title X grants may not cover 100 percent of a project's estimated costs).
[96] Heisler & Elliott, Factors Related to the Use of Planned Parenthood Affiliated Health Centers (PPAHCs) and Federally Qualified Health Centers (FQHCs) 10, Congressional Research Service (2017), *available at* https://fas.org/sgp/crs/misc/R44295.pdf.

provided where the Department's clarification reflects a policy choice for which the Proposed Rule fails to offer a justification or explanation.

- In proposed section 59.5(a)(5), the Department writes that Title X projects would be prohibited from, among other things, "presenting" abortion as a method of family planning. But this is contradicted by the preamble, which expressly assures that the regulation would not ban Title X projects from giving patients nondirective options counseling on abortion.[97] Additionally, while the preamble cites appropriations law which provides that "all pregnancy counseling shall be nondirective," this appears nowhere in the regulatory text even as the Department proposes to codify many other appropriations directives. These inconsistencies are likely to confuse Title X recipients about what is legally required or allowed under the Proposed Rule. If the Department wishes to expressly permit nondirective options counseling (as the law requires), it should do so by clarifying the proposed regulatory text to reflect, at minimum, the language of the appropriations rider. If it intends to foreclose counseling on abortion, it must at a minimum attempt to justify its policy choice by showing evidence in favor of prohibiting such counseling and the legal basis for this change. As we state above, we do not believe that the Department can legally make this change.

- The regulatory text at proposed section 59.14(b) appears to direct Title X projects to refer all patients who are "medically verified as pregnant," regardless of their wishes, to "prenatal and/or social services." Yet the preamble devotes neither explanation nor justification for this apparent policy decision. If the Department does not intend to conscript Title X providers into making prenatal appointments for all pregnant patients, it should clarify this in the proposed regulatory text. If it does intend this, at minimum, it must provide a reasoned justification for this decision and articulate a valid legal basis for its action. As we state above, we do not believe the Department can adequately justify referring all pregnant patients for "prenatal and/or social services."

- Although the proposed section 59.14(c) appears to permit "doctors" to include abortion providers in a list of referral providers in some circumstances, neither the regulatory text nor the preamble settle whether other health care professionals would be allowed to do so. Similarly, the preamble of the Proposed Rule provides that a "physician" may offer nondirective options counseling, including counseling on abortion, to a pregnant patient but nowhere does the Proposed Rule mention whether this would be permitted by other project staff.[98] The Department should clarify this in the regulatory text and provide an adequate rationale and legal basis for its choice. Again, we do not believe it can.

- At proposed section 59.14(a), the regulatory text appears to absolutely bar Title X projects from providing referrals for abortion. Yet the preamble, in cases of rape or

[97] 83 Fed. Reg. at 25507.
[98] *Id.*

incest, claims to provide for an exception to this prohibition. The Department should resolve this inconsistency in language and explain its justification.

5. *The proposal to ban referrals for abortion would violate the constitutional rights of Title X recipients.*

The Department's proposed ban on referrals for abortion violates the constitutional rights of Title X recipients. First, it would restrict speech by Title X providers in violation of the First Amendment. Second, the proposed ban on referrals for abortion would require Title X providers to adopt the Department's view of medically-appropriate options for pregnant women as their own.

a. *The ban on referrals for abortion would restrict speech by Title X grantees in violation of the First Amendment.*

While the Department notes that a previous iteration of the gag order survived a First Amendment challenge in *Rust v. Sullivan*,[99] the Department's current Proposed Rule goes further than the 1988 Rule in restricting speech, thereby raising new and unaddressed concerns regarding the infringement of First Amendment rights of Title X participants. The Proposed Rule does not merely prohibit counseling or referrals directly related to abortion. Whereas the 1988 Rule provided that a Title X project could not "provide counseling concerning the use of" or "provide referral" for abortion, the Proposed Rule increases the scope of prohibited speech by stating Title X projects cannot "promote," "refer for," "support" or "take any other affirmative action to assist a patient to secure such an abortion."[100]

As the Supreme Court recently observed in *National Institute of Family & Life Advocates v. Becerra*, "regulating the content of professionals' speech 'poses the inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to suppress unpopular ideas or information.'"[101] The regulation of medical professionals' speech in particular presents heightened concerns because "[d]octors help patients make deeply personal decisions, and their candor is crucial."[102] Furthermore, "[t]hroughout history, governments have manipulated the content of doctor-patient discourse to increase state power and suppress minorities."[103]

In this instance, the risks of suppression by the Proposed Rule are significant yet unaddressed by the Department. Title X is designed to provide voluntary family planning services for low-income families.[104] In imposing such speech restrictions on Title X recipients and in turn, the beneficiaries of those programs, many of whom may not have access to other family planning

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[99] 500 U.S. 173 (1991); *see* 83 Fed. Reg. at 25,504.
[100] 83 Fed. Reg. at 25,531 (emphasis added).
[101] 138 S. Ct. 2361, 2374 (2018) (citation omitted).
[102] *Id.* (citation omitted).
[103] *Id.* (citation and quotation marks omitted).
[104] *See* 42 U.S.C. § 300a-4(c).

information or programs, the Department restricts a vulnerable population's access to information and a doctor's ability to provide that information. It also conflicts with recent Supreme Court precedent limiting how such vital speech may be regulated.[105]

b. The proposed ban on referrals for abortion requires Title X grantees to adopt the Department's view of medically-appropriate options for pregnant women as their own.

Not only does the proposed rule unconstitutionally restrict the speech of health care providers within a Title X program, but due to the realities of administering these programs, it also impermissibly prevents Title X grantees from holding alternate views about acceptable methods of family planning outside the context of Title X.

While Congress is permitted to impose conditions on federal programs, there is a relevant distinction "between conditions that define the federal program and those that reach outside it."[106] In *AID v. All. for Open Soc'y Int'l, Inc. (AOSI)*, the Supreme Court held that a policy requirement compelling a grant recipient to adopt a particular belief in order to receive funding violated the First Amendment.[107] In contrast with the policy requirement at issue there, the Supreme Court noted in *AOSI* that the 1988 Rule in *Rust v. Sullivan* only governed the scope of Title X projects; it did not otherwise limit a grantee's ability to engage in activities outside of the project.[108]

As noted above, the current Proposed Rule, unlike the rule in *Rust v. Sullivan*, broadly prohibits even support for abortion as a method of family planning.[109] In enacting such sweeping prohibitions, the Proposed Rule will interfere with a grantee's First Amendment rights outside of the scope of a Title X project. A Title X grantee cannot realistically provide a woman with medically appropriate family planning options consistent with the Proposed Rule and yet separately inform her about other medically appropriate options such as abortion outside of Title X—the Proposed Rule requires a health care provider to affirmatively inform a woman who asks that abortion is not considered a method of family planning and to refer her for prenatal care and social services.[110] And the medical professional who provides care with Title X funds can only adopt one view or policy regarding abortion as a method of family planning: the government's.[111]

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[105] *See Nat'l Inst. of Family & Life Advocates*, 138 S. Ct. at 2375 ("[T]he best test of truth is the power of the thought to get itself accepted in the competition of the market, and the people lose when the government is the one deciding which ideas should prevail." (citation and quotation marks omitted)).
[106] *AID v. All. for Open Soc'y Int'l, Inc. (AOSI)*, 570 U.S. 205, 217 (2013).
[107] *Id.* at 218, 221.
[108] *AOSI*, 570 U.S. at 217 (citing *Rust*, 500 U.S. at 196).
[109] 83 Fed. Reg. at 25,531.
[110] *See, e.g.*, 83 Fed. Reg. at 25,532 (Example 5).
[111] *See AOSI*, 570 U.S. at 218 ("A recipient cannot avow the belief dictated by the Policy Requirement when spending Leadership Act funds, and then turn around and assert a contrary belief, or claim neutrality, when participating in activities on its own time and dime.").

As a result, the Proposed Rule necessarily reaches a Title X grantee's activity outside of the context of a Title X project.

Moreover, the Proposed Rule necessarily reaches activities beyond Title X by limiting the post-conception options medical professionals may provide. The Department notes at multiple points that Title X projects are not intended to provide post-conception care.[112] By definition, referrals of any kind provided to a pregnant woman are referrals to a program outside the scope of Title X. Even so, the Proposed Rule strictly regulates these post-conception referrals, including by requiring projects to refer all pregnant patients to prenatal or social services, and by regulating the list of health care providers given to a pregnant woman upon her request.[113] This restriction exceeds the scope of Title X and in turn, violates the Supreme Court's prohibition on conditions that reach outside of a particular program.

B. Addition of "Physical and Financial" Separation Requirement (§ 59.15).

The Department proposes to require Title X projects to ensure that project activities are "physically and financially" separate from abortion-related activities. The Department's proposal is unfounded for several reasons. First, the asserted legal basis for requiring "physical and financial" separation is flawed. Second, the Department's public policy justification for the proposed "physical and financial" separation requirement is inadequate and fails to grapple with a number of problems. Third, the regulatory text intended to give effect to the "physical and financial" separation requirement is insufficiently clear. Fourth, the imposition of this requirement would raise serious constitutional questions. Thus, the Department's proposed "physical and financial" separation requirement should be withdrawn. Also, we respond in the negative to the Department's question about whether "organizational separation" or distinct names should be required for non-Title X and Title X facilities.

1. The Department's proposal to require "physical and financial" separation rests on a flawed interpretation of federal law.

The Department's proposed "physical and financial" separation requirement is neither required nor justified by Title X. In fact, integration of Title X projects with other family planning services is consistent with Congress's goal to make effective family planning services widely available to low-income communities. The House Report emphasized that Title X was intended "to assure the *coordination*, supervision, administration, and evaluation of domestic family planning services."[114] Requiring Title X projects to be physically separated from other family planning services that might include the provision of abortion works against this goal of providing coordinated family-planning services and counseling.

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[112] *See* 83 Fed. Reg. at 25,518, 25,529.
[113] *See* 83 Fed. Reg. at 25,531.
[114] H. Rep. No. 91-1472, at *4 (emphasis added).

Subsequent congressional action also indicates a clear intent to continue to support integrated family-planning services. In reauthorizing Title X, the Senate Labor and Public Welfare Committee stated that "it is essential that there be close coordination and, wherever possible, integration of family planning services, into all general health care programs."[115] This desire for coordination and integration stemmed from the view that it would provide the most effective implementation of Title X programming. Congress was well aware that such integration of Title X programs with larger family-planning clinics could, and often did, result in the programs being located "down the hallway" from abortion providers.[116] Nonetheless, Congress has continued to favor integrated services, defeating a 1978 proposal that would have had similar effects to the rule proposed here.[117] In fact, from the beginning the Department has provided grants to facilities colocated with abortion services providers. To the extent that the Proposed Rule results in the disintegration of Title X projects and broader family-planning services, it is inconsistent with Title X's purpose.

2. *The Department offers inadequate evidence for its proposed "physical and financial" separation requirement.*

The Department focuses its policy rationale for the proposed "physical and financial" separation requirement on the need for "a clearer, more transparent system of separation and accountability," citing the "risk of intentional or unintentional use of Title X funds for impermissible purposes, the co-mingling of Title X funds, and the appearance and perception that Title X funds being used in a given program may also be supporting that program's abortion activities."[118] One would expect that allegations as serious as these would be based in convincing evidence. Yet, not only does the Department offer no evidence of actual misuse of Title X funds, the Department offers almost nothing to show any "risk," either actual or perceived, that Title X funds are being misused.

First, the Department provides zero evidence for many of the serious allegations it makes. For instance, the Department provides no examples of the "unintentional use of Title X funds for impermissible purposes" in its rationale to justify the "physical and financial" separation requirements. In other parts of the preamble, the rare examples of financial errors it does

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[115] S. Rep. No. 63, 94th Cong., 1st Sess. 65-66 (1975), reprinted in 1975 U.S. Code Cong. & Admin. News 469, 528.

[116] *See, e.g.*, 124 Cong. Rec. 37046 ("But, you mean to say, here is a good institution and they cannot run a family planning clinic because somewhere down the hallway—somewhere in an operating room—they might have at some time performed an abortion or they might perform an abortion." (statement of Rep. Rogers)).

[117] 124 Cong. Rec. 37045 (1978). Rep. Dornan's proposed amendment required that "[n]o grant or contract authorized by this title may be made or entered into with an entity which directly or indirectly provides abortion, abortion counseling, or an abortion referral services." Concerned with the alleged "difficult[y] of segregat[ing] funds" given to grant recipients such as Planned Parenthood, the amendment would have prevented organizations with family planning programs and abortion referral services from "redirect[ing] funds." Congress rejected the amendment which, in effect, would have "allow[ed] no Federal funding to such groups."

[118] 83 Fed. Reg. at 25507.

highlight are fully addressable under the current regulatory framework. The Department provides no evidence that the current regulatory framework is insufficient and does not even allege otherwise. Even more absurd is the Department's stated concern about the "intentional" misuse of funds for prohibited activities without even an iota of evidentiary support. The Department provides no evidence that "confusion" is created by the current requirements. The Department also fails to offer any evidence of the "appearance or perception" that Title X funds are being misused. And it does not provide any authority for its contention that there is "public confusion over the scope of Title X services, whether Title X projects provide abortion services, and whether the Federal government (and, ultimately, Federal taxpayers), is funding abortion services provided by organizations that are recipients (or subrecipients) of Title X grants/funds."[119] As central as these statements are to the Department's rationale for its proposed "physical and financial" separation requirement, the Proposed Rule contains nothing in support of them.

As evidence of this alleged risk, the Department cites a series of Guttmacher Institute reports, the most recent of which was from 2014, showing an increase in both the proportion of abortions provided at "nonspecialized clinics" (clinics whose primary services are not abortion) and the proportion of such clinics offering abortion between 2008-2014, while the number of "abortion clinics" dropped.[120] The Department speculates that perhaps these clinics could be recipients of Title X funds.[121] Yet the reports provide no information about how many nonspecialized clinics are Title X service sites, so the Department cannot draw this conclusion.[122] This apparently dramatic growth in the provision of abortion at Title X service sites is also contradicted by the Department's later estimate of abortion providers in Title X. In the Proposed Rule's Regulatory Impact Analysis, based on a Congressional Research Service report, the Department estimates that no more than 10 percent of Title X service sites also provide abortion.[123] In sum, the Department is unable to show that an actual risk exists at all.

This hypothetical risk, moreover, certainly would not rise to a level of seriousness that would warrant the Department's proposed "physical and financial" separation requirement. Even if the Department were able to reliably show that an increasing number of Title X-funded facilities also offer abortion (it cannot), this would not mean that Title X funds are being, or even might be, misused for abortion. This is simply not enough to justify the Department's costly and intrusive proposal. Common sense dictates that the Department must, using evidence, take the additional step of locating this alleged hazard somewhere on the wide continuum between minor and serious risks. Then, based on this objective evaluation, the Department must decide whether regulation is warranted in the first place; and if so, the proposed regulatory solution

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[119] *Id.*
[120] *Id.*
[121] *Id.*
[122] *See, e.g.*, Jones, R.K., Jerman, J., Abortion incidence and service availability in the United States, 2014, Guttmacher Institute Perspectives on Sexual and Reproductive Health (Jan. 17, 2017), available at https://www.guttmacher.org/sites/default/files/article_files/abortion-incidence-us.pdf.
[123] 83 Fed. Reg. at 25,525 ("A Congressional Research Service report estimates that 10 percent of clinics that receive Title X funding offer abortion as a method of family planning separately from their Title X-funded activities.").

would have to be proportionately tailored to the estimated risk. To do otherwise would waste the Department's resources and impose unnecessary costs on regulated entities. It would also introduce inconsistency in the current administration's approach to regulation, which aims to "make regulation efficient, effective, and appropriately tailored."[124] The Department's reference to the mere risk of perceived confusion is radically inadequate to justify the proposed regulatory solution.

Finally, the Department's contends that its proposed "physical and financial" separation requirements would solve the imaginary confusion caused by the current requirements by instituting a "bright-line rule."[125] Yet the characterization of the Proposed Rule's regulatory text as a "bright-line rule" or "clearer [and] more transparent" is plainly false. In reality, the Proposed Rule would grant broad discretion to the Department to evaluate an individual Title X recipient's compliance with a "facts and circumstances" test. In its assessment, the Department would be instructed to consult the four factors enumerated at proposed section 59.15(a)-(d). This resembles more closely a multi-factor standard than a "rule," let alone a "bright-line" one with definitive, predictable results.[126] Under the nebulous proposed standard, regulated entities are given almost no notice of what would be required to comply. Nowhere does the rule constrain the Department's latitude in making judgments about compliance, encouraging arbitrary enforcement. Any guidance on how each factor would be weighted or operationalized in the Title X health care setting is conspicuously absent. Recipients of Title X funds, at a loss to divine the Department's intent, would be thrown into deep, costly uncertainty after decades of successful adherence to the existing regulatory framework for separation. In sum, if the Department's objective is to clarify what is required, its proposed "physical and financial" separation standard cannot be recommended over the current regime.

3. The Department fails to address a number of problems with its proposed "physical and financial" separation requirement.

On top of doing little to show why the proposed "physical and financial" separation requirement is needed, the Department entirely avoids discussion of a number of the proposal's obvious defects and costs. It appears that these problems, together, would amount to harms far in excess of the proposal's asserted benefits. The Department's failure to grapple with these costs render its policy rationale inaccurate and incomplete.

First, the Department vastly underestimates the number of entities that would have to comply with its proposal. The Department assumes that the "physical and financial" separation

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[124] Exec. Order No. 13772, Core Principles for Regulating the United States Financial System, 82 Fed. Reg. 9965 (Feb. 3, 2017).
[125] 83 Fed. Reg. at 25507.
[126] "A legal directive is 'rule'-like when it binds a decisionmaker to respond in a determinate way to the presence of delimited triggering facts" while "[s]tandards allow the decisionmaker to take into account all relevant factors or the totality of the circumstances." *See* Kathleen M. Sullivan, *The Justices of Rules and Standards*, 106 Harv. L. Rev. 22, 58-59 (1992).

requirement would apply only to the estimated 20 percent of Title X service sites that offer abortion or that "may share resources with unaffiliated entities that offer abortion as a method of family planning."[127] But this does not reflect an accurate reading of the Proposed Rule.

As provided in proposed section 59.15, "[a] Title X project must be organized so that it is physically and financially separate . . . from activities that are prohibited under section 1008 of the Act and §§ 59.13, 59.14, and 59.16 from inclusion in the Title X program." This presumably extends the separation requirement with the same force to a range of conduct beyond providing abortion services to patients. For instance, it also applies to entities that refer for, promote, or support abortion, or that take "any other affirmative action to assist a patient to secure" an abortion (proposed section 59.14). The requirement also applies to entities that encourage or advocate for abortion (proposed section 59.16). This includes lobbying and political activity related to abortion; paying dues to certain organizations; and the provision of information "promoting a favorable attitude" toward abortion. It follows from the terms of the Proposed Rule that any recipient of Title X funds that engages in any of these activities would have to comply with the "physical and financial" separation requirement. All Title X-funded services sites at minimum currently refer for abortion upon request, and many undoubtedly perform some of the other activities prohibited by the provisions cited in proposed section 59.15.

As we mention above, some Title X service sites will decline to continue to participate as Title X recipients if the Proposed Rule is made effective. Other Title X service sites may forfeit performing any abortion-related activities, such as providing referrals for abortion, in order to continue participating in Title X without incurring prohibitive compliance costs under the "physical and financial" separation requirement. However, the remaining Title X service sites must take steps to avoid noncompliance with the Department's proposed "physical and financial" separation requirement. This will be far higher than the 20 percent of service sites that the Department identifies in its Proposed Rule, and the Department must properly assess these costs. If, for purposes of these Comments, we assume that the number will be approximately 50 percent of current service sites, even under the Department's estimated average cost per service site of $20,000, which as explained below, is far too low, this would imply costs of $40.0 million ($20,000 x 1,949) in the first year.[128]

The Department estimates that, on average, each affected Title X service site would incur $20,000 in costs in order to come into compliance. The Department does not support this estimate with any evidence based in actual practice. In fact, our experience assisting local affiliates that are renovating or building new facilities leads us to believe this significantly underestimates the total compliance costs.

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[127] 83 Fed. Reg. at 25,525.

[128] Fowler, C. I., Gable, J., Wang, J., & Lasater, B., Family Planning Annual Report: 2016 national summary (Aug. 2017), available at https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf (reporting 3,898 service sites in 2016).

To start with, the Department provides an underestimate of the resources needed to initially evaluate compliance at the service site- and grantee-levels. As shown above, the proposed "physical and financial" separation requirement amounts to a "facts and circumstances" standard under which the Department has significant latitude to make judgments about a Title X-funded entity's compliance. The use of a multi-factor test creates administrative costs that are not anticipated in the Proposed Rule. For example, it will be time-intensive to predict precisely how the proposed standard will be interpreted and applied in particular circumstances—either by the Department to a recipient, or by a recipient to its subrecipients. This uncertainty, moreover, also has other effects on the behavior of Title X recipients that is relevant to the costs of the Proposed Rule. Since the proposed regulatory text is so unclear, errors are more likely to occur in the administration of the "physical and financial" separation requirement: both incorrect judgments by the Department about what is allowable, and erroneous interpretations on the part of recipients. Unable to ascertain the precise boundaries of the regulation, risk-averse recipients are more likely to take precautions that are, strictly speaking, unnecessary and costly in order to avoid the risk of noncompliance. This confusion is made worse because the Proposed Rule, after instructing the Department to use a case-by-case approach, implies that "two distinct services collocated within a collocated space" would be banned,[129] and that "separate facilities—one facility providing Title X services and one providing abortion"—would be required.[130] Partially as a consequence of this oversteering, the costs borne by Title X-funded entities are likely to exceed the Department's estimated costs for evaluation.

On top of the costs of initial evaluation, Title X-funded entities will have to absorb the costs necessary to implement any changes required to "physically and financially" separate abortion-related activities from Title X project activities. These costs will exceed the Department's estimate by a large margin. We begin with the cost of building and renovating facilities in order to comply. The Proposed Rule would instruct the Department to look to "the degree of separation from facilities (e.g., treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites) in which prohibited activities occur and the extent of such prohibited activities." In the Proposed Rule, this is sometimes referred to as prohibiting the "collocation" of abortion-related activities and Title X activities. To avoid noncompliance, Title X-funded entities would have to either renovate existing facilities or build entirely new ones depending on the circumstances of each individual Title X service site.

To estimate the cost of these activities, we use top-line construction cost estimates from a report produced by Capital Link.[131] Although the report is based on a survey of community health centers, based on our extensive experience assisting local affiliates with constructing and renovating health centers, the costs presented for these facilities closely resemble the costs associated with family planning centers. In assessing costs, Capital Link recommends selecting

[129] 83 Fed. Reg. 25,519.
[130] *Id.*
[131] Capital Link, *Estimating Capital Project Costs for Health Centers* (2011), *available at* http://www.caplink.org/images/stories/Resources/publications/Pub.EstimatingCapitalProjectCosts.pdf.

an estimate between the median and the 75th percentile.[132] So, for these Comments, we assume that new construction will cost $400 per square foot while renovation will cost $330 per square foot. Furthermore, an average family planning center, based on our experience, is between 3,000 and 3,500 square feet, with a central estimate of 3,250 square feet. And although the Capital Link report does not provide an estimate for the cost of acquiring new commercial property, in our experience rental costs range from $50 to $100 per square foot, with a central estimate of $75 per square foot.

For those properties where a renovation of an existing facility is possible (*e.g.*, the addition of separate rooms, exits and entrances, and so on), we assume that at least half of the site's total area would need to be renovated. For such properties, we estimate that costs would be approximately $536,250 per facility (1,625 sq. ft. x $330). Where renovation is not possible, an entirely new location would be needed. For new locations where a pre-existing building exists, the necessary renovations are likely to cost approximately $1.1 million per facility (3,250 sq. ft. x $330), and site acquisition costs would come to approximately $243,750 (3,250 sq. ft. x $75), for an estimated total of $1.3 million per facility. Moreover, new properties with no existing physical plant would incur costs in the range of $1.3 million in new construction costs (3,250 sq. ft. x $400), and site acquisition costs would come to approximately $243,750 (3,250 sq. ft. x. $75), for an estimated total of $1.5 million per facility. We assume, conservatively, that only 10 percent of the service sites that would have to take steps to avoid noncompliance would establish new locations, equally divided between properties that have and do not have a pre-existing building. For the rest, it is assumed that only renovation of existing facilities would be required. We estimate that, even based on these conservative assumptions and assuming 50 percent of the current service sites must take steps to comply, building and renovation costs alone would total $1.2 billion in the first year after the regulation is finalized. This comes to an average cost of nearly $625,000 per affected service site.

In addition to costs directly related to purchasing and building, we note for the Department that obtaining the necessary approvals for locating a facility, especially an abortion facility, is often a lengthy and drawn-out process, implying additional costs for permitting, licensure, and meeting the requirements of targeted regulations. The Department has failed to account for any of these costs.

On top of these building and renovation costs, the Department's proposed "physical and financial" separation standard would appear to require the duplication of certain expenses by Title X-funded entities, including contracts for goods and services and staff time, which would also imply significant costs that the Department fails to acknowledge in the first year and every subsequent year. For example, proposed section 59.15(c) would instruct the Department to look to "the existence of separate personnel, electronic or paper-based health care records, and workstations." It appears that the Proposed Rule would necessitate duplicating contracts for goods and services for each separate facility established to avoid noncompliance with the

[132] Id.

"physical and financial" separation requirement. This would at minimum include duplicate contracts for security vendors, cleaning, medical waste, laboratory services, utilities, electronic health care record systems (including separate licenses for each provider under each software product), phone systems, and web services. Also, additional clinical staff time would be necessary to staff and oversee separate facilities. We estimate this would amount to a permanent increase in clinical staff time of between 50-100 percent, depending on the volume of patients seen at a Title X service site and whether establishing a separate location would be required to avoid noncompliance. We arrive at this 50-100 percent estimated increase because staff roles that would have to be duplicated for each individual facility include, at minimum, a provider to see and treat patients (*e.g.*, physician or other advance practice clinician), 1-2 staff members positioned at the front desk, and 1-2 staff members facilitating patient care (*e.g.*, conducting laboratory work, intake, and follow-up). Moreover, additional back-office staff time would be necessary to perform the additional purchasing and contracting described above. An increase in staff time of this magnitude would almost certainly be accompanied by Human Resources and payroll staff time as well.

Having abandoned its duty to accurately assess compliance costs, the Department also fails to estimate the effect of these unreasonable costs on Title X recipients, many of whom would find it financially impractical, if not impossible, to continue their participation in Title X as a result. As we explain above, the departure of a large number of Title X-funded providers, especially reproductive health-focused providers, would reduce access to family planning care with attendant negative impacts on health outcomes and population health.[133] To summarize, Planned Parenthood and other reproductive-health focused providers play an outsized role in serving Title X patients and are more likely than other types of providers to offer a broad range of quality family planning services. If these providers are forced to exit the program, the Department would, in many communities, find it difficult or impossible to identify alternative entities that are able to serve the same volume of patients with the same range of services at the same level of care. Forced to delay or forgo basic preventive services as a result, many patients that previously were able to access Title X-funded care from Planned Parenthood or other reproductive health-focused providers would experience adverse health consequences, including unintended pregnancies, undetected STDs, and other poor health outcomes. This would create costs for patients, the health care system, and the public.

Also, for the few entities that are willing and able to absorb these costs, the proposed "physical and financial" separation requirements would harm patients by interfering with quality of care, care coordination, and integration of services. For example, patients benefit from immediate, onsite access to a range of contraceptive methods after an abortion. According to a 2010 Guttmacher Institute survey of abortion patients, two-thirds expressed a desire to leave their appointment with a contraceptive method and slightly more than half indicated a preference for receiving contraceptive information and services during their abortion care rather than in other

[133] *See supra*, p.15.

health care settings.[134] Yet the provision of same-day post-abortion contraception funded by Title X appears to be severely restricted or barred entirely under the proposed "physical and financial" separation requirement. Instead, two separate visits to separate facilities would be necessary. This implies unnecessary costs to patients and providers that are unaccounted for by the Department and interferes with the integration of care. Furthermore, to the extent that this creates an obstacle for patients to obtain effective methods of contraception, the risk of unintended pregnancy among abortion patients may increase as a result.

On top of interruptions to same-day services, the Department's proposal to consider separate electronic health care records in its determination of compliance with the "physical and financial" separation requirement poses considerable health risk to patients. A qualitative study of multiple electronic medical records within a single health care organization found "clear limitations" to this approach, the primary limitation being "the risk to patient safety."[135] "The greatest risk of multiple EMR use is the risk of missing data and any corresponding decision support that impact patient safety," for example, missing information about allergies or drug interactions; lab tests, imaging studies and procedures; "missing pregnancy or lactation information leading to inappropriate medication ordering, missing recent changes in renal function leading to inappropriate use of IV contrast dye, and incomplete or inaccurate past medical history or family history leading to inaccurate risk assessments."[136] These same risks would likely arise in the implementation of the Department's proposed "physical and financial" separation requirement. The same study notes that "to safely and efficiently use more than one EMR, a considerable amount of IT work is necessary," implying necessary additional expenditures by Title X projects to ensure patient safety.[137]

4. The Department's regulatory text would give recipients insufficient notice of the conduct prohibited under the "physical and financial" separation requirement.

We draw the Department's attention to two areas in particular where the proposed "physical and financial" separation requirement fails to communicate the precise conduct that would be prohibited under the Proposed Rule. We believe the regulatory text therefore does not give Title X recipients sufficient notice about their obligations under the Department's proposal. While we believe that the Department should withdraw the proposal altogether, the Department at a minimum should clarify the following areas, and the Department's clarification should provide a reasoned justification for its policy choice:

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[134] Megan K. Donovan, "Postabortion Contraception: Emerging Opportunities and Barriers," Guttmacher Policy Review (Oct. 2017), *available at* https://www.guttmacher.org/gpr/2017/10/postabortion-contraception-emerging-opportunities-and-barriers (citing the 2010 report).
[135] Payne, Fellner, et al, "Use of more than one electronic medical record system within a single health care organization," Applied Clinical Informatics (Dec. 2012), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3613036/.
[136] *Id.*
[137] *Id.*

- As mentioned above, although the proposed regulatory text at section 59.15 directs the Department to use a multi-factor "facts and circumstances" test in assessing Title X recipients' compliance with the "physical and financial" separation requirement, the preamble repeatedly implies otherwise. For instance, the Department repeatedly and incorrectly characterizes the proposed standard as a "bright-line rule" requiring "one facility providing Title X services and and one providing abortion as a method of family planning."[138] And elsewhere, the Department implies that the regulatory text would absolutely bar the "collocation" of Title X services within the same facility at which abortion-related activities are performed.[139] These inconsistencies compound the opacity of the regulatory text itself, which provides little guidance for Title X-funded entities seeking to avoid noncompliance.

- Also, the regulatory text contains errors that make it difficult to discern precisely what types of prohibited activities are subject to the proposed "physical and financial" separation requirement. For example, proposed section 59.15 requires separation from "activities that are prohibited under section 1008 of the Act and §§ 59.13, 59.14, and 59.16." Yet the "physical and financial" separation standard does not integrate proposed section 59.5(a)(5), which would require that projects "[n]ot provide, promote, refer for, support, or present abortion as a method of family planning." Also, while the regulatory text would require the separation of activities prohibited under proposed section 59.13 from Title X project activities, that section does not itself prohibit any conduct at all. Rather, that section proposes to require recipients to provide assurances to the Department that it will meet a number of abortion-related requirements. The Department should address these errors.

5. The proposed "physical and financial" separation requirements would violate the constitutional rights of Title X recipients.

The Proposed Rule also impermissibly—and unconstitutionally—burdens a Title X grantee's ability to perform abortions or provide counselling or referrals for abortion outside of the Title X project. In Rust v. Sullivan, the Supreme Court held that while the federal government can "refuse[] to fund" abortion-related activities "out of the public fisc," it cannot "den[y]" recipients of Title X funds "the right to engage in [such] activities."[140] In *Agency for International Development v. Alliance for Open Society International, Inc.*, the Supreme Court reaffirmed this restriction, holding that the government cannot impose conditions on a program receiving federal funding if "the condition by its very nature affects 'protected conduct outside the scope of the federally funded program.'"[141]

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[138] 83 Fed. Reg. at 25,507, 25,519.
[139] 83 Fed. Reg. at 25,519.
[140] *Rust v. Sullivan*, 500 U.S. 173, 198 (1991).
[141] 570 U.S. at 218–19 (*AOSI*) (quoting *Rust*, 500 U.S. at 197).

The Proposed Rule does exactly that. It takes aim at a fundamentally protected right and places such strict conditions on the recipients of federal funding so as to essentially "prohibit[ ] the recipient from engaging in the protected conduct outside the scope of the federally funded program."[142] The Department could (permissibly) prevent the expenditure of public money for prohibited abortion-related activities by requiring Title X grantees to use "counseling and service protocols, intake and referral procedures, material review procedures, and other administrative procedures" to ensure that abortion-related activities are not part of the Title X project, and to pro-rate the cost of shared facilities and resources, such as waiting rooms, staff, and health record systems.[143] But the Proposed Rule instead would require Title X grantees to separate their abortion-related activities to such an extent that they are essentially being performed by a separate entity and would impose prohibitive costs on Title X grantees wishing to perform those activities. Such a condition on federal funds is unconstitutional.

First, mandating the creation of a separate, abortion-free entity is not a permissible condition on federal funds. In *AOSI*, the Supreme Court held that the government could not condition a *project's* funding on an entire *organization's* adoption of the government's stance on an issue. Here, compliance with the Proposed Rule would require changes to the grantee outside its Title X project, including to its public image and non-Title X services. The Proposed Rule requires such strict separation that the public will no longer recognize the Title X project as being connected to the same entity that is providing abortion-related services outside of the Title X program. In other words, an organization must purge all of its aspects that are contrary to the government's stance on abortion—just what *AOSI* prohibits.[144]

Second, given the high costs of complying with the physical separation requirements, facilities would have to sacrifice their non-Title X program to continue to receive Title X funding, or vice versa. For example, the Proposed Rule suggests that grantees will have to establish separate office entrances and exits, phone numbers, email addresses, websites, health care records, and workstations.[145] These requirements would compel grantees to establish and maintain two facilities (including, possibly, two buildings), two sets of staff, and two health record systems. Such onerous requirements would force many Title X grantees to choose between receiving Title X funds and providing abortion-related services. As such, these requirements are not just conditions "that define the federal program" but ones that "reach outside it" because they necessarily affect the organization's non-Title X projects.[146]

Indeed, the Proposed Rule would adopt some of the requirements that were initially included—and subsequently rejected—in the 1988 Rule. For example, the Proposed Rule

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[142] *Rust*, 500 U.S. at 197.
[143] *See Provision of Abortion-Related Services in Family Planning Services Projects*, 65 Fed. Reg. 41281, 41282 (July 3, 2000).
[144] *See AOSI*, 570 U.S. at 220-221 (the government cannot condition its award of funds so as to require grantees "to pledge allegiance to the Government's policy").
[145] 83 Fed. Reg. at 25532.
[146] *AOSI*, 570 U.S. at 217.

mentions separate office entrances and exits. Although the proposed 1988 Rule included a similar requirement, the administrative record demonstrated that it would be difficult for public organizations and rural sites to comply, and the 1988 Rule rightly abandoned that requirement. Similarly, the final 1988 Rule did not include a proposed prohibition on shared telephone numbers and receptionists. The Proposed Rule also suggests a separation of electronic or paper-based health care records. A similar requirement was objected to in 1988 because of the challenges that it might pose to providing continuous and consistent care and the risk for poor medical management. These concerns are perhaps even more acute today given the widespread use of electronic record systems.

Supreme Court decisions in this area are instructive and demonstrate that the proposed separation requirements fall well on the side of impermissible conditions. For example, in *F.C.C. v. League of Women Voters of California*, the Supreme Court struck down a ban forbidding any noncommercial educational station receiving federal funds from editorializing.[147] In *AOSI*, the Supreme Court explained its holding in *League of Women Voters* as resting on the fact that "the law provided no way for a station to limit its use of federal funds to noneditorializing activities" and that the prohibition thus "went beyond ensuring that federal funds not be used to subsidize" a certain activity.[148] Similarly here, compliance with the strict separation requirements will necessarily affect any Title X grantee's non-Title X programming, not just the Title X project itself. Compliance with the Proposed Rule will require changes to any Title X grantee's other programming—specifically the type of restriction prohibited in *League of Women Voters*.

The conditions imposed here are also not like the conditions upheld in *Regan v. Taxation with Representation of Washington*. There, the Supreme Court upheld the conditioning of tax exemptions for § 501(c)(3) organizations on a requirement that the organization not engage in lobbying.[149] In a concurrence, Justice Blackmun emphasized that the Court's holding that the condition did not violate the First Amendment rested on the assumption that a § 501(c)(3) non-profit organization and a § 501(c)(4) lobbying affiliate need only to be "separately incorporated and keep records adequate to show that tax deductible contributions are not used to pay for lobbying."[150] Justice Blackmun concluded that "[a] § 501(c)(3) organization's right to speak is not infringed, because it is free to make known its views on legislation through its § 501(c)(4) affiliate without losing tax benefits for its nonlobbying activities."[151] In other words, the constitutionality of the condition turned on the fact that maintaining two separate organizations was practicable. That is not the case here. The Proposed Rule goes far further in its separation requirements and, as such, limitations on the use of funds for the Title X project cannot be distinguished from the Title X grantee's other programming and impermissibly affect its ability to operate.

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[147] 468 U.S. 364, 399 (1984).
[148] 570 U.S. at 216.
[149] 461 U.S. 540, 550 (1983).
[150] *Id.* at 553 (Blackmun, J., concurring) (citation omitted).
[151] *Id.*

In short, the Proposed Rule gives organizations an unconstitutional choice: take funding for Title X projects and eliminate abortion from their organization, or pass on the funds.

If grantees do take the funds under this condition and abandon their abortion services, then the Proposed Rule will also place an undue burden on a woman's ability to seek an abortion by overly restricting access. Under Casey, "a statute which, while furthering [a] valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends."[152] In particular, "[u]nnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right."[153] As explained by the Court in *Whole Woman's Health*, an assessment of whether a regulation imposes an undue burden "requires that courts consider the burdens a law imposes on abortion access together with the benefits those laws confer."[154]

Here, the Proposed Rule will place substantial burdens on a woman's access to abortion. The implementation of stringent, costly, and more restrictive factors by which "[t]he Secretary will determine whether such objective integrity and independence exists" is likely to make it prohibitively expensive for recipients of Title X funding to provide abortion services outside of their Title X project, thus resulting in the elimination of abortion services. To the extent that Title X grantees are forced to cease providing abortion services, this will mean "fewer doctors, longer waiting times, and increased crowding" for the providers that remain.[155]

On the other side of the balance, the Proposed Rule does not convey any benefits to either the government or the recipients of Title X services. Indeed, the Proposed Rule actually runs counter to the purposes of Title X by risking diminished access for low income families to health care. While the Proposed Rule mentions "case-by-case determinations" of physical separation, the Proposed Rule also repeatedly refers to the benefits of establishing a bright-line rule through the proposed requirements. Even a case-by-case approach is likely to impose significant costs because unclear rules, which will incentivize facilities to over-comply for fear of being in violation.

To justify the separation requirements, the Proposed Rule cites concerns about the misuse of Title X funds for abortion services. However, the Proposed Rule at the same time concedes that there are "only a few cases involv[ing] documented misuse of Title X funds or violation of Title X's financial requirements,"[156] and the Department cites no evidence to show that the misuse of funds for a prohibited purpose is a legitimate state concern that will be remedied by

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[152] *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 877 (1992); *see also Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016), *as revised* (June 27, 2016).
[153] *Whole Woman's Health*, 136 S. Ct. at 2309 (quoting *Casey*, 505 U.S. at 877).
[154] *Id.*
[155] *Id.* at 2313.
[156] 83 Fed. Reg. at 25,510.

the proposed separation requirements. Accordingly, the benefit of preventing potential misuse of Title X funds is severely outweighed by the burden of the substantial costs imposed by these separation requirements and the likely closure of many abortion-providing facilities.

In sum, the Proposed Rule will impose significant burdens on any recipient of Title X funding through its stringent separation requirements. These burdens, which outweigh any of the Proposed Rule's benefits, will not only have the effect of diminishing access to abortions but also more broadly affect any Title X grantee's programming, both inside and outside of the Title X project.

6. The Department should not require "organizational separation" or different names for Title X and abortion providing entities.

The Department asks whether it should require even more than "physical and financial" separation between Title X project and abortion activities, "such as a requirement for a Title X clinic to operate under a distinct name from a facility that provides abortion as a method of family planning, or for organizational separation."[157] In suggesting these potential regulatory options, the Department attempts to appeal to the "confusion" that it claims is created by Title X and non-Title X facilities sharing the same name or belonging to the same organization.[158] It also suggests that a lack of "organizational separation" may make enforcement more difficult.[159]

The Department, however, provides no evidence supporting either of the proposals it advances. While the Department speculates that patients would be "confused" about whether abortion is included as a Title X-funded service, as we show above, the Department fails to provide any evidence of "confusion" under the current regulations. And, even if we were to accept the Department's conjecture that this confusion exists, there are many less costly and less intrusive ways to make the public aware that Title X funds are not used for abortion. For example, the Department could require this message to be integrated into each Title X project's community outreach activities or written materials. But no alternative means to reduce the alleged "confusion" are discussed in the Proposed Rule. This absence is noteworthy considering the costly changes that are proposed. Moreover, though the Department worries that a lack of "organizational separation" may make enforcement more difficult, it makes no effort to elaborate on its concern. Instead, the Department provides, apparently as an example of its enforcement concerns, a hypothetical situation: a patient seeking Title X services mistakenly goes to a non-Title X facility because it shares a name with, or belongs to the same organization as, a Title X service site. It turns out that abortion is provided at the non-Title X facility.[160] We find no rational connection between the hypothetical lost patient and the Department's predicted enforcement difficulties. Indeed, enforcement aside, it is not clear what to make of the

[157] 83 Fed. Reg. at 25,519.
[158] *Id.*
[159] *Id.*
[160] *Id.*

Department's example. Surely the lost patient, unable to obtain Title X services at the location in question, would draw the conclusion that the facility does not receive Title X funding.

It is also obvious that this question is intended as yet another way to affect the participation in the program by Planned Parenthood health centers in particular, despite the fact that, as laid out in detail elsewhere in these comments, Planned Parenthood health centers have decades of experience providing services as part of the Title X program and typically provide superior services compared to other providers. The Department's desire to make it impossible for Planned Parenthood, in particular, to participate in the program is not a valid regulatory justification.

Because these proposals would only serve to expand the effect of the Title X rules on non-Title X activities, for the reasons we give above, we also believe neither of these options would be consistent with the Department's statutory authority under Title X, nor would they be constitutional.

C. New Requirements on The "Appropriate Use of Funds" (§ 59.18).

The Department proposes new requirements governing the "appropriate use of funds," including restrictions on the use of Title X funds to "build infrastructure for purposes prohibited with these funds, such as support for the abortion business of a Title X grantee or subrecipient."[161] There are a number of problems with the proposed requirements. First, the Department's proposed infrastructure restriction lacks a basis in law. Second, the Department's policy rationale for its proposed requirements on the use of Title X funds is insufficient. Finally, the Department's proposed regulatory text is unclear. We therefore urge the Department to withdraw its proposed requirements on the "appropriate use of funds."

1. *The Department's proposed restrictions on the use of Title X funds lack a basis in law.*

The legislative history of Title X and section 1008 does not support the prohibition on infrastructure-building at proposed section 59.18(a). Indeed, the legislative history does not reflect a concern about using Title X for infrastructure building or that such use might result in an inappropriate fungibility of assets. Infrastructure is barely mentioned in the legislative history of Title X, but to the extent it is, concerns about the need for improved infrastructure for family planning are cited as a reason *in favor* of additional funding.[162] Moreover, the use of Title X funds to build infrastructure supports the broader purposes of Title X: to make "comprehensive voluntary family planning services readily available to all persons desiring such services."[163]

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[161] *Id.* at 25,533.
[162] *See, e.g.*, Family Planning Services and Population Research Act of 1970, Pub. L. No. 91-572, § 2, 84 Stat. 1504 (1970) ("How can the States, the State of California, or the other 49 States, create the infrastructure they need for family planning unless they receive the necessary funds to do so?").
[163] *Id.*

Congress's primary goal was to expand the *availability* of family-planning services to low-income communities, and infrastructure is an essential component of expanding availability. There is no indication that Congress was concerned with limiting the uses of infrastructure built with Title X funds. As long as the funds serve their primary purpose of expanding availability to family-planning services, there is no prohibition on using infrastructure built with Title X funds for other purposes; the objectives of Title X are in no way impeded by such use.

2. *The Department offers little evidence that its proposed requirements on "the appropriate use of funds" are necessary.*

The Department is unable to justify its new requirements on the "appropriate use of funds" using evidence or data. We first address the deficient rationale advanced by the Department to implement restrictions on the use of Title X funds for infrastructure at proposed section 59.18(a). Then, we turn to the inadequate evidence presented by the Department to support its proposal to impose other requirements on Title X projects regarding the use of grant funds.

a. *The Department's rationale for its proposed infrastructure restrictions is deficient.*

At proposed section 59.18(a), the Department proposes to ban the use of Title X funds to "build infrastructure for purposes prohibited with these funds, such as support for the abortion business of a Title X grantee or subrecipient." The same provision would also require that Title X projects "use the majority of grant funds to provide direct services to clients," and any change in the use of funds would have to be reflected in newly required reporting. According to the Department, these changes are motivated by a concern that "the current flexibility in the usage of Title X funds permits an interchangeability of assets that grantees may have used to build infrastructure for non-Title X purposes, including abortion services."[164] The Proposed Rule, however, cites no data or evidence underlying such concerns or showing that Title X funds are in fact used as "fungible assets" to build infrastructure to provide abortion services.

The Proposed Rule relies on the faulty premise that Title X funds used for infrastructure building are in fact used to build infrastructure for abortion services. There is no evidence to support this contention. The Guttmacher Institute papers cited in the Proposed Rule show that Title X funds help support critical infrastructure to provide more access to family planning.[165] In this regard, the Guttmacher Institute's research shows that Title X has been an effective method for women with low incomes to receive high-quality family planning and preventive health care, including

[164] *Id.* at 25,521.

[165] *See, e.g.*, Gold, R. B., Stronger Together: Medicaid, Title X Bring Different Strengths to Family Planning Effort, Guttmacher Institute (May 17, 2007), https://www.guttmacher.org/gpr/2007/05/stronger-together-medicaid-title-x-bring-different-strengths-family-planning-effort ("Title X funds provide the essential infrastructure support that enables clinics to go on and claim Medicaid reimbursement for the clients they serve.").

through the support of health centers' infrastructure.[166] At the same time, the Guttmacher Institute's research does not indicate that such funds are being used to build infrastructure for abortion services—the critical justification on which the Proposed Rule rests. Moreover, the Department does not show any evidence that the current regulations are not sufficient to ensure Title X funds are not used in this manner.

The Proposed Rule cites as its policy justification that "Title X is the only discrete, domestic, Federal grant program focused solely on the provision of cost-effective family planning methods and services."[167] But this cannot support the Proposed Rule, as any restriction on the use of Title X funds for building infrastructure runs contrary to the stated priority of using Title X funding for family planning. Indeed, the existence of a proper infrastructure is necessary to the provision of any family planning services and promotes increased access to such services.

The Proposed Rule is arbitrary and capricious insofar as it seeks to restrict the use of Title X funding for infrastructure building without any valid or supported justification for such a restriction.

b. The Department's evidence for its proposal to impose additional requirements on the expenditure of grant funds Title X projects is inadequate.

