

National  
**Family Planning**  
& Reproductive Health Association

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US Department of Health and Human Services  
Attention: Family Planning  
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Washington, DC 20201

**Attn: "Compliance with Statutory Program Integrity Requirements" NPRM, RIN 0937-ZA00**

The National Family Planning & Reproductive Health Association (NFPRHA) is pleased to provide comments on the US Department of Health and Human Services' (HHS) notice of proposed rulemaking ("2018 NPRM" or "NPRM"), "Compliance with Statutory Program Integrity Requirements," RIN 0937-ZA00.

NFPRHA is a national, nonprofit membership organization that advances and elevates the importance of family planning in the nation's health care system and promotes and supports the work of family planning providers and administrators, especially those in the safety net. NFPRHA envisions a nation where all people can access high-quality, client-centered, affordable, and comprehensive family planning and sexual health care from providers of their choice.

NFPRHA represents more than 850 health care organizations and individuals in all 50 states, the District of Columbia, and the territories. NFPRHA's organizational members include state, county, and local health departments; private, nonprofit family planning organizations (including Planned Parenthood affiliates and others); family planning councils; hospital-based clinics; and federally qualified health centers. NFPRHA's members operate or fund a network of more than 3,500 health centers that provide high-quality family planning and related preventive health services to more than 3.7 million low-income, uninsured, or underinsured individuals each year.

NFPRHA's members include more than 80% of the current Title X grantees and, similarly, a large segment (66%) of Title X subrecipients. A central part of NFPRHA's work, as the professional and advocacy organization for publicly funded family planning organizations, involves the education, training, and support of Title X providers, and representation of their interests nationally, to enable them to effectively and efficiently provide high-quality family planning care to Title X patients and meet all requirements of the Title X program.

NFPRHA believes the 2018 NPRM will damage this vital safety-net program and severely diminish, rather than increase, the public health benefits from the limited funding available to it. Although the proposed rule in many ways is designed to target abortion-related activities and entities that provide abortion care, it is not limited to such activities and/or providers and would have far-reaching implications for all Title X-funded entities, the services they provide, and the ability of patients to receive the confidential family planning and related sexual health care they seek. The proposed rule provides no coherent rationale nor

any evidence for why this proposed rule is needed; fails to consider the substantial harms the proposed rule would cause to the Title X providers, their patients, and the Title X program itself; is vague and internally inconsistent in many respects; does not properly consider or estimate the significant costs that would result from the proposed rule; and includes provisions that exceed HHS's statutory authority and conflict with governing law, including not only Title X but also constitutional limitations. Therefore, NFPRHA urges HHS to withdraw the 2018 NPRM.

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### **The 2018 NPRM Would Undermine the Core Purpose of the Title X Program, Which is to Make Modern Medical Methods of Acceptable and Effective Contraception Available to All, Regardless of Income**

Title X was expressly created in 1970 to make “comprehensive family planning services readily available to all persons desiring such services.”<sup>1</sup> Specifically, many low-income women had more children than they desired, because both the pill and the other most effective contraceptive method at the time, the copper intrauterine device (IUD), were both expensive medical methods. Congress enacted Title X to help those “medically indigent” persons – low-income individuals who desired but could not access the contraceptive methods that more affluent members of society could, and who were:

forced to do without, or to rely heavily on the least effective nonmedical techniques for fertility control unless they happen to reside in an area where family planning services are made readily available by public health services or voluntary agencies.<sup>2</sup>

For this reason, the statute requires Title X projects to “offer a broad range of acceptable and effective family planning methods and services,” and prioritizes a project’s capacity to make rapid and effective use of federal funds for family planning. The “broad range” of family planning methods that Title X-funded projects offer must “includ[e] the provision of prescription and nonprescription contraceptive drugs and devices.”<sup>3</sup> The current regulations, which have been in effect for decades, reinforce this central statutory purpose, requiring Title X projects to provide “medical services related to family planning (including physician’s consultation, examination[,] prescription, and continuing supervision, laboratory examination, contraceptive supplies” and “a broad range of acceptable and effective **medically approved** family planning methods” and services.<sup>4</sup>

The 2018 NPRM fundamentally weakens the ability of the Title X program to achieve its central mission of making modern methods of acceptable and effective contraception available to all who desire them. As discussed below, it weakens (or eliminates entirely) the requirement that Title X entities and projects provide a broad range of acceptable and effective contraceptive methods, which is exacerbated by the NPRM’s attempts to proscribe the bulk purchasing of contraceptives as a permissible Title X expense. Combined with its attempts to favor “non-traditional Title X partnering organizations” and “innovative ways to provide services” without ensuring that those entities or approaches will continue to provide access to effective contraceptive methods, the NPRM will undermine Title X’s core mission.

Specifically, the NPRM in myriad places weakens the assurances that Title X patients will be able to obtain contraceptive services. For example:

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<sup>1</sup> *Planned Parenthood Federation of America, Inc. v. Heckler*, 712 F.2d 650, 651 (D.C. Cir. 1983) (quoting S. REP. NO. 91-1004, at 2 (1970)).

<sup>2</sup> S. REP. NO. 91-1004, at 9 (1970).

<sup>3</sup> *Heckler*, 712 F.2d at 651-52. See also 42 C.F.R. § 59.5(b)(1).

<sup>4</sup> 42 C.F.R. § 59.5 (emphasis added).

- Section 59.2 of the 2018 NPRM proposes to define “family planning” to mean “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).<sup>5</sup>

- Section 59.5(a)(1) of the proposed rule, which details the requirements that must be met by a Title X project, eliminates the term “medically approved” from the longstanding regulatory requirement that projects provide “a broad range of acceptable and effective medically approved family planning methods.”<sup>6</sup>
- Section 59.5(a)(1) replaces the cautionary, caveat language of the current regulations that organizations that only provide a single method of family planning may still participate in a Title X project, but only if the entire project offers a broad range with a more permissive, even encouraging, directive that states: (i) “projects are not required to provide every acceptable and effective family planning method or service” and (ii) “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.”<sup>7</sup>
- While Title X projects currently offer information and counseling about adoption, and referrals upon request, the proposed rule would add adoption services as a type of “infertility service” that can be offered as a means of satisfying an entity’s obligation to provide a “broad range of acceptable and effective family planning methods and services.”<sup>8</sup> Today, Title X projects provide information and counseling about adoption, as well as referrals, upon request to pregnant patients in the context of nondirective options counseling. But the NPRM appears, without statutory authority, to expand Title X to cover actual adoption services. To the extent that this proposal contemplates the social services necessary to assist in placing children for adoption and facilitating adoptions, those complex and costly services are not only beyond Title X’s statutory scope but would redirect a large amount of Title X funds.

These changes appear to do two key things. First, the changes attempt to impermissibly expand the types of methods and services that a Title X project can offer to satisfy the “broad range” requirement. Second, the changes encourage more single-method/service or limited-method/service providers within a Title X project.<sup>9</sup>

When put together, the changes in the 2018 NPRM seem to contemplate that it could be acceptable for a Title X project to, for example, provide only natural family planning and other fertility awareness-based

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<sup>5</sup> Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. 25502, 25529 (proposed June 1, 2018) (to be codified at 42 C.F.R. pt. 59).

<sup>6</sup> 83 Fed. Reg. at 25530.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> *See, e.g.*, 83 Fed. Reg. at 25516.

methods (and perhaps a single type of non-medical contraception, such as condoms) along with abstinence-only-unless-married education for adolescents and adoption services and to include multiple service sites that provide only some of these services.

This is a drastic change that would fundamentally alter the Title X program, thwart its primary goal, and leave Title X clients without access to critical health care services.<sup>10</sup> Title X-funded health centers served four million people in 2016, 88% of whom were low-income, and almost two-thirds of whom lived in poverty.<sup>11</sup> In 2015, Title X health centers provided contraceptive methods that helped women prevent approximately 820,000 unintended pregnancies.<sup>12</sup> In 2016, 62% of Title X's female patients were utilizing Title X methods of contraception classified by HHS and the Centers for Disease Control and Prevention (CDC) as "most effective" or "moderately effective" rather than the "less effective" methods such as condoms or fertility awareness-based methods. The provision of these services saves the public billions of dollars in health care costs each year.<sup>13</sup> As discussed in further detail below, directing resources away from contraception will result in more unintended pregnancies and unplanned births, at a significant cost to taxpayers and to public health. For all of these reasons, HHS should withdraw the proposed rule and maintain Title X's current emphasis on a full range of effective family planning care, including the most advanced contraceptives.

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### **The 2018 NPRM Unjustifiably Eliminates Title X's Longstanding Legal and Ethical Requirement for Nondirective Options Counseling, including All Referrals upon a Patient's Request**

The proposed rule's drastic changes to pregnancy counseling by Title X providers violate Congress' explicit, repeated mandates; contradict central principles of medical ethics; attempt to enlist clinicians in deceiving and delaying patients who seek information about or access to abortion providers; and are not in any way sufficiently justified by the NPRM. These changes, if adopted, will drive a number of Title X providers from the program, shrink and diminish the effectiveness of the Title X network, harm patients' health, attempt to exert coercion over and impose dignitary harms on patients, and damage the trusted clinician-patient relationships for which Title X is known.<sup>14</sup> Moreover, these distorted counseling parameters are in no way required for "program integrity" purposes. At the request of a patient with a positive pregnancy test or confirmed pregnancy, nondirective pregnancy options counseling, including

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<sup>10</sup> See, e.g., *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs* ("QFP"), 63 RECOMMENDATIONS AND REPORTS 1 (2014), <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>; Center for Disease Control and Prevention, *Effectiveness of Family Planning Methods* (2011), [https://www.cdc.gov/reproductivehealth/contraception/unintendedpregnancy/pdf/Contraceptive\\_methods\\_508.pdf](https://www.cdc.gov/reproductivehealth/contraception/unintendedpregnancy/pdf/Contraceptive_methods_508.pdf).

<sup>11</sup> Christina Fowler et al., *Family Planning Annual Report: 2016 National Summary* ("FPAR"), RTI INTERNATIONAL 1, 21 (August 2017), <https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf>.

<sup>12</sup> Jennifer J. Frost et al., *Publicly Funded Contraceptive Services at US Clinics, 2015*, GUTTMACHER INSTITUTE 10 (2017).

<sup>13</sup> 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 THE MILBANK Q. 667, 703 (2014), [https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/MQ-Frost\\_1468-0009.12080.pdf](https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/MQ-Frost_1468-0009.12080.pdf).

<sup>14</sup> Kinsey Hasstedt, *Why We Cannot Afford to Undercut the Title X National Family Planning Program*, 20 GUTTMACHER POLICY REVIEW 21-22 (2017), <https://www.guttmacher.org/gpr/2017/01/why-we-cannot-afford-undercut-title-x-national-family-planning-program> ("Title X-funded providers offer high-quality and timely contraceptive care."); Marion W. Carter et al., *Four Aspects of the Scope and Quality of Family Planning Services in U.S. Health Centers: Results From A Survey of Health Center Administrators*, 94 J. CONTRACEPTION 340 (2016) ("[T]he scope and quality of [] family planning services was relatively high, particularly among Planned Parenthood clinics and Title X-funded centers."); Jennifer Frost et al., *Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Women's Health Care Needs*, 22 WOMEN'S HEALTH ISSUES 519, 525 (2012), (women, including Title X patients, prefer to visit specialized family planning clinics because these clinics have respectful staff who are knowledgeable about women's health).

referrals, is a **required** part of Title X programs. Therefore, all proposed efforts to alter or limit the current regulation outlining Title X's required nondirective pregnancy options counseling (§ 59.5(a)(5)), should be abandoned, and that regulation should be maintained in full.

### **Congress Mandates that All Title X Pregnancy Counseling be Nondirective and HHS Has No Authority to Contradict that Mandate, under Which Patients are Entitled to a Discussion of All Options**

Congress explicitly understands that testing for, information about, and counseling about pregnancy regularly occurs as part of Title X programs and has mandated for decades that, in Title X projects, "all pregnancy counseling shall be nondirective."<sup>15</sup> The current § 59.5(a)(5) implements that legislative mandate by requiring all Title X projects "to 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." It 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."

Contrary to the proposals in the NPRM, HHS has no regulatory authority to depart from Congress' requirement of this nondirective counseling and would violate Congress' clear specifications for the use of Title X funds if it were to adopt the proposed §§ 59.5(a)(5), (b)(8), 59.14, and 59.16. As explained below, however, it is not only congressional direction but medical ethics and other requirements of appropriate care that show these proposals should be abandoned. Yet, the NPRM does not consider these factors at all, gives them inadequate weight, or tries to dismiss them with irrational distinctions, to attempt to justify improper new regulations dictating the information and referrals that can be provided to pregnant Title X patients. As HHS has recognized "[t]he 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 ... [T]his policy is also consistent with the prevailing medical standards recommended by national medical groups such as the American College of Obstetricians and Gynecologists (ACOG) and the American Medical Association."<sup>16</sup>

And as HHS has explained, "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."<sup>17</sup> Indeed, as the NPRM itself notes, Congress has explained that "nondirective counseling is the provision of information on all available options without promoting, advocating, or encouraging one option over another."<sup>18</sup>

The 2018 NPRM fails to describe or establish evidence of any proper and sufficient justification for abandoning the strong rationale that HHS itself has repeatedly laid out for the longstanding requirement of accurate and complete nondirective options counseling, including when it adopted the current version of

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<sup>15</sup> This language was first included in Omnibus Consolidated Rescissions and Appropriations Act of 1996. Public Law 104-134 (1996), and has been included in every appropriations act since that includes the Department of Health & Human Services; see also Angela Napili, *Title X (Public Health Service Act) Family Planning Program*, CONG. RESEARCH SERV. (2017), <https://fas.org/sgp/crs/misc/RL33644.pdf>.

<sup>16</sup> Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, 65 Fed. Reg. 41270, 41273 (proposed July 3, 2000) (citations omitted).

<sup>17</sup> *Id.*

<sup>18</sup> 83 FR 25512 n. 41 (quoting Family Planning Amendments Act of 1991, 138 Cong. Rec. H2822-02 (April 30, 1992)).

the Title X regulations in 2000.<sup>19</sup> Nor, given the express congressional mandate that all pregnancy counseling be nondirective, could it do so.

