



## **Amendments to the Title X Regulations: *Compliance with Statutory Program Integrity Requirements***

### **Frequently Asked Questions *Updated August 13, 2019***

**Note: These FAQs are current as of August 13, 2019, and may not reflect subsequent HHS or court activity.  
For the most recent information regarding compliance, see Section V.**

#### **I. Background Regarding Title X Program**

##### **What is Title X?**

Established in 1970, the Title X program, which was authorized by Title X of the Public Health Service Act, provides funding “to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents).” The Title X program is administered by the Office of Population Affairs within the U.S. Department of Health and Human Services (HHS).

##### **What are Title X services?**

The *Program Requirements for Title X Funded Family Planning Projects* issued by the Office of Population Affairs indicates that Title X services include, but are not limited to: the delivery of related preventive health services; cervical and breast cancer screening; STD and HIV prevention education, testing and referral; and pregnancy diagnosis and counseling.

##### **What does the Title X statute state regarding abortion services?**

The Title X statute states that “[n]one of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.”

#### **II. Impacted Organizations**

##### **Which organizations must comply with the Title X regulations?**

The Title X regulations are only applicable to organizations that receive Title X funding. With minor exceptions, the Title X regulations are equally applicable to Title X direct grantees, subrecipients, and contractors. Agencies and individuals providing primary care referral services on behalf of Title X projects

(including, but not limited to, health centers and hospital outpatient primary care practices) that do not receive Title X grant funds through one of those three methodologies are not required to satisfy any Title X reporting obligations or otherwise comply with Title X requirements simply by virtue of maintaining the referral relationship.

Organizations that do not receive any Title X funding are not subject to the Title X requirements.

### III. Recent Changes to Title X Regulations Set Forth in the March 4, 2019, Final Rule

**As described in Section IV of these FAQs, as of the date of these FAQs (Aug. 13, 2019) the March 4, 2019, Final Rule and the regulatory requirements described below are in effect and may be enforced by HHS<sup>1</sup>.** It is important to note, however, that federal courts in Washington, Oregon, California, Maine, Maryland, and the U.S. Courts of Appeals for the Fourth and Ninth Circuits are currently litigating whether the amendments to the Title X regulations are lawful. Such litigation may impact the implementation and enforcement of the amended Title X regulations. Title X grantees, subrecipients, and contractors should accordingly monitor the status of the litigation and closely review any guidance provided by HHS.

#### What are some of the categories of major changes recently made to the Title X program regulations?

On March 4, 2019, the Administration published a “Final Rule” amending the regulations that govern the Title X family planning program (located at 42 CFR part 59, subpart A.) A copy of the Final Rule may be obtained at <https://www.govinfo.gov/content/pkg/FR-2019-03-04/pdf/2019-03461.pdf>.

The Final Rule includes new requirements related to, but not limited to, the following issues:

- counseling on pregnancy options and mandatory referrals for prenatal care;
- responding when a pregnant woman requests a referral for an abortion;
- financial and physical separation between activities funded under Title X and any prohibited abortion-related activities;
- documenting specific actions taken to encourage family participation when caring for minors;
- establishing a plan to comply with State and local requirements regarding notification or reporting child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, or human trafficking; and
- enhanced monitoring of subrecipients.

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<sup>1</sup> As discussed below, compliance with the physical separation requirements is not mandatory until March 4, 2020.

Each of these changes is discussed below.

**Do the March 4, 2019, Title X regulations mandate, permit, or prohibit counseling regarding pregnancy options?**

*The March 4, 2019, regulations permit, but do not require, nondirective pregnancy counseling, including nondirective counseling on abortion. The March 4, 2019, regulations also establish that the pregnancy counseling may only be provided by physicians and advanced practice providers (APPs).<sup>2</sup> This is a significant change from the prior Title X regulations, which mandated that Title X projects offer pregnant women the opportunity to be provided information and counseling regarding each of the following options: prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination.*

**Do the March 4, 2019, Title X regulations mandate referrals for prenatal care for *all* pregnant women?**

Yes. According to the Final Rule, while the decision to offer nondirective counseling is subject to the discretion of physicians and APPs, referral for prenatal care is required for any patient who is pregnant because such care is “*medically necessary to maintain or improve the health of both the mother and the unborn baby.*” Note that the “referral for prenatal care” may be a referral to another provider within the same organization, albeit outside of the Title X project.