On top of the proposed restrictions on using Title X funds for infrastructure, proposed section 59.18 would require Title X projects to "fully account for, and justify, charges against the Title X grant" along with other changes. In attempting to justify both this proposed change and other proposed amendments to the Title X regulations regarding "expanded monitoring, reporting, transparency, and accountability,"[168] the Department claims that it is concerned about "the potential for misuse of Title X funds and misbilling or overbilling of other Federal or state programs by Title X grantees under the current regulatory scheme."[169] Yet the Department offers no rational explanation for this concern nor for the perceived need for additional controls on Title X funds.

The Department begins its argument by citing studies documenting trends in the misuse or overbilling of Medicaid for family planning services. But, as the Department confirms in the same paragraph, "misuse among Medicaid recipients does not necessarily predict or imply misuse of grant funds among Title X grantees."[170] We are unable to discern the Department's point in highlighting these studies. Indeed, since Medicaid, a "reimbursement" program, is quite distinguishable from federal grant programs like Title X, it is difficult to see how errors with

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[166] *See* Hasstedt, K., *Why We Cannot Afford to Undercut the Title X National Family Planning Program*, Guttmacher Institute (Jan. 30, 2017).
[167] 83 Fed. Reg. at 25,508.
[168] *Id.* at 25,510.
[169] *Id.* at 25,509.
[170] *Id.*

respect to billing Medicaid could "predict or imply" any specific practices in the Title X context. And even if we were to accept the far-fetched notion that these studies bear on the use of Title X funds, the Department fails to allege (and certainly provides no evidence) that the trends in Medicaid billing issues among family planning providers deviate significantly from the rates of payment errors among other, similarly situated Medicaid providers. Moreover, the Department does not explain why it is not considering applying similar regulatory changes to other types of recipients of federal grants that also receive Medicaid family planning reimbursements, such as FQHCs funded under section 330 of the Public Health Service Act. Nor does the Department help its case by prominently citing the "research" of the Lozier Institute, an ideologically-driven organization whose views are far outside of the scientific mainstream and which is fundamentally opposed to allowing Planned Parenthood health centers to provide any publicly funded services because of their provision of safe and legal abortion.

The Department also provides some specific examples of financial errors by Title X grantee organizations, concluding that "[t]hese examples raise concerns about the integrity of the Title X program."[171] Yet upon examination, these do not show the existence of any problem with the use of Title X grant funds. Five out of the seven examples cited are not about Title X at all.[172] As the Department notes, financial errors in other programs "do not necessarily predict or imply misuse of grant funds among Title X grantees" and cannot be used as evidence for the Department's proposed requirements.[173] In fact, the Department's search yielded only two examples of financial errors in the use of Title X grant funds.[174] To base the Department's proposed regulatory changes on a mere two examples that were resolved under the current regulatory regime is unreasonable.

Also, the Department makes broad assertions about common mistakes in the administration of federal grant programs.[175] While problems with the execution of federal grant programs writ-large may justify changes to general regulations governing the requirements on federal awards, these assertions do not illustrate a need for changes to the Title X regulations in particular.

Finally, the Department makes vague reference to Title X's abortion-related requirements in order to conclude that the pre-existing requirements are insufficient. But it fails to provide any evidence or reasoning to show why this would be the case. In fact, several of the Department's proposed requirements on the "appropriate use of funds" closely resemble or are duplicative of existing directives. Consider, for example, proposed section 59.18(a), which provides that "[f]unds shall only be used for the purposes, and in direct implementation of the funded project, expressly permitted with this regulation and authorized within section 1001 of the Public Health

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[171] *Id.* at 25,510.
[172] *Id.* at 25,509-10 (noting examples in New York, Illinois, Pennsylvania, Washington, and Wisconsin that do not involve Title X funds).
[173] *Id.* at 25,509.
[174] *Id.* at 25,509-10 (noting findings of Title X-related errors in Nebraska and Massachusetts).
[175] *Id.* at 25,510.

Service Act, that is, to offer family planning methods and services." It is unclear how this differs from existing instructions to Title X recipients. For instance, current section 59.9 of the Title X regulations provides "[a]ny funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR part 75, subpart E."[176] And Title X's Program Requirements provide

> "All funds granted for Title X family planning services projects must be expended only for the purpose for which the funds were awarded and in accordance with the approved application and budget. Funds may not be used for prohibited activities, such as abortion as a method of family planning, or lobbying. The Notice of Award (NOA) provides other stipulations regarding the use of funds. Funds must be used in accordance with the Title X family planning services projects regulations, the terms and conditions of the award, and the HHS grants administration regulations set out at 45 CFR parts 74 and 92."[177]

Similarly, proposed section 59.18(a) would require "each grantee [to] give a detailed accounting for the use of grant dollars, both in their applications for funding, and within any annually required reporting." And proposed section 59.18(c) would provide that "[e]ach project supported under Title X shall fully account for, and justify, charges against the Title X grant." But the Department fails to show how these apparently new obligations would differ, for instance, from information already provided under existing duties on applicants to provide a detailed budget and budget narrative as a part of their applications, for projects to submit quarterly and final Federal Financial Reports, and for projects to submit applications for non-competing continuation awards annually.[178] Proposed section 59(a), moreover, would require approval from the Office of Population Affairs for "any significant change in the usage of grant funds within the grant cycle." Yet the Department fails to distinguish its proposal from the general grants management rule that requires recipients to "request prior approvals from HHS awarding agencies" for major revisions to budget or program plans.[179] At a minimum, the Department must demonstrate that its proposed changes would not be duplicative of these existing requirements.

3. The Department's regulatory text is unclear.

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[176] 42 C.F.R. § 59.9.
[177] Office of Population Affairs, *Program Requirements for Title X Funded Family Planning Projects*, 10 (Apr. 2014), *available at* https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf.
[178] Department of Health and Human Services, *FY 2018 Announcement of Anticipated Availability of Funds for Family Planning Services Grants*, 24, 55-56 (Feb. 23, 2018), available at https://www.grants.gov/web/grants/view-opportunity.html?oppId=297943.
[179] 45 C.F.R. § 75.308.

In a number of areas, the Department's proposed regulatory text on this subject is unclear. The text, therefore, fails to put grant recipients on sufficient notice as to their obligations. In clarifying these areas, a reasoned justification should also be provided where the Department's clarification reflects a policy choice for which the Proposed Rule fails to offer a justification or explanation.

- In proposed section 59.18(a), the Department seeks to devote a majority of each grantee's Title X funds to the provision of "direct services." The term, however, is not defined. Its meaning is further obfuscated by the Department's statements in the preamble, which appear to classify "bulk purchasing of contraceptives or other clinic supplies, clinical training for staff, and community outreach and recruiting" as infrastructure expenses.[180] Clarification is necessary as many of these costs are closely associated with and necessary for the provision of clinical services.

- In proposed section 59.18(c), the Department provides that it will "put additional protections in place to prevent any possible misuse of Title X funds through misbilling or overbilling." Nowhere else in the Proposed Rule is this provision addressed. Given the open-ended authorization this proposed provision would grant the Department, the Department must clarify its plan to impose additional requirements, describe what form these additional requirements will take, and provide an evidentiary justification for the forthcoming changes.

D. Prohibitions on Lobbying and Political Activities (§§ 59.16, 59.18).

The Department proposes to add requirements to the Title X regulations prohibiting projects from engaging in advocacy, lobbying, and political activities. But it fails to provide sufficient evidence to justify its proposed prohibitions. Also, the proposed regulatory text meant to effectuate the Department's policy objective is unclear. So we urge the Department to withdraw its proposed prohibitions on advocacy, lobbying, and political activities.

1. The Department fails to explain why its proposed prohibitions on advocacy, lobbying, and political activities are justified.

According to the Department, its proposed revisions are justified because, without more "guidance" on the application of restrictions on the use of federal funds for advocacy, lobbying, and political activities in the context of Title X, "it possible that Title X grantees could intentionally, or unintentionally and unknowingly, use Title X funds for prohibited lobbying or political activities."[181] The Department also provides that, because of Title X's abortion-related prohibitions, the general grants-management requirements are insufficient.

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[180] 83 Fed Reg. at 25,508.
[181] 83 Fed. Reg. at 25,510.

The Department provides little evidence or argument to support its contentions. First, the mere "possibility" that Title X-funded entities could inadvertently use Title X funds for prohibited activities does not justify the proposed regulations. Beyond simple conjecture, the Department must establish, using evidence, that the level of risk crosses a threshold of seriousness to warrant specific regulations. Otherwise it is unreasonable to impose the cost of complying with the Proposed Rule on Title X projects. Yet the Department produces no supporting evidence or examples where Title X funds were used to lobby or engage in political activities. The Proposed Rule is therefore unjustified.

Nor is it necessary, given the current regime. The Department also claims that more guidance is needed on the application of existing restrictions to Title X recipients, and that existing requirements are not enough. We disagree. First and foremost, Title X recipients are repeatedly made aware that they are prohibited from using project funds to engage in *any* activities not outlined in the approved project.[182] This would necessarily prohibit lobbying, advocacy, and political activities. The Department is empowered, under 45 C.F.R. § 75.371, to use a number of approaches to remedy findings of noncompliance, including termination of the grant where necessary. Moreover, Title X recipients already receive specific guidance on complying with federal restrictions on lobbying and political activities using grant funds from the Department. For instance, the Title X Funding Opportunity Announcement itself includes a description of prohibited lobbying activities.[183] Indeed, the Funding Opportunity Announcement refers to Department-wide regulations that similarly detail prohibited lobbying activities.[184] And the Department's website devotes a webpage on compliance with restrictions on the use of federal grant funds for lobbying and political activity,[185] which includes information recounted by the Department in the preamble to the Proposed Rule. So there is no shortage of guidance already available to Title X recipients on rules related to advocacy, lobbying, and political activities. Nor does the Department lack the tools to remedy the improper use of Title X funds for advocacy, lobbying, or political activities, if any improper uses in fact take place.

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[182] 42 C.F.R. § 59.9 ("Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR part 75, subpart E."); Office of Population Affairs, *Program Requirements for Title X Funded Family Planning Projects*, 10 (Apr. 2014), available at https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf ("All funds granted for Title X family planning services projects must be expended only for the purpose for which the funds were awarded and in accordance with the approved application and budget."); 45 C.F.R § 75.403 (providing that costs must "[b]e necessary and reasonable for the performance of the Federal award and be allocable thereto under these principles [and c]onform to any limitations or exclusions set forth in these principles or in the Federal award as to types or amount of cost items.").

[183] Department of Health and Human Services, FY 2018 Announcement of Anticipated Availability of Funds for Family Planning Services Grants, 24, 55-56 (Feb. 23, 2018), available at https://www.grants.gov/web/grants/view-opportunity.html?oppId=297943.

[184] *Id.*

[185] Department of Health and Human Services, "Federal Restrictions on Lobbying for HHS Financial Assistance Recipients" (Sept. 2, 2015), available at https://www.hhs.gov/grants/grants/grants-policies-regulations/lobbying-restrictions.html.

Also, while some of the Department's proposed restrictions may be redundant within the confines of a Title X project, the proposed prohibitions would extend the reach of these restrictions to an entity's non-Title X activities. This is because the Department's proposed "physical and financial" separation requirement would apply to the activities proposed under proposed section 59.16. As is mentioned above, the Proposed Rule implies that "physical and financial" separation would require "separate facilities—one facility providing Title X services" and one engaged in abortion-related activities.[186] It follows that the performance of lobbying and political activities using private funds would be made contingent on the establishment of entirely separate facilities. Obviously, many organizations, unable to finance more space, equipment, and personnel, would find it cost prohibitive to continue these activities. The significant cost to entities and to society of deterring a wide radius of lobbying and political activity outside of the federally funded project is unacknowledged by the Department, and the imposition of these costs beyond the Title X project exceeds the Department's statutory authority and is likely unconstitutional.

2. The Department's regulatory text is unclear.

The Department's proposed regulatory text in proposed section 59.16(a)(1) is unclear. This section would prohibit the use of Title X funds for "[a]ttending events or conferences during which the grantee or subrecipient engages in lobbying" regardless of whether the lobbying in question has anything to do with abortion. Moreover, given the terms of proposed section 59.15, it follows that *any lobbying* that a recipient conducts at such events or conferences would have to be physically and financially separate from Title X activities. But even Department's own legal reasoning would certainly not justify requiring separation for activities that are not related to abortion. And if the Department truly meant to require "physical and financial" separation between Title X activities and lobbying activities that are unrelated to abortion, it must provide a reasoned justification and legal basis for its decision. We do not believe that it can do so.

E. New "Transparency" Requirements (§ 59.2, § 59.5).

The Department proposes new "transparency" requirements, including the reporting of detailed information about subrecipients, referral entities, and other partners. These new requirements are insufficiently justified in the Proposed Rule. Also, the Department's proposed regulatory text is unclear. Thus, we urge the Department to withdraw its proposed "transparency" requirements.

1. The Department fails to justify its proposed "transparency" requirements.

The Department alleges that it lacks "an accurate understanding of any grantee's subrecipients, what role each subrecipient plays in the overall function of the project, or the extent to which Title X funding supports the efforts of subrecipient."[187] In the absence of explicit requirements in

[186] 83 Fed. Reg. at 25,519.
[187] *Id.* at 25,514.

the Title X regulations requiring the submission of this information, the Department claims that it cannot properly oversee the Title X program.[188] To remove this alleged obstacle, the Department proposes to add new "transparency" requirements to the regulations.[189]

There are a number of problems with the Department's justification for its proposed "transparency" requirements. First, existing mechanisms already provide the Department with detailed information about subrecipients. For example, the recent Title X Funding Opportunity Announcement required applicants to submit "*a detailed budget and budget narrative for each subrecipient/contractor*, by agency title, along with the same supporting information referred to in these instructions," or, if the applicant plans to select subrecipients post-award, "information on the nature of the work to be delegated, the estimated costs, and the process for selecting the delegate agency."[190] Similarly, in its post-award requirements, the Funding Opportunity Announcement provides that "[m]odifications to your approved project that will require prior approval include, but are not limited to: a change in the scope or the objective(s) of the project or program (even if there is no associated budget revision, such as reduction in services, closing of service or program site(s)); . . . or the *subawarding, transferring or contracting out of any work that was not described in the approved proposal.*"[191] In addition to prior approval, under the Funding Opportunity Announcement, "grantees are expected to provide timely notice (within 30 days) to the Office of Population Affairs (OPA) through its website contractor, as well as to the appropriate HHS project officer, of any deletions, additions, or changes to the name, location, street address and email, and contact information for Title X grantees and service sites."[192] Thus, the Department's claim that it "does not have an accurate understanding of any grantee's subrecipients" is belied by the terms of its own Funding Opportunity Announcement, which requires these disclosures as a condition of funding.

Further, as with other federal grant programs, the Department's responsibility to oversee Title X is limited to the oversight of direct grantees. Grantees themselves are responsible for monitoring subrecipients. Department-wide regulations governing the administration of federal awards require direct grantees, not the federal agency, to "[m]onitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward; and that subaward performance goals are achieved."[193] The U.S. Government Accountability Office (GAO) explains that "Federal agencies hold the recipient, not the subrecipient, responsible for compliance at the subrecipient level. This responsibility includes the required repayment of any federal financial

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[188] *Id.*
[189] *Id.* at 25,516-17.
[190] Department of Health and Human Services, *FY 2018 Announcement of Anticipated Availability of Funds for Family Planning Services Grants*, 29 (Feb. 23, 2018), available at https://www.grants.gov/web/grants/view-opportunity.html?oppId=297943 (emphasis added).
[191] *Id.* at 49; *see also* 45 C.F.R. § 75.308.
[192] *Id.*
[193] 45 C.F.R. § 75.352(d).

assistance because of the subrecipient's failure to comply with federal laws and regulations."[194] If the Department wishes to ensure the monitoring of subrecipients, its primary means of doing so is to hold grantees accountable for adhering to grants management requirements relating to the oversight of subrecipients. Yet the Department does not explain whether it has attempted to do this or why it expects that using the existing enforcement tools will not suffice. The Department's proposed "transparency" requirements, insofar as they no longer entrust the supervision of subrecipients to grantees, would tread on these carefully balanced roles and responsibilities and introduce confusion into the Title X program. A departure from this tradition and the GAO's best practices would require a significant justification—something the Department fails to provide.

When it comes to the oversight of subrecipients, the Department fails to show that Title X should be treated any differently than other grant programs. The Department may be tempted to rehash its unfounded speculation about the misuse of Title X funds to justify its proposed "transparency" requirements. But we refer the Department to our above discussion on the proposed requirements on the "appropriate use of funds." Both there and here, the Department's evidence is insufficient to transform its speculation into a valid basis for policy-making.

2. The Department's proposed regulatory text is unclear.

We highlight for the Department a number of ways in which the regulatory text in this area is unclear, inconsistent, or otherwise in need of further explanation. As proposed, the Department's "transparency" requirements fail to give recipients sufficient notice of their obligations under the Proposed Rule. In clarifying these issues, a reasoned justification should also be provided where the Department's clarification reflects a policy choice for which the Proposed Rule fails to offer a justification or explanation.

- In proposed section 59.5(13)(ii), the Department would require recipients to describe their collaboration with subrecipients, referral agencies and individuals, and "less formal partners within the community." These "less formal partners," however, are not mentioned in the other "transparency" requirements proposed at 59.5(13). Neither the Proposed Rule's text nor its preamble clarify what types of collaborations would be characterized as "less formal partnerships" and therefore would be subject to this provision but not the others.

- Although the preamble to the Proposed Rule would only require the submission of information pursuant to proposed section 59.5(13) at the application stage "to the extent secured at the time of application," the regulatory text takes the form of an absolute requirement to report the information "in grant applications and all required reports." The

[194] U.S. Government Accountability Office, *A Guide for Roles and Responsibilities in Subrecipient Audits* (Jan. 1, 1992), available at https://www.gao.gov/products/146971.

regulatory text should resolve this inconsistency to reflect the Department's intended policy decision.

- Proposed section 59.5(a)(13)(iii) would require projects to explain how they will ensure adequate oversight and accountability for the effectiveness of outcomes of those who serve as referrals for "ancillary or core services." Yet the Department gives recipients no way to ascertain the distinction between ancillary and core services. It should do so. And in particular, it should address whether "ancillary" services, as opposed to "core" services, are services that could not be provided as a part of a Title X project. If so, the Department should clarify whether it intends to expand the responsibility of Title X projects to oversee the delivery of non-Title X services. The Department must also address the likely cost on recipients of performing this additional oversight, Title X projects' lack of comparative expertise in supervising these types of services, and the potential deterrent effect on the participation of otherwise willing partners that help to deliver these services. Finally, the Department must provide its legal authority to require Title X projects to oversee non-Title X services.

F. New Criteria for The Selection of Title X Grantees (§ 59.7).

The Department proposes new criteria for the selection of Title X grantees, including new eligibility requirements. There are several issues with the proposed criteria. First, the new criteria have no basis in law. Second, the Department's rationale for the implementation of the proposed criteria is deficient, and the Department fails to consider the harmful consequences that are likely to result. Finally, the Department's proposed regulatory text is unclear and confusing. We therefore urge the Department to withdraw its proposed selection criteria.

1. *The Department's new proposed criteria for the selection of Title X grantees lack a basis in law.*

The Department's proposed section 59.7 would impose new eligibility requirements on Title X applications: "The Department . . . shall require each applicant to describe their plans for affirmative compliance with each provision [of the regulation]."[195] Under the Proposed Rule, an application must meet this requirement before the Department would even review its merits: "Any grant applications that do not clearly address how the proposal will satisfy the requirements of this regulation shall not proceed to the competitive review process, but shall be deemed ineligible for funding."[196]

These proposed eligibility requirements would exceed the Secretary's authority under the statute. Title X authorizes the Secretary to "make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family

[195] 83 Fed. Reg. at 25,530.
[196] *Id.*

planning projects."[197] That authority, however, is not unconditional. In a subsection titled "factors determining awards," the statute mandates that "[i]n making grants and contracts under this section the Secretary *shall take into account*" four statutory criteria: "the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance."[198] The statute also dictates that "[l]ocal and regional entities *shall be assured* the right to apply for direct grants and contracts under this section, and the Secretary *shall* by regulation *fully provide for and protect such right*."[199] These conditions are not optional or discretionary. "The word 'shall' generally imposes a nondiscretionary duty."[200] Indeed, the Proposed Rule itself recognizes "the statutory requirement that certain factors be considered."[201]

Thus, as the U.S. District Court for the District of Columbia recently concluded, Title X's review criteria are not wholly committed to agency discretion; instead "Congress clearly laid out the purpose of Title X grants" in § 300(a), and the statute further "'circumscribe[s] agency discretion,'" in the grantmaking process, "... by instructing the Secretary to consider" the four statutory factors in § 300(b).[202] In that case, as the court recognized, plaintiffs were "not claiming that HHS failed to consider mandatory criteria."[203] But, under the Proposed Rule, the Department would do just that. "[I]t would be 'standard judicial fare' to evaluate the agency's decisionmaking process to make sure that factors that the agency must 'take into account' are in fact considered."[204]

The proposed preemptive eligibility screening, however, would contravene this statutory requirement. Interposing a new requirement for an application even to be eligible for consideration would impede rather than "assure[]," "provide for," and "protect" the right to apply for Title X funding.[205] And subordinating the mandatory statutory criteria to a threshold consideration of the Secretary's choosing would contradict the obligation to "take into account" those criteria. Simply put, the proposed rule would allow the Secretary to reject an application without considering the statutory criteria. The plain terms of the statute do not permit him to do so. "Where a statute's language carries a plain meaning, the duty of an administrative agency

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[197] 42 U.S.C. § 300(a).
[198] *Id.* § 300(b) (emphasis added).
[199] *Id.* (emphasis added).
[200] *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1354 (2018); *see also Murphy v. Smith*, 138 S. Ct. 784, 787 (2018) ("[T]he word 'shall' usually creates a mandate, not a liberty ... .").
[201] 83 Fed. Reg. at 25,511.
[202] *Planned Parenthood of Wisconsin, Inc. v. Azar*, -- F.3d --, 2018 WL 3432718, at *5 (D.D.C. July 16, 2018) (quoting *Lincoln v. Vigil*, 508 U.S. 182, 193 (1993)); *see also Delta Air Lines, Inc. v. Exp.-Imp. Bank of the U.S.*, 718 F.3d 974, 977 (D.C. Cir. 2013) (holding statutory command that bank "shall take into account" identifies factors that the Bank must consider and was subject to judicial review).
[203] *Planned Parenthood of Wisconsin*, 2018 WL 3432718, at *5.
[204] *Id.* at *13 (quoting *Delta Air Lines*, 718 F.3d at 977).
[205] 42 U.S.C. § 300(b).

is to follow its commands as written, not to supplant those commands with others it may prefer."[206]

In addition to the new threshold eligibility review, the proposed rule would alter the review criteria used for almost 50 years. The specific changes to the criteria are largely redundant of the mandatory statutory factors or the current regulatory ones. They therefore burden Title X programs unnecessarily. And to the extent the review criteria are not redundant, they are inconsistent with the text and purpose of Title X:

- Proposed Section 59.7(c)(1) is wholly unnecessary. Considering "[t]he degree to which the applicant's project plan adheres to the Title X statutory purpose and goals" is already encompassed and required by the current Section 59.7(a)(7) ("The degree to which the project plan adequately provides for the requirements set forth in these regulations.").

- Proposed Section 59.7(c)(2) contradicts the aim of Title X. Both "the relative need of the applicant" and the "capacity to make rapid and effective use of grant funds" are statutorily mandated considerations already included in the current regulations.[207] But it contradicts the statutory text and purpose to "especially" prioritize a program's capacity to use grant funds "among a broad range of partners and diverse subrecipients and referral individuals and organizations, and among non-traditional Title X partnering organizations" when considering this factor.[208] For reasons described elsewhere, Congress did not intend to prioritize having a "broad" or "diverse" group of Title X providers over maximizing the reproductive health care offered to Title X beneficiaries. Giving special priority to *nontraditional* Title X providers is especially problematic because "traditional" Title X providers are likely to be those who have spent the most time and effort developing programs in compliance with Title X's health care goals and requirements, some of them for 40 years or more. These established programs are best able to rapidly and effectively make use of grant funds, a factor the Secretary of the Department must consider under the statute. To the extent having broad, diverse, and nontraditional partners is emphasized over a program's ability to "make rapid and effective use of grant funds," the proposed rule contradicts the statute.

- Proposed Section 59.7(c)(3) is both redundant and contrary to the statutory text. To the extent it requires the Secretary to consider "the degree to which the applicant takes into account the number of patients to be served," it is redundant of the statutory text and current regulations.[209] But while the current regulations emphasize, "in particular, the

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[206] *Iancu*, 138 S. Ct. at 1355; *see also Murphy*, 138 S. Ct. at 787-88 ("If Congress had wished to afford ... more discretion in this area, it could have easily substituted 'may' for 'shall.' ... But Congress didn't choose those other words. And respect for Congress's prerogatives as policymaker means carefully attending to the words it chose rather than replacing them with others of our own.").
[207] *See* 42 U.S.C. § 300(b).
[208] 83 Fed. Reg. at 25,517.
[209] *See* 42 U.S.C. § 300(b); 42 C.F.R. § 59.7(a)(1).

number of low-income patients to be served," the proposed rule would instead emphasize "targeting areas that are more sparsely populated and/or places in which there are not adequate family planning services available."[210] To the extent sparsely populated and inadequately served areas are also low income, the current regulation addresses this concern; to the extent they are not, there is no indication Congress wanted Title X funds to serve high-income but sparsely populated areas over, for example, densely populated but low-income areas. Certainly, there are many sparsely populated or underserved areas that would benefit from Title X funds, but the proposed rule contradicts Title X's express requirement that the Secretary consider "the number of patients to be served" by emphasizing those particular areas over programs that can serve a higher number of people with low incomes.

- Proposed Section 59.7(c)(4) is redundant to the extent it considers how "family planning services are needed locally," a consideration in current Section 59.7(a)(2). It risks contradicting the statutory purpose, however, by prioritizing "innovative ways to provide services to unserved or underserved patients." As stated above, many Title X programs have existed for decades; although these programs always strive to serve more patients in the best ways possible, prioritizing applicants who "propose innovative ways" would discriminate against established programs that are best positioned to carry out Title X's health care goals for the broadest populations.

Finally, the Proposed Rule would remove current factors that further Title X's purpose: (1) the number of low-income patients to be served, (2) the adequacy of the applicant's facilities and staff, and (2) the relative availability of nonfederal resources within the community to be served and the degree to which those resources are committed to the project.[211] The Proposed Rule nowhere explains why these factors are being removed. But because Title X projects have been applying for funding with these factors in mind for decades, removing them imposes a burden that requires explanation. At a minimum, the Department must explain why failing to consider the low-income patients served, the adequacy of the facilities and staff, and the relative availability of other resources to fund projects forwards Title X's text and mission.

2. The Department's proffered justification for updating the selection criteria is insufficient.

The Department's policy explanations fail to justify the new criteria. To begin, this change would impose considerable burdens on Title X applicants. The evaluation criteria in the current regulation, which sets forth seven factors for the Department to consider in order to effect its statutory obligation, has remained unchanged since the very beginning of the Title X program.[212] In addition, since 1990, the Department has annually issued a Funding Opportunity Announcement that solicits grant applications and lays out the requirements for applications;

[210] 83 Fed. Reg. at 25,517.
[211] *See* 42 C.F.R. § 59.7(a)(1), (5), (6).
[212] *See* 36 Fed. Reg. at 18,466-18,467 (nearly identical criteria in 1971 regulations).

these criteria have *always* closely tracked the seven criteria in the current regulations, with only some additional explanatory text changing over the years. Because of this, Title X programs—for years—have applied for funds and indeed specifically been designed to comply with and compete for funds under the current selection criteria. Changing the criteria would burden the very programs Title X was designed to create, and without significant purpose.

The Department's policy goals do not justify this burden. First, the Department proposes to change the review criteria to "better achieve the statutory requirements and goals of Title X."[213] More specifically, the Department believes the grant criteria "need to be updated to more fully ensure that successful applications both meet the statutory requirements of the Title X program and are adequately responsive to the statutory goals and purposes of the Title X program."[214] But it is not clear why. The Proposed Rule does not say what deficiency in the current criteria it would cure. At a minimum, the Department needs to justify burdening Title X applicants with revised and additional criteria by explaining why the current criteria are insufficient.

If "the statutory requirements and goals of Title X" means nothing more than compliance with Section 1008's abortion prohibition,[215] these changes are overbroad and unnecessary. The Department does not explain why enforcing Section 1008 requires burdening programs with new review criteria or why it cannot consider Section 1008 within the current regulations. To the contrary, the Department says that the current regulations "give HHS significant flexibility in determining awards" and "discretion to vary the weighting of the criteria in its competitions."[216] The Department therefore need not alter the selection criteria in order to ensure that successful applicants meet the statutory requirements and goals—it merely needs to properly exercise its flexibility and discretion in selecting programs, at no additional burden to applicants. To burden applicants with revised criteria and to impose a threshold eligibility requirement that *decreases* the Department's flexibility by requiring it to reject certain applications without merits review would be arbitrary and capricious.

Second, diversity, competition, rigor, and "quality" do not justify the changed criteria or new eligibility review. Again, the Department does not suggest the Proposed Rule is necessary to effectuate these goals. Just the opposite, the Department recognizes that these goals are "permissible under the existing regulations."[217] If the Department can achieve its goals under the current regime, it would be arbitrary, capricious, and contrary the statute's purpose to instead impose additional burdens on the programs that are the very goal of Title X. At a minimum, more explanation is needed. Most obviously, the Department must explain what it considers "quality" applications and why the current regulations are insufficient to ensure it receives them. To the contrary, we are confident that quality applicants are already chosen and funded. These new criteria would impose additional administrative burdens on those programs and, ultimately,

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[213] 83 Fed. Reg. at 25,517.
[214] 83 Fed. Reg. at 25,511.
[215] *See* 83 Fed. Reg. 25,517 ("in particular section 1008").
[216] *Id.*
[217] 83 Fed. Reg. at 25,511.

may well divert funding away from them. The Department must explain how this advances Title X's text and purpose.

3. The Department fails to consider the harms that are likely to result from its proposed selection criteria.

On top of offering a defective justification for the proposed selection criteria, the Department fails to assess its likely consequences for the Title X provider network and, therefore, for the public health. Under the new criteria, which are clearly designed to redirect Title X funds to new applicants, the Department may divert funding away from Title X recipients that have for decades successfully delivered services under the program. If, appealing to its vague notions of diversity, quality, "holistic" health, and "non-traditional" partnerships, the Department replaces experienced providers of high-quality reproductive health care with other organizations, as we explain above, there is likely to be a reduction in access to a broad range of family planning methods and services with attendant negative impacts on health outcomes and population health, falling most heavily on the people that the Title X program is designed to serve. As we explain in greater detail above,[218] Planned Parenthood and other reproductive-health focused providers play an outsized role in serving Title X patients. These providers are also more likely than other types of providers to offer a broad range of quality family planning services. If these providers are forced to exit the program, the Department would, in many communities, find it difficult or impossible to identify alternative entities that are able to serve the same volume of patients with the same range of services at the same level of care. Forced to delay or forgo basic preventive services as a result, many patients that previously were able to access Title X-funded care from Planned Parenthood or other reproductive health-focused providers would experience adverse health consequences, including unintended pregnancies, undetected STDs, and other poor health outcomes. This would create costs for patients, the health care system, and the public.

4. The Department's proposed regulatory text is unclear.

In proposing these new selection criteria, the Department advances regulatory text that is unclear and confusing. These criteria, as proposed, would fail to give applicants a sufficient understanding of whether and how to apply for Title X funds. They also would provide insufficient guidance to independent review panelists who are tasked with scoring applications based on the regulatory criteria. In clarifying the criteria, a reasoned justification should be provided where the Department's clarification reflects a policy choice for which the Proposed Rule fails to offer a justification or explanation.

- In its proposed revisions to section 59.7, the Department provides that it will look at an "applicant's capacity to make rapid and effective use of grant funds, including and especially . . . among non-traditional Title X partnering organizations." But no attempt is

[218] *See supra*, p.15.

made in the Proposed Rule to define or give examples of "non-traditional" partners. Moreover, the meaning of "non-traditional" is likely to shift over time: what is "non-traditional" one day may well be considered "traditional" later on. This evolution of what counts as "non-traditional" creates a moving target for grant applicants and would confuse independent review panelists.

- In proposed section 59.7(b), the Department suggests that it will "explicitly summarize each provision of the regulation (or include the entire regulation) within the Funding Announcement, and shall require each applicant to describe their plans for affirmative compliance with each provision." Yet, as the Department is aware, many provisions in the "regulation," including proposed section 59.7 itself, do not place obligations on non-federal entities but rather direct the Department's own conduct. To ask applicants to address these parts of the Title X regulations in their applications would be confusing and unnecessary.

- While proposed section 59.7(c)(1) instructs the Department to look at an applicant's adherence to the "statutory and regulatory requirements," including the abortion prohibition, under proposed section 59.7(c), only an application that is already "deemed compliant" could advance to the competitive grant review process in the first place. In other words, it is not at all apparent that 59.7(c)(1)'s "statutory and regulatory requirements" criterion does anything at all. The Department should clarify whether the Department will be seeking different information in both stages of the process, and if not, its justification for duplicating this regulatory hurdle.

G. Assurance for Compliance with Abortion-Related Prohibitions (§59.13).

The Department proposes to require applications to provide assurance that they will adhere to the abortion-related requirements in the statute and proposed regulations. The Department provides almost no explanation for this requirement and, moreover, the proposed regulatory text is unclear. Thus, we urge the Department to withdraw its proposed required assurance.

1. *The Department fails to explain why its proposed assurance for compliance with abortion-related prohibitions is necessary.*

The Department asserts that the proposed required assurance is necessary for the Department to obtain, at the application stage, information relevant to determining whether a program or project will comply with section 1008.[219] It also claims that the current regulations do not provide sufficient guidance to ensure that Title X projects comply with abortion-related restrictions in Title X.[220]

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[219] 83 Fed. Reg. at 25,517-19.
[220] *Id.*

The Department's policy rationale, however, falls short of justifying its proposal. First, contrary to the Department's conclusion, it is clear that the proposed assurance is not necessary for obtaining information on a project's compliance with section 1008. For example, current section 59.7(a)(7) already instructs applicants to demonstrate "[t]he degree to which the project plan adequately provides for the requirements set forth in these regulations."[221] Nor is the assurance needed to give "guidance" to applicants about their obligations under the statute or regulations. Guidance about the applicability of Title X's abortion-related restrictions is already available to applicants via the Title X Funding Opportunity Announcement,[222] the statute,[223] the current regulations,[224] and in Department-issued guidance documents.[225] The Department does not say what is missing from the current regime.

Moreover, even if we accepted as legitimate the Department's stated need for additional information about an entity's plan to comply with Title X requirements, the proposed assurance adds nothing to the Proposed Rule's scheme. For instance, under proposed sections 59.7(b)-(c), applications would be deemed ineligible for funding if they do not describe how they would "affirmative[ly]" comply with each provision of the regulation. And under proposed section 59.7(c)(1), applications would be judged based on the extent to which their project plans "meet all of the statutory and regulatory requirements and restrictions, and where none of the funds . . . shall be used in programs where abortion is a method of family planning." Given these proposed provisions, the Department would already receive considerable information from applicants about their ability and willingness to comply with Title X's requirements related to abortion. The Department does not explain why its proposed assurance is not redundant.

2. The Department's proposed regulatory text is unclear.

The regulatory text of proposed section 59.13 is unclear. Both the operative text and the preamble to the Proposed Rule provide that each project would be required to provide assurance satisfactory to the Department that, "*as a Title X grantee*, it does not provide abortion and does not include abortion as a method of family planning." To interpret this proposal, we refer back to the Department's proposed definitions at 59.2, which provide that "*[g]rantee* means

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[221] 42 C.F.R. § 59.7(a)(7).
[222] Department of Health and Human Services, *FY 2018 Announcement of Anticipated Availability of Funds for Family Planning Services Grants*, 8 (Feb. 23, 2018), available at https://www.grants.gov/web/grants/view-opportunity.html?oppId=297943 ("Section 1008 of the Act, as amended, stipulates, "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.").
[223] 42 U.S.C. § 300a–6.
[224] 42 C.F.R. § 59.5 ("Each project supported under this part must . . . [n]ot provide abortion as a method of family planning.").
[225] Office of Population Affairs, *Program Requirements for Title X Funded Family Planning Projects*, 11 (Apr. 2014), available at https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf ("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.").

the entity that receives Federal financial assistance by means of a grant." "Grantee," in this sense, must be distinguished from the "project," which is the subset of activities performed by the grantee to "satisfy the requirements of the grant," and which would be subject to section 1008 and the Department's regulations. The text appears to elide this distinction. If the Department construes section 1008 and its proposed regulations to constrain all the activities of a grantee organization, the Department must squarely address this and provide both a legal basis and reasoned justification for its interpretation. Without clarification, proposed section 59.13, as currently presented, creates confusion and fails to give applicants a sufficient understanding of whether and how to apply for Title X funds.

H. Revised Definition of "Low Income Family" (§ 59.2).

The Department proposes to add to and revise the definitions in the Title X regulations. In doing so, the Department proposes to revise the definition of "low income family" in order to grant eligibility for free Title X funded-services to women with employer-based health coverage whose employers have denied them coverage for contraception for moral or religious reasons. There are a number of problems with the Department's proposed change. First, the Department's proposed re-definition of "low income family" lacks a basis in law. Second, the Department's justification for its proposed change is inadequate. Finally, the regulatory text that the Department advances to effect its policy goal is insufficiently clear. We therefore urge the Department to withdraw its proposed revisions to the Title X regulations' definitions.

1. The Department's proposed revisions to the definitions in the Title X regulations lack a basis in law.

The proposed rule would expand the definition of "low income family" in Section 59.2 to include, "[w]ith respect to contraceptive services, a woman … [who] has health insurance coverage through an employer which does not provide the contraceptive services sought by the woman because it has a sincerely held religious or moral objection to providing such coverage."[226] This definition would shift the burden of providing contraceptive services from certain employers and insurance companies to already overburdened Title X programs that, by statute, should focus on care of women with low incomes. To the extent women are already members of families whose annual income falls below the Department's poverty guidelines, the definition does nothing; its only effect is therefore to empower employers and insurance companies to shift the cost of contraceptive services for high-income workers to Title X programs.

Defining "low-income family" in this way contradicts the Secretary's statutory authority. The statute requires that a "grant may be made … only upon assurance satisfactory to the Secretary that priority will be given in such project or program to the furnishing of such services to persons from low-income families."[227] The statute states that "the term 'low-income family' shall be

[226] 83 Fed. Reg. at 25,530.
[227] 42 U.S.C. § 300a-4(c).

defined by the Secretary in accordance with such criteria as he may prescribe *so as to insure that economic status shall not be a deterrent to participation in the programs assisted under this subchapter.*"[228] The Secretary, therefore, only has the authority to define the term low-income family "in order to" ensure that economic status does not deter participation in Title X programs.[229] That phrase—"so as to insure that economic status shall not be a deterrent"—imposes a limiting factor on the criteria that the Secretary "may prescribe."[230] The current definition of "low-income family," for example, requires unemancipated minors to be considered on the basis of their own resources to ensure that their economic status, which is distinct from their parents' or family's, does not deter participation—a definition manifestly imposed so as to ensure economic status does not deter such a minor from participating in the program.

That the "so as" phrase limits the Secretary's authority is clear as a matter of statutory interpretation. Compare, for example, 18 U.S.C. § 3553(e), which prescribes a federal district court's ability to impose a below-minimum sentence: "the court shall have the authority to impose a sentence below a level established by statute as a minimum sentence *so as to reflect a defendant's substantial assistance in the investigation or prosecution of another person who has committed an offense.*"[231] That provision does not permit a court to impose a below-minimum sentence for reasons other than substantial assistance. The First Circuit Court of Appeals has made this clear, with analysis equally applicable here:

> [S]ection 3553(e) manifests an obvious purpose: once the government moves for a sentence below the statutory minimum pursuant to section 3553(e), the court has discretion to sentence below that minimum in a manner that reflects the nature and extent of the substantial assistance provided by the defendant—no more, no less. This construction is supported most clearly in the text by the placement of the limiting phrase "so as to reflect a defendant's substantial assistance," which is attached to the main clause that grants the court its authority to impose a sentence below the statutory minimum. From this placement, the only logical conclusion is that the authority granted is limited thereby. Thus, the statute opens the door for a departure below the otherwise applicable mandatory minimum—but only those reasons related to the nature and extent of the defendant's substantial assistance can figure into the ensuing sentencing calculus.[232]

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[228] 42 U.S.C. § 300a-4(c).
[229] Webster's New World College Dictionary (4th ed. 2007).
[230] 42 U.S.C. § 300a-4(c).
[231] 18 U.S.C. § 3553(e).
[232] *United States v. Ahlers*, 305 F.3d 54, 60 (1st Cir. 2002); *see also United States v. Hicks*, 980 F.2d 963, 972 (5th Cir. 1992) (interpreting the crime "'intimidating' members of a flight crew 'so as to interfere with' the performance of their duties" to prohibit "only intimidating acts or words that actually interfere with a crew member's duties").

The same is true here: the Secretary has discretion to define "low-income family" in a manner that ensures the economic status shall not be a deterrent to participation—no more, no less.[233] Here, as there, the limiting phrase is "attached to the main clause that grants" the Secretary the authority to define "low-income family" and therefore "is limited thereby."[234] Indeed, that is "the only logical conclusion."[235]

The Proposed Rule reveals, however, that "insur[ing] that economic status shall not be a deterrent to participation in the programs"[236] is not the Secretary's motivation with the proposed rule. Indeed, program participants are not the motivation at all. This change, the Proposed Rule says, "would preserve conscience protections for entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act, while providing free or low-cost family planning services for such women at risk of unintended pregnancy or who otherwise desire comprehensive, holistic, family planning services."[237] But Congress did not authorize the Secretary to define "low-income families" so as to "preserve conscience protections" for employers and insurance companies. Instead, under the statute, "only those reasons related to" ensuring that economic status does not deter participants "can figure into" the Secretary's definition of "low-income family."[238] Because the proposed definition considers other reasons—and does not consider the only statutorily authorized reason—it contradicts the Secretary's statutory authority.

It also contradicts the purpose of Title X. That Congress intends the Secretary to define "low-income family" to prioritize actual families with low incomes, rather than to burden Title X projects with the contraceptive-services costs of businesses with purported conscience objections, is clear from the legislative history, which emphasizes repeatedly that the primary purpose of the Act is to aid low-income families. On multiple occasions Congress noted that even though there are other groups that could be aided by Title X funding, it is *more* important that the funding go to low-income families. For example, the Senate Report notes that "[p]roblems of unwanted children do not occur only in low income and less educated families in this country, but the consequences are greater in this group because of the accumulation of difficulties this condition imposes upon the poor."[239] In passing the bill, Congress emphasized that "this legislation is a definite congressional mandate in support of family planning services for low-income families."[240]

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[233] *Ahlers*, 305 F.3d at 60.
[234] *Id.*
[235] *Id.*
[236] 42 U.S.C. § 300a-4(c).
[237] 83 Fed. Reg. at 25,514.
[238] *Ahlers*, 305 F.3d at 60.
[239] S. Rep. No. 91-1004, at *9 (1970); *see also* H. Rep. No. 91-1472, at *7 ("The difficulty which individual couples confront in achieving their desired family size is not limited to low-income families, although it is made much more acute for them by their lack of access to information and medical services.").
[240] 116 Cong. Rec. H10276-302, H12081 (1970) (statement of Rep. Bush).

The legislative history also details *why* Title X gives "priority" to low-income families. For example, the House Report notes that "[n]inety percent of the approximately 4,000 nonprofit general care hospitals in the United States in which low-income mothers deliver babies offer no family planning programs at all"; and that "[o]f the estimated 5 million medically indigent women who could probably use subsidized family planning services, if available, only one out of four now receive them."[241] The hearings also emphasized the important link between contraception and low-income families, noting that "[o]nly 28 percent of the poor used any [] form of contraception, compared to 85 percent of the upper-and middle-income groups."[242] From these discussions of the "low-income" family ("5 million medically indigent women') or ("28 percent of the poor"), it is clear that Congress had a particular group of individuals in mind that it considered part of "low-income" families.

Shifting the costs of contraceptive services from businesses and insurance companies with purported conscience objections to already overburdened Title X providers would therefore contravene the text and purpose of Title X.

2. *The Department's justification for its proposed revisions to the definitions is inadequate.*

In proposing to expand eligibility for free services under Title X, the Department takes as its purpose "provid[ing] free or low-cost family planning services for women at risk of unintended pregnancy or who otherwise desire it." Although Planned Parenthood shares the Department's motivation, we must warn that the Proposed Rule's approach will not only fail to accomplish this objective, but will also harm Title X patients and impose unacknowledged costs on Title X-funded providers.

First, the Department fails to consider any data or evidence in its conclusion that the Title X-funded network of providers will be able to absorb this new patient population and fails to address whether this would affect service availability for patients who are uninsured or have low incomes. It is well-documented that existing resource constraints make it impossible for Title X providers to meet the needs of women of reproductive age in need, let alone to serve women that otherwise would not be eligible to receive free or discounted services through Title X. A study authored by researchers from the Centers for Disease Control and Prevention and the Office of Population Affairs concluded that, based on state Medicaid expansion plans, "approximately $737 million would be needed to provide [Title X] family planning services to all uninsured low-income women of reproductive age in the United States."[243] By contrast, in fiscal

[241] H. Rep. No. 91-1472, at *7.
[242] Family Planning and Population Research, Senate Hearings at 68 (statements of Alan F. Guttmacher, M.D., President Planned Parenthood-World Population, and Joseph D. Beasley, M.D., Director, Center for Population and Family Studies, Tulane University).
[243] August, E. M. PhD, MPH, et al., "Projecting the Unmet Need and Costs for Contraception Services After the Affordable Care Act," Am J Public Health (Feb. 2016), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4985850/.

year 2018, Title X is funded at $286 million, less than half that level.[244] Surprisingly, the Department fails to offer data, evidence, or even a prediction of how many women would become newly eligible for free services under its proposal. For this reason, we are unable to estimate its full impact. It seems clear based on funding constraints alone, however, that the Department's proposal would not solve the problem that is created by employer exemptions to the contraceptive coverage mandate. And, to the extent that such women, regardless of income, *are* able to obtain Title X-funded services for free from a nearby Title X service site, this would reduce the capacity of Title X-funded providers to see the statutorily intended beneficiaries of the Title X program: low-income, uninsured patients. The Department, again, makes no attempt to estimate this effect. We remind the Department that the statute require Titles X projects to prioritize the provision of services to individuals from low income families.[245]

Similarly, the Department fails to consider that access to Title X-funded services is not a one-to-one replacement for birth control coverage. While employer-sponsored coverage may be used to obtain care from a variety of providers, Title X is a grant program that funds particular health center locations. Women whose employers deny them coverage for contraception may not reside in proximity to a Title X provider. This would make the Department's proposed changes to Title X irrelevant to their ability to access needed contraceptive care. The Department does not provide evidence or data to the contrary.