### **Principles of Medical Ethics and HHS's Own Standards Require Nondirective Counseling, including Referrals to Other Providers once It is Determined Patients' Needs Go beyond Title X**

Upon confirmation of a diagnosis or condition, medical providers have a duty to give patients complete information about all care options.<sup>20</sup> ACOG advises that after a pregnancy diagnosis, “[t]he patient should be fully informed in a balanced manner about all options, including raising the child herself, placing the child for adoption and abortion.”<sup>21</sup> When the care that patients seek is beyond the scope of clinicians’ practice, clinicians “fulfill their obligations to patients through referral to other professionals who have the appropriate skills and expertise to address the situations.”<sup>22</sup>

The leading national clinical standards of care for family planning, developed by HHS’s Office of Population Affairs (OPA) and the CDC and published as “Providing Quality Family Planning Services” ( QFP) reflect these ethical principles by instructing that “[pregnancy] test results should be presented to the client, followed by a discussion of options and appropriate referrals. Options counseling should be provided in accordance with the recommendations from professional medical associations, such as ACOG and AAP.”<sup>23</sup> The QFP, which currently governs Title X providers through HHS’s Program Guidelines, requires care that “is respectful of, and responsive to, individual client preferences, needs, and values; client values guide all clinical decisions.”<sup>24</sup>

### ***The proposed rule leaves unclear whether providers can mention abortion in pregnancy counseling in any manner and ignores non-physician providers***

In violation of these standards and Congress’ instructions, the proposed rule would adopt a new and absolute prohibition on Title X projects “refer[ring] for” or “presenting abortion as a method of family

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<sup>19</sup> See, e.g., 65 Fed. Reg. at 41270-75.

<sup>20</sup> See, e.g., Lois Snyder, *The Physician and the Patient: Decisions about Reproduction*, AMER. COLL. OF PHYSICIANS ETHICS MANUAL (6th ed. 2012), <https://www.acponline.org/clinical-information/ethics-and-professionalism/acp-ethics-manual-sixth-edition/acp-ethics-manual-sixth-edition>; American Medical Association (AMA) Code of Medical Ethics § 2.1.3 (“[W]ithholding information without the patient’s knowledge or consent is ethically unacceptable.”); *Counseling the Adolescent about Pregnancy Options*, 101 PEDIATRICS 938, 938-40 (1998), <http://pediatrics.aappublications.org/content/pediatrics/101/5/938.full.pdf> (“When consulted by a pregnant adolescent pediatricians should be able to make a timely diagnosis and help the adolescent understand her options and act on her decision to continue or terminate her pregnancy.”); *Guidelines for Ethical Conduct for the PA Profession*, AMER. ACAD. OF PHYSICIAN ASSISTANTS I (2013), <https://www.aapa.org/wp-content/uploads/2017/02/16-EthicalConduct.pdf> (“[Physician Assistants] have an ethical obligation to provide balanced and unbiased clinical information about reproductive health care.”).

<sup>21</sup> American College of Obstetricians and Gynecologists (ACOG), *GUIDELINES FOR WOMEN’S HEALTH CARE: A RESOURCE MANUAL* 719-20 (4th ed. 2014).

<sup>22</sup> *Id.* at 100-01; see also *id.* at 82-83 (“Once a physician is aware that a patient’s medical needs may fall outside” his or her practice, “appropriate care should be arranged.”); AMA Code of Medical Ethics § 1.2.3 (“Physicians’ fiduciary obligation to promote patients’ best interest and welfare can include ... referring patients to other professionals to provide care.”); World Medical Association, *International Code of Medical Ethics* (2018) (“Whenever an examination or treatment is beyond the physician’s capacity, he/she should consult with or refer to another physician who has the necessary ability.”); *Counseling the Adolescent about Pregnancy Options*, 101 PEDIATRICS 938, 938-40 (1998) (“Pediatricians ... should be prepared to support the adolescent in her decision or refer her to a physician who can.”).

<sup>23</sup> QFP at 14.

<sup>24</sup> *Id.* at 4; see also *id.* at 14 (“Referral to appropriate providers of follow-up care should be made at the request of the client, as needed.”).

planning,” in the context of counseling for pregnant Title X patients or otherwise.<sup>25</sup> As the NPRM makes clear throughout, it aims to abolish the requirement of nondirective options counseling.<sup>26</sup>

At the same time, and confusingly, the preamble section of the NPRM states: “Recognizing, however, the duty of a physician to promote patient safety, a doctor would be permitted [though not required] to provide nondirective counseling on abortion” (83 FR 25507). It is unclear how a physician could provide “nondirective counseling” on abortion without “presenting” the option of abortion, in apparent violation of the proposed § 59.5(a)(5). It is also unclear whether such permitted counseling might be limited to safety information or to negative information about abortion. This confusing and unexplained conflict between the preamble and the actual text of the proposed regulation at a minimum requires clarification by HHS.

In addition, the statement in the preamble is limited to physicians. Does this mean HHS is allowing some statements about abortion only by physicians? There is no justification for allowing doctors but not other medical professionals to provide certain information to Title X patients. Counseling pregnant patients is often performed by and is well within the capabilities of Title X’s primary provider type: advanced practice clinicians.<sup>27</sup> If only physicians are permitted to provide some form of nondirective options counseling, this will effectively prevent such counseling in numerous Title X facilities and for many Title X patients. Physicians make up less than a quarter by type of clinical service providers within Title X, and in some regions, only 8% are physicians.<sup>28</sup> If HHS were to limit options counseling to physicians, which it should not do, that would significantly raise the cost of providing such care and substantially reduce the number of patients with those needs who could be served without any justification for doing so.

***The agency’s rationale for barring referrals is unsupported and contradicted by other portions of the Title X rule and law governing the Title X program***

The NPRM bars referrals for abortion erroneously arguing that because post-conception care is outside the bounds of Title X programs and any options counseling must be nondirective, referrals for abortion must therefore be barred to maintain “program integrity” and to avoid any “directive” counseling of Title X patients when they are confirmed pregnant. HHS claims that “[r]eferrals for abortion are, by definition, directive” and therefore contends that Title X projects can never provide abortion referral and be in compliance with Congress’ mandate, discussed above, that “all pregnancy counseling” in Title X projects “shall be nondirective.”<sup>29</sup> Yet, illogically, HHS finds no violation of the congressional mandate in its proposal here to uniquely **require** referrals for prenatal and adoption services and to require information to protect “the health of the unborn child” for all pregnant patients an approach which is directive and violative of federal law. Referrals for abortion upon the request of the patient are not directive in the context of the congressionally required Title X pregnancy counseling because the Title X provider offers medically accurate, neutral information and referral access for all three options, in accordance with direction from the patient.

In addition, it bears noting that patient referrals to other providers for all kinds of health services that are **not** included in the Title X program are an ordinary part of Title X care. Section 59.5(b)(8) of the current Title X regulations directs projects to coordinate and provide for referrals with all kinds of health service

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<sup>25</sup> 83 Fed. Reg. at 25530-32

<sup>26</sup> *Id.* at 25506 (erroneously arguing that requirement to include abortion information and referral within nondirective options counseling for pregnant patients “is inconsistent” with the Title X statute).

<sup>27</sup> 2016 FPAR Ex. 30.

<sup>28</sup> *Id.*

<sup>29</sup> *See, e.g.,* Consolidated Appropriations Act of 2018, Pub. L. No. 115-141, Div. H, Title II, 716–717 (2018).

providers in their community.<sup>30</sup> Neither HHS's definition of family planning within Title X projects as not including "post-conception care," nor the statutory requirement that "[n]one of the funds appropriated under this title shall be used in programs where abortion is a method of family planning,"<sup>31</sup> stand in the way of Title X clinicians' provision of patient-requested referrals to abortion care **outside** of the Title X program. Section 59.5(b)(8) and other sections of the existing regulations should not be amended to attempt to carve out and thwart pregnant patients' requests, when the required nondirective options counseling occurs, for abortion information and referrals to that care outside of the Title X program.

***The proposed rule involves clinicians in misleading patients and provides arbitrary and unethical limits on factual information they might provide***

Communication between clinicians and patients is further unjustifiably compromised by § 59.14(a) of the proposed rule. Section 59.14(a) provides that, if a pregnant Title X patient "clearly states that she has already decided to have an abortion," 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)."<sup>32</sup> The list, if provided, "shall not identify the providers who perform abortion as such."<sup>33</sup> All other pregnant patients, if they ask for referral information, are to be provided a similar list, but that one must exclude all abortion providers. Like the counseling limitation discussed above, this provision suffers from all of the same negative effects of limiting communication with patients solely to doctors, rather than any appropriate personnel.

Moreover, this proposed regulation goes several steps further in inappropriately limiting doctors or other clinicians' communications to such misleading and incomplete lists. When a patient "clearly" tells the physician that the patient "has already decided to have an abortion" and asks for further information on that desired next step, the proposed rule would only allow an unlabeled list of solely "comprehensive health service providers." The flaws and incorrect assumptions in this approach are legion, and the NPRM fails to discuss or even acknowledge most of them.

First, the meaning of "comprehensive health service providers" and the range necessary to be "comprehensive" is unclear, but even if this only means comprehensive prenatal care (and not comprehensive primary health or other services as well), in many parts of the country, the clinician would not have any "comprehensive health service providers" that "also provide abortion" to include on that list. In fact, the NPRM acknowledges that abortions are "increasingly performed at" more specialized health centers than at the "comprehensive health service providers" that might go on this list.<sup>34</sup> To give just one example, there are currently approximately six states with only a single abortion provider; none of those facilities currently provide prenatal care or primary care services. Thus, for women in those six states, even if they specifically state that they have decided to have an abortion, a physician cannot put the state's only abortion provider on the list of resources the physician provides to the patient. The same is true for women in countless other regions throughout the country. Contrary to the proposed rule's limited approach, Title X clinical counseling, including full factual information about and referral to providers, should focus on the real options in a region, not "comprehensive health service providers" providing abortion that do not exist.

Second, the Title X providers are directed that their only permitted, concrete response to even a clear statement that the patient has already decided on an abortion and a request for factual information about

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<sup>30</sup> Cf. 42 C.F.R. §§ 50.5(b) (1), (2) (2018).

<sup>31</sup> 83 Fed. Reg. at 25502.

<sup>32</sup> *Id.* at 25531.

<sup>33</sup> *Id.*

<sup>34</sup> *Id.* at 25507.



local providers or a referral to one of them, is to hand the patient a piece of paper with this unlabeled list. Even if there is an abortion provider that fits the extreme and unjustified limitation of being part of a “comprehensive health service provider,” that list cannot identify the provider as offering abortion services and **must** include other comprehensive health service providers that do not offer abortion. Thus, the only information the provider might be able to share, in response to a clear patient request and expectation of assistance, is a misleading list with parameters that remain unknown to patients. Given that the proposed rule itself explicitly permits a list with one or more abortion provider(s) on it to be given to some patients, it is irrational, arbitrary, and disrespectful of the patient to not permit the list to be labelled and for an abortion provider to be identified as such on the piece of paper.

Third, the proposed rule allows only an even more restricted list of providers to go to all patients other than those who have “clearly stated” a decision to have an abortion. Yet, patients are not told that such a decision must be clearly articulated in order to receive the list that **might** include abortion providers. Even patients who have made such a decision will not be treated as such, unless they figure out the need to clearly state a definitive decision. For patients who simply want complete information in order to make later choices, the proposed approach is of no use. As with so much else above, this redirects the Title X clinician from the role of trusted medical professional, properly focused on the patient’s interests and requests for information, to a participant in the proposed regulation’s game-playing.

***The proposed rule requires Title X clinicians to force unwanted information on and to breach the confidentiality of patients in violation of longstanding Title X law and medical ethics***

The proposed rule would not only restrict Title X care to severely limit or render impossible any counseling about abortion. As mentioned above, the rule further would **require** (§ 59.14) 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 the patient’s wishes or interest in such referrals.<sup>35</sup> In addition, all pregnant patients “**shall** be given assistance with setting up a referral appointment to optimize the health of the mother and unborn child.”<sup>36</sup> And Title X clinicians **must** also provide all pregnant patients “with information necessary to protect her health and the health of the unborn child until such time as the referral appointment is kept.”<sup>37</sup> These extraordinary, unwavering requirements require providers to (a) force information and referrals relevant to continuing a pregnancy on patients, even in those cases where the patient has expressed that she does not want such information and (b) forces Title X staff to breach patient confidentiality by “assisting” patients with setting up referral appointments regardless of the patient’s decisions. In so doing, the proposed requirements again instruct medical professionals to violate ethical standards, best practices, and core requirements of the Title X program, as expressed in longstanding statute and regulations.

An essential legal requirement of the Title X program has been its completely voluntary, noncoercive approach to patients using its services. From the outset, Congress has required that all Title X services be up to the individual, with no mandatory care, referral, or other counseling imposed on Title X patients without their desire for and voluntary acceptance of them.<sup>38</sup> The regulations have always echoed this statutory requirement of voluntariness and non-coercion.<sup>39</sup> They explicitly require, in a section of the regulations unaffected by the NPRM, that Title X projects must “[p]rovide services without subjecting

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<sup>35</sup> *Id.* at 25531.

<sup>36</sup> *Id.* at 25531 (emphasis added).

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

<sup>38</sup> 42 U.S.C. § 300a-5; *see also* 42 U.S.C. § 300.

<sup>39</sup> *See* 42 C.F.R. § 59.1.

individuals to any coercion to accept services ...<sup>40</sup> The regulations also require that Title X projects must “[p]rovide services in a manner which protects the dignity of the individual.”<sup>41</sup> Moreover, “[a]ll information as to personal facts and circumstances obtained by the project staff about individuals ... must be held confidential and must not be disclosed without the individual’s documented consent, except as may be necessary to provide [the Title X project’s] services or as required by law ...”<sup>42</sup>

HHS should abandon its efforts here to force prenatal or adoption referrals and “necessary” information about the health of the “unborn child” onto all Title X patients who find themselves pregnant because that effort is contrary to the Title X and other legal requirements of voluntariness and assaults the dignity of patients. The required assistance with making appointments for prenatal or adoption care would force Title X providers to set aside patients’ wishes and violate patients’ confidentiality, a further injury. For patients who seek abortion rather than prenatal care or social services assistance, the Title X staff does not have permission to make appointments with outside providers on their behalf. Title X projects cannot legally or ethically force appointments on individual patients who do not desire them. HHS should not require clinicians to attempt to force care on patients or to intrude against patients’ wishes in their communications or relationships with other providers.<sup>43</sup>

These injuries to confidentiality, dignity, and self-determination would be further compounded by the confusion and delay that the proposed changes would cause. HHS seems not to have considered the difficulties that its proposed requirements would impose on the Title X patients who, for example, “clearly state” they have decided on an abortion. Such a patient would receive a misleading list in response to that statement, starting down a path that, after considerable time and effort, the patient will discover is not the path explicitly sought. At the same time, the Title X provider would also insist on moving to make a prenatal care appointment and counseling about the health of the “unborn child.” These difficulties will delay the patient reaching needed post-conception care and serve to destroy trust in the provider.