Finally, the Department does not discuss the effect of this new eligibility category on the operations of Title X projects and any corresponding costs. For example, the Department does not explain how patients are to go about "proving" that they have been denied contraceptive coverage by their employer. Planned Parenthood affiliates report that any type of new "verification" activity on the part of Title X projects would be particularly cumbersome. It would also clearly imply new costs, which the Department does not address. The Department, moreover, does not explain whether newly eligible patients would be able to obtain other services (e.g., STD testing or Pap test) during a contraceptive visit and whether these services, too, would be free. If so, the Department should acknowledge this as an additional cost on Title X projects. If not, the Department would need to provide guidance to Title X-funded providers about how projects are to appropriately separate which components may be charged to the project, which components must be billed to insurance under the current regulations, how Title X projects are to clearly communicate this to patients, and how family planning encounters such as these are to be reported for the purposes of the Family Planning Annual Report. Moreover, the implementation of these protocols would require training, additional staff time, and revised reporting instruments, all of which would impose new costs on Title X projects that the Department entirely ignores in the Proposed Rule.

3. The Department's proposed regulatory text is unclear.

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[244] Congressional Research Service, Family Planning Program Under Title X of the Public Health Service Act (Apr. 27, 2018), available at https://fas.org/sgp/crs/misc/R45181.pdf.

[245] 42 U.S.C. § 300a–4 (providing that "priority will be given in such project or program to the furnishing of such services to persons from low-income families").

Because the proposed regulatory text is unclear, we believe the Department's proposed re-definition of "low income family" fails to provide sufficient notice to recipients as to their obligations under the Proposed Rule. In clarifying the proposed revision, a reasoned justification should be provided where the Department's clarification reflects a policy choice for which the Proposed Rule fails to offer a justification or explanation.

- According to the preamble to the Proposed Rule, the Department's re-definition of "low income family" is intended to "provid[e] free *or low-cost* family planning services" for women whose employers refuse to provide coverage for contraception because of a religious or moral objection. Yet the proposed regulatory text, which provides that a woman denied employer-sponsored coverage for birth control "can be considered from a low income family," would almost certainly give these women access to *free* Title X-funded services. That is because current section 59.5(a)(7) provides, in part, that "no charge will be made for services provided to any persons from a low-income family." The Department should clarify what it intends. And, in particular, if the Department believes some of the newly eligible women would only be able to access "low-cost" but not free services, the Department must address the myriad questions this would raise (*e.g.*, the design and implementation of a separate schedule of discounts that is not based on income, the new costs associated with altering protocols and training staff, the manner in which such encounters would be reported for the purposes of the Family Planning Annual Report, and so on).

- The Department's proposed regulatory text refers to "women" that have employer-sponsored coverage and are denied coverage for contraception because of an employer's religious or moral objection. This gender-specificity, however, may have unintended consequences. For example, individuals that do not identify as women but are able to become pregnant, including some transgender men, would appear to be excluded from receiving services under the proposed definition. Similarly, the Department should clarify the applicability of this definition where a man is the policyholder for employer-sponsored coverage used by one or more dependents who may be women or other individuals that are capable of getting pregnant that are consequently denied coverage for contraception.

- Under the proposed regulatory text, newly-eligible women "can" be considered from a low income family. This gives rise to the impression that making Title X-funded services available for this population is optional. By contrast, the preamble to the Proposed Rule implies that this would be a new requirement on Title X projects. The Department should address this inconsistency and provide a reasoned justification for its decision. If the revised definition is intended to be permissive, the Department should revisit its purported justification. In that case, the Department certainly would not be able to claim that giving under-resourced Title X service sites the option to provide free care to more

people will result in expanded services for women whose employer-sponsored insurance excludes contraceptive coverage.

I. Changes to Required Services Under Title X (§ 59.5).

Title X requires family planning projects to "offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)."[246] Under the current section 59.5, which sets forth the regulatory "requirements [that] must be met by a family planning project," a Title X project must "[p]rovide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents)."[247] The current regulation provides that single-method organizations may still participate in Title X, provided they join projects that offer a broad range of family-planning services: "If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services."

The proposed rule would make the following changes to current section 59.5(a)(1):

> Provide a broad range of acceptable and effective medically approved family planning methods (including contraceptives, natural family planning methods, and other fertility-awareness based methods) and services (including infertility services, including adoption, and services for adolescents). Such projects are not required to provide every acceptable and effective family planning method or service. ~~If an organization offers~~ A participating entity may offer only a single method or a limited number of methods of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning methods and services.

This proposal is contrary to congressional intent, insufficiently justified, and unclear and ambiguous. We therefore urge the Department not to make the proposed changes.

1. *The proposed rule would permit Title X programs that offer no contraceptives, at odds with congressional intent.*

Consistent with the text and legislative history of the statute, Title X programs must provide a broad range of contraceptive methods. The Proposed Rule, however, would permit Title X projects that provide nearly no contraceptives, or even none at all. That is because if Title X "projects are not required to provide every acceptable and effective family planning method or service" to satisfy the requirement that they offer "a broad range of family planning methods and services," then the Department could consider a project's range of methods and services to be

[246] 42 U.S.C. § 300(a).
[247] 42 C.F.R. § 59.5(a)(1).

sufficiently "broad" even with limited or no contraceptive methods. For example, a project that provides only "fertility awareness based methods," "sexual risk avoidance (or avoiding sex)," "natural family planning services, infertility services, and services for adolescents"[248] could well be deemed by the Department to provide "a broad range of family planning methods and services" under the proposed rule—despite offering no contraceptives whatsoever.

This possibility conflicts with the plain language of the Title X statute and its legislative history. When Congress first enacted Title X in 1970, it authorized the then-Department of Health, Education and Welfare "to assist in the establishment of family planning projects that offer a broad range of family planning methods, *including the provision of prescription and nonprescription contraceptive drugs and devices*."[249] This language is not ambiguous. It makes clear that the requirement that a Title X project provide a "broad range" of family planning methods includes a variety of contraceptive methods and does not simply mean just one method of contraception.

Title X's legislative history further highlights that offering a range of contraceptive care has always been a central aspect of the program. The legislative history repeatedly describes a variety of contraceptive methods to be offered through Title X projects. To give just a few examples, the Senate committee report said that the bill would help those who "have unwanted children because of the lack of safe and fool-proof methods of contraception."[250] The Senate report also described oral contraceptives and the IUD as "the two major innovations in contraceptive methods of the last decade," and framed Title X's purpose as serving the "medically indigent[,]" who were forced to do without such contraception "or to rely heavily on the least effective nonmedical techniques for fertility control."[251] Indeed, legislative discussion of Title X's family-participation provision[252] presupposes that Title X programs will offer contraceptive methods: "[T]he Committee believes that unmarried teenagers, where feasible, should be encouraged to involve their family in their decision about use of contraceptives."[253]

Requiring Title X programs to provide access to a broad range of contraceptive methods is also consistent with the Department's own guidance. The Department's current official program guidance, the Title X Program Requirements, indicates that Title X "is designed to provide contraceptive supplies and information to all who want and need them."[254] And the Department's guidance document *Providing Quality Family Planning Services*, which sets forth nationally recognized standards for family planning care developed by the Department's Office of

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[248] 83 Fed. Reg. at 25,516.
[249] *Planned Parenthood Fed'n of Am., Inc. v. Heckler*, 712 F.2d 650, 651-52 (D.C. Cir. 1983); *see also id.* at 664 (invalidating a regulation that "operates as a deterrent to teenage access to contraceptive services" as "undermining Title X's goal of reducing the teenage pregnancy rate").
[250] S. Rep. No. 91-1004, at *12 (1970).
[251] S. Rep. No. 91-1004, at 9-11 (1970).
[252] 42 U.S.C. § 300(a).
[253] S. Rep. No. 29, 94th Cong., 1st Sess. 55 (1975); *see also* H.R. Rep. No. 158, 97th Cong., 1st Sess. 82 (1981).
[254] HHS Office of Population Affairs, Program Requirements for Title X Funded Family Planning Projects (April 2014) at 5.

Population Affairs and the Centers for Disease Control and Prevention, emphasizes a patient-centered approach that, among other things, focuses on effective clinical care that offers the full range of FDA-approved contraceptives.[255]

Nor is the proposed rule necessary. The Proposed Rule states that it "would make it clear that, as contemplated by the statute, family planning is not limited to, or synonymous with, access to various methods of contraception, but includes a broader understanding of family planning methods and services,"[256] but that is already clear from the statute and current regulations—both of which expressly identify "natural family planning methods" as a family planning method under the statute.[257] No revision is necessary to include natural family planning methods under the statute, but the proposed rule would risk contravening congressional intent by allowing the *exclusion* of all or nearly all contraceptive methods.

For these reasons, we urge the Department to clarify that, even if a Title X project need not provide *every* acceptable and effective family planning method or service, a project must provide a broad range of contraceptive methods.

2. *The Department provides an inadequate justification for allowing Title X projects to exclude methods and services of their choosing.*

Especially when considering the possibility that the Proposed Rule would permit Title X projects that offer no contraceptives, the justification for the proposed language that Title X "projects are not required to provide every acceptable and effective family planning method or service" is insufficient. The Department states that Title X projects might find it undesirable to provide every acceptable and effective family planning method or service for a number of reasons, including cost, demand, staffing limitations, conscience objections, and the sheer number and technological diversity in methods now available. That may be so, and it may even justify particular service sites or subrecipient organizations focusing on particular family planning methods rather than offering all of them.

But this explanation cannot be squared with Title X's express requirement and preference for projects that provide a broad range of family planning methods and services. This proposed addition, in fact, states just the opposite: that a project that provides a narrower range of methods and services than it could—or than another project competing for the same funding—is just as good as one that provides a broader range. But the Department's grantmaking authority does not authorize this deviation from the statute: "The Secretary is authorized 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."[258] The Proposed Rule would effectively

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[255] HHS, Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs, https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6304a1.htm.
[256] 83 Fed. Reg. at 25,516.
[257] *See* 42 U.S.C. § 300(a); 42 C.F.R. § 59.5(a)(1).
[258] 42 U.S.C. § 300(a).

abrogate this statutory requirement by stating, as a "requirement[] [that] must be met by a family planning project," that Title X projects are *not* required to provide the broadest range of methods and services.

This proposed change is particularly troubling because receiving Title X funds is extremely competitive. As between two proposed projects, the statute plainly requires the Department to award Title X funds to the project that offers the broader range of methods and services (all else being equal). But the Proposed Rule would seemingly permit the Department to deviate from that congressionally intended preference, and instead award funds to projects that offer narrower ranges of methods and services if the Department preferred them for other reasons—for example, for their emphasis on "sexual risk avoidance" as an method of family planning. This statute does not contemplate or permit the Department to exercise its grantmaking authority in this way.

Further, the Proposed Rule says that the proposed rule aims to clarify the inconsistent interpretations of "broad range of methods and services," but it does no such thing. In fact it would increase the confusion, muddying whether the Department will continue to prioritize—as it must under the law—projects that offer the broadest methods and services.

We therefore urge the Department not to adopt its proposed changes.

3. The Department does not justify including "adoption services" as a required infertility service under Title X.

The proposed rule would revise current section 59.5 to require Title X programs to provide a broad range of methods "and services (including infertility services, including adoption, and services for adolescents)." But the Department does not explain or justify this addition. We are not aware of any definition of infertility services that includes adoption services, and this unexplained expansion is not in keeping with Title X's public-health focus. At a minimum, the Department must explain this change.

In the Department's comments in the Proposed Rule, the Department states that "Title X specifically identifies natural family planning, infertility services, and services for adolescents" as "mandatory for each Title X project."[259] If that is so, and infertility services "includ[e] adoption," then the proposed rule may well be read to require Title X projects to provide adoption services. If that is what the Proposed Rule in fact intends, it is a sea change in current Title X program requirements that requires a great deal more attention and consideration. If that is not what the Proposed Rule intends, then it must be clarified to eliminate the ambiguity. And, even if the Proposed Rule does not intend to make adoption services mandatory, the Department must justify why adoption services are being added to section 59.5(a)(1) as a fertility service at all, since that is altogether unexplained in the Proposed Rule.

4. The Department's justification for removing the "medically approved"

[259] 83 Fed. Reg. at 25,516.

language is flawed.

The Proposed Rule would remove the requirement that Title X programs provide a broad range of *medically approved* acceptable and effective family planning methods and services.

The justifications for this change are facially insufficient. The Proposed Rule accurately observes that the phrase "medically approved" does not specify which "particular agency or accreditation body" must give approval[260]—but a lack of specificity is no reason to eliminate the requirement altogether. Similarly, the Proposed Rule suggests "medically approved" may be redundant, since "[i]f a family planning method is, as required by the statute, 'acceptable and effective,' it is likely to be approved by at least some medical sources"—but that potential redundancy is no reason to permit a family planning method that is not medically approved, and for which this requirement is therefore not redundant, to qualify for Title X support. The same argument applies to the NPRM's observation that "[m]edical doctors and professional organizations can differ on which methods of health care they approve . . . based on differing areas of expertise, or differing views of the health care method"[261]—which is certainly true, but offers no reason to grant Title X support to the rare family planning method that *no* medical doctors or professional organizations approve. Finally, the Proposed Rule's extended discussion of the scope of the FDA's regulatory jurisdiction is a *non sequitur*, since the Proposed Rule itself has already acknowledged that the term "medically approved" does not require "that a family planning method be regulated, approved, or certified by any particular agency or accreditation body," including the FDA.

The Department's only other justification for removing the "medically approved" requirement is its potential for confusion. That language "may cause confusion about the type of family planning methods or services that a project may or should provide, and the type of approvals (if any) necessary before a Title X project can provide such method or service." This is an abstract, hypothetical concern that the Department does not support with any evidence. And the proposed solution—to rely exclusively on the phrase "acceptable and effective"—would do nothing to resolve even this hypothetical confusion, since that phrase too is undefined by the stature and is open to broader interpretations than "medically approved."

Finally, removing "medically approved" would send a harmful signal to Title X programs and recipients. It would send the message that Title X is no longer concerned with its supported family planning methods being accepted within and approved by the broader medical communities. Frankly put, removing "medically approved" sends the message that low-income patients who rely on Title X for care do not merit the medically approved treatments offered to higher-income patients. The Department's meager explanation for the change, most of which are internally inconsistent and deficient on their face, do not justify sending this message to the people Title X is meant to serve.

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[260] 83 Fed. Reg. at 25,515.
[261] *Id.*

J. New Primary Care Requirements (§ 59.5).

The Department proposes to add a new requirement that Title X service sites either directly provide primary care services or have a "robust referral linkage" with nearby primary care providers. We find the Department's proposed primary care requirement problematic for several reasons. First, the Department fails to articulate any legal basis for its requirement. Second, the Department's justification for its proposed requirement is inadequate. Finally, the regulatory text intended to implement the primary care requirement is unclear. For these reasons, we urge the Department to withdraw its proposed primary care requirement.

1. The Department offers no legal basis for its proposed primary care requirement.

There is no statutory basis for the Department's proposal that Title X projects "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."[262] Title X is specifically designed to support projects that "offer a broad range of acceptable and effective *family planning* methods and services,"[263] not primary care.[264]

Congress clearly understood the distinction between family planning services, provided under Title X, and primary health care, which it supported elsewhere. Title X is an amendment of the Public Health Service Act.[265] Within the larger statute, Congress created a separate program to ensure people with low incomes have access, principally through FQHCs, to primary medical care such as laboratory and radiology services, cholesterol screening, emergency medical services, and pediatric eye, ear, and dental examinations.[266] Consistent with that separation, the Department's regulations have long recognized that Title X family planning providers should refer patients elsewhere for necessary primary health care.[267] Title X programs play a different role than programs that support providers of primary health care.

2. The Department fails to adequately justify its proposed primary care requirement.

Congress's mandate to provide comprehensive family planning care is most effectively met by family planning specialists. Experience has shown that Title X health centers that specialize in reproductive health provide more comprehensive and accessible care than generalist,

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[262] Proposed 42 C.F.R. § 59.5.
[263] 42 U.S.C. § 300(a) (emphasis added).
[264] *See also* Family Planning Services and Population Research Act of 1970, Pub. L. No. 91-572 § 2, 84 Stat. 1504 (1970) (purpose of the Act is "to assist in making comprehensive voluntary family planning services readily available to all persons desiring such services").
[265] Pub. L. No. 78-410, 58 Stat. 682, codified at 42 U.S.C. § 201 *et seq.*
[266] *See* 42 U.S.C. § 254b(b)(1); *see generally id.* § 254b et seq.
[267] *See* 42 C.F.R. § 59.5(b)(8).

primary-care focused facilities like FQHCs.[268] Specialized providers provide the most up-to-date services and information including a wide range of contraceptive options, which primary care providers on the whole are simply unequipped to offer. Indeed, that is why many primary care providers refer patients to specialized health centers for reproductive health care. Furthermore, many patients prefer and affirmatively seek providers at specialized health centers because those providers are both knowledgeable about and sensitive to issues relating to sexual and reproductive health.[269]

Research from the Guttmacher Institute suggests that primary care providers would not be able to serve all of the women who rely on different types of providers for Title X-supported services.[270] In particular, the proposed rule overlooks the challenges facing people in rural and underserved areas that may not have "primary health providers . . . in close physical proximity."[271] Excluding family planning clinics from the Title X program because they do not offer comprehensive primary care or are not near a primary care provider could make it more difficult for these women to access the full range of family planning services that are available under the current program. As explained in greater detail above,[272] reproductive-health focused providers play an important role in serving Title X patients and are more likely than other types of providers to offer a broad range of quality family planning services. If these providers are forced to exit the program, the Department would, in many communities, find it difficult or impossible to identify alternative entities that are able to serve the same volume of patients with the same range of services at the same level of care. Forced to delay or forgo basic preventive services as a result, many patients that previously were able to access Title X-funded care from Planned Parenthood or other reproductive health-focused providers would experience adverse health consequences, including unintended pregnancies, undetected STDs, and other poor health outcomes. This would create costs for patients, the health care system, and the public.

4. The Department's regulatory text is unclear.

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[268] *See* Frost et al., Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols at 31, The Guttmacher Institute (2016).

[269] *See* Susan Wood et al., Health Centers and Family Planning: Results of a Nationwide Survey vii, 47-48, The George Washington University School of Public Health & Health Services (2013) (noting that many patients "desire separate systems of health care for primary care and family planning needs" and that independent centers "foster[] more access points," offer "more choice in providers," and "separat[e] out … one's general family practice provider from a provider of confidential family planning services"), available at https://hsrc.himmelfarb.gwu.edu/cgi/viewcontent.cgi?article=1059&context=sphhs_policy_facpubs.

[270] Kinsey Hasstedt, *Beyond the Rhetoric: The Real-World Impact of Attacks on Planned Parenthood and Title X* (2017), available at https://www.guttmacher.org/gpr/2017/08/beyond-rhetoric-real-world-impact-attacks-planned-parenthood-and-title-x ("FQHC sites alone could not sustain the current reach of Title X. If asked to serve all of the women who rely on many different types of providers for Title X-supported services, FQHC sites providing contraceptive care would have to at least double their contraceptive client caseloads in 41 states.… In 27 of those states, these FQHC sites would have to at least triple their capacity. Nationwide, this adds up to an additional 3.1 million clients.").

[271] Proposed 42 C.F.R. § 49.3(a)(12).

[272] *See supra*, p.15.

The Department's proposed primary care requirement is unclear. As proposed, the regulatory text would fail to give sufficient notice to Title X recipients about their obligations under the Proposed Rule. In clarifying these issues, a reasoned justification should be provided where the Department's clarification reflects a policy choice for which the Proposed Rule fails to offer a justification or explanation.

- At proposed section 59.5(a)(12), the Department states that Title X providers "should" either provide primary care services onsite or have robust referral linkages. The use of "should" rather than "must" creates the impression that, while Title X providers may be permitted or even encouraged to do these things, the primary care instructions are not mandatory. As shown above, the meaning of this provision will be of great consequence to Title X recipients, so the Department should clarify in rule language what is meant.

- While proposed section 59.5(a)(12) gives Title X service providers the option to either provide primary care services onsite or "have a robust referral linkage" with nearby providers, the Department fails to define the meaning of the term "robust." It is unclear, for example, whether ordinary referral arrangements would suffice to meet this standard, or whether a particular number or type of arrangement would be necessary. This, too, should be explained in greater detail.

K. New Notification and Reporting Requirements (§ 59.17).

The Department proposes to add to the Title X regulations a number of new requirements relating to state laws on notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking. Planned Parenthood shares the Department's concern with abuse and exploitation of any kind. As an experienced nationwide provider of Title X services, we comply fully with all applicable state law requirements. Still, we find several problems with the Department's proposed requirements. First, the Department lacks the legal authority to enforce these state law provisions. Second, the proposed requirements lack sufficient justification. Finally, the regulatory text put forth to implement these requirements is unclear. So, we urge the Department to withdraw its proposed notification and reporting requirements.

1. *The Department lacks the legal authority to enforce state notification and reporting requirements.*

Under the Proposed Rule, the Department seeks to establish itself as the arbiter of compliance with state notification and reporting requirements regarding child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking. The Proposed Rule interprets the language from the appropriations law to create an affirmative obligation on Title X providers to prove, via "documentation or other assurance," compliance to the Department with state law requirements. Yet the Department does not cite any legal support for its authority to

measure compliance with these state laws. The appropriations law certainly does not place the responsibility in the hands of the Department. Rather, it merely notes that Title X projects are not exempt from certain state law notification requirements. Given the complexity of state notification requirements,[273] the Department has not demonstrated that it has the capacity or the authority to assume the responsibility of measuring compliance with these requirements.

2. *The Department's proffered justification for its proposed notification and reporting requirements is inadequate.*

The proposed notification and reporting requirements lack a sufficient policy rationale. We specifically contest two points underpinning the Department's proposed new state reporting and notification requirements. First, the Proposed Rule provides that "[s]ome practitioners have proposed that providers avoid soliciting or determining the age of the adolescent or the age of their sexual partner as a means of assuring the adolescent of confidential services and, thus, avoiding the potential responsibility of reporting."[274] Yet, having provided no evidence or explanation for this serious allegation, the Department cannot rely on it as a basis for policy-making. Second, in concluding that efforts to secure compliance with state notification and reporting laws should be strengthened, the Department cites a 2005 Report by the Department's OIG. In the Department's summation, the HHS OIG "could not determine the extent to which grantees actually comply with [state notification and reporting] requirement."[275] But this is a blatant mischaracterization. Nowhere does the 2005 Report claim that the HHS OIG attempted (let alone failed) to determine grantees' actual compliance with these state law requirements. Rather, it set out to "determine how OPA informs its grantees of their reporting requirements and monitors its grantees regarding these requirements."[276] And it learned, unsurprisingly, that "OPA has informed and periodically reminds Title X grantees of their responsibilities regarding State child-abuse and sexual-abuse reporting requirements" and "OPA includes State reporting requirements in its reviews and site visits of grantees."[277] So the 2005 Report does not constitute evidence for the Department's notion that existing efforts to monitor compliance with these state laws are inadequate.

3. *The Department's regulatory text is unclear.*

The proposed regulatory text to implement the Department's new requirements is unclear as proposed. This language does not give Title X recipients sufficient notice about their obligations under the Proposed Rule. In clarifying these issues, a reasoned justification should be provided

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[273] *See* HHS OIG, *Letter on Federal Efforts to Address Applicable Child Abuse and Sexual Abuse Reporting Requirements for Title X Grantees (OEI-02-03-00530)* (Apr. 25, 2005), available at https://www.hhs.gov/opa/sites/default/files/child-abusereporting-requirements.pdf.
[274] 83 Fed. Reg. at 25,520.
[275] *Id.*
[276] HHS OIG, *Letter on Federal Efforts to Address Applicable Child Abuse and Sexual Abuse Reporting Requirements for Title X Grantees (OEI-02-03-00530)* (Apr. 25, 2005), available at https://www.hhs.gov/opa/sites/default/files/child-abusereporting-requirements.pdf.
[277] *Id.*

where the Department's clarification reflects a policy choice for which the Proposed Rule fails to offer a justification or explanation.

- Proposed section 59.17(b)(1)(iv) would require Title X projects to implement a plan that includes a "*[c]ommitment* to conduct a preliminary screening of *any teen* who presents with" an STD, pregnancy, or any other suspicion of abuse" (emphasis added). Yet the same provision would also "*require*" such screening for patients that are "*under the age of consent* in the state" (emphasis added). The Department should clarify whether this represents two distinct instructions to Title X projects depending on whether a teen Title X patient is "under the age of consent." If it does not, the Department should rewrite the provision to reduce confusion.

- This same proposed section provides that "[p]rojects are permitted to diagnose, test for, and treat STDs." Currently, Title X projects are permitted to provide STD services, including testing, diagnosis, and treatment services, in certain circumstances. The Proposed Rule, moreover, reinforces that "[f]amily planning services include . . . prevention, diagnosis, and treatment of infections and diseases which may threaten childbearing capability or the health of the individual, sexual partners, and potential future children." The Department should clarify whether, by the addition of this text, it intends to expand or alter the circumstances in which recipients may provide STD services as a part of a Title X project. If the Department intends to expand the provision of STD services within Title X projects, it must consider the costs and operational implications that are likely to result.

L. Transition Provisions (59.19).

The Department proposes two different periods to allow affected entities to transition to the new requirements established under the Proposed Rule. In proposed section 59.19(a), the Department allows for one-year of transition period to come into compliance with the physical separation requirements as modified by the proposed section 59.15. In proposed sections 59.19(b) and (c), the Department provides for a 60-day transition period to come into compliance with the financial separation requirements and all other provisions of the Proposed Rule. The Department provides absolutely no information about how it arrived at the lengths of time proposed, and it is clear that they do not allow adequate time for transition.

As laid out in detail in the rest of our comments, this Proposed Rule will require extensive changes to the way that the Title X program operates, including significant changes for Title X providers—changes for which 60 days are clearly inadequate. Investing in and changing record keeping systems, creating and formalizing referral arrangements, developing protocols for the oversight of referral partners, and implementing new training systems will all require significant investments of time and money that cannot be accomplished within such a truncated timeframe.

For example, the proposed section 59.17's new reporting requirements will require significant modifications to existing electronic health record systems, revisions to practices and protocols, and significant training. None of these things can be accomplished within 60 days. Similarly, the proposed section 59.5(a)(12)'s primary care requirements may require the establishment of additional services onsite or the establishment of a "robust referral linkage," potentially entailing the formation of new partnerships or the formalization of existing ones. In our experience, these types of changes could require many months to make. And while not entirely clear, the proposed section 59.5(a)(1) seems to imply that all Title X projects would be required to provide adoption services as a part of their infertility service offering. Many Title X projects do not currently provide adoption services. Developing this capability could certainly take longer than one year. Another example is the proposed re-definition of low-income in section 59.2, which may require the implementation of and training on new verification practices, new billing practices, revisions to the sliding fee scale, and other operational shifts. Other provisions of the rule will similarly require extensive changes that necessitate a more reasonable transition period.

As to the physical separation requirements in particular, one year is radically insufficient to allow Title X providers to make the kinds of changes that would be required under this proposal. As explained in greater detail above,[278] compliance with these provisions will require locating and constructing new sites, what can easily be a multi-year process.

Federal regulatory changes frequently provide transition periods of one or more years. Given that there is no statutory or regulatory requirement to make the terms of this rule effective within any particular timeframe, there is absolutely no reason to provide such truncated transition periods. If the Department moves forward with its intention to issue this rule despite all the reasons laid out as to why it should not do so, it should allow a transition period of at least three years for the physical separation requirements and at least one year for the other provisions. Moreover, the Department should schedule the changes to take effect at the end of the project period during which the rule is finalized, so that Title X participants are not forced to comply with entirely new requirements in the middle of their grants, nor confused about what is required from them under their current grants.

II. The Department Should Extend The Comment Period for The Proposed Rule by at Least 60 Days to Allow Meaningful Public Input.

Planned Parenthood requests an extension of the Department's public comment period for the Proposed Rule. We believe meaningful public input cannot be provided within the current 60-day public comment period. We therefore ask the Department to extend the public comment period for at least an additional 60 calendar days.

[278] *See supra*, at p.30.

The Department's Proposed Rule is too complex, its effects are too wide-ranging, and its consequences are too important to permit meaningful public participation in the existing 60-day comment period. The Administrative Procedure Act (APA) provides that "the agency shall give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments."[279] Meaningful opportunity for comment, under the APA, means giving the public "enough time with enough information to comment and for the agency to consider and respond to the comments."[280] The Proposed Rule raises a range of sophisticated questions, including questions relevant to the Department's statutory authority, the constitutionality of the Proposed Rule, its interaction with other federal and state requirements, its economic and health-related impacts, and its other effects. Still more, the Proposed Rule does not cite or account for important data and evidence, and the Department has failed to undertake a comprehensive analysis of its consequences, shifting the burden of analysis and commentary to the public. To meet this challenge, the many stakeholders that would be affected by the Proposed Rule should be given more than 60 days to conduct a thorough appraisal of its terms and offer the Department comment on the myriad issues that are raised.

In requesting this extension, we underscore the unusual lack of notice prior to the Proposed Rule's submission to the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB/OIRA); the alarming speed at which the Proposed Rule emerged from review at OMB/OIRA; and the noteworthy lack of public engagement with stakeholders prior to its issuance. For instance, there was no mention of the proposal in the Fall 2017 or Spring 2018 Regulatory Agenda. To the best of our knowledge, there was no early outreach to affected stakeholders as is policy under Executive Order 13563 and associated OMB/OIRA guidance. After the Proposed Rule was received by OMB, all meeting requests submitted pursuant to Executive Order 12866 were denied. And despite this lack of public engagement and engagement with regulated entities, the rule was discharged from OIRA in less than two weeks.

This seems to belie Department's commitment to understanding and considering the various interests affected by the Proposed Rule. While we and thousands of local, state and federal stakeholders have done our best to comment within the allotted time, additional time would allow us to more fully evaluate the impact of the rule. Other stakeholders are likely eliminated from the rulemaking process entirely because of the Department's abbreviated timeline. As a leading partner in the Title X program for nearly 50 years, Planned Parenthood is well-qualified to provide the Department with data and information relevant to its decision-making process given sufficient notice. We can see no benefit to expediting this rulemaking at the cost of this valuable information.

III. The Department Has Not Assessed All The Costs and Benefits of The Proposed Rule and Its Regulatory Alternatives.

[279] 5 U.S.C. § 553(b).
[280] *Prometheus Radio Project v. F.C.C.*, 652 F.3d 431, 450 (3d Cir. 2011).

The Department's Proposed Rule would generate no meaningful benefits while imposing substantial costs on Title X recipients, the health of the public, and the economy overall. Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of proposed regulations. Agencies, moreover, have an obligation to engage in "reasoned decisionmaking," and "reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions."[281] The Department's deeply flawed and cursory attempt to produce a regulatory impact analysis is insufficient. The Department has failed to consider or adequately recognize a number of costs associated with its proposal and makes other significant errors. In fact, the Department's analysis does not even conform to guidance produced within the Department on the performance of Regulatory Impact Analysis.[282] Critically, the Department:

- Ignores the considerable health-related costs that would result from the Proposed Rule.
- Dramatically underestimates the compliance costs that would result from the Proposed Rule.
- Is silent on the Proposed Rule's distributional effects on groups that face inequities in health care.
- Fails to demonstrate any benefits arising from the Proposed Rule.
- Makes errors and fails to justify crucial steps in its regulatory impact analysis.
- Does not properly consider regulatory alternatives.

Our initial analysis leads us to conclude that, contrary to the Department's contentions, the Proposed Rule will waste public and private resources and harm the health of innumerable people who are uninsured and have low incomes, many of whom are people of color, in order to "solve" a nonexistent problem where the Department acknowledges there are zero quantifiable benefits. After correcting the Department's inappropriately low estimate of the Proposed Rule's costs, we also conclude that the Department erred in its determination that the Proposed Rule is not "economically significant" as measured by the $100 million threshold as well as its impact on the public health. We urge the Department to withdraw its rule. If the Department proceeds regardless, we urge it to undertake a comprehensive analysis that accounts for the issues we highlight.

A. The Department ignores the considerable health-related costs that would result from the Proposed Rule.

The Department entirely avoids discussion of a number of the proposal's obvious defects and costs. It appears that these problems, together, would amount to harms far in excess of the proposal's asserted benefits. The Department's failure to grapple with these costs render its

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[281] *Michigan v. E.P.A.*, 135 S. Ct. 2699, 2707 (2015); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983).

[282] Office of the Assistant Secretary for Planning and Evaluation (ASPE), *Guidelines for Regulatory Impact Analysis* (2016), *available at* https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.

policy rationale inaccurate and incomplete. As shown below, the Proposed Rule's likely consequences on the health of Title X patients would "adversely and materially affect[] . . . public health,"[283] therefore constituting a significant regulatory action under Executive Order 12866.

1. Several provisions in the Proposed Rule would force reproductive health-focused providers such as Planned Parenthood out of Title X, resulting in significant health-related costs.

At least three of the Department's proposed revisions would contribute to the reduced participation of reproductive health-focused providers, including Planned Parenthood, in the Title X program. First, the Department's proposed ban on abortion referrals at section 59.14 is fundamentally at odds with the professional and ethical obligations of health care professionals. For this reason, Planned Parenthood and other Title X recipients—including Washington,[284] New York,[285] Hawaii,[286] and Oregon[287]—have announced that, if the Proposed Rule is finalized and made effective, they would be forced to decline Title X funds. Second, the Department's proposed "physical and financial" separation requirement at section 59.15 would place impracticable financial burdens on Title X service sites that would force many health care providers to exit the program, as well. Third, the Department's proposed revisions to the eligibility and selection criteria for Title X grants at revised section 59.7 would have the likely effect of redirecting Title X grant funds away from experienced reproductive health-focused providers such as Planned Parenthood, and toward other "diverse" grantees with little or no experience providing family planning services. The Department fails to estimate the serious negative consequences these changes in the nationwide network of Title X-funded providers would have on access to care, health outcomes, efficiency, and other costs.

Together, these proposals would reduce patients' access to a broad range of quality family planning methods and services. Planned Parenthood health centers serve more family planning patients than other safety-net providers. Of the 6.2 million female contraceptive patients at

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[283] 83 Fed. Reg. at 25,521.
[284] Press Release, Washington Governor Jay Inslee, Inslee Statement on Protecting Washington Women from Trump Gag Rule (July 30, 2018), available at https://www.governor.wa.gov/news-media/inslee-statement-protecting-washington-women-trump-gag-rule
[285] Press Release, New York Governor Andrew M. Cuomo, Governor Cuomo Issues Letter to HHS Secretary Threatening Legal Action if Title X Rule Changes are Adopted (July 30, 2018), available at https://www.governor.ny.gov/news/governor-cuomo-issues-letter-hhs-secretary-threatening-legal-action-if-title-x-rule-changes-are
[286] Press Release, Hawaii Governor David Ige, Governor Ige Opposes Trump Administration's Attempt to Limit Women's Health Care Services (July 30, 2018), available at https://governor.hawaii.gov/newsroom/latest-news/office-of-the-governor-news-release-governor-ige-opposes-trump-administrations-attempt-to-limit-womens-health-care-services/.
[287] Press Release, Oregon Governor Kate Brown, Governor Brown on Federal Title X Rollbacks on Access to Reproductive Health (July 30, 2018), available at https://mailchi.mp/oregon/news-release-governor-brown-on-federal-title-x-rollbacks-on-access-toreproductive-health?e=351baaef1c.

publicly funded family planning clinics in 2015, 32 percent received care at Planned Parenthood health centers.[288] On average, each Planned Parenthood health center serves more family planning patients than other individual provider; for instance, Planned Parenthood health centers had an average annual contraceptive caseload of 2,950 patients per site, compared to 320 per site at FQHCs.[289] Although Planned Parenthood health centers represent only 13 percent of Title X service sites, they serve over 40 percent of the program's patients.[290]

Other safety-net providers would face an enormous strain in attempting to absorb the patients that would lose access to services. In order to serve all the women who currently obtain contraceptive care at Title X–supported Planned Parenthood health centers in the 50 states and the District of Columbia, other Title X providers would need to increase their client caseloads by 70 percent, on average.[291] In 13 states, other Title X providers would have to at least double their capacity—and in many, to an even greater degree—to maintain the current reach of their states' Title X networks.[292] If demand is to be met, these increases in capacity would require investment, which the Department does not account for. Also, many Planned Parenthood health centers serve communities that lack alternative providers of Title X services. Fifty-six percent of Planned Parenthood health centers are in health provider deserts, where residents live in areas that are medically underserved and they may have nowhere else to go to access essential health services without Planned Parenthood. Even in communities where alternative entities could be identified, they would incur unnecessary costs on the front-end in readying systems, revising protocols and policies, entering into contracts and other agreements, and training staff, all while the existing capabilities of former participants would be wastefully sidelined.

The patients who are able to shift from Planned Parenthood to other safety-net providers, in addition to suffering a costly and harmful disruption in access to services, would likely receive inferior care. First, the disruption caused by having to switch providers itself would impose costs on patients who would have to engage in the time-intensive process of locating, evaluating, and selecting a suitable alternative provider, as well as harm to their health from potentially delayed access to care. And second, once a provider is selected, this new provider may not offer the same range of services at the same level of quality as a patient's previous Title X-funded provider. Planned Parenthood and other providers that specialize in reproductive health typically offer a broader range of reproductive health services than other safety-net providers. In a study by the administrators of Title X evaluating service delivery characteristics of Title X providers,

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[288]Guttmacher Institute, "Publicly Funded Contraceptive Services At U.S. Clinics, 2015" (2016), available at https://www.guttmacher.org/sites/default/files/report_pdf/publicly_funded_contraceptive_services_2015_3.pdf.

[289] *Id.*

[290] *Id.*

[291]Kinsey Hasstedt, Beyond the Rhetoric: The Real-World Impact of Attacks on Planned Parenthood and Title X, Guttmacher Policy Review, (Aug. 2017), available at https://www.guttmacher.org/gpr/2017/08/beyond-rhetoric-real-world-impact-attacks-planned-parenthood-and-title-x.

[292] *Id.*

Planned Parenthood health centers were associated with a higher quality and scope of family planning services when controlling for other health center characteristics, including the onsite availability of each contraceptive method, comprehensive counseling, and adolescent-friendly services.[293] In general, 99 percent of Planned Parenthood health centers provide at least 10 reversible contraceptive methods on site, compared with 71 to 81 percent of other provider types.[294] Planned Parenthood health centers are more likely than all other types of clinics to provide a Long Acting Reversible Contraceptive (LARC) method (98 percent versus 69 percent to 77 percent); are more likely than FQHCs and "other" clinics to provide pill supplies on-site (83 percent versus 34 to 56 percent); and are more likely than any other types of clinics to provide same-day IUD insertions (81 percent versus 30 to 48 percent). Eighty-three percent of Planned Parenthood health centers provide initial oral contraceptive supplies and refills on-site, compared with only 34 percent of FQHCs.[295] Planned Parenthood health centers also typically have shorter waiting periods—an average of 1.2 days for an initial contraceptive visit—and appointments can often be made the same day.[296] By contrast, one study found that the average wait time for an FQHC appointment was nine days.[297] A shift to other providers, moreover, may cause additional costs on patients or third-party payers. For example, because federal law provides that Medicaid payments made to FQHCs must be above a minimum standard, patients shifting from other providers to FQHCs could result in greater costs to state Medicaid programs.[298]

Additionally, Title X patients may prefer to see a provider that specializes in reproductive health. Research has shown that patients prefer to receive care at specialized clinics, like Planned Parenthood health centers, because such clinics can offer better or faster services such as having oral contraceptives available on site or same day IUD insertion.[299] Also, women trust OB/GYN specialists and are generally more likely to talk with them about health concerns both within and outside the scope of sexual and reproductive health care.[300] For instance, women are twice as likely to talk with OB/GYN's about birth control and HIV than internal or family medicine

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[293] Carter, et al., *Four aspects of the scope and quality of family planning services in US publicly funded health centers: Results from a survey of health center administrators*, 94 J. Contraception 340 (2016), http://dx.doi.org/10.1016/j.contraception.2016.04.009.
[294] Zolna, M. R., & Frost, J. J., *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols* (2016), available at https://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.
[295] *Id.*
[296] *Id.*
[297] Rhodes, K. V., Kenney, G. M., Friedman, A. B., Saloner, B., Lawson, C. C., Chearo, D., &; Polsky, D., *Primary Care Access for New Patients on the Eve of Health Care Reform*, JAMA Internal Medicine, 174(6), 861-69 (2014).
[298] Kaiser Family Foundation, "Medicaid Benefits: Federally Qualified Health Center Services," available at https://www.kff.org/medicaid/state-indicator/federally-qualified-health-center-services/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.
[299] Frost, J.J., Gold, R.B., 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, 22(6) (2012), e519-e525.
[300] PerryUndem, "Research Findings: Women + OB/GYN Providers," (Nov. 2013), available at https://www.plannedparenthood.org/files/4914/0656/5723/PPFA_OBGYN_Report.FINAL.pdf.

providers and are more likely to talk to OB/GYN's about substance abuse.[301] Thirty-five percent of women report their OB/GYN being their primary health care provider.[302]

Reduced access to a broad range of quality family planning care resulting from the Department's proposed ban on abortion referrals would translate to worse health outcomes for Title X patients. These adverse consequences are likely to include, among others, more unintended pregnancies. In 2015, the Guttmacher Institute estimated that Planned Parenthood's provision of contraceptive services averted 430,000 unintended pregnancies.[303] If 10 percent fewer pregnancies were averted as a result of the Proposed Rule, this would create considerable cost to patients and the health care system. In Medicaid, the average total maternal and newborn charges for care with vaginal or cesarean births are $29,800 and $50,373, respectively.[304] So, at minimum, even a 10 percent increase in births resulting from the Proposed Rule would impose $128.1 million in costs (4,300 x $29,800). Similarly, a study in California found that removing free or low-cost access to family planning services would result in patients using less effective methods of contraception with correspondingly higher rates of failure.[305] Moreover, for every public dollar spent on publicly funded family planning, the public saves $7.09 in costs related to unintended pregnancies and other related reproductive health issues. Unintended pregnancy can put the health of women and children at risk.[306] It is also likely that a decrease in contraceptive use would result in a rise in the rate of abortions.[307]

Furthermore, reduced access to family planning care also means STDs will go undetected or be detected later, leading to higher rates of STDs and more severe consequences for patients experiencing them. STDs among women can result in pelvic inflammatory disease, a major

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[301] *Id.*
[302] *Id.*
[303] Guttmacher Institute, *Unintended Pregnancies and Abortions Averted by Planned Parenthood*, (Jun. 2017), available at https://www.guttmacher.org/infographic/2017/unintended-pregnancies-and-abortions-averted-planned-parenthood-2015.
[304] Truven Health Analytics, The Cost of Having a Baby in The United States: Executive Summary (Jan. 2013), available at https://transform.childbirthconnection.org/wp-content/uploads/2013/01/Cost-of-Having-a-Baby-Executive-Summary.pdf.
[305] M. Antonia Biggs et al., *California Family Planning Health Care Providers' Challenges to Same-Day Long-Acting Reversible Contraception Provision*, 126 Obstetrics & Gynecology 338, 338 (2015).
[306] ACOG, *Committee Opinion No. 654, Reproductive Life Planning to Reduce Unintended Pregnancy* (2016), https://journals.lww.com/greenjournal/Fulltext/2016/02000/Committee_Opinion_No__654___Reproductive_Life.53.aspx; ACOG, *Frequently Asked Questions No. 182, Obesity and Pregnancy* (2016), https://www.acog.org/Patients/FAQs/Obesity-and-Pregnancy; ACOG, *Frequently Asked Questions No. 142, Diabetes and Women* (2016), https://www.acog.org/-/media/For-Patients/faq142.pdf?dmc=1&ts=20180724T1744238808.
[307] Lawrence B. Finer & Mia R. Zolna, *Declines in Unintended Pregnancy in the United States, 2008-2011*, 374 N. Engl. J. Med. 843, 846-47 (2016) (finding that approximately 40 percent of unintended pregnancies end in abortion).

cause of infertility, ectopic pregnancy, and chronic pelvic pain.[308] Certain STDs, including syphilis and gonococcal infections, also facilitate the transmission of HIV.[309] In 2010, publicly funded family planning sites, including Planned Parenthood health centers, averted 99,100 cases of chlamydia; 16,240 cases of gonorrhea; 410 cases of HIV; 13,170 cases of pelvic inflammatory disease (PID) that would have led to 1,130 ectopic pregnancies; 2,210 cases of infertility.[310] These preventable infections are costly to patients and the health care system. For example, the Guttmacher Institute estimates that the total burden of the nine million new cases of STDs that occurred among 15-24-year-olds in 2000 was $6.5 billion, with HIV and the human papillomavirus (HPV) the most costly STDs by far in terms of total estimated direct medical costs, accounting for 90% of the total burden ($5.9 billion).[311] In addition to a rise in unintended pregnancies and STDs, reduced access to Planned Parenthood's Title X services would likely have other negative effects on health, as well.

Unfortunately, we already have seen the negative health consequences of laws and policies that restrict the ability of providers like Planned Parenthood to serve patients with low incomes. For example, one study found that the exclusion of Planned Parenthood from a state publicly funded family planning program in Texas was associated with adverse changes in the provision of contraception, including a 35 percent decline in the use of the most effective methods of contraception and an increase in unintended pregnancy leading to a 27 percent increase in childbirth covered by Medicaid.[312]

2. *A number of additional health-related costs would result from the Proposed Rule.*

Under the Proposed Rule, patients who are not denied Title X-funded care altogether will experience inferior care as a consequence of the Department's proposed ban on abortion referrals at section 59.14 and the proposed "physical and financial" separation requirement at section 59.16.

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[308] Centers for Disease Control and Prevention, *Pelvic Inflammatory Disease (PID) – CDC Fact Sheet* (2014), available at https://www.cdc.gov/std/pid/pid-fact-sheet-july-2014-press.pdf; Kristen Kreisel et al., *Prevalence of Pelvic Inflammatory Disease in Sexually Experienced Women of Reproductive Age—United States 2013-2014*, 66 Morbidity & Mortality Wkly Rpt. 80, 80 (2017).
[309] CDC, Sexually Transmitted Disease Surveillance 2015, at 6, 43, 54, 55 (2016), available at https://www.cdc.gov/std/stats15/std-surveillance-2015-print.pdf.
[310] Jennifer J. Frost et al., *Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program*, 92 Milbank Q. 667, 668 (2014).
[311] Guttmacher Institute, The Estimated Direct Medical Cost of Sexually Transmitted Diseases Among American Youth, 2000, (2004), available at https://www.guttmacher.org/journals/psrh/2004/estimated-direct-medical-cost-sexually-transmitted-diseases-among-american.
[312] Stevenson, A. J., Flores-Vazquez, I. M., Allgeyer, R. L., Schenkkan, P., & Potter, J. E., *Effect of Removal of Planned Parenthood from the Texas Women's Health Program*, New England Journal of Medicine, 374(9) (2016), 853-60.

For those Title X-funded entities that will be subject to the terms of the proposed ban on abortion referrals or would be allowed to withhold counseling, the Department fails to consider the probable negative effects on the quality of patient care at Title X-funded sites, including interference with care coordination, and the burdens it places on patients. Full information is critical to positive health outcomes. In a meta-analysis of studies examining care management plans, the authors conclude that "patient health outcomes can be improved with good physician-patient communication," which includes the need for patients to feel "that they are active participants in care and that their problem has been discussed fully."[313] Suppressing a provider's discussion with a patient about where and how to access abortion, as per the Department's proposal, interferes with such "full discussion." Referrals are also an important part of care coordination. For example, a survey on care coordination from the Department's Agency for Healthcare Research and Quality asks patients whether they were able to obtain a needed referral from their primary care provider to see another health care professional in the past year.[314] The Department must assess these costs.

The proposed ban on referrals for abortion would also harm patients seeking an abortion by introducing extraordinary difficulties into the already arduous process of obtaining one. It would do this not only by forcing providers to decline to offer any guidance to patients seeking abortion, but also by coercing or confusing patients into unwanted appointments for prenatal care. Under proposed section 59.14, only in the narrow circumstance where a pregnant patient "clearly states that she has already decided to have an abortion" would the rule allow a doctor to give that patient a list of "comprehensive health service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care)" without identifying which providers on that list actually offer abortion. All other pregnant patients could only be given a list of "comprehensive health service providers (including providers of prenatal care) who do not provide abortion as a part of their services" under the proposed rule. In addition to banning abortion referrals, the Proposed Rule would appear to require Title X projects to not only refer any pregnant patient for "appropriate prenatal and/or social services," but to also give the patient "assistance with setting up a referral appointment to optimize the health of the mother and unborn child."[315] This appears to require Title X projects to set up an appointment for a patient for "prenatal care and delivery, infant care, foster care, or adoption" even if the patient has declined to be connected to those services, or worse, even if the patient had already clearly expressed her intent to have an abortion.[316]

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[313] Moira Stewart, PhD, *Effective Physician-Patient Communication and Health Outcomes: A Review*, Canadian Medical Association Journal, (May 1995), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1337906/pdf/cmaj00069-0061.pdf.
[314] Agency for Healthcare Research and Quality, "Care Coordination Measure for Primary Care Survey" (Jul. 2016), available at https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/prevention-chronic-care/improve/coordination/ccqmpc/ccqm-pc-survey-instructions.pdf.
[315] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25,531.
[316] *Id.*

Whether because patients are coerced into making an appointment with a provider that they never asked to see, or simply because of the deliberately confusing nature of the Department's approved "referral list," the Proposed Rule virtually guarantees that many abortion-seeking patients will be pressured or misled into scheduling one or more unnecessary in-person office visits for unwanted services. The Department fails to account for the costs this will cause for Title X patients (many of whom have low incomes and lack health insurance) who would be forced to pay for an unnecessary visit with another health care provider, arrange for transportation, and take time off from work or school—only to find out that they must do so once more to actually obtain an abortion. Studies of mandatory waiting periods for abortion confirm that imposing delays on access to abortion burdens patients and results in later-term abortions.[317] These extra visits would also impose unwarranted costs on health care providers, and would unnecessarily burden other publicly funded programs and/or health plans. Moreover, the Department fails to consider that the proposed referral ban would shift the burden of gathering and evaluating information about where and how to obtain an abortion to the patient. As the patient is much less likely than the provider to have a complete understanding of the available options and to be able to weigh the comparative advantages of each, the patient would have to engage in this process without guidance and at great personal expense. Thus, there are considerable costs to requiring additional, unnecessary visits for patients.

Moreover, the Department's proposed "physical and financial" separation requirement would harm patients by interfering with quality of care, care coordination, and integration of services. For example, patients benefit from immediate, onsite access to a range of contraceptive methods after an abortion. According to a 2010 Guttmacher Institute survey of abortion patients, two-thirds expressed a desire to leave their appointment with a contraceptive method and slightly more than half indicated a preference for receiving contraceptive information and services during their abortion care rather than in other health care settings.[318] Yet the provision of same-day post-abortion contraception funded by Title X appears to be severely restricted or barred entirely under the proposed "physical and financial" separation requirement. Instead, two separate visits to separate facilities would most likely be necessary. This implies unnecessary costs to patients and providers that are unaccounted for by the Department and interferes with the integration of care. Furthermore, to the extent that this creates an obstacle for patients to

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[317] *See, e.g.*, Michael Lupfer and Bohne Goldfarb Silber, "How Patients View Mandatory Waiting Periods for Abortion," Family Planning Perspectives, (Mar. 1981), available at https://www.jstor.org/stable/2134696?seq=1#page_scan_tab_contents; Frances A. Althaus and Stanely K. Henshaw, "The Effects of Mandatory Delay Laws On Abortion Patients and Providers," Family Planning Perspectives, (Sept. 1994), available at https://www.jstor.org/stable/2135944; Joyce, Henshaw et al., "The Impact of State Mandatory Counseling and Waiting Period Laws on Abortion: A Literature Review," Guttmacher Institute (Apr. 2009), available at https://www.guttmacher.org/report/impact-state-mandatory-counseling-and-waiting-period-laws-abortion-literature-review.

[318] Megan K. Donovan, "Postabortion Contraception: Emerging Opportunities and Barriers," Guttmacher Policy Review (Oct. 2017), available at https://www.guttmacher.org/gpr/2017/10/postabortion-contraception-emerging-opportunities-and-barriers (citing the 2010 report).

obtain effective methods of contraception, the risk of unintended pregnancy among abortion patients may increase as a result.

On top of interruptions to same-day services, the Department's proposal to consider separate electronic health care records in its determination of compliance with the "physical and financial" separation requirement poses considerable risk to patients. A qualitative study of multiple electronic medical records within a single health care organization found "clear limitations" to this approach, the primary limitation being "the risk to patient safety."[319] "The greatest risk of multiple EMR use is the risk of missing data and any corresponding decision support that impact patient safety," for example, missing information about allergies or drug interactions; lab tests, imaging studies and procedures; "missing pregnancy or lactation information leading to inappropriate medication ordering, missing recent changes in renal function leading to inappropriate use of IV contrast dye, and incomplete or inaccurate past medical history or family history leading to inaccurate risk assessments."[320] These same risks would likely arise in implementation of the Department's proposed "physical and financial" separation requirement. The same study notes that "to safely and efficiently use more than one EMR, a considerable amount of IT work is necessary," implying necessary additional expenditures by Title X projects to ensure patient safety.[321]

Additionally, the proposed "physical and financial" separation requirement would likely reduce access to abortion referrals even for non-Title X patients. The "physical and financial" separation requirement expressly requires referrals for abortion to be provided separately from Title X services, necessitating separate facilities. As discussed below, the costs of avoiding noncompliance with the proposed separation standard would be financially impractical for many entities. Faced with the prospect of having to make costly investments to establish separate facilities, some recipients may instead forfeit their the provision of abortion referrals entirely in order to continue to participate in Title X. This would effectively withhold referrals from patients who seek non-Title X care from recipients, imposing harms and costs on these patients similar to those assessed for Title X patients above.

B. The Department dramatically underestimates the compliance costs that would result from the Proposed Rule.

Furthermore, as we show below, the Proposed Rule's likely compliance costs alone easily exceed the $100 million threshold for "economically significant" regulations. The proposed "physical and financial" separation requirement alone would force Title X recipients to bear enormous costs which receive no attention from the Department in its justification.

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[319] Payne, Fellner, et al, "Use of more than one electronic medical record system within a single health care organization," Applied Clinical Informatics (Dec. 2012), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3613036/.
[320] *Id.*
[321] *Id.*

1. The Department underestimates the number of Title X service sites that would bear costs under the proposed "physical and financial" separation requirement.

The Department vastly underestimates the number of entities that would have to comply with its proposal. The Department assumes that the "physical and financial" separation requirement would apply only to the estimated 20 percent of Title X service sites that offer abortion or that "may share resources with unaffiliated entities that offer abortion as a method of family planning."[322] But this does not reflect an accurate reading of the Proposed Rule.

As provided in proposed section 59.15, "[a] Title X project must be organized so that it is physically and financially separate . . . from activities that are prohibited under section 1008 of the Act and §§ 59.13, 59.14, and 59.16 from inclusion in the Title X program." This presumably extends the separation requirement with the same force to a range of conduct beyond providing abortion services to patients. For instance, it also applies to entities that refer for, promote, or support abortion, or that take "any other affirmative action to assist a patient to secure" an abortion (proposed section 59.14). The requirement also applies to entities that encourage or advocate for abortion (proposed section 59.16). This includes lobbying and political activity related to abortion; paying dues to certain organizations; and the provision of information "promoting a favorable attitude" toward abortion. It follows from the terms of the Proposed Rule that any recipient of Title X funds that engages in any of these activities would have to comply with the "physical and financial" separation requirement. All Title X-funded services sites at minimum currently refer for abortion upon request, and many undoubtedly perform some of the other activities prohibited by the provisions cited in proposed section 59.15.

As we mention above, some Title X service sites will determine that the program's rules are inconsistent with medical ethics and decline to continue to participate as Title X recipients if the Proposed Rule is made effective. Other Title X service sites may forfeit performing any abortion-related activities, such as providing referrals for abortion, in order to continue participating in Title X without incurring prohibitive compliance costs under the "physical and financial" separation requirement. However, the remaining Title X service sites must take steps to avoid noncompliance with the Department's proposed "physical and financial" separation requirement. This will be far higher than the 20 percent of service sites that the Department identifies in its Proposed Rule, and the Department must properly assess these costs. If, for purposes of these Comments, we assume that the number will be approximately 50 percent of current service sites, even under the Department's estimated average cost per service site of $20,000, which as explained below, is far too low, this would imply costs of $40.0 million ($20,000 x 1,949) in the first year.[323]

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[322] 83 Fed. Reg. at 25,525.

[323] Fowler, C. I., Gable, J., Wang, J., & Lasater, B., *Family Planning Annual Report: 2016 national summary* (Aug. 2017), *available at* https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf (reporting 3,898 service sites in 2016).

2. *Unassessed costs implied by the "physical and financial" separation requirement include building and renovation, personnel, and contracting.*

The Department estimates that, on average, each affected Title X service site would incur $20,000 in costs in order to come into compliance. Yet the Department does not support this estimate with any evidence based in actual practice, and it appears to be nothing more than an arbitrary number picked by the Department. The Department cannot satisfy its obligation to prepare a Regulatory Impact Statement, or to weigh the costs and benefits of the Proposed Rule, with unsupported estimates of cost. In fact, our experience assisting local affiliates that are renovating or building new facilities leads us to believe this significantly underestimates the total compliance costs.

To start with, the Department provides an underestimate of the resources needed to initially evaluate compliance at the service site- and grantee-levels. As shown above, the proposed "physical and financial" separation requirement amounts to a "facts and circumstances" standard under which the Department has significant latitude to make judgments about a Title X-funded entity's compliance. The use of a multi-factor test creates administrative costs that are not anticipated in the Proposed Rule. For example, it will be time-intensive to predict precisely how the proposed standard will be interpreted and applied in particular circumstances—either by the Department to a recipient, or by a recipient to its subrecipients. This uncertainty, moreover, also has other effects on the behavior of Title X recipients that is relevant to the costs of the Proposed Rule. Since the proposed regulatory text is so unclear, errors are more likely to occur in the administration of the "physical and financial" separation requirement: both incorrect judgments by the Department about what is allowable, and erroneous interpretations on the part of recipients. Unable to ascertain the precise boundaries of the regulation, risk-averse recipients are more likely to take precautions that are, strictly speaking, unnecessary and costly in order to avoid the risk of noncompliance. This confusion is made worse because the Proposed Rule, after instructing the Department to use a case-by-case approach, implies that "two distinct services collocated within a collocated space" would be banned,[324] and that "separate facilities—one facility providing Title X services and one providing abortion"—would be required.[325] Partially as a consequence of this oversteering, the costs borne by Title X-funded entities are likely to exceed the Department's estimated costs for evaluation.

On top of the costs of initial evaluation, Title X-funded entities will have to absorb the costs necessary to implement any changes required to "physically and financially" separate abortion-related activities from Title X project activities. These costs will exceed the Department's estimate by a large margin. We begin with the cost of building and renovating facilities in order to comply. The Proposed Rule would instruct the Department to look to "the degree of separation from facilities (e.g., treatment, consultation, examination and waiting

[324] 83 Fed. Reg. 25,519.
[325] *Id.*

rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites) in which prohibited activities occur and the extent of such prohibited activities." In the Proposed Rule, this is sometimes referred to as prohibiting the "collocation" of abortion-related activities and Title X activities. To avoid noncompliance, Title X-funded entities would have to either renovate existing facilities or build entirely new ones depending on the circumstances of each individual Title X service site.

To estimate the cost of these activities, we use top-line construction cost estimates from a report produced by Capital Link.[326] Although the report is based on a survey of community health centers, based on our extensive experience assisting local affiliates with constructing and renovating health centers, the costs presented for these facilities closely resemble the costs associated with family planning centers. In assessing costs, Capital Link recommends selecting an estimate between the median and the 75th percentile.[327] So, for these Comments, we assume that new construction will cost $400 per square foot while renovation will cost $330 per square foot. Furthermore, an average family planning center, based on our experience, is between 3,000 and 3,500 square feet, with a central estimate of 3,250 square feet. And although the Capital Link report does not provide an estimate for the cost of acquiring new commercial property, in our experience rental costs range from $50 to $100 per square foot, with a central estimate of $75 per square foot.

For those properties where a renovation of an existing facility is possible (*e.g.*, the addition of separate rooms, exits and entrances, and so on), we assume that at least half of the site's total area would need to be renovated. For such properties, we estimate that costs would be approximately $536,250 per facility (1,625 sq. ft. x $330). Where renovation is not possible, an entirely new location would be needed. For new locations where a pre-existing building exists, the necessary renovations are likely to cost approximately $1.1 million per facility (3,250 sq. ft. x $330), and site acquisition costs would come to approximately $243,750 (3,250 sq. ft. x $75), for an estimated total of $1.3 million per facility. Moreover, new properties with no existing physical plant would incur costs in the range of $1.3 million in new construction costs (3,250 sq. ft. x $400), and site acquisition costs would come to approximately $243,750 (3,250 sq. ft. x. $75), for an estimated total of $1.5 million per facility. We assume, conservatively, that only 10 percent of the service sites that would have to take steps to avoid noncompliance would establish new locations, which would be equally divided between new properties that have and do not have a pre-existing building. For the rest, it is assumed that only renovation of existing facilities would be required. We estimate that, even based on these conservative assumptions and assuming 50 percent of the current service sites must take steps to comply, *see supra*, p.85, building and renovation costs alone would total $1.2 billion in the first year after the regulation is finalized. This comes to an average cost of nearly $625,000 per affected service site.

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[326] Capital Link, *Estimating Capital Project Costs for Health Centers* (2011), *available at* http://www.caplink.org/images/stories/Resources/publications/Pub.EstimatingCapitalProjectCosts.pdf.
[327] Id.

In addition to costs directly related to purchasing and building, we note for the Department that obtaining the necessary approvals for locating a facility, especially an abortion facility, is often a lengthy and drawn-out process, implying additional costs for permitting, licensure, and meeting the requirements of targeted regulations. The Department has failed to account for any of these costs—an omission inconsistent with the Department's own guidance for performing Regulatory Impact Analysis.

On top of these building and renovation costs, the Department's proposed "physical and financial" separation standard would appear to require the duplication of certain expenses by Title X-funded entities, including contracts for goods and services and staff time, which would also imply significant costs that the Department fails to acknowledge in the first year and every subsequent year. For example, proposed section 59.15(c) would instruct the Department to look to "the existence of separate personnel, electronic or paper-based health care records, and workstations." It appears that the Proposed Rule would necessitate duplicating contracts for goods and services for each separate facility established to avoid noncompliance with the "physical and financial" separation requirement. This would at minimum include duplicate contracts for security vendors, cleaning, medical waste, laboratory services, utilities, electronic health care record systems (including separate licenses for each provider under each software product), phone systems, and web services. Also, additional clinical staff time would be necessary to staff and oversee separate facilities. We estimate this would amount to a permanent increase in clinical staff time of between 50-100 percent, depending on the volume of patients seen at a Title X service site and whether establishing a separate location would be required to avoid noncompliance. We arrive at this 50-100 percent estimated increase because staff roles that would have to be duplicated for each individual facility include, at minimum, a provider to see and treat patients (*e.g.*, physician or other advance practice clinician), 1-2 staff members positioned at the front desk, and 1-2 staff members facilitating patient care (*e.g.*, conducting laboratory work, intake, and follow-up). Moreover, additional back-office staff time would be necessary to perform the additional purchasing and contracting described above. An increase in staff time of this magnitude would almost certainly be accompanied by Human Resources and payroll staff time as well.

3. *To avoid noncompliance, recipients may have to bear other unmentioned costs.*

The Department fails to consider a number of other likely compliance costs. For instance, proposed section 59.5(a)(13)(iii) would require Title X projects to explain how they will ensure adequate oversight and accountability for the effectiveness of outcomes of those who serve as referrals for "ancillary or core services." If, by this proposal, the Department intends to expand the responsibility of Title X projects to oversee the delivery of non-Title X services, projects would have to bear additional costs to perform this oversight. In calculating these costs, the Department must also consider Title X projects' lack of comparative expertise in supervising these types of services, and the potential deterrent effect on the participation of otherwise willing partners that help to deliver these services, a potential set of "negative benefits."

C. The Department ignores the Proposed Rule's negative distributional effects on populations that already experience inequalities in health care.

As a part of its evaluation of the effects of its Proposed Rule, the Department is instructed to analyze "distributional effects," which consists of "the impact of a regulatory action across the population and economy, divided up in various ways (e.g., income groups, race, sex, industrial sector, geography)."[328] Yet the Department makes no attempt to identify and evaluate these effects. It is obvious, however, that the Proposed Rule's harmful effects on health would not be apportioned equally. Rather, the health consequences established above would disproportionately burden some groups for whom Title X-funded services are particularly crucial. Some of these groups, moreover, already face significant inequities in health care which the Department's proposal only threatens to exacerbate. The Department must, at minimum, account for the distributional unfairness of its proposal. We provide several examples below.

- *Income*. Serving people with low incomes is the central aim of the Title X program.[329] Moreover, patients with low incomes without health coverage are eligible for free or low-cost family planning care from Title X providers.[330] According to the Family Planning Annual Report (FPAR), in 2016, "88% (3.5 million) of users had family incomes that qualified them for either subsidized or no-charge services. Sixty-four percent (2.6 million) of users had family incomes at or below poverty, 24% (956,567) had incomes ranging from 101% to 250% of poverty, and 7% (297,988) had incomes over 250% of poverty."[331] Because of these demographic characteristics, reductions in access to Title X-funded reproductive health care would have a concentrated effect on populations with limited financial resources.

- *Sex*. Of the 4 million family planning users served in 2016, 3.6 million (89 percent) were identified as female in the Department's annual report.[332] Given the vast proportion of Title X clients that are female, reductions in the availability or quality of Title X services would have a significant and disproportionate impact on women.

- *Age*. Given its focus on services for adolescents and strong confidentiality guarantees, the Title X program is designed to benefit young people.[333] Indeed, according to the

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[328] Office of Management and Budget, *Circular A-4, re: Regulatory Analysis*, (Sept. 17, 2003), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.
[329] *See* 42 U.S.C. § 300a–4 (priority will be given . . . to the furnishing of such services to persons from low-income families").
[330] *See* 42 C.F.R § 59.5(a)(6)-(9).
[331] Department of Health & Human Services., *Title X Family Planning Annual Report: 2016 National Summary* (2017), *available at* https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.
[332] *Id.*
[333] 42 U.S.C. § 300(a) (providing that projects "shall offer a broad range of acceptable and effective family planning methods and services (including . . . *services for adolescents*)"); 42 C.F.R. § 59.11 (confidentiality).

FPAR, the vast majority of Title X patients are young. In 2016, 707,401 (18 percent) of family planning users were under 20, and an additional 1.9 million (48 percent) were between the ages of 20 and 29.[334] The Proposed Rule's effects on the availability of quality family planning care would place a particular burden on young people.

- *Race and ethnicity*. The Title X program plays a critical role in serving communities of color and other populations that, by virtue of race or ethnicity, may otherwise lack access to appropriate care because of systemic barriers. For example, according to the FPAR, 30 percent of Title X patients self-identified within a nonwhite OMB race category in 2016.[335] This includes a large proportion of patients that identify as African American or Black (21 percent).[336] It also includes a range of other race categories, including Asian, Native Hawaiian or Pacific Islander, American Indian or Alaska Native, or more than one race. Moreover, 32 percent of Title X patients identified as Latino or Hispanic.[337] Thus, the Proposed Rule's negative consequences on health would have a significant impact along racial and ethnic lines.

- *LGBTQ status*. Although the Department does not disclose demographic information about Title X patients' gender identity or sexual orientation, Title X services are critical to LGBTQ populations. LGBTQ people frequently report lacking access to culturally appropriate care.[338] Care delivered under Title X is governed by the CDC's Quality Family Planning guidelines, the national standard of clinical family planning care which, among other things, provides that LGBTQ patients should be offered culturally competent care.[339] Moreover, LGBTQ people have unique sexual and reproductive health needs which Title X providers are well-equipped to address. For instance, lesbians and bisexual women obtain Pap tests at low rates and face unintended pregnancy at high rates.[340] And LGBTQ people face a disproportionate STD burden,

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[334] Department of Health & Human Services., Title X Family Planning Annual Report: 2016 National Summary (2017), available at https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.
[335] *Id.*
[336] *Id.*
[337] *Id.*
[338] The Fenway Institute, *The Case for Designating LGBT People as a Medically Underserved Population and as a Health Professional Shortage Area Population Group*, available at http://fenwayhealth.org/wp-content/uploads/COM1050_MUP_HPSA-Brief_WebReady.pdf.
[339] Centers for Disease Control and Prevention, "Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs," Morbidity and Mortality Weekly Report (Apr. 2014), available at https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf.
[340] Hodson, K., et al., *Lesbian and bisexual women's likelihood of becoming pregnant: a systematic review and meta-analysis* (Dec. 2015), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5299536/; The Fenway Institute, *The Case for Designating LGBT People as a Medically Underserved Population and as a Health Professional Shortage Area Population Group*, available at http://fenwayhealth.org/wp-content/uploads/COM1050_MUP_HPSA-Brief_WebReady.pdf.

including HIV.[341] So the Department's proposed changes are likely to cause LGBTQ populations that rely on Title X to go without needed care.

D. The Department identifies few, if any, benefits that flow from the Proposed Rule.

For the Proposed Rule to overcome the major underestimate of costs described above, the benefits would need to be substantial. But, strikingly, many of the benefits predicted by the Department are totally speculative or implausible. Whether a regulation's effect counts as a benefit depends on the baseline it is measured against.[342] Yet nearly all the benefits of the Proposed Rule posited by the Department rely heavily on a baseline that is not supported by evidence, data, or common sense. We stress that the Department's purported benefits must be compared, not with the Department's worst fears about the Title X network it inherited, but with the actual state of affairs and history of success of the Title X program under the current regulatory framework. On this view, few if any of the Department's stated benefits survive, and they certainly cannot justify even the Department's conservative cost estimate. We note, too, that the Department fails to attempt to quantify any of the benefits it identifies.

- *Expanding the number of entities interested in participating in Title X and protecting conscience.* The Department states that its Proposed Rule is "expected to increase the number of entities interested in participating in Title X," and will better respect the conscience rights of providers. But as we point out above, the Proposed Rule contains not even one example of an entity that would participate in Title X but for the program's counseling and referral requirements. In fact, the Department itself extinguishes this problem when it proclaims its belief that, given existing statutory conscience laws and nothing more, the counseling and referral requirements in the current regulations already "cannot be enforced against objecting grantees or applicants."[343] Moreover, this supposed benefit cannot justify the ban on abortion referrals or counseling, the separation requirements, or the compliance reporting requirements.

- *Ensuring program integrity and enhancing compliance*. The Department alleges its Proposed Rule would lead to increased "accountability" and "transparency"; "mitigate confusion about what services the Federal government supports and funds"; and "increase the amount of Title X funds that are used to deliver family planning services."[344]

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[341] Kaiser Family Foundation, *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender (LGBT) Individuals in the U.S.* (May 2018), available at https://www.kff.org/report-section/health-and-access-to-care-and-coverage-lgbt-individuals-in-the-us-health-challenges/.

[342] Office of Management and Budget, *Circular A-4, re: Regulatory Analysis*, (Sept. 17, 2003), available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf ("You need to measure the benefits and costs of a rule against a baseline. This baseline should be the best assessment of the way the world would look absent the proposed action.").

[343] 83 Fed. Reg. at 25,506.

[344] *Id.*

Yet in the above discussion we demonstrate that the Department's fears are not based in the facts. For example, the Department is unable to show why its new "accountability" and "transparency" rules are necessary and how they would differ from existing monitoring and enforcement tools already at the Department's disposal. All the Department can provide, moreover, is mere speculation that "confusion" currently exists about how Title X funds are used. It is manifest within the Department's authority and expertise to investigate the issues and determine whether there is misuse of funds or confusion; the Department failure to support its assertions with any evidence is telling. Also, the Department's proposal to narrow the use of Title X funds to support only "direct services" intimates a deep misunderstanding of the delivery of family planning services in the United States.

- *Enhanced patient service and care*. The Department makes a number of vague assertions about how its Proposed Rule would improve care for patients. As this comment demonstrates with substantial evidence, nothing could be further from the truth. As we point out above, many aspects of the Department's proposal appear designed to drive out expert providers of reproductive health care. This and other components of the Proposed Rule are likely to result in reduced access to a "broad range" of family planning methods and services for low-income, uninsured patients. Moreover, the Department's proposed "physical and financial" separation requirement and the proposed ban on referral for abortion would cause serious interference with quality of care, care coordination, and patient safety.

E. The Department makes errors in and fails to justify crucial steps in its regulatory impact analysis.

In addition to inaccurately estimating the Proposed Rule's costs and failing to justify its benefits, the Department makes other errors and fails to explain or justify the steps it takes in its regulatory impact analysis. For example:

- *The Department does not adjust for inflation*. Although the Department evaluates the effects of the Proposed Rule beginning in 2019, it measures these effects in 2016 dollars and does not account for inflation.[345] This results in an artificially low total cost estimate. For example, using Consumer Price Index (CPI) projections to adjust to 2019 dollars, the Department's estimated present value cost of $88.6 million rises to $94.5 million in 2019.[346] The Department should use inflation-adjusted costs to accurately represent the Proposed Rule's potential burden.

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[345] *Id.* at 25,522.

[346] See Congressional Budget Office, The Budget and Economic Outlook: 2018 to 2028 (Apr. 2018), available at https://www.cbo.gov/system/files?file=115th-congress-2017-2018/reports/53651-outlook.pdf (providing CPI of 2.1, 2.2, and 2.2 for 2017, 2018, and 2019, respectively).

- *The Department does not estimate application costs.* The Department predicts that the Proposed Rule will result in increased competition for Title X funding. It estimates that 200 percent of the number of grantees and subrecipients in 2016 will be eligible for and/or interested in applying for funds as a consequence of its proposed changes. Although the Department attempts to account for the time required to learn about the Proposed Rule's requirements, it assumes no cost for the increased number of applications that will be assembled and submitted to the Department or, for potential subrecipients, to the grantee. We think this is implausible. Thus, the cost of the application process for a greater number of entities must be accounted for in the Department's overall cost estimate.

- *The Department provides no evidence for its estimates of the number of hours required for staff to comply with the Proposed Rule.* For example, the Department estimates that "learning the rule's requirements and determining how to respond would require an average of 20 hours for potential grantees and an average of 10 hours for potential subrecipients, divided evenly between managers and lawyers, in the first year following the publication of the rule."[347] The Department provides similar staff time estimates for training, the submission of assurances, documenting compliance, monitoring and enforcement activities, physical separation, and encouraging parental involvement in family planning services.[348] Yet the Department provides no evidence or documentation for its estimates. In our experience, these estimates under-represent the time required to comply. Also, regarding the Department's estimate of additional staff time for training in particular, while the Department suggests that costs in subsequent years would simply disappear, it does not base its conclusion on evidence or past practice. On the contrary, we believe training costs would continue past the first year.

F. The Department fails to adequately consider regulatory alternatives.

The Department only even attempts to evaluate two regulatory alternatives: its chosen course of action and the status quo.[349] In doing so, it gives little attention to the costs and benefits of the different regulatory provisions presented in the Proposed Rule, and it avoids examination of a wide range of options located on the continuum between the two polar extremes it identifies. We remind the Department that the purpose of its evaluation of alternatives is not to work backwards from its decision, but to "discover which of various possible alternatives would be the most cost-effective."[350] The Department's evaluation does not accomplish this.

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[347] *Id.* at 25,524.
[348] *Id.* at 25,524-25.
[349] Office of Management and Budget, *Circular A-4, re: Regulatory Analysis*, (Sept. 17, 2003), available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf ("It is not adequate simply to report a comparison of the agency's preferred option to the chosen baseline.").
[350] *Id.*

Below, we discuss examples of regulatory alternatives that, although connected to the Department's stated objectives, are not seriously considered in the Proposed Rule. Although Planned Parenthood does not necessarily support these options, their absence is evidence of the Department's unsatisfactory analysis.

- *Exemptions for objecting entities*. Though the Department seeks to ensure that entities with religious or moral objections to providing information about abortion can participate in Title X, there are less restrictive ways to do this than banning *all* Title X-funded entities from referring for abortion, and removing the nondirective options counseling requirement for *all* entities. Yet the Department fails to consider the costs and benefits of providing exemptions for objecting entities while maintaining the program's general rules for other entities.

- *Information rather than regulation*. The Department's proposed restrictions related to abortion, including the proposed "physical and financial" separation requirement, are in large part predicated on an alleged perception among the public that Title X funds are being used for abortion.[351] This hypothetical problem of public awareness could be resolved through honest communication with patients and taxpayers about Title X's statute and program requirements and their enforcement mechanisms, which have for decades prevented the use of Title X funding for abortion. Still, the Department did not consider this alternative, even though it is far less expensive and would impose fewer burdens on Title X-funded entities.

- *Adjustments to timing*. The Department failed to evaluate the costs and benefits of allowing different time windows between finalization and requiring compliance. As we discuss above, the lead times for the implementation of the "physical" separation requirement (one year) and the remaining provisions of the rule (60 days) are insufficient. The timing of a regulation often has an effect on its costs and benefits. In particular, "a regulation that provides sufficient lead time is likely to achieve its goals at a much lower cost."[352]

IV. The Department Should Perform a Complete Assessment of The Proposed Rule's Effect on Family Well-Being.

Section 654 of the Treasury and General Government Appropriations Act of 1999, Public Law 105–277, sec. 654, 112 Stat. 2681 (1998), requires Federal departments and agencies to determine whether a proposed policy or regulation could affect family well-being. Agencies must assess whether the proposed regulatory action: (1) Impacts the stability or safety of the family, particularly in terms of marital commitment; (2) impacts the authority of parents in the education,

[351] *E.g.*, 83 Fed. Reg. at 25,525 (providing that the Proposed Rule would "increase transparency and assurances that taxpayer dollars are being used as Congress intended . . . [and would] mitigate confusion about what services the Federal government supports and funds").
[352] *Id.*

nurture, and supervision of their children; (3) helps the family perform its functions; (4) affects disposable income or poverty of families and children; (5) if the regulatory action financially impacts families, are justified; (6) may be carried out by State or local government or by the family; and (7) establishes a policy concerning the relationship between the behavior and personal responsibility of youth and the norms of society.[353] If the agency determines that the rule will, in fact, impact family well-being, then it must prepare an impact assessment to address criteria specified in the law.

The Department states that the proposed rule will 'not negatively affect family well-being."[354] However, it provides absolutely no evidence or justification for that position, and available evidence shows that it is significantly off base. A policy that radically undermines people's access to affordable family planning services will have a detrimental impact on family well-being, including but not limited to affecting the financial stability and disposable income of families and interfering in parents' upbringing of their children. In fact, research has shown the opposite. For example:

- Historical research has linked granting unmarried women early legal access to the pill (at age 17 or 18, rather than 21), to their attainment of postsecondary education and employment, increased earning power and a narrowing of the gender gap in pay, and later, more enduring marriages.

- Unplanned births are tied to increased conflict and decreased satisfaction in relationships and with elevated odds that a relationship will fail.

- Contraceptive access and consistent method use may also affect mental health outcomes by allowing couples to plan the number of children in their family.

- People are relatively less likely to be prepared for parenthood and develop positive parent-child relationships if they become parents as teenagers or have an unplanned birth. Close birthspacing and larger family size are also linked with parents' decreased investment in their children. All of this, in turn, may influence children's mental and behavioral development and educational achievement.[355]

Moreover, the Department's own Guidelines for Regulatory Impact Analysis[356] suggest that the Proposed Rule will result in changes in Quality Adjusted Life Years (QALYs) as a measure of

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[353] Treasury and General Government Appropriations Act, 1999, Public Law 105–277, sec. 654, 112 Stat. 2681, 2681–528–2681–530 (1998).
[354] 83 Fed. Reg. at 25527
[355] Sonfield A et al., The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children, New York: Guttmacher Institute, 2013, available at https://www.guttmacher.org/sites/default/files/report_pdf/social-economic-benefits.pdf.
[356] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Guidelines For Regulatory Impact Analysis (2016), available at https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.

well being. The Department suggests that a QALY should be valued at about $230,000. Since increased unintended pregnancies undoubtedly reduces QALYs, the Proposed Rule would only need to have an impact of 435 QALYs to, by itself, amount to a cost of more than $100 million, the results of the Proposed Rule would far exceed this cost.

The Department itself acknowledged in a 1993 proposed rule issued on Title X that it is, in fact, encouraging and facilitating access to family planning care and to all necessary referrals that benefits family well-being. The Department stated at that time that leaving important decisions about reproductive health care to families and individuals would: "promote the stability of the family, support parental influence, reduce governmental intrusion on family activities, enhance the role and autonomy of the family in decision-making, and require less Federal involvement in monitoring activities . . . . The rules . . . below also support the message to young people that they should engage in responsible decisionmaking about their reproductive health and choices."[357] The Department is required to explain its abrupt change of course, particularly given the evidence to the contrary laid out above. Therefore, the Department must perform a complete assessment of the rule's effect on family well-being prior to moving forward with the policy or much more adequately explain its failure to do so.

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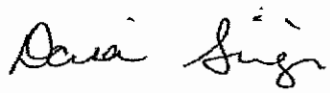
For all of these reasons and more, Planned Parenthood urges the Department to put the health and lives of all people in this country—including women, people of color, young people, and LGBTQ communities—first and foremost and work towards fulfilling, rather than undermining, the Department's responsibility of ensuring that the American people can access high-quality care at affordable prices. Therefore, we strongly recommend that you withdraw the proposed rule.

Respectfully,



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[357] 58 Fed. Reg. 7185, 7465 (Feb. 5, 1993).

July 31, 2018

Office of Population Affairs, Attn: Family Planning
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Attn: RIN 0973-ZA00 (Compliance with Statutory Program Integrity Requirements)

On June 1, 2018, the Office of Population Affairs (OPA) published a proposed rule that seeks to significantly revise the regulations governing the Title X national family planning program. I am pleased to submit the following comments on the proposed rule on behalf of the Guttmacher Institute, a nonprofit research and policy organization committed to advancing sexual and reproductive health and rights in the United States and globally.

We strongly oppose the proposed regulatory changes, which if finalized and implemented, stand to fundamentally overhaul the Title X program. Specifically, the proposed regulatory changes seem intended to alter the purpose and scope of services supported by Title X; eliminate nondirective counseling and referral for all of a pregnant patient's options; reduce access to care by reshaping the network of providers; infringe on Title X patients' ability to obtain family planning services confidentially; and divert Title X funds to address gaps in contraceptive coverage created by other administration regulations.

Altering the Purpose and Scope of Title X–Supported Services

The proposed rule would impose a new definition of "family planning" that would alter the scope of services Title X providers would be required to offer. This shift would be at odds with nearly 50 years of legislative, administrative and operational history of the program, undermining Congress's clear intent that Title X patients have free and informed contraceptive choices that will help them avoid unintended pregnancies.

Current Title X regulations are in line with Congress's intent. They require that all family planning "projects" provide "a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents)." This mandate is intended to guarantee patients a true choice of contraceptive methods, and has been interpreted and implemented as such for decades. Ensuring that patients can choose from a truly broad range of contraceptive options is essential to guaranteeing their choices are voluntary and free from coercion—cornerstones of Title X–supported care. This principle is articulated

in the *Quality Family Planning* guidelines, national, evidence-based clinical recommendations published by the Office of Population Affairs and the Centers for Disease Control and Prevention in 2014[1] and updated as recently as December 2017.[2] The proposed rule would depart from these regulations and guidelines in multiple harmful ways.

Reducing contraceptive choice

The proposed definition of "family planning" would deemphasize the provision of modern contraceptive methods, particularly those approved by the Federal Drug Administration (FDA). Moreover, instead of further clarifying what it means to offer a meaningfully "broad range" of contraceptive methods and related services as it purports to do, the proposed rule would create confusion and raise serious concerns about the scope of services that Title X projects would be required to make available in their communities.

The proposed rule does this via a combination of multiple proposed changes. It removes the requirement that the range of family planning methods offered by a Title X project include methods that are "medically approved," suggesting this deletion "provides better guidance for the types of methods and services that Congress sought to fund." It also suggests that modern contraceptives are but one of a few categories of contraceptive options that Title X projects might offer (the others being natural family planning, other fertility awareness–based methods and abstinence).

The Department further suggests in the preamble that as methods of family planning have evolved, "it has become increasingly difficult and expensive for a Title X project to offer all acceptable and effective forms of family planning." It notes that "staffing limitations, technological capacity, economics (including costs and demand), and conscience concerns may be taken into account" in determining the scope of methods offered by a Title X project. And although Title X projects have never been required to offer all available contraceptive methods, the preamble and proposed rule reiterate that fact multiple times, suggesting a willingness for projects to offer fewer as opposed to greater numbers of contraceptive options.

Finally, the proposed rule seems to disregard a long-standing interpretation of the statutory requirement that Title X projects provide a "broad range of acceptable and effective family planning methods and services." Historically, it has been understood that projects must provide a broad range of contraceptive options, in addition to related services. Instead, the proposed rule seems to suggest it would be permissible for a Title X project to offer a broad range of services, defined to include modern contraceptive care as but one of multiple—but not necessary—choices for projects to consider and make available. For instance, it appears possible that the proposed rule would allow a Title X project to include only abstinence-only-until-marriage counseling for adolescents, natural family planning and adoption services (see below), together representing a "broad range" of methods and services.

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[1] Gavin L et al., Providing quality family planning services: recommendations of CDC and the U.S. Office of Population Affairs, *Morbidity and Mortality Weekly Report*, 2014, Vol. 63(No. RR-4), https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html.

[2] Gavin L, Pazol K and Ahrens K, Update: providing quality family planning services—recommendations from the CDC and the Office of Population Affairs, *Morbidity and Mortality Weekly Report*, 2017, Vol. 66(50): 1383–1385, https://www.cdc.gov/mmwr/volumes/66/wr/mm6650a4.htm.

Collectively, these proposed changes would be a remarkable departure from the Title X program's mission. Title X's core purpose has always been clear: to help people obtain patient-centered care that best enables them to determine for themselves whether and when to have children. For the vast majority of Title X clients, this means obtaining contraceptive services and counseling: In 2016, 80% (2.8 million) of all female patients at Title X sites left their visit having newly started or continuing use of some method of contraception; among those patients, the vast majority are using contraceptive methods deemed most or moderately effective at preventing pregnancy, all of which require a prescription or services provided by a medical professional.[3]

For decades, the Title X program has helped to ensure that patients have a true choice of contraceptive options. Compared with publicly funded health centers that do not receive Title X funding, sites supported by Title X are more likely to offer the full range of contraceptive methods.[4] Moreover, Title X–supported providers make it easier for women to obtain highly effective and long-acting reversible contraceptive methods, as these health centers are particularly likely to offer on-site insertion of IUDs and implants on the same day as a client's initial appointment. Similarly, nearly three-quarters of Title X sites offer initial supplies of oral contraceptives and refills on-site, enabling women who choose the pill to avoid additional trips to a pharmacy. Plus, nearly nine in 10 Title X providers allow women to delay a pelvic exam when medically appropriate in initiating hormonal contraceptives, and nearly nine in 10 use the "quick-start" protocol, enabling a client to start the pill on the day of her visit, regardless of where she is in her menstrual cycle.

Although projects have never been required to provide all available contraceptive methods, it is misguided to suggest that Title X providers should not be expected to provide patients with a true choice of methods. Doing so discounts the importance of patient-centered and voluntary care. Moreover, the evidence is clear that individuals' ability to obtain and use whatever methods of contraception will work best for them is critical to ensuring satisfaction with their methods.[5] This in turn enables patients to use those methods consistently and correctly, increasing their likelihood of successfully avoiding unintended pregnancies: The two-thirds of women at risk for unintended pregnancy who consistently and correctly use a contraceptive method account for only 5% of unintended pregnancies.[6]

We urge the Department to reject its revised definition of "family planning" at Sec. 59.2 and to return to the current regulatory definition, and to reject its deletion of "medically approved" at Sec. 59.5. We also urge the Department to return to its long-standing interpretation of the statute to require Title X projects to offer a meaningfully broad range of contraceptive methods, in addition to related services.

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[3] Fowler CI et al., *Title X Family Planning Annual Report: 2016 National Summary*, Research Triangle Park, NC: RTI International, 2017, https://www.hhs.gov/opa/title-x-family-planning/fp-annual-report/index.html.

[4] Zolna MR and Frost JJ, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*, New York: Guttmacher Institute, 2016, http://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

[5] Sonfield A, Why family planning policy and practice must guarantee a true choice of contraceptive methods, *Guttmacher Policy Review*, 2017, 20:103–107, https://www.guttmacher.org/gpr/2017/11/why-family-planning-policy-and-practice-must-guarantee-true-choice-contraceptive-methods.

[6] Sonfield A, Hasstedt K and Gold RB, *Moving Forward: Family Planning in the Era of Health Reform*, New York: Guttmacher Institute, 2014, https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform.

Prioritizing fertility awareness–based methods and natural family planning

The proposed definition of "family planning" inappropriately promotes one particular approach to family planning over ensuring patients' true choice of contraceptive methods. The proposal emphasizes fertility awareness–based methods (FABMs)—specifically, natural family planning. Natural family planning methods are a subset of FABMs that are calendar-based, rely on abstinence (as opposed to using a back-up contraceptive method) during fertile windows, and are often motivated by religious convictions.

The rule would make natural family planning the only contraceptive option that each Title X project must make available to patients as part of a range of Title X–supported services. Moreover, it explicitly seeks to direct Title X funds to "specialized, single-method [natural family planning] sites," based on an inaccurate assertion that these options have historically not been adequately available to Title X patients.

The federal government promoting any single family planning method within Title X would actively undermine the program's mandate to ensure patients' choices are wholly voluntary and free from coercion. Furthermore, actively directing Title X funds toward natural family planning is unnecessary: It has always been provided for under the statute, and 93% of Title X–funded sites specifically report offering "natural family planning instruction or supplies."[4]

Moreover, less than 0.5% of female Title X contraceptive users rely on some type of FABM, including natural family planning, as their primary method.[3] This is likely in part because these methods do not meet a number of different needs that women have for their methods of birth control. Their effectiveness is highly sensitive to a couple's ability to correctly and consistently use them, which can lead to high failure rates; they require the cooperation of a male sexual partner; and they do not offer protection against STIs. A study on contraceptive features preferred by women at high risk of unintended pregnancy conducted in 2010 found that natural family planning specifically was tied with withdrawal for having the fewest features women find important in a contraceptive method.[7]

We urge the Department to reject its revised definition of "family planning" at Sec. 59.2 and to return to the current regulatory definition, and to reject its deletion of "medically approved" at Sec. 59.5. We also urge the Department to eliminate language in the preamble that prioritizes natural family planning and other FABMs over other contraceptive methods.

If the Department does not remove this language, we ask the Department to clarify whether it intends to prioritize and promote natural family planning and other FABMs for Title X patients over other contraceptive options, and if so, to provide its justification for so undermining patients' ability to obtain voluntary care free from coercion.

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[7] Lessard LN et al., Contraceptive features preferred by women at high risk of unintended pregnancy, *Perspectives on Sexual and Reproductive Health*, 2012, 44(3):194–200, https://www.guttmacher.org/journals/psrh/2012/09/contraceptive-features-preferred-women-high-risk-unintended-pregnancy.

Supporting the provision of adoption services and abstinence-only messaging
The proposed rule would expand the definition of family planning services supported by Title X to include two new areas: adoption services and abstinence-only-until-marriage messaging.

The rule would newly define "infertility services" to include adoption services. Infertility services have long been provided for under Title X statute, but have previously been understood and implemented as clinical services intended to help people experiencing infertility. For example, the *Quality Family Planning* guidelines advise that "infertility visits to a family planning provider are focused on determining potential causes of the inability to achieve pregnancy and making any needed referrals to specialist care."[1] These services are to be provided to patients who want to have children but are experiencing difficulty becoming pregnant, and should include counseling, medical histories, sexual health assessments and physical exams, as well as referrals for specialized care or social supports as needed.

Nowhere in these clinical recommendations, or in Title X statute, regulations or programmatic guidelines, is adoption suggested as a service that is necessary or appropriate for family planning providers to offer directly. Similarly, there is no precedent for providing Title X funds to support the work of adoption agencies. Notably, the proposed rule offers no rationale for such a radical shift in its definition of family planning and infertility services, nor for diverting limited Title X funds away from medical family planning care and toward adoption services (which have other, dedicated sources of government funding).

Similarly, the proposed rule explicitly includes "choosing not to have sex" among the range of contraceptive "choices" supported by Title X. The preamble further explains that abstinence-only-until-marriage messaging—which the Department refers to as "sexual risk avoidance"—would be considered a method that would be supported by Title X. The Department also advanced abstinence-only messages as a Title X–funded service in its fiscal year 2018 Title X services grant funding opportunity announcement, misrepresenting the body of available evidence on these approaches in doing so.[8,9]

The proposed rule and earlier funding announcement together suggest the Department seeks to advance abstinence not within the context of comprehensive family planning counseling for younger patients, but by seeking to advance abstinence-only programming as a family planning method for all Title X patients. This is in direct contrast with clinical recommendations from the federal government and professional medical associations; these recommendations consistently advise that counseling on abstaining from sexual activity should be one piece of a broader, patient-centered approach for adolescent patients, and that factual information on remaining abstinent should be provided to adolescent patients interested in that approach, along with contraceptive and STI prevention services

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[8] Hasstedt K, Big four threats to the Title X family planning program: examining the administration's new funding opportunity announcement, *Health Affairs* Blog, Mar. 5, 2018, https://www.guttmacher.org/article/2018/03/four-big-threats-title-x-family-planning-program-examining-administrations-new.

[9] Lindberg LD and Hasstedt K, The Trump administration's irresponsible use of research in pushing its abstinence-only agenda into Title X, *News in Context*, May 16, 2018, https://www.guttmacher.org/article/2018/05/trump-administrations-irresponsible-use-research-pushing-its-abstinence-only-agenda.

for sexually active adolescents, as appropriate.[1,10,11,12] The administration's proposal is deeply concerning, given that extensive evidence demonstrates that this programming can cause considerable harm to young people,[13] and that public policies seeking to restrict the sexual activity of unmarried adults do not meet the sexual and reproductive health needs of most single adult women.[14]

We urge the Department to reserve the Title X program's limited resources for the medical family planning services that the program has supported so effectively for decades. Specifically, we urge the Department to eliminate regulatory language at Sec. 59.2 and 59.5 that include adoption as an infertility service, and to eliminate language at Sec. 59.2 around "choosing not to have sex" and language in the preamble around "sexual risk avoidance."

If the Department does not remove this language, we ask the Department to clarify whether it intends for Title X dollars to be directed to adoption services and agencies and to the promotion of abstinence-only-until-marriage messaging, and if so, to offer its justification for so dramatically altering the scope of services supported by Title X.

Eliminating Nondirective Pregnancy Options Counseling and Referral

The proposed rule would eliminate the Title X program's long-standing commitment to neutral, factual information on and nondirective counseling for all of a pregnant patient's options—including maternity and infant care, foster care and adoption, and abortion—and referral, on request, for services related to any of these options. The rule would do so by eliminating the requirement for nondirective counseling, undermining or possibly banning counseling on abortion, barring abortion referral, and mandating referral for prenatal care even against a patient's wishes.