Despite these and other destructive aspects of the proposed rule, the NPRM claims without any support or analysis that “[i]f finalized and implemented as proposed, 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.”<sup>44</sup> To the contrary, patients will not continue to visit Title X sites if its providers do not listen to their patients stated needs and treat them as captives, coercively subject to required appointments with prenatal care providers. The proposed rules around counseling and referral create gaps in service rather than closing them.

Altogether, these changes violate congressional requirements that pregnancy counseling be nondirective and voluntary; deprive patients of information necessary to get timely and safe access to care; and ignore medical ethics and standards of care in multiple ways. Moreover, these extreme changes and limitations on providers’ ability to offer appropriate care would push health care entities and clinicians to avoid participating in Title X networks, divert resources from family planning, diminish the quality of care at the Title X sites that remain, and impose serious injuries on patients. They are advanced with incoherent

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<sup>40</sup> 42 C.F.R. § 59.5(2).

<sup>41</sup> 42 C.F.R. § 59.5(3).

<sup>42</sup> 42 C.F.R. § 59.11.

<sup>43</sup> AMA Code of Medical Ethics, § 2.1.1(a) (stating that patients must “make an independent, voluntary decision about care.”); ACOG, *Committee Opinion No. 664: Refusal of Medically Recommended Treatment During Pregnancy*, 127 *OBSTETRICS & GYNECOLOGY* 175-82 (2016) (“It is never acceptable for obstetrician-gynecologists to attempt to influence patients toward a clinical decision using coercion.”); Snyder, *The Physician and the Patient: Decisions about Reproduction* (physicians have a “duty to foster a patient’s free, uncoerced choices”).

<sup>44</sup> 83 Fed. Reg. at 25505.

explanations and lack any proper grounding in the legal framework governing Title X or in the provision of high-quality, comprehensive, medically accurate and effective family planning care and should be withdrawn.

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### The Refusal Statutes that HHS Cites Do Not Justify Abandoning Title X's Current, Uniform Program Requirements for Counseling and Referral, nor Should Title X Funds Subsidize Employers' Refusals to Comply with the ACA's Contraceptive Coverage Requirements

In two significant and harmful respects, the proposed rule further attempts to alter the Title X program – not for any purported reasons related to family planning – but to advance HHS's separate initiatives to expand the reach of the Church, Coats-Snowe, and Weldon Amendments (refusal statutes) and to support employer refusals to provide no-cost contraception coverage through their employee insurance plans, as required by the Affordable Care Act (ACA).<sup>45</sup> First, the NPRM errs in contending that Title X's regulations somehow require changes to make them consistent with the separate refusal statutes. Second, this safety-net program must prioritize care for genuinely low-income people.<sup>46</sup>

The Title X statute and the existing regulations establish uniform, national requirements for the effective provision of high-quality family planning care that bind all Title X projects. Thus, contrary to assertions in the NPRM, there is no "discrimination" in the Title X scheme that singles out certain grant applicants, grantees, or subrecipients for different treatment with regard to offering necessary nondirective counseling, including factual information about and referrals for abortion, when requested by a patient: all Title X projects must do so for all pregnant patients.<sup>47</sup> The NPRM falsely asserts that the nondirective counseling requirement "is inconsistent with" the Coats-Snowe and Weldon Amendments, when those amendments narrowly forbid, only in the specified contexts to which they apply, discriminatory actions against health care entities that refuse to provide abortion referrals.<sup>48</sup> Discrimination connotes **different** treatment **without** the kind of justification provided by the necessary, general programmatic requirements of Title X. As NFPRHA commented in response to HHS's recent NPRM concerning the refusal statutes, rules against "discrimination" cannot be expanded beyond their ordinary meaning to provide immunity for institutions to refuse to perform uniformly required aspects of a federal program like Title X. HHS should consider the proper requirements and regulations for the Title X family planning program without reference to the refusal statutes.

Indeed, Congress has included its explicit requirement of nondirective counseling for pregnant Title X patients in HHS's annual, comprehensive appropriations bills since fiscal year 1996.<sup>49</sup> The related requirement for abortion referrals upon patient request, in the context of that nondirective counseling, has been an essential part of the Title X program throughout that entire period. The Weldon Amendment became a distinct piece of each of those same HHS appropriations bills starting in 2004. Thus, Congress has repeatedly renewed the nondirective counseling requirement in the same enactments that include

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<sup>45</sup> See *Protecting Statutory Conscience Rights in Health Care*, 83 Fed. Reg. 3880 (proposed January 26, 2018) (to be codified at 42 C.F.R. pt. 88); *Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47792, 47838 (proposed October 13, 2017) (to be codified at 26 C.F.R. pt. 54).

<sup>46</sup> 42 U.S.C. § 300a-4(c).

<sup>47</sup> 42 C.F.R. § 59.5(a)(5).

<sup>48</sup> 83 Fed. Reg. at 25506. The NPRM also mentions the Church Amendment, but that amendment concerns only the actual performance of abortion or sterilization, and not referrals. 42 U.S.C. § 300a-7. Here, the Title X statute excludes abortion as a method of family planning from Title X-funded projects, and thus the Church Amendment is especially inapposite to any proposed Title X rulemaking.

<sup>49</sup> Omnibus Consolidated Rescissions and Appropriations Act of 1996. Public Law 104-134 (1996).

Weldon. Congress clearly does not perceive the “inconsistency” that HHS asserts here. Properly read, the Weldon Amendment, like the other refusal statutes, stands separate and apart from Title X’s program requirements; those refusal statutes offer no authority or basis for changes to the Title X regulations; and the refusal statutes should not be referenced as purported justification in any Title X rulemaking.

It is similarly inappropriate to attempt to hijack Title X programs and divert their extremely limited federal funds in service of individual employers’ religious or moral refusals to provide ACA-required contraceptive coverage in their insurance plans for employees by proposing to redefine “low income” for the purpose of Title X to include non-low-income patients without contraceptive coverage. Title X funds are not intended to subsidize employees or others with incomes over 250% of the federal poverty level (FPL) who have insurance policies that are separately required to cover the cost of access to contraceptives.<sup>50</sup> HHS should not attempt to further its religious- or moral-refusal initiatives by impermissibly prioritizing populations not included in the statute, to the detriment of those who need this vital program most. Not only would this irrational redefinition of “low income” run directly contrary to the requirements and aim of Title X—to serve the truly low-income and “insure that economic status shall not be a deterrent to participation” in family planning<sup>51</sup>—but it also would impermissibly allow government funding to subsidize one particular religious viewpoint. To allow Title X projects to prioritize and fully subsidize the care of insured patients seeking contraceptive care because their employers oppose contraception on religious or moral grounds and therefore are refusing to provide coverage in their insurance plan, though the ACA requires it, would constitute a violation of the Establishment Clause. This is hardly the way to assure “taxpayers and stakeholders” that tax dollars are being properly spent, which HHS cites as an overarching purpose for the proposed rule.<sup>52</sup>

In addition, the NPRM goes even further in attempting to benefit one religious or moral viewpoint. The NPRM asserts that a benefit of ending the requirement of nondirective counseling and forbidding abortion referrals is “open communication in the doctor-patient relationship” that includes discussion of religious or spiritual matters.<sup>53</sup> But that “open communication” could only include, under these proposed regulations, religious discussion that did not “present,” “support,” or otherwise endorse the option of abortion.<sup>54</sup> Individuals whose religious beliefs support a woman having access to abortion if that is what she decides is best for her are not able to express their views. Such use of federal funding to encourage communication about and to benefit one particular private religious or moral viewpoint runs afoul of the Constitution.

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<sup>50</sup> 42 C.F.R. § 59.5(a)(9).

<sup>51</sup> 42 U.S.C. § 300a-4(c).

<sup>52</sup> 83 Fed. Reg. at 25525.

<sup>53</sup> *Id.* at 25526.

<sup>54</sup> *Id.* at 25530-32.

## There is No Current Confusion about Title X Rules nor Lack of Authority for Effective Grants Management; Rather, the NPRM Would Introduce Unclear Standards, Create New Obstacles to Title X Family Planning, and Diminish Transparency in Grants Enforcement

The proposed rule repeatedly argues that it is necessary to address “confusion” and to provide greater transparency and accountability in how Title X funds are used.<sup>55</sup> In fact, there is evidence that program is well-administered.<sup>56</sup> Yet, the NPRM does not provide any evidence of current confusion—either among grantees, the public, or anyone else—about the scope of the program or its existing regulatory requirements.

Likewise, the NPRM fails to show that, as it contends, “general grants management requirements” are not sufficient to maintain the transparency and accountability that already characterize the heavily-monitored Title X program.<sup>57</sup> In fact, it is the NPRM that will cause confusion and obscure the transparent operation of this essential program. In addition, its proposed new requirements spread the confusion well beyond the proper bounds of Title X projects, to create new obstacles and severe administrative headaches for grantees that will siphon off resources from patient care and make it much more difficult to serve Title X’s purpose, for no valid or sufficient reason.

For example, the newly proposed § 59.5(13) requires exhaustive information, in any application and every required periodic report, not only about grantees and subrecipients within the Title X project, but also about **any** “referral agencies and individuals” (undefined) or “less formal partners within the community” (also undefined). This proposed section asks for “detailed descriptions” that “demonstrate a seamless continuum of care” extending far beyond family planning, as well as a “[c]lear explanation of how the grantee will ensure adequate oversight and accountability for quality and effectiveness of outcomes” among, *inter alia*, its referral network of other providers, in an unlimited variety of fields. But, there is no explanation as what “effectiveness of outcomes” means in this context, or how Title X providers could possibly track any results from patients referred outside of the Title X network of sites for non-family planning care.

Generally, neither community “partners” nor “referral agencies or individuals” receive any Title X funds. It is extraordinarily difficult and time-consuming to get information from these kinds of community connections in other areas of medical or social service practice, even if they function as excellent resources to offer patients for non-Title X services, because they are consumed with their own patient care and their own record-keeping requirements. Title X grantees are simply not able to obtain repeated, detailed descriptions from them about their services or to evaluate these independent providers’ separate, confidential non-family planning patient care for “effectiveness of outcomes,” whatever is meant by that term, nor would doing so advance the Title X family planning program. Even among subrecipients that do receive funds to provide Title X family planning methods and services, “effectiveness of outcomes” is not defined, seems dependent on events well beyond the quality of care, and would evade any immediate or ready measurement. These unclear, unnecessary new requirements would distract Title X grantees from their primary purpose, maximizing the public benefit of Title X funds.

Similarly, there are numerous other unclear phrases or standards in the proposed rule that would cause significant difficulty for Title X grantees, leave them guessing how even to attempt to comply, and allow

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<sup>55</sup> See, e.g., *id.* at 25503, 25506, 25507.

<sup>56</sup> Institute of Medicine. 2009. *A Review of the HHS Family Planning Program: Mission, Management, and Measurement of Results*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/12585>.

<sup>57</sup> *Id.* at 25510.

arbitrary, non-transparent enforcement. For example, how “comprehensive” must “comprehensive health service providers” be to allow their inclusion on the lists described in § 59.14? What types of expenses fit within providing “direct services to clients” under § 59.18, versus impermissible “infrastructure” spending? What is contemplated by § 59.18(c): why are any “additional protections ... to prevent possible misuse of Title X funds” necessary, and if so, why are these planned “additional protections” not spelled out in the proposed rule?

Likewise, the purported “bright-line rule” for physical and financial separation is anything but that – in fact, it articulates a subjective rule that is up to the Secretary serving at any particular time and that official’s “review of facts and circumstances.” Section 59.15 references “objective integrity and independence” but then leaves the actual standard up to the current political appointee and the Secretary’s determination of that vague phrase. Moreover, the non-exhaustive factors that the Secretary must consider, according to proposed § 59.15, seem to indicate an extreme, counterproductive approach to separation between the Title X program and non-Title X-funded activities that extends far beyond what Section 1008 of Title X contemplates. Imposing such uncertain, unnecessary, and improper separation requirements can only serve to push effective family planning providers out of the Title X program, diminish patient access, and greatly destabilize what is now vital safety-net care.

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### **The 2018 NPRM Broad Prohibitions on Permissible Conduct and Onerous, Subjective Separation Requirements are Unnecessary, will Harm Patients, and Impair Constitutional Rights.**

In compliance with the statutory prohibition on use of Title X funds “in programs where abortion is a method of family planning,”<sup>58</sup> the current regulations (adopted in 2000), make clear that Title X funds cannot be used for abortion care.<sup>59</sup> HHS also published a formal, detailed guidance in 2000 that elaborates on the separation that is required between permissible and impermissible uses of Title X funds with regard to abortion and abortion-related activities.<sup>60</sup> These restrictions and requirements are well understood and adhered to by Title X recipients. Nonetheless, the NPRM would eschew these well-established and effective standards and replace them with requirements that are both unclear and unduly burdensome, and that will harm patients and impermissibly constrain protected First Amendment activity.

HHS has previously provided its own clear rationale for why some of the provisions of the 2018 NPRM, which expand on the prohibitions and requirements of the 1988 domestic gag rule—including its physical separation requirements and prohibitions on activities associated with abortion—are unnecessary. As explained by HHS in finalizing the 2000 Title X regulations:

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 reinstated 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 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 ...

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<sup>58</sup> 42 U.S.C. § 300a-6.

<sup>59</sup> 42 C.F.R. § 59.5(a)(5).

<sup>60</sup> Provision of Abortion-Related Services in Family Planning Services Projects, 65 Fed. Reg. 41281 (proposed July 3, 2000).

The audits of 14 Title X grantees conducted by the GAO and of the 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.<sup>61</sup>

HHS's 2000 guidance document was the "more specific guidance" on compliance with the separation and funding-use limits recommended by these reviews.<sup>62</sup> The Title X network has functioned effectively since then in complying with the regulations and detailed guidance.

The 2018 NPRM offers no suggestion that any circumstances have changed from the facts HHS laid out in the 2000 rule that would require the changes outlined in the proposed rule, no other concrete basis for such a drastic overhaul, nor any support indicating that the proposed policies would be effective, workable, and not constrain many forms of permissible and constitutionally protected activities.

Instead, HHS offers solely theoretical harms that have no evidentiary basis: it speculates that a lack of physical separation "create[s] a risk of the 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."<sup>63</sup> This speculation makes no sense because a Title X program does not have "abortion activities." The statute itself already prescribes and makes crystal clear that no Title X funds can "be used in programs where abortion is a method of family planning" (42 U.S.C. § 300a-60).<sup>64</sup> HHS, as its own attempts at explanation reveal, is relying on hypothetical "potential co-mingling and confusion" that does not exist, much less in any way that might support this broad and destructive regulatory overhaul.

A hypothetical risk regarding the impermissible use of funds under the current regulatory scheme — particularly when HHS lacks evidence of such impermissible, unchecked uses occurring—is not sufficient justification for the harms this rule will cause patients and the significant costs, confusion, and constraints it will impose on providers attempting to comply with it, particularly its physical separation requirement and its excessive attempts to limit what the proposed rule terms "encourage[ing] abortion."