More specifically, the proposed rule would eliminate the long-standing guarantee that all pregnant patients at Title X–funded sites be offered unbiased, factual and comprehensive counseling on all pregnancy options. Instead, providers would be given the authority to deny patients information on abortion—even when a patient directly requests it. Moreover, given the proposed rule's extensive and confusing additional restrictions on "activities that encourage, promote or advocate for abortion," it seems difficult if not impossible for Title X–funded providers to counsel pregnant patient on abortion as one of their options. At the very least, the proposed rule may create a "chilling effect," whereby even providers dedicated to delivering high-quality care are deterred from offering comprehensive and unbiased pregnancy options counseling for fear of losing Title X funding.

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[10] Ott MA, Sucato GS and Committee on Adolescence, Contraception for Adolescents, *Pediatrics*, 2014, 134: e1257–e1281.
[11] Society for Adolescent Health and Medicine, Sexual and reproductive health care: a position paper of the Society for Adolescent Health and Medicine, *Journal of Adolescent Health*, 2014, 54(4):491–496, https://www.jahonline.org/article/S1054-139X%2814%2900052-4/fulltext?code=jah-site.
[12] American College of Obstetricians and Gynecologists (ACOG), Adolescent pregnancy, contraception, and sexual activity, *Obstetrics & Gynecology*, 2017, 129(5):965–966, https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Adolescent-Health-Care/Adolescent-Pregnancy-Contraception-and-Sexual-Activity.
[13] Boyer J, New name, same harm: rebranding of federal abstinence-only programs, *Guttmacher Policy Review*, 2018, 21:11–16, https://www.guttmacher.org/gpr/2018/02/new-name-same-harm-rebranding-federal-abstinence-only-programs.
[14] Lindberg LD and Singh S, Sexual behavior of single adult American women, *Perspectives on Sexual and Reproductive Health*, 2008, 40(1): 27–33, https://www.guttmacher.org/journals/psrh/2008/sexual-behavior-single-adult-american-women.

On the subject of counseling, the proposed rule would bar clinicians from referring pregnant patients to appropriate providers for abortion services. If a pregnant patient who has already decided to have an abortion clearly states this intent and asks for referral, the proposed rule would give providers only two options: either deny the request entirely, or provide an intentionally misleading list of "comprehensive health services providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care);" that list cannot identify which sites actually provide abortion. Beyond denying patients abortion referral, the proposed rule would mandate that all pregnant patients at Title X sites be referred for prenatal and social services (such as infant or foster care, or adoption), regardless of the patient's wishes.

The Department's justifications for these changes are seriously flawed. For example, the Department claims a bar on abortion referral is necessary to comply with federal law, asserting that "[r]eferrals for abortion are, by definition, directive," and therefore abortion referrals are not in compliance with the requirement that all pregnancy options counseling be "nondirective" under Title X. However, the Department's reasoning is inconsistent: It does not find referral for prenatal or social services to be similarly directive, and the proposed rule goes so far as to prescribe referral for those services to all pregnant patients in a highly directive, and in fact coercive, manner. The Department claims this referral—even against a patient's wishes—is necessary "to optimize the health of the mother and the unborn child." This use of subjective rather than medical language belies the Department's ideological motivations and willing departure from clinical standards.

Similarly, the Department asserts that its elimination of the requirement to provide nondirective counseling on abortion is justified out of "respect for conscience" among providers who object to the procedure. This prioritization of provider beliefs over patient needs is particularly troubling given the Department's express interest in directing Title X funds to entities "that refuse to provide abortion counseling and referrals."

Contrary to the Department's assertions, Title X's long-standing counseling and referral requirements do not violate the Title X statute. Rather, they are essential to ensuring informed consent in reproductive health care—a bedrock principle of modern medical practice in the United States deeply rooted in legal, ethical and medical standards developed over the course of decades.[15] The proposed rule constitutes an unacceptable repudiation of the doctrine of informed consent by denying Title X patients factual, unbiased information on abortion.

In effect, the proposed rule rejects clinical recommendations from professional medical associations, including the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics, which state that providers must offer appropriate referrals for needed follow-up care to all pregnant patients—even if a patient requests information on services to which an individual provider personally objects, such as abortion.[16,17] Similarly, many leading professional medical organizations have ethical guidelines that unequivocally and consistently call for comprehensive,

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[15] Hasstedt K, Unbiased information on and referral for all pregnancy options are essential to informed consent in reproductive health care, *Guttmacher Policy Review*, 2018, 21:1–5, https://www.guttmacher.org/gpr/2018/01/unbiased-information-and-referral-all-pregnancy-options-are-essential-informed-consent.

[16] ACOG, Informed consent, Committee Opinion No. 439, Obstetrics & Gynecology, 2009, 114(2):401–408, https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Ethics/Informed-Consent.

[17] Committee on Adolescence, American Academy of Pediatrics, Counseling the adolescent about pregnancy options, Pediatrics, 1998, 101(5):938–940.

unbiased counseling on all pregnancy options.[17,18,19,20] These recommendations are echoed in the national *Quality Family Planning* guidelines for providing high-quality family planning services.[1]

If implemented, the proposed rule would impose substandard care on those who rely on Title X–funded providers and services. Denying or delaying Title X patients' ability to obtain abortions jeopardizes the health and well-being of those who have decided to terminate their pregnancies in a number of ways, including: denying patients necessary information to appropriately compare the safety of their medical options; interfering with pregnant patients' ability to obtain additional services in a timely manner; and obstructing pregnant patients with complicating medical conditions from obtaining potentially life-saving abortions.[15] Similarly, dictating that all patients must be referred to "comprehensive health services providers" rather than allowing for referral to whatever provider best meets individual patients' unique needs, such as those offering specialized care, could cause further harm.

Moreover, and particularly troubling, the proposed rule stands to further entrench existing health disparities. Many who rely on Title X–funded providers and services are already marginalized and often facing other obstacles to obtaining care: two-thirds of Title X patients have incomes at or below the federal poverty limit (currently $12,140 annually for a single person[21]), 43% are uninsured, 13% have limited English proficiency, 30% identify with one or more nonwhite race categories and one-third identify as Hispanic or Latino.[3]

Forcing clinicians to sabotage the rapport and trust they have built with patients stands in sharp conflict with patients' right to self-determination. It may also cause patients to retreat, possibly from seeking health care for other needs; this may be particularly true for women of color, low-income women and others who have historically experienced coercive treatment in the context of reproductive health care.[22,23] In the words of former U.S. Senate Majority Leader George Mitchell in opposing a previous attempt by the Department to impose similar restrictions: "A society like ours, based upon the fundamental principle of equality, ought not tolerate, let alone encourage, even less insist upon a system in which there are two standards of care: One for the wealthy, the affluent, the powerful; and another, lower standard, for the poor."[24]

We urge the Department to rescind its proposed changes to the regulations at Sec. 59.5(a)(5) (which eliminate the requirement to provide nondirective pregnancy options counseling and referral upon request) and to rescind its proposed additions at Sec. 59.14 (which bars abortion referral and mandate

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[18] ACOG, Guidelines for Women's Health Care: A Resource Manual, fourth ed., Washington, DC: ACOG, 2014.
[19] American Academy of Physician Assistants, Guidelines for Ethical Conduct for the PA Profession, 2013, https://www.aapa.org/wp-content/uploads/2017/02/16-EthicalConduct.pdf.
[20] Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), AWHONN position statement: Health care decision making for reproductive care, *Journal of Obstetric, Gynecologic & Neonatal Nursing*, 2016, 45(5):718, http://www.jognn.org/article/S0884-2175(16)30229-5/fulltext.
[21] Office of the Assistant Secretary for Planning and Evaluation, HHS, U.S. federal poverty guidelines used to determine financial eligibility for certain federal programs, 2017, https://aspe.hhs.gov/poverty-guidelines.
[22] SisterSong, National Latina Institute for Reproductive Health and Center for Reproductive Rights (CRR), *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care*, New York: CRR, 2014, https://www.reproductiverights.org/document/reproductive-injustice-racial-and-gender-discrimination-in-us-health-care.
[23] Gold RB, Guarding against coercion while ensuring access: a delicate balance, *Guttmacher Policy Review*, 2014, 17(3): 8–14, https://www.guttmacher.org/gpr/2014/09/guarding-against-coercion-while-ensuring-access-delicate-balance.
[24] The Alan Guttmacher Institute, Bill to reauthorize Title X, overturn gag rule is sent to president, *Washington Memo*, New York: Guttmacher Institute, Sept. 22, 1992.

directive referral for prenatal care) and at Sec. 59.16 (which bars "activities that encourage, promote or advocate for abortion" and will have at least a chilling effect on abortion counseling).

If the Department does not rescind these changes and additions, we ask that it articulate the rationale behind its decision to prioritize an antiabortion agenda and the religious and moral objections of antiabortion providers over the medical and ethical importance of facilitating patients' informed decisions about their own reproductive health care—particularly in the context of a publicly funded program.

Similarly, we ask the Department to clarify its reasoning behind and inconsistent application of the standard that all pregnancy options counseling be nondirective.

We also ask the Department to clarify whether the proposed rule would, in practice, allow for unbiased, factual and comprehensive pregnancy options counseling that includes information on abortion.

Reducing Access to Care by Reshaping the Network of Providers

The proposed rule stands to drastically alter the types of agencies that receive Title X funding, which would fundamentally shift the program's intent and impact. Specifically, the proposed rule would: bar agencies that provide abortion; discourage participation by agencies that provide abortion counseling and referral; favor primary care–focused health centers over specialized reproductive health providers; and open the door to entities that provide an inadequate package of medical care. These moves would all significantly diminish patients' access to care. Moreover, they would fundamentally disregard the important role Title X providers play in their patients' lives as entry points into the healthcare system: For six in 10 women who obtain contraceptive care at a Title X–funded sites, that provider was their only source of medical care over the past year.[25]

Barring agencies that provide abortion

By imposing extensive physical and financial separation requirements, the proposed rule would effectively exclude from Title X any safety-net health center that provides abortion using non-federal funds. Specifically, Title X–funded entities would have to maintain separate accounting records, physical spaces (such as waiting and exam rooms, entrances, and exits), workstations, phone numbers, email addresses, staff, patient health records, educational programs, and signs. The Department seems willing to go even further, asking for public comment on whether these requirements are enough or if additional considerations should be added.

The proposed separation requirements would harm the people who rely on the Title X program for family planning services. Most immediately, these proposed requirements would directly impact the approximately one in 10 Title X sites that offer abortion using non-federal funds, including health centers operated by Planned Parenthood affiliates, and entities such as hospitals and independent agencies.[4] All of these sites—and potentially sites that do not offer abortion but are in some way

[25] Kavanaugh ML, Zolna MR and Burke K, Use of health insurance among clients seeking contraceptive services at Title X-funded facilities in 2016, Perspectives on Sexual and Reproductive Health, 2018, 50(3), https://www.guttmacher.org/journals/psrh/2018/06/use-health-insurance-among-clients-seeking-contraceptive-services-title-x.

affiliated with those that do so—could be barred from Title X. Losing these qualified providers from the program would put unrealistic expectations on other Title X sites, which are already stretching to meet their communities' needs and unable to readily fill such a gap. This would make it more difficult for people in many parts of the country to obtain high-quality, affordable family planning services.

This provision is a clear attempt to bar health centers operated by Planned Parenthood affiliates, a move that would have considerable ramifications and severely diminish women's access to care. Planned Parenthood health centers serve 41% of women who rely on Title X sites for contraceptive care.[26] In order to serve all the women who currently obtain contraceptive care at Title X–supported Planned Parenthood health centers nationwide, Guttmacher analyses estimate that other Title X sites would have to increase their client caseloads by 70%, on average (see Table 1, attached).[27] The impact would vary by state; without Title X–supported Planned Parenthood sites, other providers in 13 states would have to at least double their contraceptive client caseloads to maintain the program's current reach in their states.

In addition, research shows that Planned Parenthood sites are better able to deliver high-quality contraceptive care to greater numbers of women than other types of safety-net providers.[28] Planned Parenthood sites are particularly likely to offer same-day appointments and extended evening or weekend hours, and they have half the average wait times of all other types of safety-net providers.[4] Nearly all Planned Parenthood health centers offer the full range of FDA-approved reversible contraceptive methods, compared with about two-thirds of health departments and half of FQHCs. Planned Parenthood sites are also particularly likely to offer same-day insertion of IUDs and implants, on-site provision of oral contraceptives, and protocols to help patients initiate hormonal contraceptives immediately, regardless of where they are in their menstrual cycle. And, among Title X–funded sites, on average, Planned Parenthood health centers serve 3,340 contraceptive clients each year, compared with only 610 clients at health department sites and 750 clients at FQHC sites.[26]

The proposed separation requirements are unwarranted: Title X funds have been prohibited from going toward abortion services since the program's inception. Current regulations thoroughly operationalize that statutory requirement, and are not confusing to Title X-funded health centers. Furthermore, the Department fails to identify failures of compliance or other evidence sufficient to justify its proposed overhaul of the Title X network. Indeed, the Department bases its rationale for physical separation on "the appearance and perception that Title X funds being used in a given program may also be supporting that program's abortion activities," and the "potential for co-mingling and confusion."

The Department additionally hinges its proposed requirements on the argument that spending government money on family planning "frees up" private dollars to be used for abortion. That concept,

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[26] 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.

[27] Frost JJ and Zolna MR, Response to inquiry concerning the impact on other safety-net family planning providers of "defunding" Planned Parenthood, memo to Senator Patty Murray, Senate Health, Education, Labor and Pensions Committee, New York: Guttmacher Institute, June 15, 2017, https://www.guttmacher.org/article/2017/06/guttmacher-murray-memo-june-2017.

[28] Hasstedt K, Understanding Planned Parenthood's critical role in the family planning safety net, *Guttmacher Policy Review*, 2017, 20: 12–14, https://www.guttmacher.org/gpr/2017/01/understanding-planned-parenthoods-critical-role-nations-family-planning-safety-net.

referred to as "fungibility," is one that the Department is applying to abortion but not anywhere else.[29] The U.S. government has a long tradition of involving private-sector organizations in achieving its goals in areas like public health, social welfare and global development. For example, many billions of federal and state dollars go to religious organizations and charities every year, and, in fact, Title X dollars may go to religious organizations under the proposed rule. By the logic of fungibility, all of that money would free up private funding to proselytize or engage in other religious activities—something that would be have to be considered a violation of the U.S. Constitution's Establishment Clause, since it would indirectly subsidize religion.

In advancing this "fungibility" argument, the Department disingenuously utilizes Guttmacher analyses to justify its assertion that Title X–funded family planning services must be provided wholly apart from sites that also offer abortion, using non-federal funds. The preamble quotes at length from Guttmacher publications on Title X, citing these analyses as supposed proof that Title X funds support the physical "infrastructure" of sites that also provide abortions—and thereby abortions themselves.

This framing is inaccurate and misleading. The Guttmacher work cited in the preamble unambiguously refers to the basic and underlying infrastructure of the family planning safety net, the systems and activities necessary to providers' ability to deliver high-quality family planning services to those who need them. These investments include activities such as stocking contraceptive methods, training and paying staff, modernizing patient health records, covering brick-and-mortar costs, and engaging in outreach and education activities—all in direct service of sustaining the delivery of family planning care provided for under the statute, regulations and legislative mandates governing Title X.

Such expenditures are wholly appropriate uses of Title X funds. A 2009 panel convened by the Institute of Medicine to provide an independent evaluation of the Title X program "Title X grants are not limited to specific expenses but allow recipients flexibility to pay for overhead and infrastructure (facilities, equipment, information technology), staffing and staff training, supplies, and costs associated with needs assessments and reporting. This support is critical to keeping the clinics functioning and to meeting patients' needs."[30]

Moreover, the panel recommended that "Title X should receive the funds needed to fulfill its mission of providing family planning services to all who cannot obtain them through other sources and to finance such critical supplemental services as infrastructure, education, outreach, and counseling that many other financing systems do not cover. Consistent with legislative intent, financing for the program must also support research and evaluation, training, the development and maintenance of needed infrastructure, and the adoption of important new technologies."[31]

The proposed rule's preamble also highlights safety-net providers' need for the flexibility of Title X funds, particularly as the range of available contraceptive methods has expanded to meet patients' unique needs. The Department notes: "family planning projects are confronted with a variety of pharmacological, technological, or medical device options to consider in service delivery, with widely

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[29] Dreweke J, "Fungibility": the argument at the center of a 40-year campaign to undermine reproductive health and rights, *Guttmacher Policy Review*, 19:53–60, https://www.guttmacher.org/gpr/2016/10/fungibility-argument-center-40-year-campaign-undermine-reproductive-health-and-rights.

[30] Institute of Medicine, *A Review of the HHS Family Planning Program: Mission, Management, and Measurement of Results*, Washington, DC: The National Academies Press, 2009, https://www.nap.edu/read/12585/chapter/6#123.

[31] Institute of Medicine, *A Review of the HHS Family Planning Program: Mission, Management, and Measurement of Results*, Washington, DC: The National Academies Press, 2009, https://www.nap.edu/read/12585/chapter/2#14.

varying costs." However, the Department makes this observation in support of the erroneous conclusion that this means Title X providers should be given latitude to offer fewer rather than more contraceptive method options. In fact, the opposite is true: Title X funds' ability to cover those very costs is what enables the providers supported by the program to deliver patient-centered care that helps patients to choose from and obtain the best possible methods of contraception for them.[4]

We urge the Department to rescind the proposed rule, particularly Sec. 59.15 on physical and financial separation, and to eliminate language in the preamble that inaccurately cites Guttmacher analyses. We also urge against any further separation requirements.

Discouraging participation by agencies that provide abortion counseling and referral

In addition to barring Title X participation by providers who offer abortion, the proposed rule would likely lead to the exclusion of numerous other family planning providers. As noted above, the rule's proposed ban on abortion referral and its chilling effect (or possibly an effective ban) on abortion counseling are repudiations of ethical and professional standards around informed consent and have the potential to harm patients and undermine the patient-provider relationship. It is likely that many providers would deem it unethical and be unable to remain in Title X under these counseling and referral restrictions.

Similarly, the proposed restrictions on "activities that encourage, promote or advocate for abortion"—which include providing speakers or educators, attending conferences, paying membership dues, and developing or disseminating materials—are likely to have additional chilling effects on providers' willingness to participate in Title X. Collectively, the proposed restrictions are so broad and so vague that many providers may determine that Title X participation would put them in legal jeopardy.

The full impact of these restrictions on the Title X provider network and the patients who rely on them cannot be readily quantified in advance of the rules' implementation. However, it is clear that by dissuading dedicated, high-quality family planning providers from participating in Title X, these restrictions would make it more difficult for patients to receive the family planning care they need.

As noted above, we urge the Department to rescind its proposed changes to the regulations at Sec. 59.5(a)(5) and to rescind its proposed additions at Sec. 59.14 and Sec. 59.16.

Favoring primary care–focused sites over reproductive health–focused sites

The proposed rule requires Title X providers to "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." In doing so, the rule displays a clear preference for funding sites that offer family planning services in the context of broader primary care, such as federally qualified health centers (FQHCs). Shifting funding to primary care–focused sites would inevitably come at the expense of safety-net centers focused on reproductive health.

This proposed provision represents an inappropriate emphasis on primary care services. It also poses considerable potential for confusion and abuse in the awarding of funds, as "close physical proximity" is left undefined.

Furthermore, the provision is unnecessary to promote referral and linkages between Title X and primary care. The current Title X regulations require Title X projects to "provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs."[32] Moreover, the national *Quality Family Planning* guidelines already emphasize the need for family planning providers to screen for numerous health issues (such as high blood pressure, diabetes and depression) and to establish referral arrangements both to and from other providers.[1] According to a recent Guttmacher Institute analysis, nearly all Title X-funded providers reported making referrals to other providers: 97% reported that they refer clients to other public providers and 90% reported that they refer clients to other private providers.[4]

Shifting funding from reproductive health–focused sites to primary care–focused sites would undermine the Title X network and its ability to care for patients. Title X has long relied on a robust and diverse network of safety-net providers operated by many different types of agencies—most of which specialize in providing reproductive health services.

Overall, 72% of Title X sites focus on reproductive health, including all of those operated by Planned Parenthood affiliates, and a majority of those operated by public health departments (81%), hospitals (70%), and other independent providers (86%).[33] Excluding sites operated by FQHCs, reproductive health–focused sites provide contraceptive care to an estimated 2.7 million women each year, or seven in 10 who rely on Title X for such services.[33,34]

Moreover—and further demonstrating that the proposed rule stands to impact providers far beyond Planned Parenthood—excluding reproductive health–focused sites would collectively impact 81% of centers operated by health departments, hospitals and other independent providers.[33] Together, these sites provide contraceptive care to an estimated 1.2 million women, or 32% of those relying on Title X–supported care.[33,34]

Denying people access to reproductive health–focused providers means denying many people access to providers they trust. Six in 10 women who choose reproductive health–focused providers for their contraceptive care do so even when there is a primary care–focused site available; for the remaining four in 10 of these women, that reproductive health–focused provider is their only source of care.[35] Top reasons women cite for this decision include feeling respected by staff, being able to obtain confidential services, and feeling that staff are well-versed in women's health. It is unacceptable for Title X patients to be denied their preferred, trusted source of care.

Moreover, reproductive health–focused providers are often able to offer more comprehensive and more timely family planning services to their patients. Compared with primary care–focused sites, those focused on reproductive health are more likely to offer the full range of reversible contraceptive

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[32] 42 CFR 59.5.

[33] Zolna MR and Frost JJ, special analysis of the Guttmacher Institute's 2015 Publicly Funded Family Planning Clinic Survey, https://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

[34] Zolna MR and Frost JJ, special analysis of the Guttmacher Institute's 2015 Publicly Funded Family Planning Clinic Census, https://www.guttmacher.org/report/publicly-funded-contraceptive-services-us-clinics-2015.

[35] Frost J, 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):519–525, https://www.guttmacher.org/article/2012/11/specialized-family-planning-clinics-united-states-why-women-choose-them-and-their.

methods; to offer same-day insertion of IUDs and implants; to offer supplies of oral contraceptives on-site; to use protocols that help patients start their contraceptive method quickly; and to offer advance provision of emergency contraceptive pills for a client to keep at home.[4]

Of course, primary care–focused sites and FQHCs specifically have become an increasingly integral part of the Title X provider network.[26] However, these providers serve far fewer contraceptive clients each year compared to sites that focus on reproductive health care, and Guttmacher analyses show that FQHC sites alone could not sustain the current reach of Title X: Nationwide, six in 10 report delivering contraceptive care to at least 10 women each year (the threshold to be counted among the nation's safety-net family planning centers).[36] If asked to serve all of the women who rely on many different types of providers for Title X–supported contraceptive care, these FQHC would have to at least double their contraceptive client caseloads in 41 states, and at least triple them in 27 states (see Table 2, attached).[36] Nationwide, this would add up to an additional 3.1 million contraceptive clients FQHCs would need to serve.

At the local level, there are Title X sites in just over 2,000 U.S. counties.[36] In 33% of these counties, there is no FQHC site providing contraceptive services, meaning women living there could lose access to Title X–supported services altogether. In another 47% of these counties, the FQHC sites that offer contraceptive care would have to at least double their contraceptive client caseloads in order to serve all of those currently served by other Title X sites. In 24% of all counties with a Title X site, FQHCs would have to serve at least six times their current number of contraceptive clients.

Put another way, 2.8 million (91%) of the contraceptive clients currently served by Title X–supported centers that are not FQHCs are in the 1,625 counties where FQHC sites would have to at least double their capacity, or where there is no FQHC site providing contraceptive care.[36]

FQHCs are already struggling to meet a rapidly increasing demand for services, and they do not—and cannot—specialize in reproductive health care. Expecting them to expand their capacity to serve millions of additional clients, and to consistently provide family planning services in a way comparable to reproductive health–focused providers, is unrealistic.[37] According to a 2017 national survey, FQHCs themselves report they could not handle large increases to their client caseloads; only 6% said they could sustain a caseload increase of 50% or greater, and the majority said they could increase their caseloads by at most 24%.[38] That is far below what Guttmacher's analysis projects those FQHCs would have to do in most states, if they were to take the entire Title X client load.

Moreover, a recent expert analysis has raised questions as to whether FQHCs could legally participate in Title X were the proposed rule to go into effect, which could result not only in no new FQHCs stepping into the gap left by excluding others from Title X, but in a departure of sites currently

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[36] Frost JJ and Zolna MR, Response to inquiry concerning the availability of publicly funded contraceptive care to U.S. women, memo to 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.

[37] Hasstedt K, Federally qualified health centers: vital sources of care, no substitute for the family planning safety net, *Guttmacher Policy Review*, 2017, 20:67–72, https://www.guttmacher.org/gpr/2017/05/federally-qualified-health-centers-vital-sources-care-no-substitute-family-planning.

[38] Wood SF et al., *Community Health Centers and Family Planning in an Era of Policy Uncertainty*, Menlo Park, CA: Kaiser Family Foundation, 2018, https://www.kff.org/report-section/community-health-centers-and-family-planning-in-an-era-of-policy-uncertainty-report/.

receiving Title X from the program.[39] Indeed, the National Association of Community Health Centers has stated its grave concerns with the proposed rule, urging the Department to withdraw it.[40]

We urge the Department to rescind its proposed addition at Sec. 59.2(a)(12), which unduly emphasizes primary health services.

Funding sites that provide an inadequate package of care

By drastically altering the scope and purpose of the services Title X can support, and by pointedly undermining patients' right to informed consent in their own health care, the proposed rule opens the door for organizations and programs to receive Title X funds despite providing inadequate medical care. The preamble further illustrates the Department's intent, stating it hopes these changes will engage entities "that refuse to provide abortion counseling and referrals," those that serve "patients who seek providers who share their religious or moral convictions," and "specialized, single-method [natural family planning] service sites."

Sites that offer only a single contraceptive method have always been permitted as part of a Title X project, as long as the project overall makes a broad range of methods available to clients. However, the preamble's explicit invitation to single-method sites, its emphasis on natural family planning in particular, and its call for particular applicants seem to open the door to entities like antiabortion counseling centers (or "crisis pregnancy centers"). Those entities most commonly do not have any medical staff and are not able or willing to provide many or all modern and FDA-approved methods of contraception. The proposed rule also suggests the Department's interest in funding abstinence-only-until-marriage programs, an intent put forward in the fiscal year 2018 funding opportunity announcement.

Collectively, these proposed changes herald a sharp and concerning shift away from the fundamental purpose of the Title X program, which is to offer access to a broad range of family planning methods and services. Entities such as antiabortion counseling centers and abstinence-only programs approach family planning in a way that actively undermines Title X's core tenets of ensuring patients' contraceptive choices are voluntary and free from coercion. Moreover, shifting Title X dollars to such entities—and away from qualified health care providers that are able and equipped to provide comprehensive, patient-centered contraceptive and related services—would jeopardize individuals' ability to obtain such care, and advance an unacceptably coercive agenda on Title X patients.

We urge the Department to reconsider and rescind this redirection of Title X funds and programming.

Infringing on Patient Confidentiality

The proposed rule threatens the Title X program's strong, decades-old protections for patient confidentiality, particularly for adolescent clients. It has the potential to do so in two main ways: by instituting increased and inappropriate pressure on Title X providers and their clients—particularly

[39] Rosenbaum S et al., The Title X family planning proposed rule: what's at stake for community health centers? *Health Affairs* Blog, June 25, 2018, https://www.healthaffairs.org/do/10.1377/hblog20180621.675764/full/.
[40] National Association of Community Health Centers, New: NACHC statement regarding the proposed rule for Title X funding, 2018, http://www.nachc.org/news/new-nachc-statement-regarding-the-proposed-rule-for-title-x-funding/.

adolescents—to involve family members in their family planning decision-making, and by improperly inserting the Secretary into the enforcement of state reporting laws.

The Title X statute encourages familial involvement in family planning decisions "to the extent practicable," but does not mandate such involvement. The proposed rule disregards this important statutory limitation. Sec. 59.2 of the proposed rule adds a requirement that Title X providers document in the medical records of unemancipated minors "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." Without this documentation (and putting aside an extremely limited exception for circumstances where child abuse or incest is suspected), an unemancipated minor would appear to be barred from receiving confidential services for free. In addition, Sec. 59.5(a)(14) requires Title X projects to ensure that the records for every minor "document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged)."

However, when taking a health history, clinicians sometimes learn of circumstances (short of abuse) in a minor's family that make it not "practicable," or unrealistic or even harmful, to encourage the minor to involve their parents or guardians. In these situations, clinicians should not be required to take "specific actions" to encourage the minor to do so (and then document those specific actions) as the proposed rule requires. Doing so would violate medical ethics, and could deter adolescent clients concerned about maintaining their confidentiality from seeking needed family planning services.[41]

On the subject of reporting requirements, Title X projects are required by law to comply with state law requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, and incest. Clinicians providing services in Title X-funded already abide by and make reports in compliance with state and local reporting obligations. Appropriately, states and localities are charged with determining providers' compliance with these laws.

Sec. 59.17 of the proposed rule expands these reporting requirements to include intimate partner violence and human trafficking. It also may dramatically expand the Department's authority to substitute its own judgment for that of the responsible state or locality: It would require Title X projects to provide "appropriate documentation or other assurance satisfactory to the Secretary" that it has met compliance requirements, and gives the Secretary the authority to review records "for the sole purpose of determining compliance" with reporting obligations. Such expanded authority on the part of the Department and Secretary would be inappropriate, and the threat of revoking Title X funding may result in harmful over-reporting on the part of providers.

Further, Sec. 59.17 creates a problematic and entirely new requirement that requires providers to "conduct a preliminary screening of any teen" who has an STI or is pregnant "to rule out victimization." It is unclear whether this provision is to be applied to minors (those under the age of consent, or 18 years old) or to all teens, which would include 18- and 19-year old young adults who are not subject to child abuse reporting laws. Regardless, this requirement is an unnecessary step beyond

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[41] Fuentes L et al., Adolescents' and young adults' reports of barriers to confidential health care and receipt of contraceptive services, *Journal of Adolescent Health*, 2018, 62(1):36–43, https://www.guttmacher.org/article/2017/11/adolescents-and-young-adults-reports-barriers-confidential-health-care-and-receipt.

federal and state reporting requirements—one that stigmatizes sexually active adolescents and could discourage them from seeking the care they need.

Collectively, these proposed changes stand to undermine Title X's long-standing commitment to patient confidentiality. Indeed, Title X's longstanding and strong confidentiality protections are cited by patients as an important reason for seeking care at Title X–supported sites.[35,42] The Department's proposed rule demonstrates distrust in providers' professional judgment and would harm the provider-patient relationship by turning health care providers into interrogators. Furthermore, the proposed changes could stigmatize adolescents who are sexually active, lead them to withhold information from providers, discourage them from seeking care they need and potentially make care unaffordable for them. Ultimately, that would undermine patients' health and safety.

We urge the Department to rescind its proposed changes at 59.2 (regarding free care for unemancipated minors), 59.5(a)(14) (regarding documentation of family participation), 59.11 (adding new language expressing distrust in providers' judgement around confidentiality and reporting) and 59.17 (expanding requirements around potential abuse of minors).

Diverting Already-Inadequate Program Resources

The proposed rule would explicitly enable, and may in fact require, Title X–funded entities to provide free contraceptive care to patients whose employer-based insurance does not cover contraception without cost-sharing because of the employer's religious or moral opposition. This represents a radical and unjustified expansion of eligibility for free or reduced-cost services under Title X that could be costly and difficult for providers to implement.

The statute requires that priority for Title X–funded services be given to "persons from low-income families," and that services be free for those individuals, "except to the extent that payment will be made by a third-party payer." Long-standing regulations define "low-income" as an individual or household whose income is at or below the federal poverty level, and further provide that patients whose incomes are between 100% and 250% of the poverty level receive services discounted on a sliding fee scale. The statute gives the Secretary authority to define "low-income," explaining that definition should "insure that economic status shall not be a deterrent to participation in the program."

At a minimum, the proposed rule would allow Title X sites to deliver contraceptive methods and counseling free of charge (as opposed to on a sliding fee scale) to individuals who have insurance through their employer, but whose employer denies such coverage under exemptions from the Affordable Care Act's (ACA) contraceptive coverage guarantee. The proposed rule states these individuals "can" be considered low-income for purposes of eligibility under Title X, and the preamble states the rule would provide "free or low-cost family planning services for such women."

It is also seems possible the proposed rule intends to not just allow, but mandate, that all of these individuals receive care for free. The preamble explains "this proposed rule would amend the definition of 'low-income family' to include women who are unable to obtain certain family planning services under their employer-sponsored health insurance policies." By definition, "low-income" individuals are to receive free care under Title X. Moreover, because the ACA's contraceptive coverage guarantee

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[42] English A, Adolescent confidentiality protections in Title X, June 5, 2014, https://www.nationalfamilyplanning.org/document.doc?id=1559.

promises contraceptive methods, services and counseling without additional out-of-pocket costs, it seems any proposed "substitute" would be expected to deliver similarly free care.

Regardless of whether these individuals are to receive free or reduced-cost services, Title X is simply not intended to—nor can it—meet the needs of insured individuals with incomes above 250% of poverty. The proposed change is not in keeping with the statutory requirement that the Secretary define eligibility for free services based on individuals' "economic status." Rather, it seems intended to fill a gap the Department itself is creating, by drastically expanding exemptions to the ACA's contraceptive coverage guarantee.[43] This would redirect limited Title X funding away from helping to deliver affordable contraceptive care to the low-income individuals who need it, and whom Congress clearly intended the Title X program to prioritize and support.

Title X funding is already not able to keep pace with that need: According to Guttmacher's most recent estimates, in 2014, Title X–funded providers were able to meet only 19% of the need for publicly funded contraceptive care.[44] This is a marked decline from previous years, likely due in part to reductions in Title X funding—and therefore providers' capacity to meet the need for care—and to increasing proportions of individuals with health insurance coverage, specifically for contraceptive care without additional cost-sharing, under the ACA.

It is unclear how many of those insured individuals would look to Title X for free care under the proposed rule, as the Department has not implemented any mechanism to track which organizations avail themselves of the exemption from the ACA's contraceptive coverage guarantee, or how many enrollees and dependents would be affected by those exemptions.[43] Thus, it is not feasible for the Department to appropriately estimate the economic impact of this provision of the proposed rule, nor to appropriately request and allocate funds in response to this type of new demand for Title X–funded services.

Implementing this new definition would also likely prove difficult and costly for service providers. They would have no clear way to determine eligibility for free or reduced-cost services, because employers objecting to contraceptive coverage are not required to report their use of the exemption to the Department. Moreover, if the Department intends for some services to be delivered at "low cost" (rather than free) as stated in the preamble, it is unclear how Title X–funded sites would be expected to implement a sliding fee scale for these individuals, many of whom likely earn more than 250% of poverty.

We urge the Department to rescind this expanded definition of "low income family" in Sec. 59.2 and to abandon its effort to divert Title X resources to fix a problem of its own creation.

If the Department does not rescind these changes, we ask the Department to clarify whether it intends for all individuals affected by exemptions from the ACA's contraceptive coverage guarantee to be provided free contraceptive methods, services and counseling by all Title X–funded sites, in all circumstances.

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[43] Sonfield A, Despite leaving key questions unanswered, new contraceptive coverage exemptions will do clear harm, *Health Affairs* Blog, Oct. 17, 2017, https://www.guttmacher.org/article/2017/10/despite-leaving-key-questions-unanswered-new-contraceptive-coverage-exemptions-will.

[44] Frost JJ, Frohwirth LF and Zolna MR, *Contraceptive Needs and Services, 2014 Update,* New York: Guttmacher Institute, 2016, https://www.guttmacher.org/report/contraceptive-needs-and-services-2014-update.

We further ask the Department to specify how it would appropriately allocate funding based on this additional demand. And we ask the Department to specify how Title X providers would be expected to implement this requirement, including how they would be expected to verify that a prospective patient's employer-based insurance is in fact refusing to cover contraceptive care.

Underestimating the Economic Impact of the Proposed Rule

The Department claims that the proposed rule would not be "economically significant," meaning that it would not have an impact of $100 million or more in any one year. It makes similar claims around whether the rule would be an unfunded mandate for state, local or tribal governments or the private sector (with a $150 million threshold). We believe the Department is dramatically underestimating the potential economic costs of the proposed rule, has not properly conducted the required analyses to make those estimates, and has not shown sufficient data to support its contentions that the proposed rule would not be economically significant or constitute an unfunded mandate.

According to Guttmacher Institute estimates from 2010 (the most recent year for which these data are available), the services provided within the Title X network saved approximately $7 for every public dollar invested, by helping patients avoid unintended pregnancies, STIs, cervical cancer and other health outcomes that have costs for Medicaid and other public health programs.[45] This amounted to an estimated $7 billion in net federal and state government savings in a single year. The $100 million threshold for the rule to be economically significant would amount to only 1.4% of this $7 billion in savings to federal and state governments. The $150 million threshold for unfunded mandates would amount to only 2.1% of $7 billion.

Available data suggests the proposed rule would result in far more than 2% of Title X's contraceptive clients losing access to the comprehensive, high-quality services they need to avoid unintended pregnancies, STIs, cervical cancer, and other negative and potentially costly health outcomes.

For example, the proposed rules seems designed to make it impossible for sites affiliated with Planned Parenthood to participate in Title X. As noted above, Planned Parenthood sites currently serve 41% of women who rely on Title X sites for contraceptive care and other Title X sites would have to dramatically increase their client loads in order to compensate for the loss of Planned Parenthood.[27] In many areas, that simply would not be possible: According to a 2016 nationally representative survey of clients at Title X–funded health centers, 24% percent of clients at a Planned Parenthood site reported that it was the only place they could get the services they need.[25] It is difficult if not impossible to imagine a scenario where the loss of Planned Parenthood from the Title X network does not result in an economic impact that is many times greater than $100 million per year.

Similarly, the proposed rule would directly bar participation in Title X by entities that offer abortion with non–Title X dollars. In 2015, 10% of Title X–supported sites offered medication or surgical abortion with non-Title X funds.[33] Losing those sites alone from the Title X network could have an economic impact well above the $100 million threshold, if the Department reallocated the Title X grant money to entities that do not provide high-quality, comprehensive contraceptive care.

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[45] Frost JJ et al., Return on investment: a fuller assessment of the benefits and cost savings of the US publicly funded family planning program, *Milbank Quarterly*, 2014, 92(4):696–749, http://onlinelibrary.wiley.com/enhanced/doi/10.1111/1468-0009.12080/.

In addition, the proposed rules would clearly disadvantage reproductive health–focused providers in the allocation of Title X grants. These reproductive health–focused sites include 81% of Title X–funded sites operated by health departments, hospitals and other independent providers.[33] Collectively, these 1,840 sites provide contraceptive care to an estimated 1.2 million women, or 32% of those who look to Title X for such services.[33,34] Again, the loss of these sites from the Title X network could easily have an economic impact well in excess of $100 million, assuming that the Department instead funded entities that lower quality and less-comprehensive contraceptive care.

More broadly, 21% of Title X sites are in counties that do not have another safety-net family planning center (see Table 3, attached). Moreover, in 21% of all 3,142 U.S. counties, a Title X site is the only safety-net family planning center. Many of these sites may end up losing Title X funding under the proposed rule—for instance, because they cannot or will not comply with rule's unethical restrictions on abortion counseling and referral or its efforts to undermine patient confidentiality, or because the Department uses the rule as a means of funneling Title X funds toward unqualified entities such as antiabortion pregnancy centers.

We urge the Department to conduct proper, thorough analyses of the proposed rule's economic significance and its potential to create an unfunded mandate, as required by federal law.

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In sum, the proposed rule seeks to: impose unwarranted and harmful requirements for the separation of Title X–supported family planning from abortion services, impose substandard care on some of our nation's most marginalized communities, and fundamentally subvert the very purpose of the Title X program. We strongly urge the Department to rescind the proposed rule in its entirety.

If you need additional information about the issues raised in this letter, please contact Kinsey Hasstedt in the Institute's Washington office. She may be reached by phone at 202.296.4012, or by email at khasstedt@guttmacher.org.

Thank you for your consideration.

Sincerely,

Rachel Benson Gold
Vice President for Public Policy

Table 1. Estimated impact on contraceptive client caseload among other types of Title X–funded centers if there were no Title X–funded Planned Parenthood centers, by state, 2015

State	Contraceptive clients served at Title X–funded centers:			% increase in contraceptive client caseload among non–Planned Parenthood Title X–funded centers if there were no Title X–funded Planned Parenthood centers*
	Number served at all centers	Number served at Planned Parenthood centers	% served at Planned Parenthood centers	
Alabama	86,180	0	0%	0%
Alaska	5,290	3,360	64%	174%
Arizona	31,820	16,750	53%	111%
Arkansas	51,510	4,590	9%	10%
California	1,014,320	704,630	69%	228%
Colorado	50,280	0	0%	0%
Connecticut	46,790	41,330	88%	757%
Delaware	13,480	4,200	31%	45%
District of Columbia	30,750	0	0%	0%
Florida	149,950	11,020	7%	8%
Georgia	59,450	0	0%	0%
Hawaii	19,750	960	5%	5%
Idaho	12,610	660	5%	6%
Illinois	119,730	50,340	42%	73%
Indiana	30,750	9,640	31%	46%
Iowa	35,970	19,360	54%	117%
Kansas	25,530	1,800	7%	8%
Kentucky	47,950	3,260	7%	7%
Louisiana	40,580	0	0%	0%
Maine	18,200	7,060	39%	63%
Maryland	67,410	26,390	39%	64%
Massachusetts	72,150	19,160	27%	36%
Michigan	67,250	40,520	60%	152%
Minnesota	61,280	43,400	71%	243%
Mississippi	46,920	0	0%	0%
Missouri	56,540	22,720	40%	67%
Montana	18,090	7,720	43%	74%
Nebraska	22,520	6,570	29%	41%
Nevada	10,310	0	0%	0%
New Hampshire	17,680	8,210	46%	87%
New Jersey	82,950	59,530	72%	254%
New Mexico	22,900	0	0%	0%
New York	275,510	144,640	52%	111%
North Carolina	111,010	12,860	12%	13%
North Dakota	9,620	0	0%	0%
Ohio	76,580	44,290	58%	137%
Oklahoma	56,290	8,520	15%	18%
Oregon	48,990	20,000	41%	69%
Pennsylvania	169,700	65,280	38%	63%

Table 1. Estimated impact on contraceptive client caseload among other types of Title X–funded centers if there were no Title X–funded Planned Parenthood centers, by state, 2015

State	Contraceptive clients served at Title X–funded centers:			% increase in contraceptive client caseload among non–Planned Parenthood Title X–funded centers if there were no Title X–funded Planned Parenthood centers*
	Number served at all centers	Number served at Planned Parenthood centers	% served at Planned Parenthood centers	
Rhode Island	25,510	6,190	24%	32%
South Carolina	73,500	0	0%	0%
South Dakota	7,750	0	0%	0%
Tennessee	88,420	3,940	4%	5%
Texas	163,980	29,960	18%	22%
Utah	35,570	30,120	85%	553%
Vermont	8,200	8,200	100%	§
Virginia	70,320	3,460	5%	5%
Washington	82,520	66,210	80%	406%
West Virginia	46,680	660	1%	1%
Wisconsin	30,850	24,240	79%	367%
Wyoming	9,790	0	0%	0%
Total	**3,827,650**	**1,581,760**	**41%**	**70%**

*Percentage increase takes into account the additional number of clients that existing sites would need to serve if there were no Title X–funded Planned Parenthood centers. §In 2015, there were no non-Planned Parenthood Title X–funded centers in the state.

Notes: Counts may not sum to total due to rounding. For more detailed information on how many additional contraceptive clients other Title X–funded centers would have to serve, by type of center and by state, see Table 2 here: https://www.guttmacher.org/article/2017/06/guttmacher-murray-memo-june-2017.

Source: Zolna MR and Frost JJ, special analysis of the Guttmacher Institute's 2015 Publicly Funded Family Planning Clinic Census, https://www.guttmacher.org/report/publicly-funded-contraceptive-services-us-clinics-2015.

Table 2. Summary data on numbers of contraceptive clients served at Title X–funded centers and at Federally Qualified Health Center (FQHC) sites, and level of increased capacity needed among FQHCs in order to serve all contraceptive clients obtaining care at non–FQHC Title X–funded centers, all by state, 2015

State	Number of contraceptive clients served at Title X–funded centers:		Number of contraceptive clients served at all FQHCs (Title X and not Title X–funded):		% increase in contraceptive client caseload among FQHCs if serving all Title X clients*
	All	Not FQHC	Current caseload	Caseload if serving all Title X clients	
Alabama	86,200	78,900	16,860	95,760	468%
Alaska	5,290	5,290	8,850	14,140	60%
Arizona	31,820	28,080	31,060	59,140	90%
Arkansas	51,560	51,510	3,410	54,920	1521%
California	1,014,340	772,160	600,420	1,372,580	129%
Colorado	50,320	37,310	36,060	73,370	103%
Connecticut	46,800	41,710	18,260	59,970	228%
Delaware	13,480	10,350	3,460	13,810	299%
District of Columbia	30,750	-	31,460	31,460	0%
Florida	149,970	130,340	65,570	195,910	199%
Georgia	59,450	7,090	64,110	71,200	11%
Hawaii	19,750	3,000	17,380	20,380	17%
Idaho	12,640	12,610	5,200	17,810	243%
Illinois	119,750	75,790	106,620	182,410	71%
Indiana	30,760	17,620	28,430	46,050	62%
Iowa	35,980	33,000	7,580	40,580	437%
Kansas	25,570	25,530	6,770	32,300	378%
Kentucky	48,010	43,060	21,280	64,340	202%
Louisiana	40,620	40,030	16,240	56,270	247%
Maine	18,210	15,460	6,950	22,410	223%
Maryland	67,440	58,290	25,950	84,240	225%
Massachusetts	72,160	46,720	50,870	97,590	92%
Michigan	67,240	64,600	26,660	91,260	242%
Minnesota	61,300	61,280	8,580	69,860	714%
Mississippi	46,970	41,920	13,190	55,110	318%
Missouri	56,540	51,290	22,590	73,880	227%
Montana	18,110	15,090	6,120	21,210	247%
Nebraska	22,530	16,180	9,490	25,670	171%
Nevada	10,340	10,060	2,740	12,800	369%
New Hampshire	17,660	12,480	6,990	19,470	179%
New Jersey	82,970	68,600	35,480	104,080	193%
New Mexico	22,930	19,320	15,660	34,980	123%
New York	275,540	228,500	149,120	377,620	153%
North Carolina	111,040	108,380	16,970	125,350	639%
North Dakota	9,620	9,620	840	10,460	1144%
Ohio	76,630	74,700	34,080	108,780	219%
Oklahoma	56,300	55,720	8,270	63,990	676%
Oregon	49,020	39,500	23,760	63,260	166%
Pennsylvania	169,710	146,370	47,600	193,970	308%

Table 2. Summary data on numbers of contraceptive clients served at Title X–funded centers and at Federally Qualified Health Center (FQHC) sites, and level of increased capacity needed among FQHCs in order to serve all contraceptive clients obtaining care at non–FQHC Title X–funded centers, all by state, 2015

State	Number of contraceptive clients served at Title X–funded centers:		Number of contraceptive clients served at all FQHCs (Title X and not Title X–funded):		% increase in contraceptive client caseload among FQHCs if serving all Title X clients*
	All	Not FQHC	Current caseload	Caseload if serving all Title X clients	
Rhode Island	25,520	7,150	21,600	28,750	33%
South Carolina	73,540	73,500	19,250	92,750	381%
South Dakota	7,770	4,850	3,930	8,780	124%
Tennessee	88,470	88,130	18,720	106,850	472%
Texas	163,990	140,680	98,520	239,200	143%
Utah	35,560	35,570	6,070	41,640	586%
Vermont	8,210	8,200	4,470	12,670	184%
Virginia	70,430	68,210	10,660	78,870	643%
Washington	82,510	75,420	39,360	114,780	192%
West Virginia	46,700	19,180	35,930	55,110	53%
Wisconsin	30,860	30,850	13,300	44,150	232%
Wyoming	9,800	6,930	3,690	10,620	188%
Total	**3,827,650**	**3,116,100**	**1,875,710**	**4,991,810**	**166%**

*Percentage increase takes into account the additional number of clients that existing FQHC sites would need to serve if there were no Title X–funded centers.