Without any justification, the changes proposed in the NPRM create at least two other significant problems. First, the separation requirements apply to a host of activity that is not barred by the statutory prohibition on using funds in a program where abortion is a method of family planning. Second, the separation requirements are unduly burdensome and lack clarity as to what is sufficient to satisfy them. As a result, if not withdrawn, the rule would bar entities from providing appropriate care to patients and would otherwise act as an effective bar to constitutionally protected activities by Title X entities.

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<sup>61</sup> *Id.* at 41271-72.

<sup>62</sup> *Id.* at 41281.

<sup>63</sup> 83 Fed. Reg. at 25507.

<sup>64</sup> In addition, "family planning projects that receive Title X funds are [already] closely monitored to ensure that federal funds are used appropriately and that funds are not used for prohibited activities such as abortion." Napili, *Title X (Public Health Service Act) Family Planning Program* at 22 (noting that existing "[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 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.")

As an initial matter, the NPRM includes an expansive list of activities that would be subject to the proposed rule's physical and financial separation requirements, but, as discussed elsewhere, it is unclear what the rule would require a Title X-funded entity to do to comply or how Title X entities could determine exactly what is prohibited. What is apparent, however, is that the rule would interfere with legitimate uses of Title X funds as well as other constitutionally protected activity that an entity participating in Title X may seek to engage in outside of the Title X project or through other programs or organizations.

In particular, proposed §§ 59.15 and 59.16 are far broader than the statutory prohibition in U.S.C. § 300a-6 requires or permits. The breadth of these sections and the proposed rule's lack of clarity will limit the ability of Title X providers to conduct otherwise-permissible activities. For example, as discussed *supra* at [CK], despite some contradictory language in the preamble, the NPRM's prohibition on, *inter alia*, "present[ing] abortion as a method of family planning" appears to prohibit nondirective options counseling, including abortion referrals, within the Title X program. As a result of §§ 59.13 and 59.15, then, any such nondirective options counseling and referral by an entity that participates in a Title X project would have to be undertaken outside its Title X project and with full physical separation—with, for example, separate entrances, counseling rooms, and personnel to provide nondirective counseling that includes abortion information and referral **without** Title X funds.

Similarly, the NPRM prohibits dues payments to "any group that, as a more than insignificant part of its activities" advocates abortion as a method of family planning "and does not separately collect and segregate funds used for lobbying purposes."<sup>65</sup> Thus, in order to avoid running afoul of the proposed rule, Title X projects will have to err on the side of caution and zealously avoid paying dues to any organization that at some point might participate in some "more than insignificant" advocacy of abortion. As the examples in the proposed § 59.15 make clear, this new rule could even prevent a Title X project from paying dues to a state medical association on behalf of its medical director, and in furtherance of efforts to build relationships with other medical professionals, if the state medical association periodically files briefs in court to protect the accessibility of abortion. This proposed limitation would harm the Title X project and unduly limit the medical connections available to its patients throughout the state, even though such dues would be for a proper Title X purpose and would **not** be "used in any programs where abortion is a method of family planning," the operative statutory limitation here.<sup>66</sup>

The same is true with respect to the provision of abortion, which the statute does prohibit from being provided within the Title X program. The NPRM's physical separation requirements are so stringent (and as discussed above unnecessarily so) that it would make it impossible for most Title X-funded entities to undertake these constitutionally protected activities outside of their funded projects.

Given these unwarranted prohibitions and the lack of clarity surrounding others, entities receiving Title X funding will not be able to engage in numerous activities within the Title X project that are beneficial to the project and that HHS has formerly treated as permissible. The harm does not stop there: because the physical and financial separation requirements set forth in the NPRM will in many instances be so extreme and prohibitive in terms of cost and feasibility, many Title X entities will be forced to forego numerous

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<sup>65</sup> 83 Fed. Reg. at 25532.

<sup>66</sup> In addition, the examples in proposed § 59.16 that ask questions regarding whether projects, grantees or subrecipients can use Title X funds to engage in lobbying are unnecessary and confusing: Lobbying, whether related to abortion or not, is generally prohibited with federal grant funds, and Title X grantees are warned with every grant to refrain from that use of funding. There is no evidence that members of the Title X network of grantees or providers are not heeding this clear prohibition on the use of federal funds and no need for new, unclear, and confusing regulations that aim at limiting conference attendance or other legitimate and protected activities by grantees and subrecipients in the name of prohibiting nonexistent federally funded lobbying.



types of constitutionally protected activity altogether—whether or not the activity is permissibly prohibited within the Title X program. Thus, taking the earlier example, in order for a Title X entity to pay dues to a state medical organization, a Title X-funded entity under the NPRM **may not only have to pay such dues with non-Title X funds but also from a separate physical facility than the one operating its Title X project.** This is not only completely unnecessary and unjustified but also not economically or operationally feasible.

The lack of clarity about precisely what is required and the virtually unchecked discretion in HHS leaves entities without a discernible standard with which to attempt to comply. Thus, Title X-funded entities would have a difficult, if not impossible, task in ascertaining what activities could run afoul of these new prohibitions, and then, if they could even attempt to do so, expending substantial resources trying to accomplish sufficient separation without any guarantee that their efforts will satisfy HHS. As such, the proposed rule will have a significant chilling and prohibitory effect on a wide variety of otherwise-permissible activities, including those paid for with non-Title X funds outside of Title X projects, and will do nothing to advance the purposes of Title X or improve the family planning programs of Title X providers.

Despite these onerous proposed requirements and the negative impact they would have, HHS seeks comment on whether additional, even more exacting separation requirements are required, such as complete organizational separation from and no name affiliation with an entity that provides abortion care or conducts other abortion-related activities that are targeted by the NPRM. NFPRHA submits that the rule, as currently proposed, already goes much too far and is unnecessary.

To prevent the harms to patients and to constitutionally protected rights, HHS should withdraw the proposed rule's new physical separation scheme and retain the 2000 regulation and guidance.

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### **The 2018 NPRM Proposes Unnecessary and Confusing New Infrastructure Prohibitions and Requirements Based on “Concerns” over a Flawed Premise of “Fungibility”**

HHS states that it is particularly concerned over what it terms “Infrastructure Building That Creates Fungibility Concerns Related to Abortion Services.”<sup>67</sup> In addition to the physical and financial separation requirements of § 59.15, the 2018 NPRM proposes a new section (§ 59.18) prohibiting 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.”

Yet, for at least three reasons, the entire premise of HHS's supposed rationale for this new section—that there are “concerns about the fungibility of assets that could be used ...to build infrastructure for abortion services”<sup>68</sup>—is flawed. Moreover, the proposed rule would only confuse Title X grantees and cause them to avoid spending funds on **proper** expenditures for running their Title X programs, or add “additional protections” of unnecessarily duplicative record-keeping and oversight for no reason, burdening a federal safety-net program that has no resources to spare.

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<sup>67</sup> 83 Fed. Reg. at 25508.

<sup>68</sup> *Id.*

First, Title X funds are not allowed to be used to pay for the full cost of Title X services, as HHS explicitly acknowledges in the proposed rule.<sup>69</sup> Every Title X project must raise funds in addition to the federal grant in order to fund its HHS-approved budget. Even where there is a third-party payer for specific services provided, those reimbursements may only cover a portion of the true cost of providing such care; Medicaid reimbursement, for example, generally covers less than half the actual cost of providing family planning services.<sup>70</sup> Furthermore, the Title X program is chronically underfunded to meet the family planning needs among low-income persons. Between 2010 and 2016, Congress cut funding for Title X by 10%, even as the need for publicly funded contraceptive services and supplies increased by 5% over the same period.<sup>71</sup> If all low-income women of reproductive age who require family planning services received Title X services, the annual level of Title X funding required would have ranged from \$628 million to \$763 million in 2016.<sup>72</sup> The actual annual funding level for the program was \$286.5 million then and still is. The idea that somehow Title X funding is left over from Title X program expenses and could be used fungibly to “free up” non-Title X funding to pay for abortion or other “purposes prohibited with these funds” simply has no basis in reality. It is the other way around: all Title X projects require supplementary funding from other sources.

HHS also does not offer evidence of its “fungibility” concern being based on any gap in Title X oversight. While the new § 59.18 proposes to require Title X grantees to “give a detailed accounting for the use of grant dollars” in their grant applications and required reporting, and for Title X projects to “fully account for, and justify, charges against the Title X grant” in order to “ensure that [T]itle X funds are used for the purposes expressly mandated by Congress,”<sup>73</sup> the existing statute and regulations, along with Title X grantees’ current accounting and reporting requirements, already ensure that each project “fully account[s] for, and justif[ies] charges against the Title X grant.” HHS has no evidence to demonstrate there is an actual “fungibility” problem or any other “misuse” that requires “additional protections” of an unspecified nature.

Second, the proposed infrastructure prohibitions of § 59.18 are even more unnecessary because the onerous physical and financial separation requirements proposed by the 2018 NPRM would further eliminate the “threat” of infrastructure fungibility, a point that HHS explicitly acknowledges in the proposed rule’s preamble.<sup>74</sup> This raises the question of why HHS proposed § 59.18 at all and highlights the third problem – the confusion created over what HHS considers to be potentially inappropriate “infrastructure” and the lack of any apparent boundary for that concept under this proposal.

Section 59.18 prohibits Title X funds from being “used to build infrastructure for purposes prohibited with these funds, such as support for the abortion business of a Title X grantee or subrecipient. Funds 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 Title X statute. In the preamble, in explaining this

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<sup>69</sup> *Id.* (“By law, Title X providers must secure other sources of revenue to leverage Title X grants. See 42 CFR 59.7(c) (‘No grant may be made for an amount equal to 100 percent for the project’s estimated costs.’)).

<sup>70</sup> Adam Sonfield et al., *Assessing the Gap Between the Cost of Care for Title X Family Planning Providers and Reimbursement from Medicaid and Private Insurance*, GUTTMACHER INSTITUTE 1, 3-4 (2016), [https://www.guttmacher.org/sites/default/files/report\\_pdf/title-x-reimbursement-gaps.pdf](https://www.guttmacher.org/sites/default/files/report_pdf/title-x-reimbursement-gaps.pdf).

<sup>71</sup> Jennifer J. Frost et al., *Contraceptive Needs and Services, 2014 Update*, GUTTMACHER INSTITUTE 1, 1 (2016), [https://www.guttmacher.org/sites/default/files/report\\_pdf/contraceptive-needs-and-services-2014\\_1.pdf](https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-and-services-2014_1.pdf).

<sup>72</sup> E.M. August et al., *Projecting the Unmet Need and Costs for Contraception Services After the Affordable Care Act*, 106 AM. J. PUBLIC HEALTH 334-41 (2016) (Women in need of publicly funded family planning are women ages 15-44 with incomes at or below 250% of the FPL.).

<sup>73</sup> 83 Fed. Reg. at 25521.

<sup>74</sup> *Id.* at 25508 (“Because Title X projects would not share any infrastructure with abortion-related activities, direction of Title X funds toward such infrastructure would no longer threaten to divert funds to impermissible activities.”)

new proposal, HHS describes infrastructure as including “securing physical space, developing or acquiring health information technology systems (including electronic health records (EHR)), bulk purchasing of contraceptives or other clinic supplies, clinical training for staff, and community outreach and recruiting.”<sup>75</sup>

Thus, it appears, though is in no way clear, that HHS is suggesting that using Title X funds to pay for the things included in the preamble—including EHR, bulk purchasing of contraceptives, and clinical training—would be potentially prohibited under the rule. There is no logical reason behind nor sense in singling out the activities included as “infrastructure” in the preamble: if HHS intends for § 59.18’s prohibition to forbid activities that could be used for prohibited abortion activities, for example, bulk purchasing of contraceptives has no relation to the provision of abortion care, so there is no potential for such purchasing to be used for abortion. Moreover, bulk purchasing of supplies reflects how Title X grants are operated: they are grants to establish and efficiently run **projects**, not funds for individual reimbursement or individualized purchasing. A bar on bulk purchasing of contraceptives would only serve to waste Title X dollars on more expensive ways of purchasing those supplies.

It is equally unclear whether these activities are included in the preamble because HHS intends to prohibit them as something other than in “direct implementation” or “expressly permitted,” other phrases used in the proposed § 59.18. Yet, these activities are entirely allowable under the Title X statute and existing regulations and have always been permitted. Indeed, HHS acknowledges in the proposed rule why this would be the case: “unlike Title X, which is a grant program, Medicaid is a reimbursement program. By their very nature, grants afford greater latitude and versatility to grantees on how funds are used.” Put another way, while Medicaid pays some of the costs of services already rendered (and only for those who are eligible for it), Title X helps ensure the patient can receive those services at all. To the extent that HHS is concerned about rented facilities or equipment that may be shared between a Title X project and the other work of an organization or co-tenant, the Title X project’s access to any such shared “infrastructure” comes at a pro rata cost for the project’s use (and, as described above, the Title X funds pay only a part of that pro rata cost and other project funds must also be used).<sup>76</sup> The Title X program does not provide any “fungible” resources or subsidy to support other operations of the organization (or its co-tenants or any other separate program).

Title X is a unique, critical funding source primarily used to pay the cost of patient services—that includes a clinician’s time during a patient visit, as well as the cost of the clinical equipment, stocking the contraceptive methods that enable patients to start their method the same day, training staff on the latest contraceptive technology and standards of care, and ensuring patient medical records are accurate. These costs are all essential parts of “direct” services to patients. Section 59.18 is unnecessary, confusing, and suggests impropriety where there is none, and should be withdrawn.

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### **The 2018 NPRM Threatens Patient Confidentiality, Particularly for Minors, in Ways That will Cause Harm to Patients and Lead Patients to Avoid Seeking Critical Health Care.**

One of the hallmarks of Title X— and a critical component of its success—has been the program’s strong protections for patient confidentiality and its commitment to serving adolescents. Since the 1970s, federal law has required that both adolescents and adults be able to receive confidential family planning services in Title X projects. The 2018 NPRM weakens these protections by pushing providers to encourage family

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<sup>75</sup> *Id.*; *see also id.* at 25521.

<sup>76</sup> *See* 65 Fed. Reg at 41282.

involvement even when it could be harmful; by giving the HHS Secretary oversight authority in the enforcement of complex and nuanced state reporting laws; and by adding new inappropriate obligations on providers. In doing so, the 2018 NPRM exceeds the Secretary's authority and will harm patients, undermine the provider-patient relationship, and damage public health.

Family planning services address some of the most sensitive and personal issues in health care and therefore require strong confidentiality protections. Patients seeking family planning services encompass a broad spectrum of patient populations.<sup>77</sup> Certain groups, including adolescents and young adults, and people at risk of domestic or intimate partner violence, have special privacy concerns that require particularly strong protection.<sup>78</sup>

The Title X confidentiality regulations<sup>79</sup> are among the strongest in current law, and research shows these confidentiality protections are one of the reasons individuals choose to seek care at Title X sites.<sup>80</sup> The current regulations contain exceptions that allow health providers to disclose patient information without documented consent, only if necessary, to provide services to the patient or if the disclosure is required by law; but even then, appropriate safeguards for confidentiality must be in place.<sup>81</sup> The regulatory requirements and related Title X program guidance<sup>82</sup> represent the gold standard in confidentiality protections across the nation's health system.<sup>83</sup>

The need for Title X's strong confidentiality protections is supported by both research and medical practice standards. Of particular relevance, the Title X confidentiality protections are grounded in research about the effect of confidentiality on health care access. Decades of research findings have shown that privacy concerns influence the behavior of patients, particularly adolescents and young adults, with respect to whether they seek care, where they do so, which services they accept, and how candid they are with their health care providers.<sup>84</sup> Adolescents are especially concerned about disclosures to their parents or guardians of their use of family planning services.<sup>85</sup> For example, numerous studies demonstrate that

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<sup>77</sup> Rachel B. Gold, *A New Frontier in the Era of Health Reform: Protecting Confidentiality for Individuals Insured as Dependents*, 16 GUTTMACHER POLICY REVIEW 2, 2 (2013), <https://www.guttmacher.org/pubs/gpr/16/4/gpr160402.pdf>.

<sup>78</sup> Pamela J. Burke et al., *Sexual and Reproductive Health Care: A Position Paper of the Society for Adolescent Health and Medicine*, 54 J. ADOLESCENT HEALTH 491, 491-496, (2014), [https://www.adolescenthealth.org/SAHM\\_Main/media/Advocacy/Positions/Apr-14-Sexual-Repro-Health.pdf](https://www.adolescenthealth.org/SAHM_Main/media/Advocacy/Positions/Apr-14-Sexual-Repro-Health.pdf); Diane M. Reddy, Raymond Fleming, & Carolyn Swain, *Effect of Mandatory Parental Notification on Adolescent Girls' Use of Sexual Health Care Services*, 288 J. AM. MED. ASS'N 710, 710-714 (2002); Rachel K. Jones et al., *Adolescents' Reports of Parental Knowledge of Adolescents' Use of Sexual Health Services and Their Reactions to Mandated Parental Notification for Prescription Contraception*, 293 J. AM. MED. ASS'N 340, 340-348; Liza Fuentes, Meghan Ingerick, Rachel Jones, & Laura Lindberg, *Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services*, 62 J. ADOLESCENT HEALTH 36, 36-43; *National Consensus Guidelines on Identifying and Responding to Domestic Violence Victimization in Health Care Settings*, Family Violence Prevention Fund (2004), <http://www.futureswithoutviolence.org/userfiles/file/HealthCare/consensus.pdf>.

<sup>79</sup> 42 C.F.R. § 59.11.

<sup>80</sup> Frost et al., *Specialized Family Planning Clinics in the United States*.

<sup>81</sup> 42 C.F.R. § 59.11.

<sup>82</sup> Office of Population Affairs, *Program Requirements for Title X Funded Family Planning Projects* (2014), <http://www.hhs.gov/opa/pdfs/ogc-cleared-final-april.pdf>.

<sup>83</sup> Abigail English, Center Adolescent Health & Law & National Family Planning & Reproductive Health Ass'n, *Adolescent Confidentiality Protections in Title X* (June 5, 2014), <http://www.nationalfamilyplanning.org/document.doc?id=1559>.

<sup>84</sup> Pamela J. Burke et al, *Sexual and Reproductive Health Care: A Position Paper of the Society for Adolescent Health and Medicine*, 54 J. ADOLESCENT HEALTH 491, 491-496, (2014), [https://www.adolescenthealth.org/SAHM\\_Main/media/Advocacy/Positions/Apr-14-Sexual-Repro-Health.pdf](https://www.adolescenthealth.org/SAHM_Main/media/Advocacy/Positions/Apr-14-Sexual-Repro-Health.pdf); Alina Salganicoff, Usha Ranji, Adara Beamesderfer, and Nisha Kuran, *Women and Health Care in the Early Years of the ACA: Key Findings from the 2013 Kaiser Women's Health Survey*, Henry J. Kaiser Family Foundation, 28, 38-39 (2014), <https://kaiserfamilyfoundation.files.wordpress.com/2014/05/8590-women-and-health-care-in-the-early-years-of-the-affordable-care-act.pdf>.

<sup>85</sup> Reddy et. al, *Effect of Mandatory Parental Notification on Adolescent Girls' Use of Sexual Health Care Services* at 710-714 (2002); Jones et al., *Adolescents' Reports of Parental Knowledge of Adolescents' Use of Sexual Health Services and Their Reactions to Mandated Parental Notification for Prescription Contraception* at 340-348; Liza Fuentes et al., *Adolescents' and Young Adults' Reports of Barriers to*

requiring parental notification would drive minors out of family planning health centers and away from critical health care, including contraception and testing and treatment for sexually transmitted diseases.<sup>86</sup>

Cognizant of the key role confidentiality plays in access to health care and in the provision of high-quality health care services, numerous medical organizations have issued ethical guidelines, practice standards, and policy statements highlighting the necessity of protecting confidentiality for adolescents. More than 20 organizations of medical and health care professionals have issued such documents, many of which specifically address family planning services.<sup>87</sup> In particular, the organizations of medical and health professionals most often directly involved in the care of adolescents, such as the American Academy of Pediatrics and the Society for Adolescent Health and Medicine, have repeatedly stressed the importance of confidentiality.<sup>88</sup>

Individuals affected by intimate partner violence also have a particular need for confidentiality protections. Consensus guidelines developed by a national advisory group emphasized the central role of confidentiality in the provision of health services to those who experience intimate partner violence, noting that inappropriate disclosures, even to law enforcement or other state officials, can jeopardize patient safety and even endanger the lives of those affected by intimate partner violence.<sup>89</sup>

The 2018 NPRM threatens Title X's longstanding and critical protections for patient confidentiality, particularly for minors, in ways that will cause harm to patients and will undermine the trust Title X patients have in their providers. The proposed rule threatens confidentiality in two primary ways. First, it mandates that Title X providers encourage involvement of family members including parents in situations in which doing so violates the health care provider's professional judgment and medical ethics. Second, it improperly inserts the Secretary into the enforcement of state reporting laws. This is particularly problematic because young people and individuals affected by intimate partner violence often do not have other options for accessing low- or no-cost confidential family planning services.

### ***Increased pressure for family involvement***

The Title X statute requires providers to encourage family involvement in the family planning decisionmaking of minors but only "[t]o the extent practical"<sup>90</sup> (meaning a realistic and appropriate option). Section 59.2 of the NPRM disregards this important statutory limitation. Instead, that proposed section would require Title X providers to document in the minor's medical record "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" with only a single, extremely limited exception for

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*Confidential Health Care and Receipt of Contraceptive Services* at 36-43; *Contraception and Adolescents*, 120 PEDIATRICS 1135, 1137 (2007) ("The primary reason that adolescents may hesitate or delay obtaining family planning or contraceptive services is concern about lack of confidentiality).

<sup>86</sup> See, e.g., Reddy, *Effect of Mandatory Parental Notification on Adolescent Girls' Use of Sexual Health Care Services*, at 710.

<sup>87</sup> Center for Adolescent Health & the Law, *Policy Compendium on Confidential Health Services for Adolescents*, 2d Ed. (2005). <http://www.cahl.org/PDFs/PolicyCompendium/PolicyCompendium.pdf>.

<sup>88</sup> E.g., Carol A. Ford, Abigail English & Garry Sigman, *Confidential Health Care for Adolescents: Position Paper of the Society for Adolescent Medicine* 35:2 J. ADOLESCENT HEALTH 160-67 (2004).

<sup>89</sup> *National Consensus Guidelines on Identifying and Responding to Domestic Violence Victimization in Health Care Settings* Family Violence Prevention Fund (2004), <http://www.futureswithoutviolence.org/userfiles/file/HealthCare/consensus.pdf>; see also A.C. Gielen et al., *Women's Opinions About Domestic Violence Screening and Mandatory Reporting*, 19 AM. J. PREVENTIVE MED. 279-85 (2000); M.A. Rodriguez et al., *Mandatory Reporting of Intimate Partner Violence to Police: Views of Physicians in California*, 89 AM. J. PUB. HEALTH 575-78 (1999).

<sup>90</sup> 42 U.S.C. § 300 (2018).

circumstances where the provider suspects the minor is the victim of child abuse or incest, and the provider has reported the situation to the relevant authorities, consistent with and if permitted or required by applicable state or local law.

Such a requirement is not only unnecessary, but it is also harmful to patients and public health. Title X providers, guided by their expertise, training, and experience, as well as extensive practice standards and recommendations, already assist adolescents to involve their families in decisions about family planning services and other key health care matters when realistic and appropriate. Consistent with this practice on the part of providers, most adolescents already involve their families in decisions about family planning or seek family planning services with their parents' knowledge.<sup>91</sup>

However, when taking a careful 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 guardian. Every minor presents differently over a series of visits with providers, and providers need to be able to meet each patient where they are at each visit in order to build trust; providers have to be given the room to evaluate and adapt to a patient's individual needs, circumstances, and concerns. For example, some patients are not at all open about their situations, and providers must take their time rather than pushing a patient in ways that can actually make them even more reluctant to talk; other patients are very clear that their home situations do not support their family's involvement. In these situations, they should not be required to take "specific actions" to encourage the minor to do so (and then document those specific actions) as the NPRM requires. Doing so is not only contrary to medical ethics, but it also undermines the relationship between the minor and the health care professional and is likely to drive some minors away from returning for critical health care services, including contraception and testing and treatment for sexually transmitted diseases.<sup>92</sup>

Moreover, by requiring documentation of steps taken to encourage family participation in situations in which it is not practicable to do so, the NPRM exceeds Congress' clear limitation. For all of these reasons, the unduly expanded requirements for encouraging parental involvement and associated documentation should be withdrawn.

### ***Compliance with reporting requirements***

Title X providers are required by state law to comply with a variety of reporting requirements. Congress has made clear that nothing in Title X exempts providers from compliance with a specific set of reporting laws, namely "any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest."<sup>93</sup>

Professionals providing services in Title X-funded sites are aware of these reporting obligations, already receive training on them, and make reports in compliance with these requirements. Health care

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<sup>91</sup> Rachel K. Jones, et al., *Adolescents' Reports of Parental Knowledge of Adolescents' Use of Sexual Health Services and Their Reactions to Mandated Parental Notification for Prescription Contraception* at 340-48.

<sup>92</sup> See Reddy et al., *Effect of Mandatory Parental Notification on Adolescent Girls' Use of Sexual Health Care Services* at 710-14; Rachel K. Jones et al., *Adolescents' Reports of Parental Knowledge of Adolescents' Use of Sexual Health Services and Their Reactions to Mandated Parental Notification for Prescription Contraception*, at 340-48; Liza Fuentes et al., *Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services* at 36-43 (2018).

<sup>93</sup> Consolidated Appropriations Act of 2018, Pub. L. No. 115-141, Div. H, Title II, Sec. 208 (2018) ("Notwithstanding any other provision of law, no provider of services under title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.").

professionals take seriously not only their reporting obligations but also their obligations to their patients to protect them from real risks of exploitation and abuse.<sup>94</sup>

Determinations regarding compliance with these laws have properly rested with state authorities. The 2018 NPRM, however, attempts to give HHS substantial oversight over compliance with these complicated state reporting requirements and the authority to impose harsh penalties if HHS (not the state) believes a Title X project is out of compliance. 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, ultimately resulting in fewer patients seeking critical health services.

State reporting laws are complex and vary widely from state to state.<sup>95</sup> They seek a nuanced balance between the need to protect those who experience abuse and ensure that law enforcement can bring victimizers to justice with the need to ensure that patients are able to seek critical health care services they might avoid if they do not trust their health care provider. Thus, many state laws include both specific requirements that clearly trigger an obligation to make a report and others that allow for the exercise of discretion by health care professionals. For example, determinations of “reasonable suspicion” and “likelihood of harm” may be within the purview of health care providers who are mandated reporters.

Given the complexity, nuances, and variations, HHS has not and should not oversee compliance with state (or local) reporting laws, as doing so is both outside HHS’s authority and expertise and is likely to harm patients. Yet, that is precisely what the NPRM does. For example, the rule would prohibit projects from receiving Title X funds unless the project provides “appropriate documentation or other assurance satisfactory to the Secretary” that it has met the compliance requirements<sup>96</sup> and states that continuation of funding “is contingent upon demonstrating to the satisfaction of the Secretary” that the requirements have been met.<sup>97</sup> In addition, the rule seeks to dramatically expand HHS’s authority to inspect patient records, allowing the Secretary to review records **for the sole purpose** of ensuring compliance with state or local 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, based on the totality of the circumstances and the requirements of its specific laws, a Title X project or its individual providers are in compliance with them.<sup>98</sup>

By giving HHS unauthorized authority to revoke funding based on its own determination of whether a health care professional failed to comply with a state or local law, the NPRM is likely to coerce providers into reporting abuse beyond circumstances required by state law—lest they jeopardize funding for the

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<sup>94</sup> Position Paper of the American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists & Society for Adolescent Health and Medicine, *Protecting Adolescents: Ensuring Access to Care and Reporting Sexual Activity and Abuse*, 35(5) J. ADOLESCENT HEALTH 420-23 (2004).

<sup>95</sup> See, e.g., Rebecca Gudeman & Erica Monasterio, *Mandated Child Abuse Reporting Law: Developing and Implementing Policies and Training*, National Center for Youth Law and Family Planning National Training Center for Service Delivery (2014), <http://www.cardeaservices.org/documents/resources/Mandated-Child-Abuse-Reporting-Law-GUIDE-20140619.pdf>.

<sup>96</sup> 83 Fed. Reg. at 25532-33.

<sup>97</sup> *Id.* at 25533.