Notes: Counts may not sum to total due to rounding. FQHC=federally qualified health center site that served at least 10 contraceptive clients. For more detailed information on how many additional contraceptive clients FQHC sites would have to serve, see table 4 here: https://www.guttmacher.org/article/2017/05/guttmacher-murray-memo-2017.

Source: Zolna MR and Frost JJ, special analysis of the Guttmacher Institute's 2015 Publicly Funded Family Planning Clinic Census, https://www.guttmacher.org/report/publicly-funded-contraceptive-services-us-clinics-2015.

Table 3. Total number of Title X–funded centers and number that are in counties with no other publicly funded provider, and total number of U.S. counties and number with only Title X–funded centers, by state, 2015

State	Number of Title X–funded centers:		Number of U.S. counties:	
	All	In counties with no other provider	All	With at least one Title X–funded center and no other provider
Alabama	83	18	67	17
Alaska	5	0	29	0
Arizona	36	0	15	0
Arkansas	92	35	75	32
California	353	1	58	1
Colorado	64	13	64	12
Connecticut	20	0	8	0
Delaware	38	10	3	1
District of Columbia	23	0	1	0
Florida	142	12	67	9
Georgia	125	0	159	0
Hawaii	32	0	5	0
Idaho	33	10	44	10
Illinois	95	16	102	14
Indiana	33	10	92	10
Iowa	47	25	99	22
Kansas	63	47	105	46
Kentucky	128	73	120	70
Louisiana	67	13	64	12
Maine	43	6	16	2
Maryland	77	5	24	5
Massachusetts	90	1	14	1
Michigan	94	18	83	17
Minnesota	40	15	87	12
Mississippi	106	34	82	25
Missouri	79	20	115	18
Montana	26	7	56	6
Nebraska	28	13	93	13
Nevada	17	1	17	1
New Hampshire	22	4	10	3
New Jersey	49	3	21	3
New Mexico	65	3	33	3
New York	175	24	62	14
North Carolina	120	36	100	33
North Dakota	16	12	53	11
Ohio	78	21	88	20
Oklahoma	103	25	77	22
Oregon	81	8	36	6
Pennsylvania	169	21	67	15
Rhode Island	22	1	5	1
South Carolina	59	5	46	5
South Dakota	33	19	66	18

Table 3. Total number of Title X–funded centers and number that are in counties with no other publicly funded provider, and total number of U.S. counties and number with only Title X–funded centers, by state, 2015

State	Number of Title X–funded centers:		Number of U.S. counties:	
	All	In counties with no other provider	All	With at least one Title X–funded center and no other provider
Tennessee	129	37	95	30
Texas	96	14	254	13
Utah	14	0	29	0
Vermont	10	1	14	1
Virginia	135	53	133	51
Washington	64	10	39	6
West Virginia	146	45	55	20
Wisconsin	19	10	72	10
Wyoming	16	8	23	8
Total	**3,700**	**763**	**3,142**	**649**

Notes: For more detailed information on numbers and types of clinics and clients by state and county, see: https://www.guttmacher.org/report/publicly-funded-contraceptive-services-us-clinics-2015.

Source: Zolna MR and Frost JJ, special analysis of the Guttmacher Institute's 2015 Publicly Funded Family Planning Clinic Census, https://www.guttmacher.org/report/publicly-funded-contraceptive-services-us-clinics-2015.

AMA
AMERICAN MEDICAL ASSOCIATION

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July 31, 2018

The Honorable Alex M. Azar, II
Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Compliance with Statutory Program Integrity Requirements (RIN 0937-ZA00), 83 Fed. Reg. 25502 (June 1, 2018)

Dear Secretary Azar:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments to the Department of Health & Human Services (HHS) in response to the Notice of Proposed Rulemaking (Proposed Rule or NPRM) on "Compliance with Statutory Program Integrity Requirements" issued by the Office of Population Affairs (OPA). In its NPRM, HHS proposes to significantly revise the regulations governing the federal Title X family planning program (Title X). The Proposed Rule would withhold federal funds to qualified family planning providers such as Planned Parenthood that also offer abortion services; prohibit in most cases referrals for abortion and restrict counseling about abortion services; eliminate current requirements that Title X sites offer a broad range of medically approved family planning methods and nondirective pregnancy options counseling; and direct new funds to faith-based and other organizations that promote fertility awareness and abstinence as methods of family planning rather than the full range of evidence-based family planning methods.

For the reasons discussed in more detail below, the AMA strongly opposes this Proposed Rule. We are very concerned that the proposed changes, if implemented, would undermine patients' access to high-quality medical care and information, dangerously interfere with the patient-physician relationship and conflict with physicians' ethical obligations, exclude qualified providers, and jeopardize public health. Given our concerns, we urge HHS to withdraw this NPRM.

The Proposed Rule Would Interfere With the Patient-Physician/Provider Relationship

The AMA strongly opposes any government interference in the exam room, especially legislation or regulations that attempt to dictate the content of physicians' conversations with their patients. Protecting the sanctity of the patient-physician relationship, including defending the freedom of communication between patients and their physicians, is a core priority for the AMA. The ability of physicians to have open, frank and confidential communications with their patients has always been a fundamental tenet of high quality medical care.

From ancient times, physicians have recognized that the health and well-being of patients depends upon a collaborative effort between physician and patient. Patients share with physicians the responsibility for their own health care. The patient-physician relationship is of greatest benefit to patients when they bring medical problems to the attention of their physicians in a timely fashion, provide information about their medical condition to the best of their ability, and work with their physicians in a mutually respectful alliance. This relationship is built upon trust. A physician must always have the ability to freely communicate with his or her patient, providing information to patients about their health and safety, without fear of intrusion by government and/or other third parties. Regulations that restrict the ability of physicians to explain all options to their patients and refer them, whatever their health care needs, compromise this relationship and force physicians and other health care providers to withhold information that their patients need to make decisions about their care.

The Proposed Rule would violate these core principles by restricting the counseling and referrals that can be provided to patients and by directing clinicians to withhold information critical to patient decision-making. Under section 59.5(a)(5) of the current regulations, Title X projects are required to provide pregnant patients information and counseling regarding the full range of reproductive health options: prenatal care and delivery; infant care, foster care or adoption; and pregnancy termination. If a patient requests such information and counseling, projects must provide neutral, factual information and nondirective counseling on each of the options, as well as referral upon request, except with respect to any option(s) about which the patient indicates she does not want information and counseling.

Specifically, the NPRM eliminates the current requirement that Title X projects provide neutral, factual, nondirective options counseling regarding all of a pregnant patient's options—including abortion—upon request. It appears to be up to each site and organization that participates to decide whether to mention abortion as an option, and it is not exactly clear the extent to which counseling for abortion would be allowed. Although HHS states in the Preamble to the Proposed Rule that a physician—and only a physician—could continue to offer nondirective counseling on abortion as an option, the actual text of the NPRM is silent on this issue.

The Title X statute states that no federal funds appropriated under the program shall be used in programs where abortion is a method of family planning. This provision has generally been interpreted throughout the program's history as meaning that Title X funds cannot be used to pay for or support abortion, which is reflected in the current regulations. However, the NPRM adds vague and confusing language that Title X projects shall not promote, encourage, support, or present abortion as a method of family planning. These terms are not defined in the regulatory text. At the very least, this language could have a chilling effect on physicians and other providers when counseling patients on their options. Moreover, the Proposed Rule requires that Title X projects must refer pregnant patients "for appropriate prenatal and/or social services (such as prenatal care and delivery, infant care, foster care, or adoption)" regardless of a patient's wishes, interest in such a referral, or health status (Section 59.14, NPRM). Title X projects would also be required to assist patients with setting up a referral appointment "to optimize the health of the mother and unborn child." Furthermore, the NPRM would prohibit a Title X project from using prenatal, social service, emergency medical or other referrals as an indirect means of encouraging or promoting abortion as a method of family planning.

In addition to eliminating the requirement for nondirective pregnancy options counseling, the NPRM seeks to ban Title X projects from providing abortion referrals. The Proposed Rule would allow a limited exception if a pregnant patient has already decided to have an abortion and explicitly requests a referral. In this situation, a physician—and no other clinical staff—would be permitted, but not required, to

provide the patient with a list of licensed, qualified, and comprehensive health care providers, some of which may or may not provide abortion services, in addition to prenatal care. However, the list cannot identify the providers that perform abortions and the physician may not indicate which providers on the list offer abortion services. If a pregnant patient does not explicitly state that she has decided to have an abortion, but requests a referral for one, the patient can only be given list of providers which do not provide abortion but do provide prenatal care.

The proposed changes on counseling and referral described above would not only undermine the patient-physician relationship, but also could force physicians to violate their ethical obligations. The inability to counsel patients about all of their options in the event of a pregnancy and to provide any and all appropriate referrals, including for abortion services, are contrary to the AMA's *Code of Medical Ethics*, which provides that patients have the right

> "to receive information from their physicians and to have the opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives…patients should be able to expect that their physicians will provide guidance about what they consider the optimal course of action for the patient based on the physician's objective professional judgment." (Opinion E-1.1.3)

Physicians' inability to comply with their ethical obligations could not only harm the patient-physician relationship, but also could result in harm to their pregnant patients at Title X projects, especially if such patients are delayed in finding abortion providers. Moreover, any restriction on the right of patients and physicians to communicate freely would require assertion of a compelling government interest. While HHS has suggested some general rationales for its proposed amendments, it has not indicated such a compelling interest for the proposed restrictions. In fact, the AMA believes there is no such compelling interest.

The Proposed Rule Would Undermine Access to Evidence-Based Family Planning Methods

The current Title X regulations require funded projects to provide medical services related to family planning and to offer a broad range of acceptable and effective medically approved family planning methods. The NPRM eliminates the requirement that projects offer the full range of family planning methods, and further eliminates "medically approved" from the current regulatory requirement. The Proposed Rule would no longer require that sites follow the Quality Family Planning guidelines of the Centers for Disease Control and Prevention and the OPA. Instead, HHS emphasizes non-medical services, such as abstinence, natural family planning, and adoption as a way to manage infertility. HHS' emphasis on non-medical services is contradicted by data showing that fertility awareness methods are among the least effective methods of family planning, and the Food and Drug Administration has warned that these are not reliable forms of contraception.

Moreover, although the current regulations allow Title X-funded organizations to offer only a single method of family planning, the NPRM is more permissive and seems to encourage more single-method or limited number of methods within a project. These changes could result, for example, in a Title X project that provides only natural family planning and other fertility awareness-based methods, along with abstinence only education for adolescents. These revised provisions change the historic emphasis under both the Title X statute and current regulations that projects must provide a broad range of acceptable and effective medically approved family planning methods.

All individuals seeking care in Title X programs should have access to the contraceptive method that works best for their circumstances. Evidence shows that women who have access to and are able to use the contraceptive method of their choice are more likely to use contraception consistently and effectively, thereby reducing their risk of unintended pregnancy. Contrary to HHS' assertion that its proposed changes will improve access to and the quality of care at Title X projects, the AMA believes that the proposed revisions discussed above will undermine the quality and standard of care upon which millions of women depend for their reproductive health care. Moreover, the Proposed Rule threatens to reverse decades of progress in reducing unintended and teen pregnancy; the United States currently has a 30-year low in unplanned pregnancy and an all-time low in teen pregnancy. Access to affordable contraception, including through programs funded by Title X, has helped make these results possible.

The Proposed Rule Would Inappropriately Exclude Qualified Providers

The Proposed Rule would essentially disqualify any provider that offers abortion services or is affiliated with an abortion provider from receiving Title X funds. It appears designed to make it extremely difficult, if not impossible, for specialized reproductive health providers, such as Planned Parenthood, to continue to participate in Title X. The statute governing Title X requires that program funds can only go to entities where abortion is not a method of family planning. Under current regulations, Title X projects are banned from using Title X funds to pay for abortions and must keep any abortion-related financially separate from their Title X activities. The Proposed Rule, however, would require that Title X activities have full physical and financial separation from abortion-related activities. In addition to separate accounting and electronic and paper health records, providers would need to have separate treatment, consultation, examination and waiting rooms, office entrances and exits, workstations, signs, phone numbers, email addresses, educational services, websites, and staff. HHS fails to justify why physical separation is needed.

Another proposed change would require Title X projects to offer comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity. This is inappropriate since providing comprehensive primary care services is not a permissible use of Title X funds and the best referrals for Title X funds are not necessarily defined solely by physical proximity. Moreover, some stand-alone family planning clinics, especially in rural areas, may not be near primary health providers, and may not qualify for funding under this requirement.

These provisions, taken as a whole, would make it impossible for clinics like Planned Parenthood and any other provider that also offers abortion services to comply with the new requirements of the program. Furthermore, restrictions on infrastructure support and affiliations would make it impossible for them to continue to participate in Title X. It is unlikely that other providers in many areas of the country, especially in rural and medically underserved communities, would be able to adequately fill the gap left by qualified providers being forced to close.

The implications of these proposed changes are significant, putting at risk access to quality family planning and preventive care services for more than 40 percent, or nearly two million, Title X patients. In states that have excluded certain providers from their family planning programs, research shows serious public health consequences. For example, a study published in the *New England Journal of Medicine* found that blocking patients from going to Planned Parenthood in Texas resulted in a 35 percent decline in women in publicly-funded programs using the most effective forms of birth control and that denying women access to the contraceptive care they needed led to a 27 percent increase in births (among women who had previously used injectable contraception through these program).

Additional Provisions Would Negatively Impact Access to Care

Another proposed change in the NPRM would redefine "low-income family" to include women whose employer-based health insurance coverage does not cover contraception due to the employer's religious or moral objections. This expanded definition would potentially require Title X providers to provide free contraceptive services to women of all incomes. The Title X program is already underfunded and overburdened and the Proposed Rule could result in even fewer resources to serve low-income patients.

The NPRM also threatens patient confidentiality protections, particularly for adolescents. Title X has long required that both adults and adolescents receive confidential family planning services. The current regulations require sites to consider if minors qualify for free family planning services based on their income alone. While the Title X statute encourages family involvement in minors' family planning decisions, the Proposed Rule tries to make such involvement mandatory by changing the definition of "low-income family" to require that Title X providers document in the medical records of unemancipated minors the specific actions taken by the provider to encourage the minor to involve his or her family. This requirement would be a condition of allowing such minors to receive confidential services based on their own resources. This requirement could undermine the provider's expertise and judgment about whether encouraging family participation is feasible or desirable based on the minor's circumstances. In addition, new proposed documentation and reporting requirements, such as the age of each minor patient, the age of each minor's sexual partner(s), if required by law, and special screening of any patient under the age of consent who has a sexually transmitted disease or is pregnant, could undermine the relationship between the minor patient and their Title X provider and prevent such minors who have confidentiality concerns from seeking needed medical services. HHS needs to ensure that Title X projects can continue to provide confidential care for adolescents while complying with all state and federal laws.

In conclusion, Title X is the only federal program dedicated specifically to providing low-income patients with essential family planning and preventive health services and information. As such, it plays a vital role in the nation's public health safety net by ensuring that timely, safe, and evidence-based care is available to women, men, and adolescents, regardless of their financial circumstances. In addition to pregnancy prevention, Title X projects provide other important health services, including sexually transmitted infection testing and treatment, Pap tests, and clinical breast exams. The AMA believes that this Proposed Rule, if finalized, would limit access to critically needed care and services for millions of individuals who depend upon the Title X program for their care and would result in harm to patients and the public's health. We urge HHS to withdraw this proposal.

Sincerely,

James L. Madara, MD

EXECUTIVE CHAMBERS

HONOLULU

DAVID Y. IGE
GOVERNOR

July 30, 2018

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

Dear Secretary Azar:

I am writing to provide the State of Hawai'i's comments on the U.S. Department of Health and Human Services' proposed rulemaking relating to Title X of the Public Health Service Act. The Title X grant currently helps to fund more than 50 percent of our statewide family planning services on six islands. In almost all the rural and medically underserved areas of our state, Title X funded clinics are the only source for low-cost family planning services.

The proposed changes to the Title X rules will significantly reduce or eliminate both the availability and quality of family planning services for our residents.

I vehemently oppose the proposed rule changes that will undermine the rights of millions of individuals and place women's health at serious risk. Enclosed is a copy of the comments submitted on the proposed rules from the Hawai'i Department of Health which detail the harm and damage that will occur with these new rules that threaten the health and well-being of Hawai'i residents.

Should the proposed rules be enacted, Hawai'i will explore all options available to safeguard the well-being and rights of our women and the integrity of the state's family planning programs, including withdrawing from the title X program. If these proposed rules are implemented, Hawai'i will refuse federal funds for these programs and stand for our patients' rights to have access to learn about all their medical options and determine for themselves which option is best.

Hawai'i is committed to providing high quality clinical family planning and related preventive health services, including education and counseling related to family planning, and referral services with priority to low income, hard-to-reach, and at-risk populations. I urge you to reconsider the proposed changes in favor of continuing to

support high quality, science-based and medically appropriate family planning services in Hawai'i and across the nation.

With warmest regards,

David Y. Ige
Governor, State of Hawai'i

Attachment

c: Senator Mazie Hirono
Senator Brian Schatz
Representative Tulsi Gabbard
Representative Colleen Hanabusa

DAVID Y. IGE
GOVERNOR OF HAWAII

BRUCE S. ANDERSON, Ph.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
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HONOLULU, HI 96801-3378

In reply, please refer to:
File:

July 31, 2018

Diane Foley, M.D., FAAP
Deputy Assistant Secretary
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

Dear Dr. Foley:

The Hawaii Department of Health (DOH) reviewed the 2018 Notice of Proposed Rulemaking, **42 CFR Part 59, Docket No.: HHS–OS–2018–0008 (RIN 0937–ZA00) Compliance with Statutory Program Integrity Requirements for the Title X Family Planning Program.** Thank you for the opportunity to provide feedback and for considering the potential impact of this rule change on the health and wellbeing of the residents of Hawaii.

The Hawaii Department of Health administers the State's Title X family planning grant and related reproductive and women's health programs. The Title X grant helps to fund approximately 58% of our statewide family planning services. In 2016, our combined federal and state dollars provided 16,002 women and men comprehensive family planning and related preventive health services, including client centered education, counseling, and referrals. These services are provided on six islands (Kauai, Oahu, Molokai, Maui, Lanai, and Hawaii) through 12 contracts at 30 services sites. These sites include, but are not limited to, eight Federally Qualified Health Centers in medically underserved rural areas, three academic settings on Kauai, Maui, and Hawaii Islands, and one hospital-based setting on Molokai Island. In almost all of the rural and medically underserved areas of our state, these clinics are the only source for low-cost family planning services. Changes to the Title X rules will significantly reduce or eliminate both the availability and quality of family planning and preventive health services for our residents.

We have summarized below the proposed changes that would have substantial impact on Hawaii residents who rely on family planning and preventive health services provided through the DOH:

- Proposed **§ 59.2 Definitions.** ***Low Income***
  The proposed rule redefines that "*…a woman can be considered from a "low-income family" if she has health insurance coverage through an employer which does not provide the*

contraceptive services sought by the woman because it has a sincerely held religious or moral objection to providing such coverage…"

DOH Comment: This proposed rule appears to provide a different and higher priority status for employed women with other health insurance, but without employer coverage for family planning services. This rule change could potentially shift resources from the women in lower-income families with greatest need to higher income women.

- Proposed **§ 59.5 What requirements must be met by a family planning project?** The proposed rule removes language specifying that the family planning methods and services offered by a Title X project be 'medically approved'.

  DOH Comment: This proposed rule has the potential for allowing non-Food and Drug Administration (FDA) approved methods and/or other family planning methods that are not medically recommended or not evidence-based. This change may also decrease both the quality and consistency of Title X services provided across the state and country. Removing the requirement that family planning methods be medically approved undermines the Title X commitment of "*…assuring quality comprehensive family planning services statewide…*"

- Proposed **§ 59.5 What requirements must be met by a family planning project?** The proposed rule states: "*…Such projects are not required to provide every acceptable and effective family planning method or service. A participating entity may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services…*"

  DOH Comment: Non-directive option counseling that includes **all options** is a longstanding Title X regulation that is consistent with medical and ethical standards and many medical professional organizations. The proposed rule change could severely limit the family planning choices available across the state and if adopted, would significantly affect our rural and medically underserved areas of the state. In those rural communities where there are few family planning service options and limited access to multiple service providers, women and men may be forced to comply with a single method of family planning services chosen by the facility. The consequences could include unintended or unwanted pregnancy which are known to contribute to infant mortality, prematurity, and maternal mortality. These are all strategic public health priorities for the State that we would like to see decrease.

- Proposed **NEW § 59.13 Standards of compliance with prohibition on abortion.** The proposed new section states: *"A project may not receive funds under this subpart unless it provides assurance satisfactory to the Secretary that, as a Title X grantee, it does not provide abortion and does not include abortion as a method of family planning. Such assurance must also include, at a minimum, representations (supported by documentary evidence where the Secretary requests it) as to compliance with this section and each of the*

requirements in §§ 59.14 through 59.16. A project supported under this subpart must comply with such requirements at all times during the project period."

DOH Comment: It is a current requirement in all Title X funding applications to provide assurances that projects currently do not provide abortion and do not include abortion as a method of family planning. Adding Section 59.13 is potentially unnecessarily burdensome and serves no necessary purpose since current Title X requirements already prohibit providers from providing abortion or including abortion as a method of family planning.

- **§ 59.14 Prohibition on Referral for Abortion**
  The proposed rule states: *"A Title X project may not perform, promote, refer for, or support, abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion. If asked, a medical doctor may provide a list of licensed, qualified, comprehensive health service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care), but only if a woman who is currently pregnant clearly states that she has already decided to have an abortion. This list is only to be provided to a woman who, of her own accord, makes such a request. The list shall not identify the providers who perform abortion as such. All other patients 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."*

  DOH Comment: None of the Hawaii Department of Health funded family planning service providers support or encourage abortion. Similar to the comment in Section 59.5 above, non-directive option counseling that includes **all options** is a longstanding Title X regulation that is consistent with medical and ethical standards and many medical professional organizations. The proposed rule appears to remove the existing requirement that Title X projects provide nondirective option counseling on all pregnancy options. The rule also appears to restrict medical providers from being able to provide women with medically accurate and safe options. We support the current Title X rule that requires "individuals having access to evidence-based, medically accurate, and effective reproductive health services and that comprehensive reproductive, sexual, and healthy relationship education is evidence-based, scientifically and medically accurate, and culturally and linguistically appropriate."

Thank you in advance for your consideration of our concerns. Please feel free to contact me if you have any questions or need additional information.

Sincerely,

Bruce S. Anderson, Ph.D.
Director of Health

STATE OF NEW YORK
EXECUTIVE CHAMBER
ALBANY 12224

ANDREW M. CUOMO
GOVERNOR

July 30, 2018

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

Dear Secretary Azar:

I write in response to the U.S. Department of Health and Human Services' June 1, 2018 Notice of Proposed Rulemaking (NPRM) relating to Title X of the Public Health Service Act. New York has a proud history of participation in the Title X program: using both federal Title X funds and our own state funding, the Family Planning Program provides foundational reproductive health services to New Yorkers who may not be able to afford them.

The NPRM's proposed rule threatens to reverse crucial expansions of access to reproductive health care, replacing a decades-long decrease in teen and unplanned pregnancies across the U.S. with unnecessary, unethical, and potentially illegal barriers for those seeking family planning services. If enacted, it will decrease the quality and availability of Title X services and impede the rights of New Yorkers – in particular the low-income, uninsured, underserved individuals of reproductive age who rely on the Title X safety net - to access the full range of reproductive health care. It will deny women the information necessary to make their own medical decisions and could eliminate the ability of pregnant women to give informed consent on their post-conception options. The proposed rule violates long-standing principles limiting the interference of Congress in the sovereignty of individual States and impairment of private contracts.

Critically, by limiting the information and services available to Title X clients, the proposed rules pose a grave danger for the health of women. The proposed rules would reduce the quality of health care services, prevent informed medical decision making and contraceptive choice, restrict provider speech, undermine the provider-patient relationship, upend confidentiality, and overall threaten the health and well-being of New Yorkers by arbitrarily separating family planning from prenatal care and women's health care. In sum, the proposed rules demonstrate a profound disregard for science and medical best practices, including pre and post conception standards set by HHS in consultation with 35 national experts and medical associations.

I am enclosing comments on the NPRM from the New York State Department of Health outlining the harm and legal affront that the proposed rules would inflict upon the state's Family Planning Program, the health of New Yorkers, and the landscape of health services.

New York will explore all legal avenues available to us to ensure that the proposed rules' attack does not threaten the health and wellbeing of New Yorkers and the integrity of New York's Family Planning Program. If the rules are enacted as proposed, it will be impossible for New York to continue its comprehensive Title X program.

I urge you to maintain the current rules for Title X.

Sincerely,

ANDREW M. CUOMO

Enclosures
Cc: President Donald Trump

New York State Department of Health
Comprehensive Family Planning and Reproductive Health Program

Comments in Response to Title X Notice of Proposed Rulemaking

The New York State Department of Health (NYSDOH) strongly opposes proposed rule changes as outlined in the U.S. Department of Health and Human Services' (HHS) Title X Notice of Proposed Rulemaking. The proposed rules will dramatically alter the landscape of federally funded family planning services, limiting access to high-quality reproductive health care and highly effective contraceptives, and imposing barriers for women and men seeking family planning and other vital preventive health care services. If enacted, these rules will reverse a decades-long decrease in teen and unplanned pregnancies across the United States.

As written, the proposed rules will negatively impact the current Title X program by:

- **Narrowing the definition and scope of family planning services available**
- **Lowering quality of care standards**
- **Creating barriers to accessing a full range of family planning and preventive health care services**
- **Dramatically reducing available options for and access to birth control methods**
- **Compromising physicians' ethics and ability to meet a basic duty of care**
- **Eliminating the ability of pregnant women to give informed consent on all legally available post-conception services**
- **Undermining confidentiality protections and trust between patients and their health care providers**
- **Limiting opportunities for localities and states to have input on changes to the Title X network**

The proposed rules create unnecessary, unethical, and potentially illegal barriers that will limit access to free or low-cost family planning services. If enacted, these proposed rules will most negatively impact the health and well-being of the primarily low-income, uninsured, underserved individuals of reproductive age who rely on the Title X safety net for access to contraceptive and other preventive health care services.

I. Comments and Recommendations on Each Proposed Revision to 42 CFR Part 59.

Following are the NYSDOH's comments and accompanying recommendations for proposed revisions to 42 CFR Part 59. The comments and recommendations detailed below relate to both proposed changes to the existing rules, and to the proposed addition of new rules.

Proposed Changes to Existing Rules

Section 59.2. Definitions.
The proposed rule adds a definition for "family planning" that excludes post-conception care.

- The newly proposed definition of family planning explicitly excludes provision of "post-conception care" which includes obstetric care, prenatal care, and abortion, as part of services defined as "family planning." Excluding post-conception care from the scope of services that may be provided in a family planning visit unnecessarily disrupts continuity of care for family planning

clients receiving a positive pregnancy test. This separation between family planning and early prenatal care is contrary to national standards promoting early access to prenatal care, especially for high-risk pregnant women who are more likely to delay entry into prenatal care.

- This definition fails to align with nationally recognized standards of care such as those found in "Providing Quality Family Planning Services: Recommendations of the CDC and the U.S. Office of Population Affairs" (QFP). The QFP, developed by the CDC and HHS' Office of Population Affairs (OPA) itself, serves as the current Title X clinical guidance document and is based upon input from more than 35 federal and professional medical associations such as the U.S. Prevention Services Task Force and The American College of Obstetricians and Gynecologists, recommends that initial prenatal care be provided at a family planning visit when a woman receives a positive pregnancy test. The QFP specifically outlines:

> *"For clients who are considering or choose to continue the pregnancy, initial prenatal counseling should be provided in accordance with the recommendations of professional medical associations, such as American College of Obstetricians and Gynecologists (ACOG). The client should be informed that some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (e.g., an obstetrician or midwife). In addition, the client should be encouraged to take a daily prenatal vitamin that includes folic acid; to avoid smoking, alcohol, and other drugs; and not to eat fish that might have high levels of mercury. If there might be delays in obtaining prenatal care, the client should be provided or referred for any needed sexually transmitted diseases (STD) screening (including HIV) and vaccinations."* [1]

- The QFP recognizes that prenatal care is an essential public health intervention to improve pregnancy outcomes. Studies have demonstrated that prenatal care is associated with improved perinatal outcomes, and other benefits such as improved maternal health outcomes, subsequent use of pediatric care, and serves as an entry point into the health care system for women at social or economic risk.[2]
- Adequate prenatal care is a widely accepted determinant of maternal and child health. Prenatal care is considered adequate, based on the ACOG guidelines for prenatal visits in low-risk pregnancy, if it is initiated in the first trimester with regular visits of increasing frequency as term approaches.[3] Early prenatal care is associated with postpartum behaviors of initiation and longer duration of breastfeeding and contraceptive use, both associated with increased birth spacing.[4]
- Current Title X providers have demonstrated their ability to successfully provide limited post-conception support - primarily assessment, education, and referral services - in a patient-centered manner and in accordance with QFP recommendations. The post-conception services provided in a family planning visit establish a foundation for ongoing prenatal care that can be especially

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[1] Loretta Gavin, PhD, Susan Moskosky, MS, Marion Carter, PhD, et al, "Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs." MMWR 2014; 63: No.4: 1. https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

[2] Rosenberg, Deborah, Arden Handler, Kristin M. Rankin, Meagan Zimbeck, and E. Kathleen Adams. "Prenatal Care Initiation among Very Low-Income Women in the Aftermath of Welfare Reform: Does Pre-pregnancy Medicaid Coverage Make a Difference?" Maternal and Child Health Journal 11, no. 1 (2006): 11-17.

[3] Partridge, Sarah, Jacques Balayla, Christina Holcroft, and Haim Abenhaim. "Inadequate Prenatal Care Utilization and Risks of Infant Mortality and Poor Birth Outcome: A Retrospective Analysis of 28,729,765 U.S. Deliveries over 8 Years." American Journal of Perinatology 29, no. 10 (2012): 787-94.

[4] Adejoke B. Ayoola, Mary D. Nettleman, Manfred Stommel, et al. "Time of Pregnancy Recognition and Prenatal Care Use: A Population-Based Study in the United States." Birth 37, no. 1 (2010): 42.

critical for the estimated six in ten low-income and uninsured women who indicate that the family planning clinic is their primary source of medical care.[5]

- Women are at risk for late initiation into or receiving no prenatal care at all if they are young, poor, unemployed, members of minority groups, unmarried, have less than a high school education, lack health insurance, or have other children.[6] Pregnant adolescents are less likely to receive adequate prenatal care with up to 55% of adolescents entering prenatal care late or not at all.[7] Many Title X priority populations (including adolescents, low-income women, and women from racial/ethnic minorities) have historically lower rates of early entry into prenatal care than peers. Limiting a Title X provider's ability to provide initial prenatal care will create barriers that increase the likelihood that high-risk women will enter prenatal care late, or not at all, a factor that has been associated with poor health outcomes such as increased risk for prematurity, stillbirth, early neonatal death, late neonatal death and infant mortality.[8]

Recommendation:
We strongly recommend that no changes be made to the current language defining the scope of family planning services. Relying on the QFP recommendations to establish clinical standards, OPA has ensured that the Title X program may more easily update clinical services and protocols to better reflect nationally recognized standards of care as they evolve over time.

Section 59.2 Definitions.
The proposed rule adds a definition for "family planning" that includes adoption.

- The proposed definition of family planning is "the voluntary process of identifying goals and developing a plan for the number and spacing of children and the means by which those goals may be achieved." In this definition, "the means" of achieving family planning goals would: "include a broad range of acceptable and effective choices, which may range from choosing not to have sex to the use of other family planning methods and services to limit or enhance the likelihood of conception (including contraceptive methods and natural family planning or other fertility awareness-based methods) and the management of infertility (including adoption)"
- This definition is expanded to include adoption in the scope of services to be provided, going beyond existing guidelines that support referrals for adoption. The current section 59.5(a)(5) already mandates non-directive full options counseling for any pregnant client, which includes provision of information on adoption. Specifically, the QFP requires that, "Options counseling should be provided in accordance with recommendations from professional medical associations, such as ACOG and AAP."[9] Both ACOG and the AAP provide guidance on options counseling in alignment with current Title X regulations which stipulate that providers should inform patients of

[5] Frost, Jennifer J. "U.S. Women's Use of Sexual and Reproductive Health Services: Trends, Sources of Care and Factors Associated with Use, 1995-2010." Guttmacher Institute (2013).
[6] Pagnini, Deanna L., and Nancy E. Reichman. "Psychosocial Factors and the Timing of Prenatal Care among Women in New Jerseys HealthStart Program." Family Planning Perspectives 32, no. 2 (2000): 56-57."
[7] Wiemann, Constance M., Abbey B. Berenson, Leticia Garcia-Del Pino, and Sharon L. Mccombs. "Factors Associated with Adolescents Risk For Late Entry into Prenatal Care." *Family Planning Perspectives* 29, no. 6 (1997): 273.
[8] Partridge, Balayla, Holcroft, Abenhaim. "Inadequate Prenatal Care Utilization and Risks of Infant Mortality and Poor Birth Outcome: A Retrospective Analysis of 28,729,765 U.S. Deliveries over 8 Years." American Journal of Perinatology 29, no. 10 (2012): 787-94.
[9] Gavin, Moskosky, Carter, et, al, "Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs." MMWR 2014; 63: No.4. 1. pg. 14.

three medical options including: continuing pregnancy and parenting, continuing pregnancy and adoption/foster care, or terminating the pregnancy.[10]

- Including adoption in family planning services provided under Title X also pushes the bounds of a reasonable understanding of Congress' intent for the Title X program and thus the bounds of HHS's delegated authority, as discussed further *infra* pages 28-29.

Recommendation:
We strongly recommend that no changes be made to the current language defining the scope of family planning services. Relying on the QFP recommendations to establish clinical standards, OPA has ensured that the Title X program may more easily update clinical services and protocols to better reflect nationally recognized standards of care as they evolve over time

Section 59.2. Definitions.
The proposed rule amends the definition of "low-income family," requiring documentation in unemancipated minors' medical records of the efforts made to encourage family involvement in decision-making.

- The proposed amended language to Section 59.2 related to unemancipated minors requires Title X providers to indicate "the specific actions taken by the provider to encourage the minor to involve his/her family" in the decision to seek family planning services.
- A Title X legislative mandate, as outlined in the current Title X Program Guideline 9.12 [11] requires Title X grantees to encourage but not require family participation in the decisions of minors, and grantees currently must certify such encouragement as a condition of Title X funding. The current practice has proven sufficient to ensure that Title X providers adequately discuss and encourage family participation in decision making with minor patients. However, the proposed rule imposes added emphasis and seeks to prevent minors from receiving confidential services for free if both conditions of encouragement of family participation and documentation of that discussion have not been met.
- The proposed rule represents an increased emphasis on family involvement that is likely to create additional barriers between providers and adolescent patients. Already sensitive to issues around confidentiality and provider bias, adolescent patients often require extra attention and assurance from providers to develop a rapport in which they are comfortable providing accurate medical and social histories and to adhere to provider advice. Requiring greater focus on discussions of family involvement and documentation of those discussions will not only shorten the amount of time providers can spend counseling adolescent patients but will also undermine patient trust and confidentiality.
- Adding such a barrier to minors' access to the Title X program contravenes the goals of the program to be a confidential provider of services for adolescents regardless of family involvement. This intent has been recognized explicitly in the Title X statute itself since Congress amended it in 1978 and then again in 1981, and has been reaffirmed multiple times by the courts.[12]

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[10] "Diagnosis of Pregnancy & Providing Options Counseling for the Adolescent Patient" American Academy of Pediatrics, Clinical Report. 140, no. 3. September 2017

[11] "Program Requirements for Title X Funded Family Planning Projects: Version 1.0". OPA. April 2014: https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf

[12] See, e.g., Doe v. Pickett, 480 F. Supp. 1218 (S.D.W.Va. 1979); Planned Parenthood Association v. Matheson, 582 F. Supp. 1001 (D.C. Utah 1983); County of St. Charles v. Missouri Family Health Council, 107 F.3d 682 (8th Cir. 1997), rehearing denied (8th Cir. 1997), cert. denied 522 U.S. 859 (1997); Planned Parenthood Federation of America, Inc. v. Schweiker, 559 F. Supp. 658 (D. D.C. 1983); Planned Parenthood v. Heckler, 712 F.2d 650, 663 (D.C. Cir. 1983).

- The additional documentation requirements outlined in the proposed rule will also create an increased burden on staff time and electronic medical record systems that are likely to increase programmatic costs with no subsequent increase in funding to offset these expenditures.

Recommendation:
We recommend that the definition of low-income family exclude the proposed amended language related to unemancipated minors. We support and work to ensure compliance of all subrecipient agencies with the existing Title X Program Requirement 9.12 and legislative mandate[13] requiring that minor patients be counseled and encouraged to involve a family member in reproductive health care decisions. However, we believe that efforts and funds would be better used to support training for providers on the best methods to encourage family involvement.

Section 59.2. Definitions.
The proposed rule redefines "low-income" to include a woman who "has health insurance coverage through an employer which does not provide the contraceptive services sought by the woman because it has a sincerely held religious or moral objection to providing such coverage."

- The current Title X regulations require that "no charge will be made for services provided to any person from a low-income family" except to the extent that payment can be made by a third-party payer (like commercial insurance or Medicaid). Individuals with incomes above 100% of the federal poverty level (FPL) are charged on a schedule of discounts based on their ability to pay or full fee, depending on their income level. These requirements are based in the Title X statute, which requires any person from a low-income family receive services from a Title X project at no charge and authorizes the Secretary of HHS to define low-income "so as to [e]nsure that economic status shall not be a deterrent to participation in the programs assisted under this title."
- This change in definition would, when read in the context of the current regulations at §§ 59.5(a)(7) and (a)(8), explicitly enable and may require Title X-funded entities to provide free contraceptive services to women whose employers object to them having insurance coverage of contraception, regardless of their income.
- Although the proposed rule states that such women "can be considered" low income for the purposes of contraceptive services, and HHS states in the preamble that this change would allow such women to receive "free or low-cost" family planning services, the preamble also states that the proposed rule "would amend the definition . . . to include women who are unable to obtain certain family planning services" under their employer-sponsored coverage due to their employers' religious beliefs or moral convictions. This language suggests that this definitional change would be a requirement and not merely permissive.
- Title X was designed and has functioned for decades as a safety net family planning program, with statutory allowances for the Secretary to define the scope of "low income" individuals who shall be provided care without charge only "so as to insure that economic status shall not be a deterrent to participation." Twisting the definition beyond normal understanding to allow for the provision of free contraceptive services to women whose employers object to them having insurance coverage of contraception, *regardless of their income*, contravenes the intent of the program and thus stretches the bounds of the delegated regulatory authority of HHS, as discussed further *infra* pages 28-29.

[13] "Program Requirements for Title X Funded Family Planning Projects: Version 1.0". OPA. April 2014: https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf

- Furthermore, Title X is designed to subsidize a program of care, not pay all of the cost of any service or activity—the Title X statute and regulations contemplate how Title X and third-party payers will work together to pay for care, directing Title X-funded agencies to seek payment from such third-party payers. Even more, Title X is already underfunded and overburdened.
- Nor can the Title X program absorb the unmet needs of insured individuals who have incomes above 250% of the FPL. Requiring Title X projects to prioritize and pay for these patients leaves fewer already-scarce dollars to serve the low-income patients at the heart of Title X's purpose.

Recommendation:
We recommend that the definition of low-income family exclude the proposed amended language related to employer-sponsored health insurance coverage. We believe that, given limited funds, and in keeping with the statutory intent of the Title X program, Title X funding should be used to support services for those most vulnerable individuals – those who are low-income, uninsured, and/or medically underserved.

Section 59.5 Requirements of a Family Planning Project.
§ 59.5(a)(1):
The proposed rule removes the requirement that family planning methods offered by Title X providers must be "medically approved" and removes the requirement that Title X providers and programs offer more than one method of family planning.

- The term "medically approved" has been commonly interpreted as requiring that all Title X providers offer patients at least one form of each FDA-approved contraceptive method (including birth control pills, patch, shot, implant, IUD, condoms, and natural family planning/fertility-awareness based methods).
- This interpretation is in alignment with federal Affordable Care Act (ACA)[14] and New York State Medicaid contraceptive coverage requirements[15] which require coverage for most FDA-approved contraceptive drugs, devices, and products. The proposed rule is not consistent with these requirements, and represents a departure from nationally recognized standards of care, as outlined in the QFP[16] guidelines for clinical care within the Title X program, as well as the American College of Obstetricians and Gynecologists (ACOG) Committee Opinion on Access to Contraception[17] which recommend that the full range of FDA-approved contraceptives methods and counseling be offered.
- The proposed removal of the requirements that family planning methods be "medically approved" and that providers offer more than one method of family planning are in contradiction to these national and state mandates, all nationally recognized standards of care, and the health needs of women who utilize the Title X program.
- Women take numerous factors into account when selecting birth control methods, including effectiveness, lack or presence of side effects, affordability, and how easy the contraceptive is to

[14] U.S. Dept. of Health & Human Services, Affordable Care Act. "Birth Control Benefits – Healthcare.gov": https://www.healthcare.gov/coverage/birth-control-benefits/
[15] NYS Dept. of Health, Office of Health Insurance Programs, "NYS Medicaid Family Planning Services Frequently Asked Questions" NYS Dept. of Health, Office of Health Insurance Programs. May 2015. Pg.4.
[16] Gavin, Moskosky, Carter, et al, "Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs." MMWR 2014; 63: No.4: 1. Retrieved: https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf
[17] American College of Obstetricians (ACOG), Committee on Health Care for Underserved Women. "Committee Opinion: Access to Contraception." Number 615, (2015).

obtain and use.[18] Any limitation on the amount and type of contraceptive options made available will hamper the ability of each woman to select the contraceptive method that is most preferred and best suited for her health and lifestyle.

- If the family planning methods offered at Title X providers no longer represent the full range of medically accepted methods, women who rely on the Title X program may have nowhere else to go to seek the method that is best for them: 40% of women who receive services at Title X funded specialized family planning clinics indicate that it is their only source of care[19] and in some rural areas, a Title X family planning clinic may be the only provider of contraceptive care within a large geographic area.[20] Limiting the options available to women who seek care at these clinics will force them to use methods that are not their first choice, that do not have the desired level of effectiveness, or that have undesirable side effects.
- Dissatisfaction with available contraceptive method has been linked to inconsistent method use and increased rates of unplanned pregnancies.[21] By no longer requiring that Title X projects offer a broad range of medically approved contraceptive methods, women will have fewer birth control options and will be less likely to access highly effective birth control methods, which could lead to increased inconsistent birth control method use, a subsequent increased risk of unplanned pregnancies and, in turn, more abortions.
- These proposed changes could dramatically alter the ability of Title X clients to select the appropriate birth control method that best suits their needs. Currently, that means women who access contraception via a NYS Title X program have dozens of contraceptive method options made available to them, including different types of pills, patches, and rings which deliver hormones, barrier methods including condoms, diaphragms and caps, as well as behavioral interventions including abstinence and natural family planning. In the NYS FPP alone, this rule change could mean that the 203,261 women who left their Title X visit with a method of birth control in 2017 could find their available options severely limited. While oral birth control pills, condoms and hormonal injections remain popular, more and more women are expanding their birth control selection to include new options. Of those 203,261 clients roughly 21%, or over 43,000 women, selected a highly effective (LARC – long acting reversible method including IUD, IUD, or implant) birth control method, options which are associated with significantly lower failure rates than other contraceptive options. Based on 2017 NYS FPP data, NYS clients demonstrate a clear preference for selecting contraceptive methods which are often most or moderately effective, with very few women opting for natural family planning/fertility awareness methods (.012%), abstinence (3.12%), or lactation amenorrhea method (.016%). Limiting birth control methods would not only severely undermine the integrity of the program, but it would all but ensure women aren't able to identify and use a method that suits the unique medical and social needs of each and every patient.

Recommendation:

We strongly recommend that regulatory language in 59.5(a)(1) retain the current language requiring family planning methods be "medically approved" and the requirement that a broad range of family planning methods be offered by Title X providers. As a critical part of the health care safety net, Title X

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[18] Lauren N. Lessard, Deborah Karasek, Sandi Ma, et al, "Contraceptive Features Preferred by Women At High Risk for Unintended Pregnancy," *Perspectives on Sexual and Reproductive Health* 44, no. 3 (2012): 194.

[19] Frost, Jennifer J., Rachel Benson Gold, and Amelia Bucek. "Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Womens Health Care Needs." *Womens Health Issues* 22, no. 6 (2012).

[20] American College of Obstetricians and Gynecologists (ACOG) Committee on Health Care for Underserved Women. "Committee Opinion: Health Disparities in Rural Women", number 586 (2014).

[21] Lessard, Karasek, Ma, et al. 199.

clinics provide services to individuals who may not otherwise have access to health care, including contraceptive services. Title X providers should continue to offer as broad a range of medically approved contraceptive methods as possible to ensure that all women can access and select the method best suited to their unique needs, medical history, and lifestyle. Women should not be limited in contraceptive choices based on income, geography, or cost.

§ 59.5(a)(5):

The proposed rule removes all current language requiring that Title X programs provide women with a positive pregnancy test with information and counseling regarding pregnancy options, as defined in current Title X program regulation. Per § 59.5, all Title X programs are currently required to provide pregnant women the opportunity to be given information and counseling on each of three options: prenatal care and delivery; infant care, foster care, adoption; and pregnancy termination. Current regulation goes on to stipulate that when information is requested programs must "provide neutral, factual information and nondirective counseling on each of the options, referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling."[22]In addition, the proposed rule prohibits promotion, referral for, support for, or presentation of abortion.

- Removing the requirement that programs provide patients with all medically accurate health options, especially upon patient request, is in direct opposition to nearly all medically accepted standards of care, most importantly the doctrine of informed consent. Informed consent bases itself in the fundamental idea that all patients have the right to self-determination in care, determination based on a thorough understanding of their medical status and available treatment options. Removing a patient's ability to obtain information on all legally and medically appropriate options regarding pregnancy, and to discuss this information with a trusted medical provider, is to remove any ability for Title X patients to make informed consent on a range of health care issues that directly impact their life and fertility.[23]
- Implementation of this rule would serve to undermine medical ethics as defined and accepted by almost every professional physicians' association. Beginning with the American Medical Association, their Code of Medical Ethics states that "withholding information without the patient's knowledge or consent is ethically unacceptable."[24] This commitment to providing patients with information on their full range of reproductive options has been clearly supported by numerous other professional medical associations including; American Congress of Obstetricians and Gynecologists (ACOG), American Academy of Pediatrics (AAP), American Academy of Physician Assistants (APPA), Association of Women's Health, Obstetrics and Neonatal Nurses.[25] In undermining medical ethics, this rule would put providers in a precarious position of potentially violating their duty to adhere to a standard of care set forth by State law by advising and counseling a patient on all of their pregnancy options, discussed further *infra* page 33.
- Restricting physicians' speech and ability to provide full options counselling would threaten the patient/provider relationship, creating friction and barriers to care. This threat would likely be exacerbated for the Title X priority population, which includes low-income women and women of

[22] 42 U.S.C. § 300a-4. §59.5 "What requirements must be met by a family planning project": 65 FR 41278, July 3, 2000. https://www.ecfr.gov/cgi-bin/text-idx?SID=beacfd044d5a71d9fdb2a76300994972&mc=true&node=sp42.1.59.a&rgn=div6

[23] Kinsey Hasstedt. "Unbiased Information on and Referral for All Pregnancy Options Are Essential to Informed Consent in Reproductive Health Care" *Guttmacher Institute* (2018).

[24] AMA, Opinion 1.1.3: "Withholding information from patients, Code of Medical Ethics, 2016."

[25] Hasstedt, "Unbiased Information on and Referral for All Pregnancy Options"

color whose communities have historical experiences of coercion in health care settings and thus who often have an increased mistrust of medical providers.[26]

- Further, research has demonstrated that restricting information on, and access to, abortion care does not improve health or well-being for women or children in states/municipalities with restrictive abortion laws. According to assessments of child well-being indicators, states that restrict abortion access "have (a) more low birthweight babies; (b) a greater infant mortality rate; (c) a lower rate of domestic infant adoptions; (d) a lower rate of child placement in foster care; (e) less financial assistance to unmarried mothers; (f) a higher child death rate; (g) a greater percentage of children in poverty; and (h) a larger percentage of children who have repeated a school grade."[27]
- Given the high rates of unplanned pregnancy in New York state, coupled with the limited access points for low-income women seeking reproductive health care, it has been and continues to be essential to expedite entry into care for any patient seen with a confirmed pregnancy. Although unplanned pregnancy remains a public health concern for NYS, a proven template exists to address this issue as demonstrated by the overwhelming success of NYS's Teen Pregnancy Prevention activities. Serving as a model for other publicly funded family planning services, the success NYS has demonstrated in reducing both teen pregnancy and birth underscores the ability of public health programs to meet public need. Over the past 20 years, NYS has seen dramatic reductions in both teen birth, down 71% from 1991 to 2016 and teen pregnancy, down 61% from 1988 to 2013[28]. Currently, Title X guidelines emphasize using the pregnancy test visit as an opportunity to screen women for any high-risk behavior (substance use, intimate partner violence, human trafficking), provide essential information and counseling on their preferred pregnancy option, and, whenever possible and desired, facilitate their early entry into prenatal care. This seamless integration of services not only eliminates redundant visits and expenses but helps to ensure that patients with a confirmed pregnancy receive timely access to medically necessary information and services regardless of their pregnancy decisions.

Recommendation:
We recommend that regulatory language in § 59.5(a)(5) remain unchanged from the current regulations. Current language that includes a requirement for full pregnancy options counseling is consistent with the American Medical Association Code of Ethics and recommendations from numerous professional associations. This requirement will ensure that all women across the Title X program receive the same, complete information and level of care regardless of where or from whom they receive services, ensuring a level of equity in patient education necessary to ensure the health and well-being of women in New York.

§ 59.5(a)(10):
The proposed rule removes language requiring the involvement of local stakeholders in a Title X application that seeks to consolidate or otherwise impact the current operations of local and regional entities.

- Allowing local input on the Title X program is an essential component to ensuring that services offered meet the unique needs and values of the community that they are tasked with serving. One of the more complex reproductive health problems currently facing the NYS Title X is the persistent racial and ethnic disparities seen in unintended and teen pregnancy rates, as well as

[26] Hasstedt (2018).
[27] Marshall Medoff, "Pro-Choice Versus Pro-Life: The Relationship Between State Abortion Policy and Child Well-Being in the United States," *Health Care for Women International*, 37 (2016): 168.
[28] https://powertodecide.org/what-we-do/information/national-state-data/new-york

maternal mortality and morbidity. These steep disparities by race serve to underscore the reality that trying a one size fits all approach, even if that approach comes with a proven track record, across diverse communities within NYS, cannot address the complex structural and systemic issues contributing to racism and disproportionately poor health outcomes in the African American community in NYS. By proactively engaging communities to become part of building solutions, our Title X programs are leading the way in developing new and innovative strategies to address racism, poverty, and other social determinate factors that contribute to health inequities. By engaging community members to provide feedback, direction, and even decision-making authority, Title X programs have evolved over time to become more responsive to the unique needs of individual communities. This feedback has been used to determine hours of operations, locations of health centers, and the introduction of new programs to target emerging communities. Implementing this proposed rule and removing the basic mandates for community involvement would halt this forward progress and contribute to continued health inequities across NYS.

- The proposed amendment to the rule, changing the eligibility of current Title X providers, will result in the potential loss of current providers from Title X will reduce the availability and quality of family planning services without any input by local stakeholders, community members, and/or family planning experts. This could mean that long standing community service organizations, well known for providing free or low cost reproductive health services would no longer be able to meet the needs of their community. In NYS this could represent a loss in services to the over 300,000 clients who receive family planning services through the NYS Family Planning Program annually.
- The proposed rule will effectively shut out current Title X providers with local area expertise and a history of providing Title X services from participation in decision-making processes that could impact the availability and quality of family planning services in communities across the state.

Recommendation:
We recommend that regulatory language in § 59.5(a)(10) remain unchanged to preserve opportunities for local stakeholder input. By allowing community members to have a voice in shaping program goals, policies, and activities, Title X programs can actively promote health equity and improve health outcomes in some of the most disadvantaged communities in New York State, better fulfilling the intent and goals of the Title X program.

§ 59.5(a)(12):
The proposed rule adds a new requirement that Title X providers, "in order to promote holistic health and provide seamless care" offer comprehensive onsite primary care or have "robust" referral linkages with primary care providers within close geographical proximity to the Title X provider.

- The QFP, developed by the CDC and OPA, through the combined efforts of numerous health care professionals and with approval from all major family planning medical associations, currently provides clear, consistent, and factually accurate guidance on all aspects of family planning care as well as detailed instructions on expanding the scope of that care to promote preconception health among all women of reproductive age. In its current form, this document contains enough information for Title X providers to be able to meaningfully implement holistic health care for women throughout the life course.
- For women whose only source of health care is the specialized family planning clinic, the clinic serves as an entry point to the health care system, a role that presents family planning clinics with

a vital obligation.[29] The results of a recent study illustrate this vital role of specialized family planning clinics:

- One in eight (12%) of respondents made no prior visit for medical care in the past year, and 29% had only received care at the specialized family planning clinic. For these 41% of respondents, the specialized family planning clinic was their only source for medical care during the year. The majority of respondents (59%) had made at least one other visit for medical care in the prior year to a different provider, but when it came to making a visit for contraceptive or reproductive health care, they chose to visit a specialized family planning provider. 10% of visits were for pregnancy tests only.
- Uninsured women were more likely than privately insured women to have received no prior medical care or to have received all their care at the clinic--resulting in half of all uninsured women relying on the specialized family planning clinic as their only source of medical care. In contrast, only one in four (27%) women with private health insurance was relying solely on the specialized clinic for medical care.

- The proposed amended rule does recognize that family planning is an entry point for care for many women and seeks to leverage that by offering additional services and encouraging linkages to primary care. However, as written, this provision contradicts other sections of the proposed rule that place limits on the scope of services that can be delivered in a family planning clinic.
- Additionally, the amended rule does not clearly define what services would be included in "holistic" health care and fails to demonstrate how limiting the scope of expanded services through explicitly prohibiting post-conception care would improve health outcomes for Title X patients.
- Removing requirements that mandate use of the QFP and replacing them with the vague language included in this rule will only serve to undermine the intention of the Title X Program and result in women accessing fewer and lower quality health care services than what they can currently obtain in the Title X program.

Recommendation:
We recommend that the new § 59.5(a)(12) not be implemented in the Title X program. We support the continued use of the QFP as the primary guidance document to define the full scope of clinical services that should ideally be made available in a Title X program to promote holistic health and seamless care.

§ 59.5(a)(13):
The proposed rule establishes new requirements for increased reporting by including subrecipient and referral agencies and individuals by name, location, expertise and services to be provided.

- The new reporting requirements would require details about subrecipients and their referral organizations, and the extent of their collaborations to be submitted at the time of grant application, and in subsequent required reports, creating a significant undue administrative burden for Title X grantees and monitoring organizations.
- NYSDOH, as a Title X grantee, contracts with a range of subrecipient agencies who provide direct clinical services as part of the NYS Family Planning Program (FPP). Some subrecipient organizations may choose to subcontract a portion of their clinical services to other health care providers within their community, and as such NYSDOH has oversight of that subcontracting relationship.

[29] Frost, Jennifer J., Rachel Benson Gold, and Amelia Bucek. "Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Womens Health Care Needs." *Womens Health Issues* 22, no. 6 (2012).

- NYSDOH does not contract directly with, or provide Title X funds to, any referral partners of sub-recipient agencies.
- Referral partners of subrecipient agencies typically consist of a wide range of community partners meant to create a network of support to meet the medical and social needs of patients that are outside of the scope of services of the Title X clinic. Depending on the geographic region in which the Title X subrecipient agency operates and the defined community need, each subrecipient agency could potentially have hundreds of referral partners. Referral partner relationships take many forms and can exist both with and without formal written agreements. The vast majority of referral networks consist of informal or formal partnerships without a financial relationship. Those referral networks are based on assuring that patients have access to services one party does not provide, such as assistance with food or housing, and encompass a wide range of interactions from shared case management to a simple referral for services. As written, the proposed rule aims to push the boundaries of program monitoring by dramatically expanding the scope of Title X grantee oversight of subrecipient agencies' referral partners with whom NYSDOH will have no contractual or fiduciary relationship.
- For these reasons, NYSDOH is not comfortable expanding beyond its current role in monitoring the extent to which subrecipient agencies establish and maintain the appropriate referral networks to meet client need as part of the contractual relationship between NYSDOH and subrecipient agencies.

Recommendation:
We recommend that §59.5(a)(13) is not implemented in the Title X program. We recommend that subrecipient agencies continue to be responsible for identifying, evaluating, and collaborating with referral partners and that information be shared routinely with NYSDOH as the Title X grantee. We do not support requirements for Title X grantees to perform additional referral partner oversight and monitoring.

§ 59.5(a)(14):
The proposed rule requires encouragement of family participation and documentation of specific actions taken to encourage family participation in the decision of minors to seek family planning services (or reasons why such family participation was not encouraged.)

- Although a Title X legislative mandate already requires Title X grantees to encourage family participation in the decisions of minors, and grantees currently must certify such encouragement as a condition of Title X funding, the proposed rule imposes an added emphasis on this matter.
- In addition to the harm discussed *supra* page 4, the additional documentation requirements outlined in the proposed rule will create an increased burden on staff time and electronic medical record systems that are likely to increase programmatic costs with no subsequent increase in funding to offset these expenditures. These requirements will force providers to spend less time providing direct patient services and more time completing unnecessary documentation.
- No other type of family planning counseling requires that providers document the substance of their conversation. Providers are trusted to use their professional judgment and expertise when counseling patients on pregnancy options, birth control choices, sexual risk avoidance behavior, and other complex sensitive topics. To single out this one aspect of family planning practice for special attention and extra documentation is unnecessary.

Recommendation:
We recommend that §59.5(a)(14) is not implemented in the Title X program. We support and work to ensure compliance of all sub-recipient agencies within the existing Title X legislative mandates[30] requiring that minor patients be counseled and encouraged to involve a family member in reproductive health care decisions. However, we do not support the unnecessary burden of excessive documentation and believe that efforts and funds would be better used to support training for providers on the best methods to encourage family involvement consistent with minor patients' confidentiality rights, health needs, and best interests.

Section 59.7 Criteria used to determine funding for family planning projects.
The proposed rule removes previous criteria used to determine which projects will receive Title X funding and replaces it with new criteria that emphasize compliance with Title X statutory provisions restricting the provision of abortion services using Title X funds and with newly developed Title X program priorities, which were first introduced in the February 2018 FOA.

- The proposed rule amends the long-standing criteria by which Title X applicants are reviewed. Since 1971, the Title X regulations have specified that seven criteria be used for selecting Title X grantees, which has resulted in a relatively stable network of grantees and subrecipients that have developed a high level of expertise in the provision of family planning services.
- In the proposed rule these seven criteria have been eliminated and replaced with four broad criteria that emphasize statutory and regulatory compliance, and that are vague and internally inconsistent. Criteria concerning the adequacy of the applicant's facilities and staff, and the availability of non-federal resources for the project have been removed. Other criteria have been modified and made more nebulous, combining two or more previously distinct criteria into one. For example, the number of patients to be served has been modified to indicate that the applicant should also target sparsely populated areas and places in which family planning services are not available. Also, the capacity to make rapid and effective use of grant funds is now linked to applicants that make use of funds "among a broad range of partners and diverse subrecipients…and among non-traditional Title X partnering organizations." These proposed changes to the scoring criteria make any meaningful merits review scoring difficult.
- Furthermore, the proposed changes create a new avenue to quickly remove applications from consideration if they "do not clearly address how the proposal will satisfy the requirements of this regulation" and gives HHS broad discretion to disqualify applicants before any objective merits panel review has taken place. The proposed rule includes very little detail on how HHS will determine whether an application has addressed how it will satisfy regulatory requirements, and will allow HHS to advance only favored applications to the review panels.
- Based on the new changes, it will be easier for HHS to deny funding to existing providers and give preference to non-traditional organizations and provider types over proven and experienced providers of family planning services.
- Additionally, if applied retroactively, the proposed rules would alter the scoring criteria for the Title X FOA that was released in February 2018. To change the rules and scoring criteria of an FOA after applications have been submitting would be unfair to applicants that applied and to entities that decided not to apply. Applicants deserve the opportunity to fairly understand the rules and criteria on which they will be judged prior to submitting applications. The proposed changes to scoring criteria would dramatically alter what was previously known to impact scoring and, had

[30] https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/legislative-mandates/index.html

this information been public prior to the application due date, would certainly have resulted in applicants prioritizing different themes, activities, and answers in their response.

Recommendation:
We recommend that proposed changes to §59.7 are not implemented in the Title X program. All Title X applicants that meet grant eligibility requirements should continue to be reviewed by objective merit review panels, consistent with best practices for ensuring public health. Existing review criteria have been in place for decades and have provided clear guidelines for the selection of Title X grantees.

Section 59.11 Confidentiality.
The proposed rule adds language potentially limiting confidentiality protections for patients.

- Title X has had strong confidentiality protections for patients in place since the inception of the program. These confidentiality protections are one of the primary reasons that individuals choose to seek care at Title X sites.[31]
- While proposed changes align with previously applied Title X program requirements, the new rule expands language requiring intimate partner violence and human trafficking reporting, emphasizing compliance with notification and reporting laws ahead of patients' needs and confidentiality concerns, which could lead to patients withholding important information from providers or not seeking care at all from Title X providers.
- The proposed language is also vague, in that it states all Title X programs will be required to comply with "similar reporting laws" and that the project must provide "appropriate documentation or other assurance satisfactory to the Secretary of HHS," which is unclear enough that it could be translated into requirements by HHS that could force Title X programs to take action violating established medical ethics. The language also requires that Title X grantee organizations demonstrate compliance in way that could see HHS seeking individual patient medical records as a means of proving compliance, an action which would dramatically undermine Title X's longstanding commitment to confidentiality.

Recommendation:
We recommend that proposed changes to §59.11 are not implemented. We support the continued inclusion of the existing language in Title X Program Guidelines and efforts to expand opportunities to identify and support individuals at risk for or experiencing both IPV and/or human trafficking. We recommend additional funding to support enhanced training and technical assistance opportunities for Title X providers in these areas.

Proposed Addition of New Rules
The notice of proposed rulemaking includes the addition of several new sections emphasizing the existing Title X statutory prohibition on using Title X funds to provide abortion as a method of family planning. These new standards are designed to target abortion-related activities and entities that provide abortion care outside of their Title X funded services. However, there would be severe implications for *all* Title X funded entities, the services they provide, and the ability of patients to access comprehensive family planning services and reproductive health care. In New York state, the added cost and prohibitive

[31] Frost, Jennifer J., Rachel Benson Gold, and Amelia Bucek. "Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Womens Health Care Needs." *Womens Health Issues* 22, no. 6 (2012).

burdens to vital and long-standing participants in the Title X program would threaten access to family planning services for thousands of women.

Section 59.13 Standards of compliance with prohibition of abortion.
The proposed rule creates a new unnecessary requirement to demonstrate compliance with the existing statutory prohibition of abortion.

- The statutory requirement in Title X, 42 U.S.C. § 300a-6, that prohibits the use of Title X funds from being "used in programs where abortion is a method of family planning" has long been in place. Current Title X grantees and subrecipients demonstrate compliance with 42 U.S.C. § 300a-6 through annual signed assurances stating that the organization complies with this rule and regular NYSDOH monitoring and audits.
- The proposed rule imposes a new burden on Title X grantees to "provide assurance" of compliance with the provisions of 42 U.S.C. § 300a-6, which are expanded under proposed § 59.14 through § 59.16.
- As written, the proposed rule does not clearly articulate how compliance should be demonstrated, and what documentary evidence would be necessary to provide this assurance.
- Proposed § 59.14 through § 59.16, as is discussed further below, are much farther reaching than existing statutory language in that promotion and referral to abortion are prohibited, and physical and financial separation from abortion providers is required. As such, it is expected that documentary evidence needed to demonstrate compliance with these new requirements would also be much more extensive than current requirement.

Recommendation:
We recommend that §59.13 is not implemented in the Title X program. We support the continuation of existing practices to monitor Title X grantee and subrecipient compliance with the statutory prohibition on abortion.

Section 59.14 Prohibition on referral for abortion.
The proposed rule creates specific prohibitions on referrals for abortion, and requires referral for prenatal services. The sections of the proposed rule, either implemented individually or together, would compromise physicians' ethics and ability to meet a basic duty of care, and eliminate the ability of pregnant women to give informed consent on all legally available post-conception services. NYSDOH first discusses the individual sections of the rule below, and the NYSDOH recommendation for §59.14 as a whole follows.

§59.14(a):
The proposed rule creates a specific prohibition on referrals for abortion which includes detailed limitations on a physician's ability to refer patients for an abortion, even upon request.

- The proposed rule prohibits all Title X patients from receiving any information on the availability of abortion services, even if this information is specifically requested by the patient.
- The proposed rule limits the free speech and clinical oversight of Title X physicians by dictating the circumstances and manner in which they may be able to provide very limited information on abortion services, even to women with a positive pregnancy test who specifically request this information. The new rule goes so far as to give stipulations on how to compose a list of referral partners who may or may not provide abortion services, disallowing the identification of partners

who do provide abortion services even upon request, potentially confusing and misleading patients.

- As discussed further *supra* pages 8-9, such restrictions on a provider's ability to provide full options counseling and information on medical services to a patient compromises the provider's medical ethics and brings the provider into conflict with state law on duty of care.

§59.14(b):

The proposed rule prohibits the provision of any services to individuals who are "medically verified as pregnant" eliminating the ability of any Title X recipient to provide basic prenatal care and screening for women who receive a positive pregnancy test at a Title X funded site.

- As written, this requirement to refer all women with a positive pregnancy test to prenatal care regardless of their wishes is essentially directive counseling. If implemented, this proposed rule would remove any possibility of Title X patients exercising informed consent when making medical decisions related to a pregnancy diagnosis. Requiring physicians to provide directive counseling on only one option for pregnancy management will effectively force health care providers to deliberately deceive patients regarding their health care options, thus rendering them unable to make a fully informed decision. In order for patients to make decisions based on informed consent it is imperative that providers assist patients in fully understanding their health condition, in this case pregnancy, and are informed of the benefits and risks of all viable medical options to manage their condition. With the implementation of this rule, any patient receiving a pregnancy diagnosis through a Title X provider will be denied basic health care information necessary for them to exercise informed consent.
- The proposed rule limits the ability to provide early prenatal care for those women who do chose to continue their pregnancy. As discussed *supra* pages 2-3, early access to prenatal care is known to improve birth outcomes. Access to this care via a Title X provider can be especially necessary for the vulnerable populations served by the Title X program who often enter prenatal care late. Initiation of prenatal care during the first trimester is described by the Institute of Medicine as a measure of timely care.[32] The period of greatest sensitivity of the developing fetus to maternal health conditions and environmental exposures is between 4 and 10 weeks of pregnancy, that is, between the woman's first and third missed period.[33]
- A number of factors can impact the timing and adequacy of prenatal care that women access. Barriers to access may range from geography/location, lack of transportation, uninsured/underinsured, inability to find a provider that accepts her insurance, appointment wait times, lack of benefits to attend prenatal care appointments, to interpersonal violence/domestic violence issues and personal beliefs. Ensuring that all women have timely access to early prenatal care services is important in decreasing health disparities and improving maternal and infant outcomes within the United States.[34]
- Increasing the availability and access to prenatal care services may be important in preventing adverse birth outcomes especially among women suffering from partner violence.[35]

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[32] Ayoola, Nettleman, Stommel, et al. "Time of Pregnancy Recognition and Prenatal Care Use: A Population-Based Study in the United States." Birth 37, no. 1 (2010): 39.

[33] Preconception Care: A Systematic Review Carol C. Korenbrot, PhD, Alycia Steinberg, MPH, Catherine Bender, BA, and Sydne Newberry, DrPH Maternal and Child Health Journal, Vol. 6, No. 2, June 2002

[34] Women's Perceptions of Access to Prenatal Care in the United States: A Literature Review, Julia C. Phillippi, CNM, MSN, J Midwifery Womens Health 2009;54:219–225.

[35] Intimate Partner Violence and Utilization of Prenatal Care in the US Susan Cha, BA, MPH and Saba W. Masho, MD, MPH, DrPH, Journal of Interpersonal Violence 2014, Vol. 29(5) 911–927.

§59.14(c):
The proposed rule restricts the use of referrals as an indirect means of encouraging or promoting abortion.

- The proposed rule restricts the physician's ability to meet the patient's needs by requiring that referrals for abortion services be disguised within a list of providers that provide comprehensive prenatal care. This continues to limit a patient's ability to get information on abortion, even upon request
- As discussed further *supra* pages 8 and 16, by limiting a patient's ability to get information on abortion or a provider's ability to refer, this rule compromises a patient's informed consent and a provider's medical ethics.

§59.14(d):
The proposed rule clarifies that the rule should not be interpreted as prohibiting information on contraception, and that the prohibition is specifically for information related to abortion.

- Although seeming to encourage increased information and access to contraceptive information, this rule if implemented will actually do nothing substantive to ensure that Title X patients have access to or information about contraceptive options. While clarifying that Title X programs are not expressly prohibited from providing information on contraception, this rule does not require or even encourage funded projects to provide comprehensive information on all contraceptive options. Merely clarifying that an action is not prohibited cannot be interpreted as an endorsement or mandate to implement said action.
- Further, while this rule does clarify the ability of programs to provide information on contraceptive methods, it does not require that the program actually offer any of those methods to patients. Again, this rule seeks to provide the appearance of increasing contraceptive access while literally doing nothing to actually ensure that women and men being served by the Title X program have the ability to obtain any FDA approved contraceptive method of their choice.

Recommendation:
We strongly recommend that §59.14 is not implemented in the Title X program. By removing requirements for comprehensive, non-directive patient counseling on all post-conception options (including abortion care) the proposed rule infringes on the free speech rights of health care providers, requires that health care providers work contrary to almost all accepted standards of medical ethics, and removes the ability of Title X patients to give informed consent for medical care based on their knowledge of all available medical options.

Section 59.15 Maintenance of physical and financial separation
The proposed rule purports to interpret 42 U.S.C. § 300a-6's existing restriction on the use of Title X funds for "programs where abortion is a method of family planning", but dramatically expands the expectation of how non-Title X funds used for abortion services should be segregated.

- New requirements dictate that a facility that provides both Title X services and abortion care must ensure physical and financial separation between family planning and abortion services.
- This requirement fails to understand the structure of most family planning programs, which often function within the context of larger women's and other health organizations. Family planning services are viewed as one component of a broad spectrum of gynecological services available to women. This spectrum includes family planning services, health care procedures meant to enhance fertility, labor, and delivery, as well as abortion services. Arbitrarily selecting one of these commonplace services (abortion) to penalize an organization for performing, independent of their

Title X program is not only unfair but creates an undue burden to many of the most comprehensive programs.

§59.15(a):
The proposed rule specifies that separate accounting records must be maintained by all Title X subrecipient agencies that provide abortion services.

- Currently any Title X funded organization that also provides abortion care is required to apply a cost allocation methodology for program administration of Title X allowable expenses such as financial records management, accounting software, payroll software, insurance, and the agency's administrative staff between Title X allowable services and the provision of abortion.
- This proposed rule would require non-profit organizations to duplicate expenses in order to separate abortion services, creating an excessive financial burden on organizations that often run on very tight margins.
- These new requirements that would create duplicated administrative functions also run counter to the last several years of work done within the NYSFPP to reduce administrative overhead on grant funded programs by identifying beneficial financial partnerships and collaboration between Title X providers and other health care professionals. Through extensive investment in health systems improvement strategies such as Delivery System Reform Incentive Payments (DSRIP) and other Health Information Technology (HIT) activities, NYS has lead the nation in working to eliminate redundancies in the health care delivery system to lower costs for both government payors and consumers. This work has supported the consolidation of administrative functions within numerous large hospital and primary care provider systems, has funded the introduction of HIT projects and applications reducing provider workload and increasing efficiency at which providers can see and treat patients, and emphasized shared decision making to reduce the cost and burden of administrative functions within many smaller health care organizations. To add new regulations to the Title X program that knowingly expand the required cost and burden of administrative services is to run contrary to current best practices in health systems management and, specifically in NYS, negate millions of dollars of effort in health care systems reform which many current Title X programs have participated.
- Implementation of this rule would add significant additional expenses to the majority of Title X programs within NYS, none of which would go to support direct patient care. This would require potentially double the funds to support: administrative staff, fiscal staff, and fiscal operating systems (which can cost thousands of dollars annually). These additional expenses required by this rule would then mean that less funds would be spent on: clinical staff time, clinical supplies, contraceptive supplies, educational materials, education, and counseling activities, as well as essential community health prevention activities aimed at reducing the incidence of unplanned pregnancies in communities across NYS.

§59.15(b):
The proposed rule specifies that physical separation must be maintained. This proposed rule would mandate the physical separation (distinct consultation, exam, and waiting rooms) between office/exam space where abortion services are performed and the area where any Title X services are provided. In addition, the rule specifies that abortion service/provision must also have their own phone number, email address, educational services, and websites.

- These requirements fully fail to understand the way in which abortion care is integrated into the larger infrastructure of women's health organizations while still, through pro-rating shared services (i.e. time and effort reporting for staff, square footage allocation, etc.) ensure that no Title X funds ever support the provision of abortion.

- By creating a physical separation just for abortion care, this rule demonstrates a clear lack of understanding of the manner in which women choose to access obstetrical/gynecological services. Abortion care is a standard component of obstetrical/gynecological care and there is no medical or scientific reason why abortion care specifically should be segregated from other outpatient obstetrical/gynecological care. Abortion services are a common outpatient medical procedure performed in the United States. This procedure is safely completed in outpatient clinical settings across the United States and poses no additional risk that would necessitate separate facilities from those performing other semi-complex outpatient obstetrical/gynecological procedures like colposcopy, cryosurgery, and/or LEEPs (all of which are currently included in the NYS FPP).
- This new requirement is not necessary, as programs have successfully segregated abortion care without confusion by patients, subrecipient agencies, or the public, as discussed *infra* pages 23 and 26.
- If implemented this rule would serve to double expenses within many Title X programs, further limiting the amount of funds that can be allocated toward expenses that actually benefit patients (i.e. clinical staff time, contraceptive supplies, education and counseling services, etc.).
- In addition to increasing the cost burden for organizations which provide abortion services, which are already financially segregated from Title X services, requiring a physical separation would serve to highlight locations where abortion services solely are provided, an action that could likely increase the potential risk of those locations being a target of violent crime or protest. Taking action that could increase this risk runs counter to the recognition by both the federal and state governments, memorialized in 18 U.S.C.§ 248 and N.Y. Penal Law §§ 240.70-240.71.

§59.15(c):
The proposed rule specifies that distinct personnel, electronic, or paper-based health care records, and work stations must be maintained.

- Electronic health records (EHR) represent one of the most significant expenses for any family planning provider. The bulk of costs, which can often reach tens if not hundreds of thousands of dollars, are typically incurred in the set up and initial roll out of any new EHR system. If implemented, this rule would require an immediate influx of hundreds of thousands of dollars for most of the currently funded NYSDOH Title X subrecipient agencies within the first year for a new system. Adding this requirement without any increase in available funding would make implementing this change financially impossible for many of the programs, especially the smaller, rural serving organizations. Any loss of part or all of the current Title X program network would be a serious blow to patient access. Many Title X programs serve communities with few or no other health care providers and the loss of their Title X program could exacerbate already struggling provider shortage areas. Additionally, expenses related to establishing a new EHR system extend beyond the software licensing costs and typically include significant hardware and infrastructure expenses as well. Per language in the NYSDOH master contract, providers may not purchase any equipment in the final year of a grant cycle (which ends in 2019), therefore beginning 1/1/19 all NYSFPP organizations will be prohibited from purchasing equipment and therefore unable to comply with new requirements in the expected timeframe.
- NYSDOH maintains this new requirement is not necessary as programs have successfully segregated abortion care through the established practice of pro-rating expenses between the Title X program and the provision of abortion services. Budgets submitted to NYSDOH annually are reviewed by program staff with a particular emphasis on ensuring segregation of any abortion related expenses on all budgets, fee scales, formularies, and other program documents.

§59.15(d):
The proposed rule requires that signs and other ways in which the agency identifies itself remove any reference to abortion services.

- This proposed rule goes well beyond the scope of any current or former Title X program guideline or mandate. The Title X program has current regulations which emphasize community oversight and control of all Title X education, outreach, and marketing materials through a committee review process known as the "Information & Education Committee" requirements. Clearly stipulating this committee be comprised of individuals who broadly represent the communities in which the Title X program operates, this requirement stipulates that Title X programs obtain input from, and listen to the guidance of community members when developing all publicly distributed materials. This new requirement would essentially circumvent that process for signage and other agency marketing materials, removing control and oversight from communities and placing it with HHS.
- In addition to circumventing current regulations mandating community involvement in the development of marketing materials, this new rule imposes requirements on the content of materials developed well beyond the current scope of Title X contract oversight. As a grantee organization, NYSDOH does and will continue to, review and approve how programs spend the grant funds provided to them. However, NYSDOH, and HHS as its funding organization, lack the oversight to impose further requirements on how programs elect to spend other non-grant funds – including on the content of program's materials developed with other, often private funds. None of the currently funded NYS FPP agencies operate solely utilizing grant funds and supplement their grant awards with organizational funds, donor funds, and/or revenue generated from the provision of services. Therefore, it is very likely that a Title X program could opt to pay for the creation and installation of signage using funds other than those they received as part of their Title X, in which case NYSDOH contends it would lack the legal authority to dictate the content of signage paid for by private funds.

Recommendation:
We strongly recommend this proposed rule not be enacted as part of the Title X program.

Section 59.16. Prohibition on activities that encourage, promote, or advocate for abortion.
§59.16(a):
The proposed rule prohibits such activities as lobbying, paying dues to a group that advocates for abortion, and developing or disseminating materials advocating abortion.

§59.16(b):
The proposed rule provides a series of examples to illustrate what activities demonstrate compliance or non-compliance with paragraph a.

- NYSDOH continues to maintain that this rule, and its subsequent examples, are both unnecessary additions to the Title X program, and like so many of the other proposed rules in the Notice of Proposed Rulemaking are solutions in search of a problem. Current, and future NYS FPP organizations must be 501c3 eligible organizations to be eligible to apply for funding through this grant programs and as such, those organizations are clearly prohibited from funding or engaging in any kind of lobbying activities per IRS law.
- NYSDOH also contends this rule extends beyond the scope of allowable oversight by HHS and NYSDOH of the Title X program and subrecipient agencies by stipulating that Title X funds cannot be used to support organizations which engage in lobbying, even if the Title X funds used

do not support lobbying activities. Many advocacy organizations or other associations which engage in lobbying activities also provide vital educational and institutional support to Title X providers, independent of their, often separately funded, lobbying activities. Prohibiting Title X providers from using their funds to pay dues into these organizations, even if those dues are not used specifically to fund advocacy for abortion represents an overreach and fails to take into account the essential educational functions of many of these organizations. Strictly interpreted this rule could prohibit Title X agencies from paying dues to, and being able to collaborate with organizations like: American College of Obstetricians & Gynecologists, National Family Planning & Reproductive Health Association, Planned Parenthood Federation of America, and other nationally recognized organizations known for being leaders in the provision of clinical education and technical assistance to reproductive health care organizations.

Recommendation:
We strongly recommend this proposed rule not be enacted as part of the Title X program.

Section 59.17. Compliance with reporting requirements.
The proposed rule requires that Title X projects comply with all state and local reporting laws and provide satisfactory documentation to the Deputy Assistant Secretary for Population Affairs that it has complied, as a condition of receiving Title X funding.

- Current Title X guidelines clearly stipulate that information on clients cannot be disclosed, "except as required by law" which establishes the necessity of compliance with all state/federal reporting requirements. In addition, a current legislative mandate clearly outlines the requirements the reporting of any suspected child abuse or maltreatment by Title X grantees, subrecipient agencies, and their employees. The clarity of this mandate ensures consistent application among programs while allowing providers to develop and implement strategies to meet these needs that are tailor made for the individual circumstances of their own patients. Routine program monitoring includes chart reviews, a required number of which must be adolescent charts, which are specifically assessed to demonstrate compliance with these legislative mandates.
- Per NYS law all NYS licensed physicians, mid-level providers, and nurses serve as "Mandated Reporters" of any suspected of child abuse or neglect. Professionals providing services in Title X-funded sites are aware of their reporting obligations, already receive training on them, and make reports in compliance with these requirements. Health care professionals take seriously their reporting obligations and their obligations to their patients to protect them from real risks of exploitation and abuse.
- The proposed rule requires providers to conduct preliminary screening of any teen who presents with a sexually transmitted disease to rule out victimization. In addition, the proposed rule requires providers to document the age of minor patients as well as the age of the minor patient's sexual partners. Not only does this require a Title X project to maintain detailed records that include this highly personal information but it would require providers to collect that information no matter what the surrounding circumstances which could scare away, or at a minimum, disturb minor patients and cause them to no longer seek care in a Title X setting.
- The proposed rule also seeks to expand HHS' authority to inspect patient records for the sole purpose of ensuring compliance with reporting obligations. The proposed rule would thus allow HHS to substitute its own judgment for that of the state (or locality) that is actually responsible for determining compliance with these laws and is in the best position to make determinations about whether a Title X project or its individual providers are in compliance with them.

- NYSDOH contends that increased oversight by HHS, together with the addition of new requirements to collect and document specific information in Title X records, will prompt inappropriate screening and over-reporting by providers that will harm patients and undermine the provider/patient relationship.

Recommendation:
We strongly recommend this proposed rule not be enacted as part of the Title X program. Given that a Title X legislative mandate already exists, addition of this rule is not necessary, will compromise patient confidentiality (particularly for adolescents), and will drive patients away from critical health services.

Section 59.18. Appropriate use of funds
The proposed rule outlines the prohibition on use of funds to build infrastructure for abortion providers, or for activities that promote support or opposition to any legislative proposals or candidates for office. In addition, the proposed rule requires full accounting for charges against the Title X grant.

- NYSDOH contends that the addition of this rule is unnecessary within the scope of the current Title X program. Based on current statute and regulations, Title X providers are already prohibited from using funds to support abortion services for family planning, and any kind of infrastructure building for such services are outside the scope of allowable activities. Furthermore, as stated in the response to Section 59.16, in order to be eligible for the NYS FPP, organizations must be 501c3 or other eligible groups and as such, are already prohibited from engaging in any form of lobbying for proposals or candidates. Finally, the additional requirement of full accounting for Title X expenses is unnecessary as fully accounting for expenses is a key principle of any general rules of accounting and is mandatory for all NYSDOH funded programs. Current NYSFPP funded organizations are required to maintain a record of all grant related expenses, are expected to produce that information upon request, and undergo periodic audits to ensure that information is kept and can be made available when necessary.

Recommendations:
We strongly recommend this proposed rule not be enacted as part of the Title X program.

Section 59.19. Transition provisions
The proposed rule requires that entities comply with physical separation requirements within one year of publication of the final rule, and comply with financial separation and all other requirements within sixty days of publication of the final rule.

- NYSDOH contends that the aforementioned new rules regarding physical separation are unnecessary and present a substantial administrative and financial burden to agencies being required to operationalize these changes. As written, these changes would undermine the financial stability of numerous organizations throughout the NYSD FPP Provider Network and would likely result in several hundred thousand NYS residents being forced to go without life changing family planning services.

Even the addition one year's time frame in which to make these changes does nothing to effectively ease this burden, as the ongoing operational costs to maintain duplicative systems and locations would be substantial Furthermore, many subrecipient agencies are small, not-for-profit organizations which lack the capital on hand, or the ability to raise the amount of capital needed to fund these changes within such a short window of time.

Recommendations:
We strongly recommend this proposed rule not be enacted as part of the Title X program.

II. Responses to HHS Specific Requests for Comments:

The following section summarizes NYSDOH's response to HHS' specific requests for comment that appear in the preamble of the Notice of Proposed Rulemaking (NPRM). When comments relate to specific proposed rule changes the applicable sections are referenced.

Page 21-22 of NPRM
Re: HHS request for comment on the proposed rule to prohibit providers from promoting, referring for, or supporting the provision of abortion services.
NYSDOH strongly opposes the addition of this language. The current Title X statute has been in place for over 40 years to ensure that Title X funds are not used to support the provision of abortion as family planning and this statute and implementing regulations do not require updating. If enacted, the proposed regulation would compromise provider ethics, and all but end the ability of health care providers to provide care within the limits of their clinical judgment. Furthermore, this proposed rule would deny Title X patients their right to informed consent on medical services as well as medically necessary information on legally available health care procedures. Additional comments can be found under **Sections §59.13 – §59.16, discussion *supra* pages 15-21.**

Page 39-40 of NPRM
Re: HHS Request for Comment on changing the regulatory review criteria of applications to clarify "confusion" among Title X providers and the public.
NYSDOH strongly opposes the addition of this proposed rule change. As an original Title X grantee and applicant of the most recent Title X FOA, NYSDOH contends that confusion, either among clients, the general public, or potential grantees about the inclusion of abortion related activities in the Title X program does not exist. Information provided throughout the Notice of Proposed Rule Making fails to demonstrate any confusion among patients, grantees, subrecipient agencies, or the public about the appropriateness of abortion related services under the Title X program. Years of statute and regulation have clearly articulated the prohibition of using Title X funds to support the provision of abortion services and as such, this proposed rule is unnecessary. Furthermore, in applying retroactively to the currently pending FOA the proposed rule would undermine the fairness of the FOA and ensure that current applicants would be scored on criteria they were previously unaware. NYSDOH contends that the late inclusion of these measures, well after the application due date, would create a fundamentally unfair scoring process that would unjustly weight funding to organizations not capable of providing the full range of comprehensive services that have long been the benchmark of Title X care.

Page 45-46 of NPRM
Re: HHS request for comment on eliminating specific regulations as they apply to "contracts."
NYSDOH supports fair contracting practices completed through open procurement procedures and scored in alignment with Title X program guidelines as the most appropriate method to distribute federal Title X program funds. NYSDOH strongly opposes any effort to circumvent fair contracting rules to expedite allocation of funds to organizations and programs that do not submit applications as part of a competitive procurement or, as "contracts" that will not be required to follow program regulations, including basic eligibility guidelines. If implemented, this change could drastically alter the landscape of Title X providers, potentially allowing, among other things, for-profit organizations and health care providers that

do not meet the highest standards of quality care to be awarded federal funds through a non-competitive process. This would result not only in the loss of long standing provider organizations with a proven track record for contract management, but the award of public funds to organizations who may opt to use federal money to profit from serving limited income individuals seeking family planning services. NYSDOH is committed to ensuring the fair and equitable distribution of public funds to communities who through a competitive process, fairly scored, adequately demonstrate both a compelling need for funds and the ability to utilize those funds in alignment with program regulations and guidelines.

Page 50-51 of NPRM
Re: HHS request for comment on the proposed rule to expand the reporting requirement and oversight of grantee and sub-recipient agencies to all referral partner organizations of each grantee/subrecipient agency.
NYSDOH strongly opposes the implementation of this proposed rule. As written, this additional requirement would dramatically expand the oversight and reporting requirements of the Title X program to include a wide range of organizations partnering with subrecipient agencies to establish referral networks. These collaborative partnerships are non-funded partner and referral agreements, established between subrecipient agencies and their partners across the state who do not receive any federal Title X funds. This proposed rule demonstrates several fatal flaws that would make its implementation not only overly burdensome and financially unsound, but call into question the legal authority of both HHS and grantee organizations in inserting themselves into the contractual relationship of two organizations, one of whom they will have no legal or contractual relationship. NYSDOH contends that neither HHS, nor the NYSDOH as its grantee organization, can claim a legal right of oversight on the operations and activities of non-funded referral partner organizations. Lacking any legal authority to dictate the scope or type of activities, the NYSDOH would be unable to enforce the minute requirements and/or require the reporting of data as outlined in the proposed rule. Therefore, this rule is unacceptable and would be impossible to implement at any provider level. Furthermore, should there arise contractual relationships that give grantees this level of oversight, the sheer volume of analysis of all referral partners within a large Title X program would necessitate increased staff time, data processing ability, and the subsequent increase of grant funds used to support administrative overhead at the expense of funds supporting clinical patient care. For example, the NYSDOH Title X network consists of 48 subrecipient agencies, with over 170 individual clinical sites that each may have dozens of referral partner organizations. It would be impossible for the NYSDOH to maintain oversight of this large number of referral partners. Additional comments can be found under **§ 59.5(a)(13), discussion *supra* pages 11-12.**

Page 62-63
Re: HHS request for comment on whether the additional requirements related to abortion are necessary to protect the individual right to decline participation in abortion-related activities and alleviate current confusion.
NYSDOH strongly opposes the implementation of any additional requirements in this area, for reasons previously stated, which include: a failure of HHS to demonstrate any "confusion" regarding the nature of Title X services or an individual provider's role, the longstanding provision of abortion services which has successfully ensured that no Title X funds have supported the provision of abortion for nearly forty years, and unethical, potentially illegal, and contrary to medical ethics limits on physician speech that would be required to implement this rule. If enacted, this rule has the potential to jeopardize the health and well-being of women accessing reproductive health services through a Title X provider. For example, this rule could cause women seeking care through Title X providers to miss timely access to key reproductive health care services including identification of and treatment for ectopic pregnancy, molar

pregnancies, or other abnormal products of conception. Should a woman present with a medically nonviable pregnancy, this rule would allow a physician to inform her that she may opt to terminate the pregnancy, but would prohibit that provider from assisting her in obtaining and accessing a timely referral for medically necessary care. The guidance issued along with this proposed rule stipulates that this physician could only give the patient a list of alternative health service providers some (but not all) of which provide abortion and the physician would be specifically barred from indicating which providers offer abortion care. This lack of clear information, the additional burden of time required to contact and verify which provider offers her required medical service could result in a delay in accessing care which would jeopardize the health and well-being of women receiving medical care through the Title X program.

An additional concern also lies with the regulatory definition of "physician" as the sole individual permitted to provide information on abortion to any Title X patients. As with many other types of health care facilities, the vast majority of "providers" who regularly seeing patients are highly trained mid-level clinicians (i.e. Nurse Practitioners, Physician's Assistants, Nurse-Midwives) and not physicians. Therefore, the language in this rule calls into question whether or not mid-level clinicians would be prohibited from acting within their scope of practice and expertise to inform patients of the availability of abortion care when medically necessary and/or requested by a patient. Additional comments can be found under **Sections §59.13 – §59.16, discussion *supra* pages 15-21.**

Page 69-70
Re: HHS request for comment on the inclusion of additional requirements to demonstrate segregation of abortion services in any Title X program.
NYSDOH strongly opposes the inclusion of these factors within any new Title X regulations. The NYSDOH continues to be confident the long existing Title X statutory and regulatory language do ensure the separation of funds supporting Title X activities and those funding the provision of any abortion services, and those regulations have successfully ensured that segregation for well over forty years. These unnecessary, burdensome, and seemingly arbitrary points of separation included in the proposed rule will not, in any meaningful way, go further to ensure the separation of Title X fund from abortion care than current legal requirements and annual provider attestations do. The proposed rule includes onerous requirements created with a clear design to establish additional Title X regulations that would effectively prohibit any Title X funded provider from also providing abortion care even through a separate source of funding as is currently permissible within the existing Title X regulations and statute. These new rules would be difficult to implement and oversee, unfairly target specific provider types to the benefit of organizations incapable of providing a high level of quality medical care to patients, and serve to dramatically limit the number of eligible Tile X subrecipient agencies. Implementation of this rule could result in the closure of family planning clinics across NYS, resulting in loss of access to essential health care services by as many as 300,000 patients across NYS. Additional comments can be found under **Sections §59.13 – §59.16, discussion *supra* pages 15-21.**

Page 70
Re: HHS request for comment on the impact of the proposed rules requiring physical and organizational separation of Title X providers and abortion care.
NYSDOH strongly opposes the implementation of this rule and is incredibly concerned about the potential impact of this proposed rule if enacted. Opposition comes not only from the substance and content of the rule itself, but the HHS contention that confusion currently exists within the public about the separation of Title X services and abortion care. It is the position of NYSDOH that no such public confusion exists, that all currently funded Title X subrecipient agencies have an excellent track record

ensuring the separation of Title X funds from any abortion related services and that this misplaced concern demeans not only the understanding and intelligence of family planning clients, but demonstrates a fundamental lack of understanding from HHS on how most patients choose to access family planning services. Similar to the rule referenced in the section above (pgs. 69-70 of NPRM document) this new rule would create an undue burden on certain types of Title X providers, many of whom serve the bulk of Title X clients in any given service area. The new proposed requirements around financial and physical separation are not only unnecessary (as all Title X programs already clearly pro-rate space, administrative, and staff expenses to ensure separation of abortion funds) but are anathema to every other trend in health care service delivery, especially in NYS. Over the past several years billions of dollars have been spent to reform the health care service delivery system in NYS, emphasizing increased collaboration, shared administrative services, as well as opportunities for increased shared spaces among different types of community providers. This proposed rule would undue nearly a decade's worth of effort to better streamline health care delivery in NYS, would undue work to avoid administrative duplication, and would create an unfair financial burden on only some Title X providers to the detriment of the communities and patients that they serve. Additional comments can be found under **Sections §59.13 – §59.16, discussion *supra* pages 15-21.**

Page 80
Re: HHS request for comment on the value of cost/benefit of proposed rule changes.
NYSDOH strongly disagrees with the HHS proposed cost/benefit assessment of the proposed rule changes. The included analysis fails to adequately calculate the devastating financial impact of physical and administrative separation for organizations that will continue to provide legal abortion services and does not account for the likelihood that these organizations may have to decline Title X funding and/or cease operations with the addition of these arbitrary and unnecessary new rules. That lack of service providers would devastate the current landscape of Title X services across NYS and could result in up to half of all current NYS FPP clients (nearly 300,000 individuals annually) no longer being able to access Title X funded services. Furthermore, HHS has provided no factual basis for their continued assertion that there is confusion regarding the separation of abortion funds from Title X funded services or that the currently accepted safeguards (in place within the Title X program for over 40 years) have not sufficiently ensured the effective separation of funds supporting abortion care with those supporting Title X services. Without establishing the necessity of these rules to remedy confusion, HHS's claim of an added benefit of clarity to the Title X program, to the residents of NYS, or to other stakeholders if these proposed rules are adopted is not convincing.