<sup>98</sup> Notably, the NPRM also purports to give HHS oversight of state laws requiring reporting of intimate partner violence, human trafficking, “similar reporting laws,” and similar local (as opposed to state) laws despite the fact that Congress specifically mentions only State laws (not local laws) and only those requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest. 83 Fed. Reg. at 25531

entire project. Such over-reporting has real consequences: it violates patient confidentiality; it may subject a patient to serious harm;<sup>99</sup> and it risks scaring patients away from the vital health services they need.<sup>100</sup>

In addition, the proposed rule creates new requirements that, while purporting to be tied to state law, in fact go beyond what state law requires and are outside of the agency's authority to require. In particular, § 59.17 of the NPRM requires that irrespective of state requirements Title X projects commit to "conduct a preliminary screening of any teen who presents with [an STI], pregnancy, or any suspicion of abuse, in order to **rule out** victimization of a minor. Such screening would be required with respect to any individual who is under the age of consent in the state of the proposed service area."<sup>101</sup>

As an initial matter, the proposed rule is so vaguely written that it is not clear what populations must be screened under this requirement: Is it 1) teens **under the age of consent** who present with an STD, pregnancy, or any suspicion of abuse or 2) **all** teens who present with an STD, pregnancy, or any suspicion of abuse (regardless of whether they are below the age of consent) **as well as** all teens under the age of consent regardless of whether they present with an STD, pregnancy, or any suspicion of abuse? Moreover, to the extent that it requires reporting of teens beyond those under the age of consent, by using the word "teen," the proposed rule would require abuse screening of 18- and 19-year old adults (who are not subject to child abuse reporting laws) simply because they are pregnant or have an STD.

Whatever category of patients it applies to, the rule would inappropriately intrude upon the assessments that providers already conduct in ways that are harmful to patients and the provider-patient relationship. Screening for victimization, particularly among adolescents, is a delicate task. Minors rarely provide information about abuse on an initial visit to a provider; it takes time to develop a relationship of trust between a provider and a patient who has been victimized. Providers concerned about whether HHS will deem their actions sufficient may push too hard for information in that first visit, which could destroy any opportunity to build trust between the patient and provider, ultimately preventing the provider from ever being able to obtain the information about a patient's victimization. In addition, requiring a provider to perform the enhanced form of screening that the NPRM would mandate to affirmatively rule out victimization, even when there is no indication of abuse, has the real potential to leave a patient feeling stigmatized and judged simply for seeking family planning care. Patients who feel judged by their health care provider are less likely to return for care.

For all of these reasons, § 59.17 of the proposed rule should be withdrawn.

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<sup>99</sup> *National Consensus Guidelines on Identifying and Responding to Domestic Violence Victimization in Health Care Settings*, Family Violence Prevention Fund 17 (2004), <http://www.futureswithoutviolence.org/userfiles/file/HealthCare/consensus.pdf> ("Perpetrators who discover that a victim has sought care may retaliate with further violence. Employers, insurers, law enforcement agencies, and community members who discover abuse may discriminate against a victim or alert the perpetrator.").

<sup>100</sup> See A.C. Gielen et al., *Women's Opinions about Domestic Violence Screening and Mandatory Reporting* at 279-85; M.A. Rodriguez et al., *Mandatory Reporting of Intimate Partner Violence to Police: Views of Physicians in California* at 575-78.

<sup>101</sup> 83 Fed. Reg. at 25533.



## The NPRM Attempts to Give HHS Unclear and Unnecessary Expanded Oversight Powers over Subrecipients, Subcontractors, and Referral Providers, While Also Imposing Wasteful and Duplicative Administrative Burdens.

HHS's legal relationship is with the Title X grantees concerning the projects they operate, and not with the subrecipients or health centers that the grantee may subcontract with to provide family planning methods and services through a Title X project. As such, any directives from HHS must flow through the grantee to the subrecipients and health centers. Similarly, the grantee is responsible for ensuring the project's compliance with Title X's regulations. HHS's oversight of Title X (including program review) is through the Title X grantee; HHS currently has no direct oversight authority for subrecipients or health centers. This structure has worked effectively for decades and is typical of federal grant programs. Once again, HHS offers in the NPRM a solution in search of a problem. HHS presumes the need for greater regulation and the existence of confusion as to regulatory requirements where none is evident, and seeks new oversight where none is needed and would only tax Title X subrecipients unnecessarily. Indeed, creating direct relationships with and oversight of subrecipients would likely push some to exit the Title X program because now grantees—including many that specialize in and focus exclusively on grant administration—shoulder the bulk of voluminous and complex reporting and compliance requirements that govern Title X projects today. The NPRM, nonetheless, apparently seeks to expand HHS's direct regulatory and oversight powers to subrecipients, by explicitly imposing the requirements of the Title X regulations equally on grantees and subrecipients.<sup>102</sup>

Although HHS notes that it “is not aware of a history of establishing or operating Title X family planning projects by use of contracts instead of grants,” it proposes a new part in the NPRM that would make many, but not all, of the Title X regulations “applicable to the execution of contracts under Title X to assist in the establishment and operation” of Title X projects.<sup>103</sup> Section 59.1(b) would make the regulations other than §§ 59.3, 59.4, 59.8, and 59.10 applicable to federal contracts, and also would make the terms “grantee” and “subrecipient,” for example, in all of the Title X regulations interchangeable with “contractor” and “subcontractor.” The agency, however, does not explain its intentions behind § 59.1(b); any purported need justifying that provision; whether HHS plans to move from grants to federal contracts for Title X funding and if so, why; or how HHS regulation of subcontractors, for example, would work.

While HHS invites comment on “the applicability of these regulations to contracts for the provision of family planning services under Title X,”<sup>104</sup> it is impossible to provide meaningful comment without more information about what HHS intends. For example, because HHS says it would not apply the application requirements of § 59.4 or the agency-wide requirements of § 59.10 to contracts, HHS leaves unexplained how it would proceed and what it would substitute, if anything. Does this mean, for example, that objective review panels would not be used to assess applications for a Title X services contract? What would the application process be? And how would HHS enmesh itself in subcontractor relationships?

HHS has gone even further and asked for comment on whether the regulations' requirements, especially related to reporting, should be imposed on agencies that do not receive any Title X funds, but have some referral relationship or “formal or informal partnership” with Title X-funded health centers.<sup>105</sup> There is no legal basis upon which to do so. Likewise, HHS has offered no explanation of how it or grantees would

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<sup>102</sup> *Id.* at 25529.

<sup>103</sup> 83 Fed. Reg. 25513

<sup>104</sup> *Id.*

<sup>105</sup> *Id.* at 25514.

purportedly exert this oversight, nor has HHS provided any explanation or evidence of any need to so. As the agency itself repeatedly states throughout the NPRM, HHS is concerned with regulating and overseeing the use of federal funds; without such funds, its orbit ends. There is no concern, for example, that any funds appropriated under Title X will be used “in programs where abortion is a method of family planning” at organizations that receive no such funds.<sup>106</sup> Contrary to the NPRM’s contention, referral services without connection to Title X funding are not “an extension of the overall Title X service provision” and the entities that provide such services fall outside the legal scope of Title X projects.<sup>107</sup>

Thus, community partners and the wide variety of providers to whom Title X projects refer, or vice versa, are not Title X-funded entities and simply do not come within Title X’s restrictions. These community and professional relationships and networks, however, are critical in ensuring that low-income, uninsured, or underinsured individuals have access to the full range of care they need from accessible providers across the safety net. Outside providers are also overburdened and unable to generate paperwork for or take on requirements from wholly separate Title X projects. Imposing Title X requirements on non-Title X-funded organizations would be practically impossible and only serve to cut Title X providers and their patients off from referral and community connections. If implemented, such scheme would have a drastic impact on the ability of Title X providers to provide a full range of referrals and receive referrals from all kinds of other providers, and have a directly detrimental effect on patients’ health and well-being.

At the same time as the proposed rule seeks to establish regulatory oversight over subrecipients and subcontractors, or even referral and community partners, it proposes to increase the amount of information about those entities that grantees must describe to HHS in every grantee application and report, to an unnecessary and unclear degree.

Section 59.5(a)(13) would require in all grant applications and required reports: the name, location, expertise, and services provided or to be provided of every subrecipient and referral agency and referral individual; a “detailed description of the extent of the collaboration with subrecipients, referral agencies and individuals, as well as with less formal partners in the community, in order to demonstrate a seamless continuum of care for clients;” and a “clear explanation” of how the grantee “will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients and those who serve as referrals for ancillary or core services.”

The 2018 NPRM states that these reporting requirements are intended to “ensure accountability for, and wise use of, taxpayers’ money,”<sup>108</sup> but offers no evidence demonstrating a lack of such accountability and/or lack of wise use of taxpayer money under the existing requirements. Furthermore, with regard to names and locations of subrecipients and service sites, HHS already has this information—as the OPA’s regularly published “Title X Family Planning Directory”—which lists all current grantees, subrecipients, and service sites—demonstrates.<sup>109</sup> Much of the “clear explanation” that might be provided about the oversight and accountability of subrecipients to grantees would require repeated, elaborate writings that describe the structure of Title X projects with which HHS is already well familiar through its own regulations or grantees’ existing, voluminous paperwork with HHS.

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<sup>106</sup> See *id.* at 25502.

<sup>107</sup> See *id.* at 25514.

<sup>108</sup> *Id.* at 25508.

<sup>109</sup> Office of Population Affairs, Title X Family Planning Directory (2018), <https://www.hhs.gov/opa/sites/default/files/Title-X-Family-Planning-Directory-May2018.pdf>.

As for the information HHS seeks to require regarding the expertise and services provided or to be provided by every subrecipient (let alone by referral agencies), there is no demonstrable reason for HHS to seek this level of detail about (and potentially from) subrecipient agencies. Title X grantees collect a significant amount of information from subrecipients already and provide necessary information as part of the overall Title X project to HHS. When combined with the proposed rule's requirement concerning a detailed description of the extent of collaboration, "in order to demonstrate a seamless continuum of care for clients," HHS is implicitly requiring extensive information about and prioritizing care that falls outside the scope of the Title X program.

Moreover, HHS here again seeks unprecedented information about and from, and oversight of, referral agencies and community partners. As discussed above, referral agencies (that are not subrecipients) and community partners do not receive Title X funding; as such, they are not bound by Title X's requirements, nor can grantees (or HHS) claim oversight authority over those organizations. Even if some such authority existed, which it does not, getting referral providers or community partners to provide the kind of information the 2018 NPRM seeks to require would be incredibly difficult; many such organizations would be unable or unwilling to compile and submit such information to grantees or HHS for requirements under a program from which they receive no funding and for which they have no obligations. Even for subrecipients, the breadth and frequency of reporting requirements HHS now seeks to impose are likely to dissuade some from participation in the Title X program.

Once again, the NPRM proposes changes that will siphon even more time, funds, and providers away from Title X's core purpose, but sets forth no reason to do so or justification for the great volume of requirements. All of these requirements would significantly hamper the ability of Title X grantees to build robust and diverse networks of subrecipients, service sites, and referral partners, and thus, limit access to critical family planning and preventive health services. They should be withdrawn.

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### **The 2018 NPRM Inappropriately Prioritizes Providing Family Planning Grants to Entities with a Close Connection to Primary Care over Specializing Entities that Provide the Most Effective Family Planning Services.**

The purpose of the Title X program is to ensure that individuals regardless of income have access to high-quality family planning services. Although other federal funding streams cover primary care services,<sup>110</sup> Title X funding was not designed to and cannot be used to provide primary care services.<sup>111</sup>

The 2018 NPRM attempts to blur that line by calling for "a holistic approach to family planning" that dictates that, at a minimum, Title X providers "should offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site."<sup>112</sup> HHS also potentially seeks to introduce primary care or other non-family planning services to be covered by Title X funds when it vaguely refers to including grantees "focused on family planning in the context of holistic health in both the short and long term" and to "ensur[ing] that all services funded through Title X offer optimal health benefits to clients of all ages."<sup>113</sup>

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<sup>110</sup> See 42 U.S.C. § 254b(b)(1); see generally *id.* § 254b *et seq.*

<sup>111</sup> See 42 C.F.R. § 59.5(b)(8) (instructing Title X providers to refer patients elsewhere for necessary primary care).

<sup>112</sup> 83 Fed. Reg. at 25530.

<sup>113</sup> *Id.* at 25517.

If not amended, HHS's new prioritization of comprehensive primary health care in the proposed rule would result in a Title X program that is both less effective and less satisfactory to patients. Research indicates that patients prefer, and receive better, more comprehensive family planning care at providers that specialize in providing reproductive health care. Indeed, many patients choose such providers, even when there is a primary care-focused site available, because family planning patients tend to feel more respected, know they are able to obtain confidential services there, and recognize that staff members at specialized providers are especially well-versed in family planning and sexual health.<sup>114</sup> In addition, research indicates that the quality of care at specialized providers is higher: specialized family planning providers are significantly more likely to provide onsite the full range of FDA-approved contraceptives including intrauterine devices ("IUDs") and contraceptive implants.<sup>115</sup> Except for sterilization, these contraceptive methods, often called long-acting reversible contraceptives (LARCs), are by far the most effective. Moreover, a joint HHS-CDC study also showed that Title X centers consistently outperform other publicly funded providers such as non-Title X-funded federally qualified health centers in the provision of family planning care.<sup>116</sup> Requiring entities to provide (or at least providing a preference in grantmaking to entities that provide or are most closely in proximity to) comprehensive primary care would thus diminish reproductive health specialists' direct participation in the Title X program, to the great detriment of patients.

The primary justification for doing so appears to be the assertion that it will "decrease[] the overall cost and transportation challenges related to access for vital health care services that may be discovered as a result of routine family planning screening and consultation."<sup>117</sup> However, the need to schedule another appointment for patients in this scenario is commonplace. When a Title X patient needs additional care, even if there are providers on site or nearby, the patient almost always needs another appointment and another visit – this type of medical care is rarely provided on demand. The proposed rule offers no evidence to support HHS's hypothesis.

Because it will weaken the effectiveness and acceptability of the Title X program to patients and is not supported by any evidence-based justification that it will improve family planning care, § 59.5(a)(12) of the proposed rule should be withdrawn.

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### **The 2018 NPRM Impermissibly Attempts to Impose a Sweeping, Unclear, and Subjective New Eligibility Hurdle before Applicants Can Even be Considered for Grants and Proposes Muddled Changes to the Criteria for Awarding Title X Grants that Would Throw the Title X Program into a Constant State of Flux**

The current Title X regulation establishing the criteria that HHS uses to decide which grants to fund lists the same seven criteria that have successfully governed grantmaking in this program since 1971. Those seven criteria give the independent, expert review panels—a critical objective step that HHS uses for agency grantmaking—seven metrics against which to measure, score and differentiate Title X applicants.

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<sup>114</sup> See Frost et al., *Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Women's Health Care Needs*, at 519.

<sup>115</sup> See, e.g., Bocanegra et al., *Onsite Provision of Specialized Contraceptive Services: Does Title X Funding Enhance Access?*, 23 J. WOMEN'S HEALTH 428, 431-32 (2014); See also Mia R. Zolna & Jennifer J. Frost, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*.

<sup>116</sup> Carter et al., *Four Aspects of the Scope and Quality of Family Planning Services in U.S. Health Centers: Results from a Survey of Health Center Administrators* at 340.