Page 100-101
Re: HHS request for comment on the proposed rules requiring additional separations between Title X service provision and the provision of abortion services.
NYSDOH strongly opposes the additional separations between Title X services and the provision of abortion services outlined in this rule. Not only has HHS failed to meaningfully demonstrate that such separation is necessary or beneficial to the implementation of Title X, the proposed additional requirements would add significant administrative burdens to Title X programs which have already proven their ability to comply with statutory language regarding prohibition on funds supporting abortion services. Further, new requirements regarding oversight go well beyond the scope of the Title X program to implement.

While purporting to support "holistic" family planning services, the HHS proposed rule does, in fact, only serve to dramatically limit both the scope and quality of family planning services required under this program. Rather than recognizing the way in which women and men currently access family planning

services, the proposed rules draw arbitrary distinctions between allowable and unallowable services that do not align with any known standards of care or medical practice. By prohibiting the provision of any post-conception care as part of the Title X program, HHS is not only limiting the ability of agencies to provide abortion care (something already restricted by 42 U.S.C. § 300a-6) but is working contrary to medical science and best practice to increase barriers high risk women experience to accessing needed prenatal and postpartum care services in a timely manner.

Other approaches to ensure compliance with statutory language would be the continued use of attestations submitted annually detailing agency understanding and responsibility to ensure the segregation of Title X funds from the provision of abortion services combined with regular cycles of onsite program monitoring and reporting at both the grantee and subrecipient agencies. Other approaches to providing holistic services that would better align with nationally accepted standards of care and best practice in family planning would include the expansion of services of within the Title X setting to promote easier access to prenatal care, abortion care, or adoption services based on the wishes of individual patients.

Page 104
Re: HHS request for comment on the proposed annual reporting changes along with their respective impact on the Title X program.
NYSDOH strongly opposes the implementation of this rule change proposed by HHS. NYSDOH contends that the proposed rule and its associated documentation are unnecessary, undesirable, and would only serve to increase costs for Title X funded organizations and subsequently decrease availability of services. The burden detail developed by HHS fails to fully describe the total cost in both financial and labor terms of all associated changes. For example, nowhere in the provided estimation did HHS include funds to support the creation of new patient intake/consent forms with updated program language in all required languages produced by NYSDOH, per NYS Executive Order[36] and per HHS Office for Civil Rights[37]

Additionally, the current calculation fails to consider regional variations in provider salary, type and function when establishing a base salary rate for individuals who will be primarily responsible for implementing changes. Additional comments can be found under **Sections 59.3, 59.5, 59.7, 59.13, and 59.18 discussions *supra* pages 4-6, 12-13, 15, and 22.**

III. Legal Shortfalls of the Proposed Rules

The proposed rule changes, issued under Title X of the Public Health Service Act would include, among other things, restrictions on the use of funds received by grantee providers. Specifically, such grantees would be prohibited from utilizing any disbursement from this program for services associated with abortion – not merely the performance of such a procedure, but medical providers would also be prohibited from even mentioning the option of abortion to a patient during an examination/consultation. Furthermore, if a provider's menu of services includes abortion, that entire portion of services must be completely cleaved from other medical services offered if the provider wishes to be a recipient of Title X funds. This separation extends so far as to preclude maintaining patient record databases or housing administrative services within the same building. The fallout from such restrictions could include (1) a

[36] NYS Executive Order No. 26 (Oct. 6, 2011), https://www.governor.ny.gov/news/no-26-statewide-language-access-policy
[37] Executive Order No. 13166, 65 Fed. Reg. 50121 (Aug. 11, 2000), https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/guidance-federal-financial-assistance-title-vi/index.html

serious reduction in the amount of funding received by providers as any award will reflect a perceived "reduced need" if abortion services are not to be included in appropriate "family planning" options, and (2) some providers not receiving funds at all if they either cannot or will not separate abortion from other services offered as part of its family planning services.

The Scope of Regulatory Authority Under Title X

Where Congress has delegated rulemaking authority to a federal agency, such as HHS, that agency is granted deference in how it interprets and implements a statute. If it determined that Congress has not addressed an issue within a statute "unambiguously", then deference is given to the federal agency's interpretation of the provision in question. However, that deference is not without limits. First, an agency's rulemaking must be based upon a statutory interpretation that is "rational" or "reasonable," as well as not inconsistent with clear statutory language. Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 468 U.S. 837 (1984). Second, an agency's rulemaking will be struck down if it is "arbitrary, capricious, [or] an abuse of discretion." Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(A). To survive a review under the APA, an agency "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 43 (1983). The proposed rule changes go well beyond previous regulations proposed or implemented under the Title X program and stretches the reasonable bounds of Congress' intent for the Title X program.

Rust v. Sullivan, 500 U.S. 173 (1991) involved a challenge to regulations enacted by Congress to administer the Title X statutory program, and is of particular interest in the current instance as the rules proposed now share the primary goal of the 1988 rules challenged in the Rust case: the exclusion of abortion services from funding under the federal grant program designated for family planning programs for the faction of our population with limited access to healthcare services. However, the new proposed rules exceed the scope of the 1988 rules challenged in Rust. Most significantly, the newly proposed rules:

- Alter the scope of family planning services provided to no longer require that family planning methods be "medically approved", as discussed *supra* page 6.
- Require all pregnant people be referred for prenatal care, without full options counseling, regardless of their wishes for their pregnancy, as discussed *supra* pages 8 and 16.
- Restrict not only whether providers may refer for abortion, but *how* abortion & prenatal care can be discussed as discussed *supra* pages 16-17.
- Alter the decades-long existing criteria for grants as discussed *supra* page 13.
- Add extensive reporting requirements about subrecipient's referral networks, entities not receiving Title X funds or currently within the scope of Title X regulations, as discussed *supra* page 12.
- Threaten patient confidentiality – especially for minors as discussed *supra* pages 4 and 21.
- Add vague and confusing prohibitions on activities associated with abortion, as discussed *supra* pages 20-21.
- Add confusing requirements for compliance with its proposed physical separation requirement, as discussed *supra* page 19.
- Twist the definition of low-income to enable and possibly require Title X programs to provide free services to women *regardless of income* whose employers provide insurance but object to that coverage including contraceptives, as discussed *supra* page 5.

The new proposed rules, in their difference from the 1988 rules, go beyond the outer bounds of Congress' intended scope of delegated authority to HHS, contravening the intent and mission of the program and thus the principles of legislative control in Chevron. Furthermore, HHS has failed to

articulate a satisfactory explanation linking the proposed rules to any facts or data that might justify those rules, violating the APA's prohibition on arbitrary and capricious rulemaking. For example, HHS has offered no facts or data that provide a rationale to substantially broaden the requirements to separation of Title X family planning services from abortion services; there is no rational connection between the needs of Title X patients and the proposal to no longer require that family planning services be "medically approved;" and it is not a reasonable interpretation of Title X, a statute intended to provide services to low-income, uninsured, underserved individuals of reproductive age, to require that free services be provided to women regardless of income and insurance status.

Additionally, the new rules are proposed in a radically changed healthcare landscape. For example, the proposed §59.15, discussed *supra* pages 18-20, requiring separate personnel and health records for Title X services and abortion services, is both more proscriptive on its face from the 1988 rule, and the legal and practical landscape of healthcare provision now makes integrated, electronic health records (EHR) the default and the best practice for providers. Separating these records does not mean having two separate file cabinets or rooms, but instead needing to build entirely separate EHR systems, which is one of the most significant expenses for any family planning provider. This changed landscape renders HHS' rationale for the proposed rules even more suspect.

Finally, the APA requires that prior to adopting a rule, notice and opportunity to comment is afforded to the public, and that such notice be provided at least 30 days in advance of the rules effective date. 5 U.S.C. 553. An exception to this general rule permits the notice period to be waived when the agency finds that notice is "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. 553(b). In this case, HHS is seeking to impose these proposed rules retroactively on the Title X FOA that was released in February 2018. As discussed, *supra* page 13-14, changing the rules and scoring criteria of an FOA after applications have been submitting would be, at the very least, unfair to applicants that applied and to entities that decided not to apply. In the absence of any indication that providing prospective notice of these rule changes is impracticable, unnecessary or in some way contrary to the public interest, it violates HHS's obligations under the APA.

The Constitutional Issues Raised by the Proposed Rules

A. THE PROPOSED RULES THREATEN TITLE X PROVIDERS FIRST AMENDMENT SPEECH RIGHTS

In addition to failing to conform the requirements of Chevron and the APA, the differences in the current proposed rules and the 1988 proposed rules, as well as recent developments in case law, open up questions of constitutionality.

The impact of the proposed rules on First Amendment-protected speech is of particular concern. While Rust upheld the 1988 rules against a First Amendment challenge, the Court's recent decision in Nat'l Inst. of Family & Life Advocates v. Becerra, 138 S. Ct. 2361 (2018) casts the application of Rust into doubt. In Becerra, the Supreme Court ruled against a California State law that mandated that "crisis pregnancy centers" provide information about abortion services. Justice Thomas, writing for the majority, applied strict scrutiny standard of review, noting that "this Court has stressed the danger of content-based regulations in the fields of medicine and public health, where information can save lives," and that "regulating the content of professionals' speech poses the inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to suppress unpopular ideas or information." Id. (internal citations omitted). In the case of the rules proposed here, by prohibiting a Title X provider from even

mentioning the availability of abortion services and restricting the format of any information a Title X provider may give about abortion providers, HHS is clearly intending to burden content based speech. Given the broad scope of the proposed rulemaking and the lack of a compelling rationale, it is doubtful whether the federal government can demonstrate narrow tailoring to meet a compelling government interest, as is required under strict scrutiny.

Additionally, although the Supreme Court upheld the 1988 rules as valid, the decision was based upon challenges under the First and Fifth Amendments. There are other Constitutional grounds not raised by the complainants and not contemplated by the Court in its decision in *Rust* that serve to call into question the legality of the proposed legislation. We discuss these items below.

B. THE PROPOSED RULES DEMONSTRATE AN ACTION WITHIN THE FEDERAL LEGISLATIVE BRANCH THAT EXCEED THE AUTORITY GRANTED BY THE SPENDING CLAUSE

"The Spending Clause grants Congress the power 'to pay the debts and provide for the...general welfare of the United States." National Federation of Indep. Bus. v. Sebelius, 567 U.S. 519, 576 (2012) (citing U.S. Constitution Art. 1, §8, cl. 1). Furthermore, it is well-established by case law at various levels within the federal court system that "Congress may attach conditions on the receipt of federal funds" pursuant to the Spending Clause and "use this power to grant federal funds to the States, and may condition such a grant upon the States taking certain actions that Congress could not require them to take." N.Y. v. U.S., 505 U.S. 144, 166 (1992) (citing South Dakota v. Dole, 483 U.S. 203, 206 (1987) and Sebelius, 567 U.S. 519). However, there are limitations on this power that can cause an enacted law to be struck down as an impermissible use of authority granted pursuant to the Spending Clause if the federal government is seeking to improperly coerce the State.

Time and again, the Supreme Court has ruled that legislation enacted pursuant to the Spending Clause is contractual in nature and that the "legitimacy of Congress's exercise of the spending power...rests on whether the State *voluntarily* and knowingly accepts the terms of the contract." Sebelius, 567 U.S. at 577 (emphasis added) (citations omitted). This rationale grounds the Court's review by acknowledging that "this limitation is critical to ensuring that Spending Clause legislation does not undermine the status of the States as independent sovereigns in our federal system ... [a system that rests on the] insight that 'freedom is enhanced by the creation of two governments, not one.'" Id. As a result, the Supreme Court has stricken "federal legislation that commandeers a State's legislative or administrative apparatus for federal purposes." Id.

Also, while Congress "may use its spending power to create incentives for States to act in accordance with federal policies ... [b]ut when 'pressure turns into compulsion' the legislation runs contrary to our system of federalism." Id. at 577-578. This holds true whether "Congress directly commands a State to regulate or indirectly coerces a State to adopt a federal regulatory system as its own." Id. at 578.

The proposed changes to the rules and regulations related to the Title X funding program are a clear example of the federal government using the spending power to infringe upon the State's sovereignty via impermissible coercion and should be rejected or significantly revised to preserve states' sovereignty.

1. The proposed regulatory action fails to satisfy the three-prong test established by the Supreme Court for determination as to a permissible use of the Congress's power under the Spending Clause

As previously discussed, the power(s) granted to Congress under the Spending Clause are rather broad, but not without limitation. In South Dakota v. Dole, 483 U.S. 203 (1987), the Supreme court discussed three (3) points to be examined when determining whether or not legislation enacted by Congress via its spending power is legally valid. The questions to be answered are (1) is the spending power "in pursuit of the 'general welfare'"; (2) are condition(s) placed upon the State receiving the federal funds "unambiguously...enabling the States to exercise their choice knowingly, cognizant of the consequences of their participation"; *and* (3) are the conditions "unrelated to the federal interest in particular national projects or programs." Id. at 207-208. An "unofficial" additional prong is that "other constitutional provisions may provide an independent bar to the conditional grant of federal funds." Id. at 208.

There is no question that as to the first prong of review that, in passing the Title X statute and delegating authority to HHS to implement the statute, the federal government is utilizing its spending power "in pursuit of general welfare." The funds disbursed under the Title X program assists providers in the ability to serve members of the population who may otherwise not have access to quality and safe care relative to assistance with decisions and options for family planning – low-income, uninsured and underinsured women and men of reproductive age, including adolescents.

On the second point, Title X makes clear that Title X funds shall not be used "in programs where abortion is a method of family planning". 42 U.S.C. § 300a-6. In fact, as already mentioned, under the proposed rules, a provider may not even mention the option of abortion when counseling or treating a patient. Hence, Congress has clearly indicated there is a condition attached to the usage of the Title X funds. More serious questions arise involving consideration of the third prong and the "unofficial" fourth prong of review, and the failure to pass these two points vitiates the legitimacy of the proposed regulations, as all the prongs of this test are construed as a collective that must be satisfied *in toto*. South Dakota v. Dole, 483 U.S. at 208.

a. The specifics of the conditions placed upon receipt of funds by the federal government in the proposed new regulations are unrelated to a federal interest in particular projects and programs

Certainly, the regulations associated with the Title X statutory body, generally speaking, are related to a valid federal interest in particular projects and programs. The objective of this federal grant program as stated throughout the comments herein, is to assist providers in reaching and serving an otherwise underserved faction of the population to ensure access to quality care and healthy family planning services – both medical and consultative/educational services. Regulations are necessary to provide clarity and guidance for the disbursement of funds from this program to ensure the attainment of that objective. Where these proposed regulations go awry of that valid federal interest, however, is the arbitrary exclusion of abortion from the list of services deemed "appropriate" for those patients or clients in need of either counsel or medical services relative to family planning needs. This exclusion goes so far as to essentially place a "gag rule" on medical professionals and facilities brick-walling off any feature of its practice or program that is associated with abortion. Instead, the proposed regulations lean heavily toward options historically deemed "morally acceptable".

This is no place for governmental intervention. If the purpose is to ensure this vulnerable population receives medical and educational services from competent professionals regarding the aspects of family planning, this arbitrary restriction on the discussion of abortion services is not in furtherance of a legitimate and authorized federal interest in conjunction with the federal funding program. The federal government "may condition grants under the spending power *only in ways reasonably related to the purpose of the federal program.*" South Dakota v. Dole, 483 U.S. at 213 (Justice O'Connor, dissenting opinion) (emphasis added). In this instance, the proposed regulations are contrary to the "purpose of the federal spending". The statute enacted for the Title X program seeks to fund programs that will serve an "at risk" population with quality and accessible family planning services. There is no reasonable basis found within the proposed new rules which proves that the exclusion of all items of service associated with abortion – including what a doctor may counsel the patient on in the course of treatment – furthers that purpose. In fact, these rules run contrary to that purpose as access to crucial treatment and services will be unduly hampered by the delay caused by providers having to refer patients out to other providers.

b. Other constitutional provisions provide an independent bar to the conditional grant of federal funds

Tenth Amendment

The State's sovereignty is guaranteed by the Tenth Amendment of the United States Constitution, and a federal law must be struck down if in a balancing of the federal interest against this Tenth Amendment right of the State, the law "would prevent the State from functioning as a sovereign". N.Y. v. U.S., 505 U.S. at 177.

"Regulating matters of health is among the historic police powers of a state ... and [b]ecause such regulation is primarily a matter of local concern, 'States traditionally have had great latitude under their police powers to legislate under their police powers to legislate as to the protection of the lives, limbs, health, comfort and quiet of all persons.'" Zahl v. Harper, 282 F.3d 204, 211 (U.S. Ct. App. 3d Cir. 2002) (citing DeBuono v. NYSA-ILA Med. & Clinical Svcs. Fund, 520 U.S. 806 (1997) and Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)).

Pursuant to that inherent police power, New York State did indeed enact a body of law regulating the practice of medicine within the State – including regulating the standards of practice that must be adhered to in the treatment of patients and such. The enforcement of the standards of practice is achieved by the provisions of N.Y. Pub. Health Law § 230 *et seq.* which is found in Title II-A of that section of the State's statutes and is entitled "Professional Medical Misconduct." Section 230 establishes the state board of professional medical conduct, sets forth its function and purpose and how proceedings against medical professionals alleged to have violated the standards established by the State.

The proposed new regulations for the Title X program include a prohibition on what a medical professional may discuss with a patient in the course of treatment and how they must discuss it – most notably abortion care. In certain instances, a medical professional practicing within the State of New York may be required as a matter of law to advise and counsel a patient on such an option in order to fulfill the obligation to adhere to a standard of care set forth by State law and consistent with nationally accepted standards of medical ethics, *see supra* pages 8-9. If the medical professional is affiliated with a program that receives funding under the Title X program, the medical professional would be prohibited from such a discussion. Such an omission could be deemed negligent and/or below the established standard that would cause the State to initiate a misconduct proceeding against the professional. Were the medical

provider to rely on the Title X regulation as a defense, it would interfere with the State's right to enforce a standard set pursuant to its police power, when the "state regulation of the medical profession is in the public interest [and the] power to establish and enforce health standards 'is a vital part of a state's police power." Zahl, 282 F.3d at 211.

Takings Clause

Under the principles of the Fifth Amendment of the US Constitution, the federal government is prohibited from taking a property right without due process of law. In the case of Omnia Commercial Co. v. U.S., 261 U.S. 502 (1923), the Supreme Court ruled that contractual rights are indeed "property" allowing for scrutiny of federal legislation producing an impact on those rights. If the legislation is found to "appropriate" the contractual right, then the law must be deemed invalid.

"To prevail on a claim that federal economic legislation unconstitutionally impairs a private contractual right, the party complaining of unconstitutionality ... [must demonstrate] first, that the statute alters contractual rights or obligations." National R. Passenger Corp. v. Atchison, T & SFR Co., 470 U.S. 451, 472 (1985) (citing Trust Co. v. New Jersey, 431 U.S. 1 (1977)). Thereafter, if "impairment is found ... [it must be determined] whether the impairment is of constitutional dimension." Id. (citing Allied Structural Steel Co. v. Spannus, 438 U.S. 234 (1978)). Finally, "[w]hen the contract is a private one, and when the impairing statute is a federal one, ... [there is a question of whether] the legislature has acted in an arbitrary and irrational way." Id. (citing Pension Benefit Guaranty Corp. v. R.A. Gray & Co., 467 U.S. 717 (1984)).

NYSDOH, as a Title X grantee contracts with subrecipient agencies to deliver family planning services for those individuals contemplated within the establishment of the Title X program. With these contracts in place up to this point in time, if the proposed rules are implemented, the contractual rights and obligations between the NYSDOH, as a grantee, and its various subrecipient agencies will be negatively impacted. Several subrecipient agencies may decide to no longer contract with the grantee if they must re-structure their programs to ensure separation of abortion services from any family planning services. Additionally, the grantee will have to adjust the compensation contracted for in order to reflect its inability to expend Title X funds that may be used by the subrecipient for education on, or referrals for, pregnancy abortion. This end result – without question – amounts to an impairment.

This impairment is of constitutional proportions because the parties negotiated terms and conditions that would be economically feasible for the subrecipient agency to gain the requisite level of services for the grantee at crucial points in time to ensure that the needs of the underserved are met without any interruption or lack of service availability by the grantee. Each party in this contract have rights severely trampled and vitiated by the proposed rules, i.e., taken.

As these private contracts will be impaired by the proposed rules, the final question is whether HHS, in interpreting the legislature's actions, is acting in an arbitrary and irrational way. The answer to this is in the affirmative. As discussed earlier, the federal government is seeking to single out one type of service that has historically been accepted as a medically appropriate health care option without providing a rational basis for doing so, and instead choosing to attempt to exert a moral restriction upon the use of funding.

2. The financial inducement offered by Congress is so coercive as to evidence undue influence and compulsion

As discussed previously, a review of an action by Congress pursuant to its spending power includes whether or not the resultant "financial inducements" are not used to "exert a 'power akin to undue influence'...and 'pressure turns into compulsion' [thereby running] contrary to our system of federalism." Sebelius, 567 U.S. at 577-578. The extent of the fallout of the regulations is so severe that the acceptable "mild inducement," permitted of the federal government's spending powers, is surpassed to an unacceptable level of compulsion.

Since at least 1971, States have relied upon the receipt of grant funds to supplement funds garnered through budgetary appropriations each year. With the inclusion of the federal monies, the States have had more funds available so as to allow more subrecipients to receive the crucial funding needed to develop programs that provide an appropriate quality of care. These disbursements have flowed without unduly burdensome restrictions and monitoring required by the States. However, under the newly proposed rules, if the States wish to receive grant money under Title X, they would not only be compelled to comply with the condition that no aspect of services associated with abortion may receive any funding from that program, but also required to monitor subrecipients to ensure that abortion services are not even located within the same premises. If the State does not have the means to enforce these new provisions – or chooses not to do so – then it is placed in the predicament of either refusing to participate and seeking to fund all applicable programs solely from its coffers, or accepting the award and still having to seek funding sources within itself in order to help those providers that will be forced to make drastic changes due to the reduction in funding. Either option places an extreme burden on the taxpayers of the State, and of course will serve to deny those the program was meant to serve and protect of much needed care and services.

IV. CONCLUSION

As set forth above, the results of implementing the proposed rules could be devastating to providers who will be forced to reduce or eliminate services and staff in response to a reduction or complete eradication of funding. The losers in either of these scenarios are not just the providers, but more importantly the millions of women and men who rely upon providers who are to be found in the roster of Title X funding recipients: low income members of society who do not have access to insurance plans or sufficient funds to seek adequate services to address needs for safe, effective contraception options, along with associated counseling and primary care services. What is proposed by the federal government in the new rules and regulations, not only serves to seriously debilitate access to quality care for a section of the population who are the intended beneficiaries of programs like Title X, but is also contrary to established principles of constitutional law.

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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

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.[1] 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.[2] 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.[3] 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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[1] Public Law No. 115-141, § 118, https://www.congress.gov/bill/115th-congress/house-bill/1625/text.

[2] 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).

[3] 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).

expansions—and another 35 percent have coverage through Medicaid and other public programs.[4]

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.[5] 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.[6] 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.[7]

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."[8] 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).[9] Access to family planning also leads to healthier

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[4] 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).

[5] 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).

[6] 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).

[7] 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.

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

[9] 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., 114th Cong. The Economic Benefits of Access to Family Planning, available at*

relationships, better health outcomes, and better parenting.[10] 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.[11] 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.[12]

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.

[10] *Id.*

[11] 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 (last accessed 7/17/18).

[12] 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.

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.[13] 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.[14] 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[15] and helped avert 13,600 unintended pregnancies.[16]

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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[13] *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.

[14] *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).

[15] *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).

[16] *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.[17]

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."[18] As required in 42 C.F.R. Part 59, all pregnancy counseling at Title X clinics in Vermont is nondirective.[19] 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."[20]

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.[21] And, the number of teen abortions occurring in Vermont has steadily declined.[22] This is consistent with the overall drop in abortion rates in Vermont and nationwide.[23] 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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[17] Office of Population Affairs, Title X Family Planning Annual Report: Vermont (April 2017) (on file with Vermont Attorney General's Office).

[18] 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).

[19] *Id.* at 34-35.

[20] *Id.* at 1.

[21] 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

[22] *Id.* at 40.

[23] 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.[24] Of those, 400 would have been teen pregnancies.[25] 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[26] and new HIV/AIDS diagnoses[27] 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.[28]

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.[29] Of that money, the majority ($7,520,000) was saved in annual maternity and birth-related costs as a result of contraceptive services.[30] An additional $215,000 was saved in annual miscarriage and ectopic pregnancy costs.[31] Tens of thousands of dollars in public health costs were saved from STI and cancer screening at Title X clinics.[32]

C. The Fatal Deficiencies in the Proposed Rule

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[24] *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).

[25] *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).

[26] 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.

[27] 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; *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.

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

[29] *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).

[30] *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).

[31] *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).

[32] *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."[33] While Congress is free to "make a value judgment favoring childbirth over abortion,"[34] 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.[35] 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.[36] Fourth, providers are required to assist in setting up these referral appointments—unless the patient wants an abortion.[37] 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.[38]

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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[33] 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.

[34] *Rust v. Sullivan*, 500 U.S. 173, 192 (1991) (quoting *Maher v. Roe*, 432 U.S. 464, 474 (1977)).

[35] 83 Fed. Reg. 25,531 (proposed § 59.14(a), (c)).

[36] 83 Fed. Reg. 25,531 (proposed § 59.14(b)).

[37] *Id.*

[38] 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).[39] 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."[40] 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."[41] Similarly, the Code of Ethics for Nursing requires nurses to give complete – not slanted – information to patients.[42]

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[39] 83 Fed. Reg. 25,531.

[40] "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).

[41] 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).

[42] Code of Ethics for Nursing, Provision 1.4, 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.[43] 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.[44] 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.[45] 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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[43] 83 Fed. Reg. 25,531 (§ 59.14(a); *see also*, § 59.14(c)).

[44] 83 Fed. Reg. 25,523.

[45] 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."[46] The report provided the agency's view on what are "acceptable and effective family planning methods and services."[47] 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.[48]

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[46] 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").

[47] 42 U.S.C. § 300(a).

[48] 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."[49] 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,"[50] while the proposed rule eliminates "medically approved" from the requirement that projects provide a broad range of family planning methods.[51] 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,"[52] while the proposed rule offers Title X funds to a clinic that chooses to offer only a single method of family planning.[53] The CDC report states that a provider, after administering a pregnancy test, should present "options counseling" and "appropriate referrals,"[54] 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.[55] 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."[56] Indeed, it fails even to acknowledge the existence of those

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[49] *Id.*

[50] CDC Report and Recommendations at 2.

[51] 83 Fed. Reg. 25,530 (proposed § 59.5).

[52] CDC Report and Recommendations at 2.

[53] 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).

[54] CDC Report and Recommendations at 14.

[55] 83 Fed. Reg. 25,531 (proposed § 59.14).

[56] CDC Report and Recommendations at 4.

recommendations. The proposed rule lacks the "reasoned analysis" the Department concedes is required.[57]

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.[58] 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."[59] 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.[60]

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.[61] 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.[62] This is the only evidence the Department cites of potential public confusion and commingling of funds, yet

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[57] 83 Fed. Reg. 25,505.

[58] 83 Fed. Reg. 25,532 (proposed § 59.15).

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

[60] 83 Fed. Reg. 25,507.

[61] *Id.*

[62] 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.[63] 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."[64] 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."[65] 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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[63] 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.

[64] 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.

[65] *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.[66]

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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[66] 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[67] 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

[67] *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.[68]

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

[68] 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.

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."[69] This requirement is supposedly meant to "promote holistic health and provide seamless care."[70] 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."[71]

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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[69] 83 Fed. Reg. 25,530.

[70] *Id.*

[71] *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."[72] 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.[73] 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."[74]

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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[72] *Id.*

[73] *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).

[74] 83 Fed. Reg. 25,530.

requirements as a grantee or sub-recipient."[75] 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"[76] 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.[77] 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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[75] 83 Fed. Reg. 25,514.

[76] 83 Fed. Reg. 25514.

[77] 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."[78] 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."[79] 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

[78] 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 (last accessed 7/13/18).

[79] 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."[80] 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.[81] 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.[82] 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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[80] 83 Fed. Reg. 25,519.

[81] *See* Attachment 1 (map of Washington counties without Title X services if organizations that also provide abortions are removed from Title X).

[82] 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.[83] 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.[84] 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.[85] This Vermont coalition "strongly

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[83] 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.

[84] 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.

[85] *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."[86] 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.[87] 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").

[86] *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

[87] 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).

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
Washington Attorney General

Maura Healey
Massachusetts Attorney General

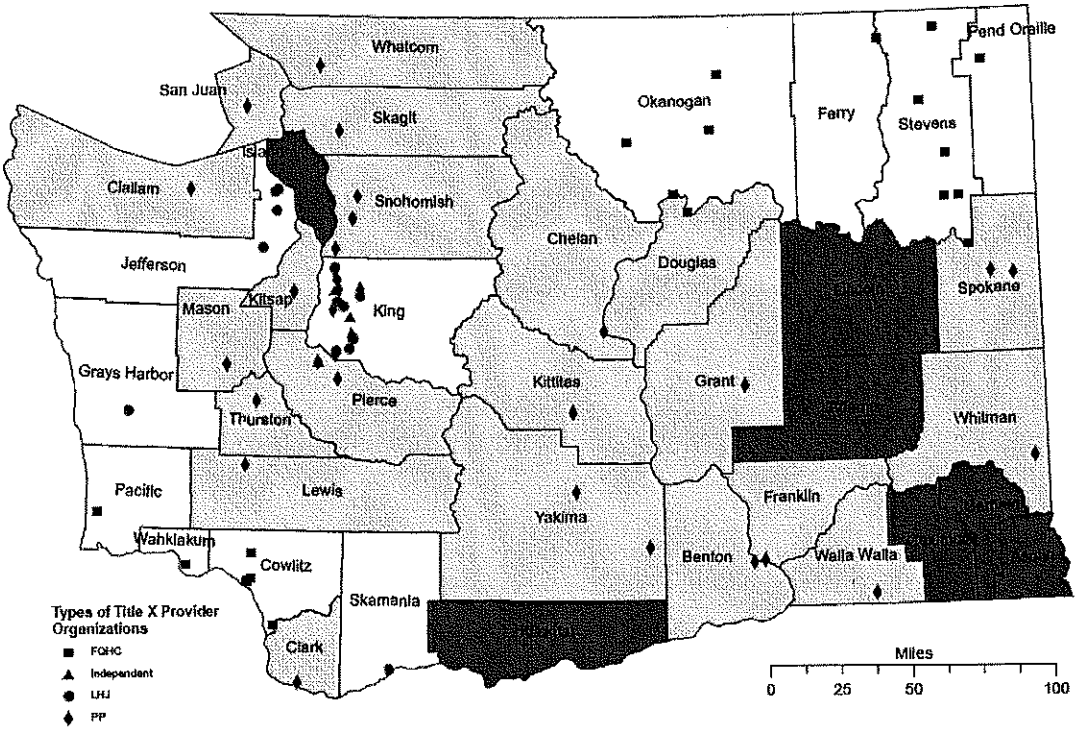
Ellen Rosenblum
Oregon Attorney General

Thomas J. Donovan, Jr.
Vermont Attorney General

Attachment 1

Washington State Counties Without Title X Services
if Organizations that also Provide Abortions are Removed from Title X

Dark shaded counties currently have no Title X provider,
Light shaded counties would have no provider if organizations that also provide abortions were removed from Title X



AMERICAN ACADEMY OF NURSING
transforming health policy and practice through nursing knowledge

July 26, 2018

Alex Azar, Secretary of Health and Human Services
Attention: Family Planning
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 716G
200 Independence Avenue SW
Washington, DC 20201

Valerie Huber, Senior Policy Advisor, Assistant Secretary for Health
Attention: Family Planning
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 716G
200 Independence Avenue SW
Washington, DC 20201

Diane Foley, Deputy Assistant Secretary for Population Affairs
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: HHS–OS–2018–0008, Proposed Rule for Compliance with Statutory Program Integrity Requirements

Dear Secretary Azar, Senior Advisor Huber, and Deputy Assistant Secretary Foley:

The American Academy of Nursing (the Academy) submits these comments[1] in response to the Department of Health and Human Services' (the Department's) proposed rule entitled Compliance with Statutory Program Integrity Requirements, which was published in the Federal Register on June 1, 2018.[2] The proposed rule would significantly and detrimentally alter the Title X Family Planning Program (Title X), the only federal program exclusively dedicated to providing low-income patients (including adolescents) with access to family planning and preventive health services and information, including health and cancer screenings, well woman exams, contraception and testing and treatment for sexually transmitted infections.

[1] Comments prepared by the Academy's Women's Health Expert Panel (Diana Taylor, chair)
[2] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502 (proposed Jun. 1, 2018) (to be codified at 42 C.F.R. pt. 59). https://www.regulations.gov/document?D=HHS-OS-2018-0008-0001

The **American Academy of Nursing** (the "Academy") serves the public and the nursing profession by advancing health policy, practice, and science through organizational excellence and effective nursing leadership. The Academy influences the development and implementation of policy that improves the health of populations and achieves health equity including advancing policies that improve ethical and evidence-based standards of care and women's access to safe, quality sexual/reproductive health care without interference with the patient-provider relationship. Specifically related to our comments on the proposed changes to Title X regulations, the Academy is on record supporting evidence-based policies that 1) ensure that all people have full access to affordable, sexual and reproductive health services,[3] 2) facilitate expansion of clinical knowledge and evidence-based women's preventive health services especially related to preventing unintended pregnancies,[4] and 3) assure that all women's health care, including reproductive health services, is grounded in scientific knowledge and evidence-based policies and standards of care.[5] [6]

Nurses are the most trusted professionals in the United Sates, and we have an ethical and moral responsibility to maintain this trust. Trust requires that health care providers give patients complete and accurate information about their health care so that patients can make meaningful, informed decisions about their own health. For nearly two decades, the Title X law has been clear—health care providers cannot withhold information from patients about their pregnancy options. **The Academy strongly opposes these proposed changes to the Title X program and urges rescission of the proposed rules.**

The proposed rules targets qualified health care providers and restricts access to medically accurate preventive health services

The proposed HHS/Title X rule further restricts state governments to apportion Title X funds based on a provider's ability to perform SRH services effectively and discriminates against certain "focused reproductive health providers" (e.g., Planned Parenthood) that have demonstrated successful outcomes in reducing unintended pregnancy, improving sexual and reproductive health (SRH) care[7], and providing essential preventive services. The proposed rule conflicts with established Medicaid/Medicare criteria for qualified providers based on professional and facility scope of practice and licensing.

Title X providers offer a broader range of SRH services (e.g., long-acting contraceptives such as IUDs, HPV vaccinations, preconception services) compared to primary care providers (community health centers (CHCs) or federally qualified health centers (FQHCs)) as evidenced by the HHS/Title X analysis of observational and experimentation data. With a loss of Planned

[3] Berg JA, Taylor D, Woods NF (2013). Where we are today: Prioritizing women's health services and health policy. A report by the Women's Health Expert Panel of the American Academy of Nursing. Nursing Outlook **61**(1): 5-15, http://dx.doi.org/10.1016/j.outlook.2012.06.004

[4] Berg JA, Olshansky E, Shaver J, Taylor D, Woods NF (2012). Women's health in jeopardy: Failure to curb unintended pregnancies: A statement from the American Academy of Nursing, Women's Health Expert Panel. *Nursing Outlook*, 60(3): 163-164. Web Access

[5] American Academy of Nursing, Writing Group of the Expert Panel on Women's Health. (1997). Women's Health and Women's Health Care: Recommendations for Transformative Changes in Health Care Services, Nursing Education and Practice. Nursing Outlook, 45(1), 7-15. Web Access

[6] Berg JA, Shaver J, Olshansky E, Woods NF, Taylor D (2013). A call to action: Expanded research agenda for women's health, 61(4):252, DOI: http://dx.doi.org/10.1016/j.outlook.2013.05.008

[7] Sexual and reproductive health (SRH) care has been defined to broaden the focus on family planning or maternal-child health. To produce optimal health outcomes, many experts believe SRH care should include the reproductive health of men and women throughout their lifespan and adolescents of both sexes with a focus on social determinants of health and health equity. Under this definition, a minimum package of SRH care accessible to all would include preconception care, contraception, pregnancy and unplanned pregnancy care, women's health/common gynecology care, genitourinary conditions of men, assessment of specialty gynecology problems including infertility, sexual health promotion, and coordination with public health and primary care services (WHO, 2011).

Parenthood (PP) health centers, which serve about one-third of the Title X patients (2 million individuals) across the country, empirical evidence indicates a decline in the use of the most effective methods of birth control and an increase in births among the women who previously used long-acting reversible contraception (Stevenson et al, 2016).[8] Comprehensive primary care providers from CHCs and FQHCs (who care for the millions of the most poor and vulnerable) rely on PP health centers to expand their SRH services since for every patient served by CHCs today, nearly three residents of low-income communities remain without access to primary health care.[9]

Recent reports from HHS clearly outline the evidence indicating that restricting specific providers of Title X services has harmful effects on access to gender-sensitive SRH services (e.g., pregnancy diagnosis/counseling, contraceptive services, basic infertility services, STD screening, and preconception health care) and is linked with increased pregnancy rates that differ substantially from rates of unaffected populations. Such restrictions also impact the education and training of health professionals and front-line health workers that provide these services since focused SRH providers serve as clinical training sites for medical and nursing students.

Nurses (primarily nurse practitioners, nurse midwives and public health nurses) have been the mainstay of SRH care in both community health clinics and Title X clinics and are crucial providers for vulnerable, low-income and ethnic populations. Nurse practitioners (NPs) comprise about 75% of clinicians employed by PP affiliates.[10] With closures of PP health centers, the lack of clinical training sites for NP students (and other health professionals) who will provide SRH services results in a workforce that varies widely in SRH exposure, knowledge, and clinical skill and reduces the pipeline of trained frontline clinicians.[11]

Planned Parenthood health centers are often located in communities where there is little to no access to health care, especially reproductive health care that offers a broad range of services. In fact, Title X services provided by PP health centers frequently serve as the sole health care source for underinsured, uninsured and low-income women in these communities.[12] Without ease of access to the most effective contraception methods available, the incidence of unintended pregnancies increases significantly (statistic is referenced in previous DHHS reports), and at a time when prematurity is on the rise along with the potential for additional global epidemics affecting maternal and fetal health is of particular concern, ease of access to contraception should be increased rather than barriers created.

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[8] Stevenson A, Flores-Vazquez IM, Allgeyer RL, Schenkkan P, Potter JE (2016). The effect of removal of Planned Parenthood from Texas women's health program. Available at https://www.nejm.org/doi/full/10.1056/nejmsa1511902

[9] Rosenbaum S (2015). Planned Parenthood, community health centers, and women's health: Getting the facts right. Health Affairs Blog, http://healthaffairs.org/blog/2015/09/02/planned-parenthood-community-health- centers-and-womens-health-getting-the-facts-right/

[10] Bednash G, Worthington S, and Wysocki S, "Nurse Practitioner Education: Keeping the Academic Pipeline Open to Meet Family Planning Needs in the United States," *Contraception*, 80, 2009, 409–411.
Fowler, C., S. Lloyd, J. Gable, et al., Family Planning Annual Report: 2010. Research Triangle Park, NC: National Summary RTI International, September 2011.

[11] Auerbach DI., Pearson ML, Taylor D, Battistelli M, Sussell J, Hunter LE, Schnyer C, Schneider EC. Nurse Practitioners and Sexual and Reproductive Health Services: An Analysis of Supply and Demand. Santa Monica, CA: RAND Corporation, 2012. http://www.rand.org/pubs/technical_reports/TR1224.

[12] Flynn, A. (2013). The Title X factor: Why the health of America's women depends on more funding for family planning. The Roosevelt Institute. Accessed on 9/28/16 from www.ROOSEVELTINSTITUTE.ORG

The proposed rule would force providers to violate professional ethics and harms the patient-provider relationship.

High-quality health care is founded on complete, accurate, and unbiased information and relies on a relationship of the utmost trust between a patient and their health care professional. Currently, consistent with the highest professional and ethical standards of care, Title X-funded providers must offer pregnant patients counseling on and referrals for all of their options, including adoption, prenatal care, and abortion.[13] [14] However, the proposed rule would inject politics and ideology into the examination room by prohibiting providers from giving patients information on how and where to access abortion. This restriction would undermine the health professional's ethical obligations and hinder open and honest conversations between patients and their providers.

As the most "honest and ethical" profession, nurses guard against any erosive policy that hinders patients from making meaningful, informed decisions about their own health, or that blocks access to care. The Code of Ethics for Nurses outlines that the nurse's primary commitment is to the patient, whether an individual, family, group, community, or population. This proposed rule interferes with that relationship and violates basic ethics of the profession.[15]

In addition, the Code of Ethics for Nurses stipulates that patients have the right "to be given accurate, complete, and understandable information in a manner that facilitates an informed decision,"[16] and the American Nurses Association's position is that health care providers must "share with the client all relevant information about health choices that are legal and to support that client regardless of the decision the client makes."[17]

These ethical obligations recognize that a patient's informed consent and access to medically appropriate care is dependent upon both having all treatment options presented and referrals to appropriate providers. In short, the proposed rule places Title X providers in a situation whereby they would have to violate their professional ethics in order to participate in Title X, which is an untenable position for any health care provider.

The proposed rule undermines the decades long successes of the Title X program and the HHS goals and past efforts

In 1999, the Centers for Disease Control and Prevention (CDC)—an HHS division—declared family planning as one of the 10 greatest public health achievements of the twentieth century.[18] In a

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[13] Christina Fowler, et al., *Family Planning Annual Report: 2016 National Summary,* RTI International (Aug. 2017), available at https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf ("FPAR 2016").

[14] Simmonds, K. and F. E. Likis (2011). Caring for women with unintended pregnancies." Journal of Obstetric, Gynecologic, & Neonatal Nursing **40**(6): 794-807. Cappiello, J., M. W. Beal, et al. (2011). Applying ethical practice competencies to the prevention and management of unintended pregnancy. Journal of Obstetric, Gynecologic, & Neonatal Nursing **40**(6): 808-816.

[15] American Nurses Association. (2016). The nurse's role in ethics and human rights: Protecting and promoting individual worth, dignity, and human rights in practice settings (position statement). Silver Spring, MD: Author. https://www.nursingworld.org/~4af078/globalassets/docs/ana/ethics/ethics-and-human-rights-protecting-and-promoting-final-formatted-20161130.pdf

[16] American Nurses Association. (2015). *Code of ethics for nurses with interpretive statements*. Provision 1.4. Silver Spring, MD. Retrieved from http://www.nursingworld.org/code-of-ethics.

[17] American Nurses Association. *Position Statement: Reproductive Health* (1989, 2010). https://www.nursingworld.org/practice-policy/nursing-excellence/official-position-statements/id/reproductive-health/

[18] CDC (Centers for Disease Control and Prevention). 1999. Ten great public health achievements: United States, 1900–1999. Morbidity and Mortality Weekly Report 48(12):241–243.

2009 review of the HHS Family Planning Program, an Institute of Medicine review panel[19] reported the role and history of family planning policies and programs in the United States: The provision of family planning services has important benefits for the health and well-being of individuals, families, communities, and the nation as a whole. Planning for families—helping people have children when they want to and avoid conception when they do not—is a critical social and public health goal. The federal government has a responsibility to support the attainment of this goal. There is an ongoing need for public investment in family planning services, particularly for those who are low income or experience other barriers to care.

The federal government's continuing recognition of the contribution of family planning and reproductive health to the public well-being is evidenced by their inclusion in the nation's top health priorities as outlined in the HHS Strategic Plan and Healthy People 2010. A 2015 report of federally funded family planning programs demonstrated that Title X–supported services alone helped women to avoid more than 822,000 unintended pregnancies (out of 1.3 million unintended pregnancies avoided by all safety-net family planning centers), thus preventing 278, 000 abortions (out of 453,400 abortions avoided by safety-net family planning centers overall).[20] Along with yielding important public health benefits, every public dollar invested in Title X saves $7.[21] In spite of this history of successful public health outcomes supported by decades of evidence, current government policy and regulatory proposals will deal a devastating blow to safety-net family planning providers and the communities who rely on them.

The nation's 4 million nurses are deeply committed to ensuring that all people have access to affordable health care, including preventive services as intended by the Affordable Care Act and the Title X programs. Nurses know and understand the importance of women having seamless and comprehensive reproductive health care to protect their health and ability to work, both of which are essential for the economic security of families across America.[22] Specifically, the **American Academy of Nursing is opposed to the following changes in the Title X program**:

- Imposes new rules that are designed to make it impossible for millions of patients to get birth control or preventive care from reproductive health care providers like Planned Parenthood.
- Restricts doctors, nurses, hospitals, and community health centers who could no longer refer their patients for safe, legal abortion.
- Removes the guarantee that people get full and accurate information about health care from their health care providers.
- Creates a new policy stipulating that Title X projects do not have to provide every effective and acceptable method of birth control. This is a sharp departure from the way the program has been operating, where HHS put an emphasis on ensuring women have access to all 18 FDA-approved contraceptive methods.

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[19] IOM (Institute of Medicine). 2009. A Review of the HHS Family Planning Program: Mission, Management, and Measurement of Results. Washington, DC: The National Academies Press. Available at https://www.nap.edu/download/12585

[20] Frost JJ, Frohwirth LF, Blades N, Zolna MR, Douglas-Hall A, Bearak J. Publicly funded contraceptive services at US clinics, 2015. Guttmacher Institute. 2017. Available at: https://www.guttmacher.org/ report/publicly-funded-contraceptiveservices-us-clinics-2015.

[21] Sonfield A. Beyond preventing unplanned pregnancy: the broader benefits of publicly funded family planning services. Guttmacher Policy Rev. 2014;17(4): 2–6. Available at: https://www.guttmacher.org/gpr/2014/12/beyondpreventing-unplanned-pregnancybroader-benefits-publicly-fundedfamily-planning#table3

[22] Berg JA, Taylor D, Woods NF (2013). Where we are today: Prioritizing women's health services and health policy. A report by the Women's Health Expert Panel of the American Academy of Nursing. Nursing Outlook 61(1): 5-15, http://dx.doi.org/10.1016/j.outlook.2012.06.004

- Allows women to receive family planning services under the Title X program if their employer refuses to cover contraceptive care based on religious or moral objections, regardless of their income. Redefining "low income" to include this population will divert scarce resources away from serving the low-income patients at the heart of Title X's purpose.

Final Statements

As the nation's health policy center, the Department of Health and Human Services (HHS) policies and activities must be firmly based on scientifically valid and appropriate terms and evidence. Instead, the Department makes several false and misleading statements in these proposed rules to undermine the Title X program. Furthermore, these rules prioritize ideology over evidence-based professional recommendations and the government's own independent evaluations.

The proposed Title X rules undermine the decades long successes of the Title X program and HHS goals by eroding access to sexual and reproductive health care and individual freedom to make reproductive health decisions. The Academy unequivocally opposes the Departments' effort to undermine the Title X program. We urge HHS to remain religiously and morally neutral in its funding, policies, and activities to ensure that individuals receive do not receive a limited scope of services and that the ethical obligations of healthcare providers are not compromised.

We stand in opposition to the proposed rule and any other policy proposals that interfere with the patient-provider relationship, violate professional ethics, and limit access to high-quality, affordable family planning care under the Title X program.

Sincerely,

Karen S. Cox

Karen S. Cox
President
American Academy of Nursing

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of June, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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