<sup>117</sup> 83 Fed. Reg. at 25516.

The NPRM does not describe any problems, failures, or issues with the existing criteria as they have been used over the past decades, and there is no evidence the existing criteria need changing or are “inadequate.”<sup>118</sup> The NPRM claims, however, that its proposed changes would “[i]ncrease competition” and rigor in the process and “better ensur[e] quality applicants will be selected.”<sup>119</sup>

To the contrary, if the changed criteria for the selection of grantees are implemented, HHS will have unchecked discretion to exclude applicants and diminish competition prior to the merits review panel process; the review panels and HHS will operate under only a few very broad and in some instances internally inconsistent criteria, making rigorous evaluation more difficult; and change within the Title X network will be prioritized in each grant cycle. HHS should maintain the current § 59.7, a proven and effective set of criteria, and not cause these harms with its proposed new and unworkable set. Moreover, no different or additional criteria are needed to ensure that grantees align with “the statutory requirements and goals of Title X” and will use best clinical practices to advance “health benefits to clients of all ages” – they already do.<sup>120</sup> The operative HHS Policy Guidelines for Title X (which should also be maintained) and the QFP assist applicants and grantees in doing so.

In collapsing the existing seven criteria into four, and garbling several of those four, HHS unnecessarily introduces confusion and seriously undermines the usefulness of the criteria for their purpose of differentiating the best applications and best uses of Title X funds. The new proposed criterion number (1) simply points to all of the Title X statutory and regulatory requirements, but all projects must satisfy those (and do today), and therefore, it is unclear how review panels or HHS are to differentiate between applicants using that criterion.

The applicant’s capacity to “make rapid and effective use of the” federal funds for family planning has always been an important, separate criterion for Title X grantmaking.<sup>121</sup> Yet, now the NPRM proposes in its criterion number (2) to abolish that as a standalone consideration, and instead use “relative need of the applicant” combined with its capacity to make rapid and effective use of grant funds, “including and especially among a broad range of partners and diverse subrecipients and referral individuals and organizations, and among non-traditional Title X partnering organizations.”<sup>122</sup> Apparently, the involvement of “non-traditional Title X partnering organizations” and the applicant organization’s own need for funds, for example, are to be jumbled in with capacity to make rapid and effective use for Title X purposes to create one score.<sup>123</sup> This proposed blended criterion (2) would thus benefit Title X projects that include organizations that have never participated in Title X before, that have diversity among their organizational connections, and/or that have great relative need for funds, even if the proposed project is less promising on the essential factor of capacity to make rapid and effective use of the grant for the benefit of Title X patients.

Similarly, criteria numbers (3) and (4) seem to overlap, merge various concepts, and provide little in the way of any clear, useful standard for objective scoring on each criterion and for fair grantmaking. The proposed criteria would be far less effective as evaluative tools and provide much less rigor to the application review process than the current 42 C.F.R. § 59.7. These changes would make application targets less clear for those applying, make meaningful, independent, and objective review almost

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<sup>118</sup> *Id.* at 25505.

<sup>119</sup> *Id.* at 25517.

<sup>120</sup> *Id.*

<sup>121</sup> 42 U.S.C. § 300(b) (2018); 42 C.F.R. § 59.7(4) (2018).

<sup>122</sup> 83 FR 25530 at (proposed § 59.7(c)(2)).

<sup>123</sup> *Id.* at 25531.

impossible, and facilitate unbounded HHS decisionmaking as it assesses competing projects. The NPRM offers no evidence or explanation to show how the fewer and much less precise criteria would “better ensur[e] the selection of quality applicants” or make “the strongest prospective grantees” more likely to be selected.<sup>124</sup> They would not.

Instead, they highlight non-traditional Title X providers, innovative proposals, and increasing the different kinds (“diversity”) of subrecipients and referral organizations in ways that prioritize newness and change, even if traditional Title X organizations and tried-and-true methods of reaching patients would better use Title X funds most rapidly and effectively to serve the most patients. The NPRM marshals no support for the notion that non-traditional Title X subrecipients or partnering organizations would improve the effectiveness of the program. Furthermore, putting these “newness” criteria into the regulation would mean that introducing new organizations is not just a short-term goal but would be considered a priority in every grant cycle. HHS is proposing to require that applicants continually propose non-traditional partners and different kinds of subrecipients, with “innovative” ideas, to keep the Title X network churning. This is the opposite of what creates effective, reliable health care resources that are accessible for low-income patients in all communities.

Over time, the existing network of Title X grantees and subrecipients has been relatively stable, which has allowed the network’s providers to develop deep expertise in family planning and wide webs of connections they can offer to patients—characteristics that profoundly benefit the communities they serve and make their Title X projects extremely effective and efficient. Many service sites are specialized family planning centers, whether run by nonprofit providers or within government health departments, with clinicians focused on family planning care. Compared with non-Title X-funded health care providers, Title X sites provide higher quality care and are better able to help patients start and effectively use their chosen method of family planning.<sup>125</sup> These providers are more likely to provide the full range of FDA-approved contraceptives, including IUDs and contraceptive implants, onsite.<sup>126</sup> In addition, many patients prefer accessing care through a specialized Title X provider.<sup>127</sup> The NPRM provides no supporting evidence that there are lots of “non-traditional” Title X organizations and different kinds of new subrecipients out there that could somehow cycle into Title X care and improve low-income patients’ access to high-quality family planning services— rather than diminish the program’s effectiveness for its purpose. There are, however, many non-clinical organizations without experience in family planning who could steer the program away from its proper purpose and use Title X funds less effectively.

Even more concerning is the unchecked discretion HHS seeks to give itself to prevent applications from even reaching the real, objective review process that now governs the awarding of grants. The proposed § 59.7(b) states:

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

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<sup>124</sup> See *id.* at 25511.

<sup>125</sup> See, e.g., Hasstedt, *Why We Cannot Afford to Undercut the Title X National Family Planning Program* 21-22; Kinsey Hasstedt, *Understanding Planned Parenthood’s Critical Role in the Nation’s Family Planning Safety Net*, 20 GUTTMACHER POL’Y REV. 12-13 (2017), <https://www.guttmacher.org/gpr/2017/01/understandingplanned-parenthoods-critical-role-nations-family-planning-safety-net>.

<sup>126</sup> See, e.g., Bocanegra et al., *Onsite Provision of Specialized Contraceptive Services: Does Title X Funding Enhance Access?*, at 431-41; see also Zolna & Frost, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*.

<sup>127</sup> Jennifer J. Frost et al., *Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Women’s Health Care Needs*, at 525.

shall be deemed ineligible for funding. The Department 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.<sup>128</sup>

If, and only if, HHS deems an application sufficient on this blanket score – “clearly address[ing]” how the applicant will satisfy every requirement of “the regulation” – will the application be assessed by objective reviewers and actually considered for funding. Rather than fully protecting as wide a competition as possible, and ensuring that expert objective reviewers evaluate each proposal’s merits, this puts HHS in complete and virtually unfettered control of which applicants are truly allowed to compete. The proposed rule is unclear on whether “this regulation” is § 59.7 or the Title X regulations as a whole, and includes no details as to how HHS purports to determine whether an application has “clearly addressed” everything, nor is there any mechanism for oversight of HHS’s peremptory ability on this vague basis to remove applicants from the process. This new proposed authority evades objective review, makes fair and transparent competition impossible, and seems designed, along with the “newness” criteria, to be used to reshape the Title X network as HHS sees fit by allowing only favored applications to even reach the review panels and full, proper assessment of their applications.

As a matter of policy, this would fundamentally undermine the demonstrated success of Title X, which has promoted standards of excellence, relationships with communities served, and widespread access to family planning care throughout its history. This shift would supplant the expertise of merits review panels and the effective seven criteria that already exist for HHS decisionmaking with the unbounded, ideologically driven decisions of whomever is in office. An emphasis on newness will lead not only to inconsistencies from year to year, but to significant, ongoing disruptions in the Title X network, to the severe detriment of patients.

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### **The NPRM Fails to Come Close to Properly Estimating the Public Health Harms and Other Costs of the Proposed Rule and Offers No Evidence of Countervailing Benefits that Could Justify these Extraordinary Costs.**

The 2018 NPRM would, if adopted, fundamentally compromise the Title X program and is likely to lead to a significant public health crisis. In particular, if adopted the NPRM will lead to a significant increase in unintended pregnancies and undiagnosed and untreated sexually transmitted diseases as well as associated infertility. Moreover, because thousands of low-income patients are likely to lose access to lifesaving cancer screenings, the proposed changes will result in lost lives. Yet, shockingly, the NPRM includes no discussion of the human or even the economic costs associated with these public health outcomes.

Currently, the Title X program serves approximately four million patients each year.<sup>129</sup> In 2016, 2.8 million of those patients were using FDA-approved forms of contraception.<sup>130</sup> Title X-funded services helped women avert an estimated 822,300 unintended pregnancies in 2015 alone, thus preventing 387,200

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<sup>128</sup> 83 Fed. Reg. 25530.

<sup>129</sup> 2016 FPAR at ES-1.

<sup>130</sup> *Id.* at ES-2.

unplanned births and 277,800 abortions.<sup>131</sup> Without services provided by these providers, the US unintended pregnancy rate would have been 31% higher and the rate among teens would have been 44% higher.<sup>132</sup> Title X-funded health centers also provide a broad range of preventive health screenings. Title X-funded cervical and breast cancer screening services contribute to early detection and treatment.<sup>133</sup> In 2010 (the last year for which data is available) services provided within the Title X network also prevented 87,000 pre-term or low-weight births, 7,000 cases of pelvic inflammatory disease, 63,000 sexually transmitted infections, and 2,000 cases of cervical cancer.<sup>134</sup> 2016 data show that Title X-funded STD and HIV services continue to prevent transmission and adverse health consequences for their clients through the millions of tests performed each year.<sup>135</sup> Overall, the Title X program results in incredible government savings, with every dollar of public money invested resulting in \$7 of savings.<sup>136</sup>

The current structure of the Title X program ensures that these critical services go to those most in need, primarily low-income women. In 2016, more than 89% of Title X clients were female and two-thirds were under age 30.<sup>137</sup> Title X programs serve a racially and ethnically diverse population, including a disproportionately high percentage of black and Latina clients.<sup>138</sup> The vast majority of clients qualified for subsidized or no-charge services; 88% of clients had incomes at or below 250% FPL and 64% had incomes at or below 100% FPL.<sup>139</sup>

If adopted, the NPRM will cause the unraveling of this effective and critical safety-net program. The NPRM eliminates the requirement (and potentially bans) nondirective pregnancy options counseling and bans referrals for abortion, imposes cost-prohibitive separation requirements, imposes mandates for invasive and unnecessary actions against patients' wishes, and requires compliance with myriad new costly and time-consuming requirements, all of which are destined to drive highly qualified providers from the program. In addition, the NPRM would grant entities the ability to receive Title X funding, even if they do not offer modern methods of effective contraception, and prioritize funding for entities that provide primary care over specialists in family planning care that provide higher quality and more comprehensive care. Together, this means that if the NPRM is adopted, it will radically change the makeup of the Title X network, leaving patients without access to critical care in many instances and requiring subpar, ineffective care in others.<sup>140</sup>

If it attempts to continue with the NPRM, HHS must undertake an evidence-based, real-world assessment of its impact. Doing so will demonstrate that the public health and financial costs cannot possibly be

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<sup>131</sup> Frost et al., *Publicly Funded Contraceptive Services at US Clinics, 2015* at 10.

<sup>132</sup> Zolna & Frost, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*.

<sup>133</sup> 2016 FPAR at ES-3.

<sup>134</sup> Frost et al., *Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program*.

<sup>135</sup> 2016 FPAR at ES-3.

<sup>136</sup> Hasstedt, *Why We Cannot Afford to Undercut the Title X National Family Planning Program*.

<sup>137</sup> 2016 FPAR at ES-2.

<sup>138</sup> *Id.* (54% of program users identified as white, 21% as black or African-American, 32% identified as Hispanic or Latina, 3% as Asian, and 1% as either Native Hawaiian or Other Pacific Islander or American Indian or Alaska Native; 13% reported having limited English proficiency.)

<sup>139</sup> *Id.* at A-16 (Exhibit A-7a).

<sup>140</sup> HHS offers no factual basis (and there is none) for its assertions that the NPRM will result in an increased number of health care providers seeking to participate, that patient access to family planning would increase, or that the quality of service is "expected to improve." 83 Fed. Reg. at 25525. Indeed, when the NPRM attempts to provide some description of the purported "patient/provider benefits," it refers solely to primary care services, provider refusal statutes, and other topics beyond the scope of Title X, not to any benefits in family planning – the purpose for this federal funding. *Id.* at 25526.



justified. These comments highlight only a few examples of the many costs not factored into this proposed rulemaking.

### *Loss of access to effective contraceptives, STD and cancer screening, and associated costs*

As explained above, the extensive regulatory, administrative, and economic burdens of the proposed rule will be more than many Title X grantees and subrecipients can bare, and will undoubtedly lead to organizations leaving Title X. This will result in staff layoffs, and health centers that scale back their hours or close their doors altogether. The NPRM does not account for any costs associated with such consequences, such as unemployment for laid-off staff or the cost to patients in trying to find a new, trusted provider.

Furthermore, many displaced patients will likely not be able to find an affordable, high-quality provider when they need it, resulting in patients delaying care or not receiving it at all. Research has shown that when publicly funded family planning sites close, the majority of those patients lose their only access to health care.<sup>141</sup> Following substantial changes to Texas's family planning program, for example, many health centers reduced their hours or shut down and women reported difficulty accessing contraceptive services, which resulted in a spike in unintended pregnancy.<sup>142</sup> Research demonstrates that other health centers cannot meet the need if specialized family planning providers are forced to leave the Title X network.<sup>143</sup>

Even if displaced patients find some family planning care, they are likely to find access to less effective contraceptive methods rather than the most effective methods such as LARCs, again resulting in more unintended pregnancies. In 2016, 62% of Title X clients had adopted or continued use of a contraceptive method that HHS has categorized as a most or moderately effective method.<sup>144</sup> Health centers with a reproductive health focus, which currently make up 72% of all Title X providers,<sup>145</sup> are far more likely to offer these most and moderately effective methods and to use a variety of practices and protocols that help patients' initial use and continuation of these methods.<sup>146</sup> For example, virtually all Planned Parenthoods, which currently serve over 40% of all Title X contraceptive clients,<sup>147</sup> were found to perform strongly on nearly all measures aimed at facilitating patients' timely access to and continuation of a wide

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<sup>141</sup> Hasstedt, *Why We Cannot Afford to Undercut the Title X National Family Planning Program* (For four in ten women who obtain their contraception care from a safety net family planning center that focuses on reproductive health, that provider is their only source of care); see also Hasstedt, *Understanding Planned Parenthood's Critical Role in the Nation's Family Planning Safety Net* (26% of clients at a Planned Parenthood cite reported it was the only place they could get the services they need).

<sup>142</sup> See, e.g., Amanda J. Stevenson, et al., *Effect of removal of Planned Parenthood from the Texas Women's Health Program*, 374 *NEW ENG. J. MED.* 853 (2016); C. Junda Woo et al., *Women's Experiences after Planned Parenthood's Exclusion from a Family Planning Program in Texas*, 93:4 *CONTRACEPTION* 298; Kari White et al., *The Impact of Reproductive Health Legislation on Family Planning Clinic Services in Texas*, 105 *AM. J. PUB. HEALTH* 851-58 (2015).

<sup>143</sup> See Kinsey Hasstedt, *Federally Qualified Health Centers: Vital Sources of Care, No Substitute for the Family Planning Safety Net*, 20. *GUTTMACHER POL'Y REV.* 67 (2017). <https://www.guttmacher.org/gpr/2017/05/federally-qualified-health-centers-vital-sources-care-no-substitute-family-planning>.

<sup>144</sup> 2016 FPAR at A-21; *Id.* at 28 (The most effective methods are vasectomy, female sterilization, implant or IUD. The moderately effective methods are injectable contraception, vaginal ring, contraceptive patch, pills, diaphragm or cervical cap.).

<sup>145</sup> Frost et al., *Publicly Funded Contraceptive Services at U.S. Clinics*, 2015.

<sup>146</sup> Zola & Frost, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols* (practices and protocols that help patients' uptake and continuation of these methods include providing initial oral contraceptive pills and refills on-site, providing initial oral contraceptive pills using the quick start protocol, allowing women to delay their pelvic exam when initiating hormonal contraceptives, providing LARC methods to adolescents or nulliparous women, and offering same-day insertion of LARC methods).

<sup>147</sup> Frost et al., *Publicly Funded Contraceptive Services at U.S. Clinics*, 2015.

range of contraceptive services and supplies.<sup>148</sup> The NPRM adopts requirements that will push these kinds of specialized reproductive health providers out, and aims to bring primary care or non-clinical providers into Title X. If the Title X program is revamped as proposed by these regulations, patients would be receiving reduced access to the full array of effective contraceptives.

As just one illustration of the huge public health costs that will result, the Guttmacher Institute estimates, as cited above, that Title X health centers' services in 2015 alone helped women avert 822,300 unintended pregnancies, thus preventing 387,200 unplanned births.<sup>149</sup> Most of those affected patients would have incomes under 200% FPL, given Title X's priority for low-income patients, and thus those patients' births, if they occur, would likely be Medicaid-funded.<sup>150</sup> The average cost of a Medicaid-funded birth is \$7,950.<sup>151</sup> If even 20,000 additional Medicaid-funded births occurred, rather than being prevented, with the diminished access to effective contraceptives that the NPRM will produce—a number at the far low end of conceivable outcomes, and being offered here as purely illustrative, in order to show how these costs quickly multiply—those additional Medicaid-funded births would cost federal and state governments \$159 million. This number does not consider any of the other social welfare costs that state and federal governments would incur if low-income individuals lost access to contraceptives, or the many societal cost savings that will disappear if access to and the positive impact of Title X contraceptive services shrinks.

The costs for such a change will extend to more untreated STDs, including HIV, and fewer cervical cancer screenings, leading to higher rates of infertility and less early detection of cancer. Public health officials have noted that such changes to the Title X program will make STD testing and treatment harder to obtain at a time when STD infection rates are at an all-time high<sup>152</sup> because state and local governments have come to depend on Title X health centers to provide this care.<sup>153</sup> That is especially true for young people ages 15-24 who accounted for half of all new STD cases in 2016,<sup>154</sup> and who often take their concerns about STDs to a health center that gets Title X funding, where they can get confidential and no- or low-cost care. As a warning of the negative effect on public health that would occur if this NPRM is implemented nationwide, in Indiana, funding cuts to Planned Parenthood, the only provider of HIV testing in some rural counties, forced health centers to close and an outbreak of HIV infections followed.<sup>155</sup> Moreover, the costs of lost care through site closures and less effective practices does not include costs that will result from increased administrative and regulatory burdens for the Title X providers that remain, or from the new focus on adoption services and holistic primary care access that will also divert Title X funds.

The federal government has many resources for data collection and analysis, and it is HHS's obligation to undertake the work necessary to accurately estimate the full costs of this proposed Title X program overhaul. What is clear is that the proposed rule's costs, in terms of both public health outcomes and taxpayer dollars resulting from the loss of access to effective and acceptable Title X-funded family planning, will be enormous. And these are exactly the costs that Congress sought to avoid when creating the Title X program in the first instance – more unintended pregnancies, less individual control over the

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<sup>148</sup> Zolna & Frost, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*.

<sup>149</sup> Frost et al., *Publicly Funded Contraceptive Services at US Clinics, 2015*, at 10.

<sup>150</sup> Frost et al., *Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program* at 703.

<sup>152</sup> Centers for Disease Control and Prevention, *Sexually Transmitted Disease Surveillance 2016*.

<sup>153</sup> Michelle Andrews, *Trump's Redirection of Family Planning Funds Could Undercut STD Fight*, NAT'L PUB. RADIO (June 12, 2018), <https://www.npr.org/sections/health-shots/2018/06/12/618902785/trumps-redirection-of-family-planning-funds-could-undercut-std-fight>.

<sup>154</sup> Center Disease Control, *STDs in Adolescents and Young Adults* (Sept. 26, 2017), <https://www.cdc.gov/std/stats16/adolescents.htm>.

<sup>155</sup> Laura Bassett, *Indiana Shut Down Its Rural Planned Parenthood Clinics and Got an HIV Outbreak*, HUFFINGTON POST (Mar. 31, 2015).

timing and spacing of any children, and greater costs to society both in the medical care and other government services required for those births and with regard to the parents' economic future.

The NPRM considers none of them. On public health grounds alone, therefore, this proposal is a "significant regulatory action," as defined in Executive Order 12866, with an impact on the economy of \$100 million or more in one year, and thus it must be subject to a formal regulatory impact analysis, among other requirements.<sup>156</sup> The NPRM's extremely abbreviated and inadequately substantiated assessment of purported benefits and costs does not present the rule's true impact, and the NPRM, as a whole, fails to provide any evidentiary support that could possibly justify the expansive public health harms and other costs that will result from it.

### ***Oversight, record-keeping, and reporting costs***

Though HHS does purport to estimate some administrative and oversight costs associated with the NPRM's proposals, its discussion of such costs dramatically underestimates the compliance, record-keeping and reporting expenses that would result from it. At every turn, the NPRM underestimates the number of staff or consultants, the amount of time, and the scope of the tasks involved, which are not merely administrative but require grantees, subrecipients, and others to assess information and activities, and undertake ongoing added training or program steps, to assure compliance.

As just one example, HHS drastically underestimates the amount of time that would be necessary to comply with new proposed §§ 59.5(13) and 59.7(b), if grantees and subrecipients could even gather and supply all of the requested information, which is not possible. In the face of requirements for new, "detailed descriptions" of ongoing activities with "subrecipients, referral agencies and individuals," to be filed at multiple times, and repeated "clear explanation[s]" of oversight and how grantees satisfy all requirements, HHS includes only the vast underestimate of four hours per year at each grantee and subrecipient. Attempting to gather the information HHS seeks related to subrecipients, referral agencies, and individuals, as well as compiling narratives regarding each Title X-funded entity's complete compliance and effective oversight, will certainly take much more than the four hours each year. Instead of less than one million dollars, these types of new costs would amount to many millions across all grantees, subrecipients, referral agencies, and individuals. Moreover, these costs are unnecessary because they add to reporting and compliance systems that are already adequate.

The NPRM also fails to adequately consider the cost of new requirements related to encouragement of family participation, screening of minors for victimization, and mandating additional medical record-keeping, including necessary changes to electronic medical records systems.

As an initial matter, the proposed rule would impose new requirements to document compliance with both new screening requirements and the specific actions taken by a Title X project to encourage minors to involve family in their decisions to seek family planning services in a minor's medical record. It is unclear whether HHS takes the screening documentation into account at all, and it estimates that new medical record-keeping (apparently only about family participation) would encompass only the work of "a physician assistant" for two minutes per patient, for a total of \$2 million per year for approximately 600,000 adolescents. This underestimates the costs on multiple scores: it misidentifies the type of personnel likely involved; underestimates the time that would be required; and undercounts the number of adolescent patients (approximately 800,000) for whom such documentation would be required in order for Title X providers to prove compliance.

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<sup>156</sup> 83 Fed. Reg. at 25521

Even more significantly, HHS fails to acknowledge the expensive changes to electronic health record (EHR) systems that would be necessary in order to capture newly required minor screening and encouragement of parental involvement information in a manner that reports can be run and compliance proven to HHS. To comply with the reporting requirements proposed by the 2018 NPRM, Title X entities would need to make the changes to their EHR systems in order to: document in the minor's medical records the specific actions taken to encourage family participation in the minor's decisions to seek family planning services; document new affirmative HHS screening requirements to rule out victimization of minors; and maintain records that would identify the age of any minor clients served, the age of their sexual partner(s) where required under these rules, and what reports or notifications were made to appropriate state agencies. While some of this information may already be routinely collected, in order to comply with the NPRM, Title X-funded entities would need to record it in the EHR in a manner that could be compiled into periodic reports or compliance reviews for HHS. For entities that use EHR, which include the majority of Title X providers, that means new costs in adding data elements, templates, and drop-down menus, so that the added record-keeping could occur and be proven across all records.

According to an OPA Sustainability Survey in 2016, 69% of all Title X-funded service sites utilize EHR.<sup>157</sup> (These numbers are likely higher now two years later.) But even assuming this lower number, that means approximately 2,664 of 3,861 Title X service sites use EHRs. By NFPRHA's very rough estimates, the costs for each Title X entity using EHR could easily run \$10,000 to \$30,000 just to create the modified templates and other record-keeping changes in EHR systems that could accommodate HHS's proposed new requirements. Even assuming changes for only 2,000 entities at \$20,000 each, these changes would cost \$40 million. Moreover, all clinical staff would then need to be trained on the new templates and other modifications to EHR, another large cost that HHS omits.

Furthermore, it will not be feasible to make the required changes within the 60-day transition period provided under the NPRM. Rather, changes such as these will require, at minimum, approximately six months, according to businesses that provide modification and implementation of changes within EHR systems. None of these realities or costs is considered by HHS in the proposed rule.

### ***Physical and financial separation costs***

Another large expense virtually ignored by HHS's cost estimates are the onerous new physical and financial separation requirements the proposed rule attempts to impose. The NPRM emphasizes that any sharing of physical facilities would not sufficiently delineate separation of abortion-related activities (83 FR 25527) and also appears to require complete separation of staff, record-keeping systems, phone lines, websites, etc. (83 FR 25532) (proposed § 59.15).

The economic analysis of this provision is deficient in at least two respects: it is based on a significant underestimate of the number of entities that would be required to separate, and it drastically undervalues the costs involved in such separation.

With the respect to the first issue, the NPRM appears to estimate that just 15% of service sites would need to "come into compliance with physical separation requirements" in the first year, if those sites were to remain in the Title X program.<sup>158</sup> There is no legitimate rationale for this low estimate, which among other

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<sup>157</sup> Office of Population Affairs, *Service Delivery Infrastructure: Title X Sustainability Assessment*, <https://www.hhs.gov/opa/title-x-family-planning/title-x-service-delivery-improvement/infrastructure/index.html>

<sup>158</sup> 83 Fed. Reg. at 25525.

flaws appears to be premised on the falsehood that the separation requirements will only impact entities that provide abortion outside their Title X projects. In using this number, HHS ignores the broad scope of its own rule, the sweep of its physical separation mandate, and the significant prohibitive effect it will have on Title X entities' ability to continue to perform otherwise-permissible activities with non-Title X funds. It also ignores the reality that providing nondirective options counseling, including referrals upon request, for pregnant patients, upon their request, is the medical standard of care, and that satisfying the NPRM's full physical separation requirements is likely to be deemed necessary for organizations to be able to continue providing those services to any patients.

Even for the gross underestimate of 15% of the sites that HHS acknowledges would have to come into compliance (e.g. set up a separate facility, with separate staff, and separate medical records), HHS includes only a single sentence in the NPRM that might address some cost of physically transforming facilities, though that one sentence is unclear. HHS estimates that it would cost between \$10,000 and \$30,000 per site "to come into compliance with physical separation requirements" in the first year, with no explanation of how this number is derived or whether it includes only managerial time or instead purports to include any cost for the actual building or leasing and equipping of separate facilities.

In fact, any creation of a physically separate site would cost orders of magnitude more than these numbers. It would cost hundreds of thousands of dollars or more to locate and open a facility, staff it, purchase separate workstations, set up separate record-keeping systems, etc. Many, if not most, Title X entities will not be able to afford the cost of creating separate facilities, and thus will either have to forego activities they should be able to continue or have to leave the program. But even if a few sites undertake these massive costs of building and equipping a separate facility—even 200 sites (roughly 5%)— they would quickly amass costs far exceeding HHS's estimates for creating physical separation: 200 construction and outfitting projects of just \$300,000, likely far below the actual average cost for such projects, would be \$60 million. This physical transformation, moreover, does not include staffing and other operational costs, such as utilities and other overhead. Furthermore, HHS ignores the ongoing, annual cost to entities to continue maintaining a separate facility, with its separate staffing and other numerous ongoing costs.

These types of outlays are simply not possible for most Title X family planning organizations, but if even a small percentage of sites attempt them, the costs are exorbitant and not justified by any need for further separation. Title X projects already operate all of their non-Title X activities separately from their Title X work, and have done so consistently under the 2000 HHS guidance for almost 20 years without any significant compliance issues, and certainly HHS has offered none (either actual or potential) that are not already addressed under current rules and effectively handled through existing grants management powers.

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For all of these reasons, the entire NPRM and each aspect of it addressed above should be withdrawn, and the Title X program should continue to operate under its current regulations, the QFP, HHS's existing Program Guidelines, and HHS's 2000 guidance on separation.

NFPRHA appreciates the opportunity to comment on the Title X NPRM, "Compliance with Statutory Program Integrity Requirements." If you require additional information about the issues raised in these comments, please contact Robin Summers at [rsummers@nfprha.org](mailto:rsummers@nfprha.org) or 202-552-0150.

Sincerely,

A handwritten signature in cursive script that reads "Clare M. Coleman". The signature is written in a dark ink and is positioned above the printed name.

Clare Coleman  
President & CEO