**Do the March 4, 2019, Title X regulations mandate, permit, or prohibit abortion referrals?**

*Other than in limited circumstances (e.g., medical emergency and rape and/or incest), the March 4, 2019, Title X regulations prohibit Title X projects from referring patients for abortions (referred to in the Final Rule as “abortions for family planning purposes”), and from taking other affirmative action to assist a patient to secure such an abortion.*

In addition, under the March 4, 2019, Title X regulations, Title X providers have the option -- but are not required - to give a single list of providers to any pregnant woman, regardless of whether the pregnant woman asks for the list. All providers named on the list must be licensed, qualified comprehensive primary health care providers (including providers of prenatal care). Some (but not the majority) of the providers on the list may provide abortion in addition to comprehensive primary care. The Title X staff must not identify to the woman which, if any, providers on the list offer abortion, and the list cannot otherwise be used to indirectly refer for abortion or to identify abortion providers to a client.

**What should a Title X provider do if a pregnant woman requests an abortion or abortion referral?**

The Final Rule sets forth that “*in the circumstance where a pregnant woman asks for an abortion or an abortion referral for family planning purposes, the project’s response would be to say it does not refer for abortions, and then to offer her, if she desires, a list of comprehensive primary health care providers*”

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<sup>2</sup> APPs are defined as including physician assistants and advanced practice registered nurses (APRN). Examples of APRNs include certified nurse practitioners (CNPs), clinical nurse specialists (CNSs), certified registered nurse anesthetists (CRNAs), and certified nurse-midwives (CNMs).

*(including providers of prenatal care); that list could include (but not identify) such providers that also perform abortions.”* As noted in the previous question, some – but not the majority – of the providers on the list may provide abortion in addition to comprehensive primary care.

The prohibition on referring patients for an abortion is a significant change from the prior Title X regulations, which indicated that a Title X project must provide a patient with a “*referral upon request.*”

### **What are the financial and physical separation requirements under the March 4, 2019, Title X regulations?**

The March 4, 2019, Title X regulations set forth that a Title X project must be organized so that it is physically and financially separate from abortion activities which are otherwise prohibited under the regulations (*e.g.*, providing abortion services, promoting abortion, referring patients for an abortion for family planning purposes). In order to be physically and financially separate, a Title X project must have an objective integrity and independence from such prohibited abortion activities. Mere bookkeeping separation of Title X funds from other monies would not be sufficient. Whether such objective integrity and independence exists is assessed based on a review of facts and circumstances. The March 4, 2019, Title X regulations specify that factors relevant to this determination include:

- The existence of separate, accurate accounting records;
- The degree of separation of the Title X activities from facilities (*e.g.*, treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites) in which prohibited activities occur and the extent of such prohibited activities;
- The existence of separate personnel, electronic or paper-based health care records, and workstations;
- The extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent.

The above requirement under the March 4, 2019, Title X regulations to maintain physical and financial separation is a significant change from the prior regulations, which mandated financial, but not physical, separation between the Title X project and the abortion activities of the Title X grantee/subrecipient (*e.g.*, the prior regulations permitted shared facilities, common staff, and a single file system).

Compliance with the physical separation requirements is not mandatory until March 4, 2020.

### **Do the March 4, 2019, Title X regulations amend the requirements applicable to encouraging family participation in minors’ decision to seek family planning services?**

Yes. To ensure compliance with the requirement that Title X projects encourage family participation in the decision of minors to seek family planning services, the March 4, 2019, Title X regulations require Title X projects to document in each minor’s medical records the specific actions taken to encourage such

family participation or the specific reason why such family participation was not encouraged. This documentation is not required if the Title X provider documents in the medical record that (1) the minor is suspected to be the victim of child abuse or incest and (2) it has, if permitted or required by applicable State or local law, reported the situation to the relevant authorities.

**Do the March 4, 2019, Title X regulations address obligations to report child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, or human trafficking to appropriate State/local agencies?**

Yes. The March 4, 2019, Title X regulations set forth that Title X projects must comply with State and local requirements regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, or human trafficking. The March 4, 2019, Title X regulations further require that Title X projects have in place a plan to implement the specific reporting requirements that apply to the project's State (or jurisdiction), as well as to provide annual training for all Title X personnel with respect to these requirements. Such plans must include protocols to identify individuals who are victims of sexual abuse or targets for underage sexual victimization and to ensure that every minor who presents for treatment is provided counseling on how to resist attempts to coerce minors into engaging in sexual activities. The March 4, 2019, Title X regulations also require Title X projects to conduct a preliminary screening of any minor who presents with an STD, pregnancy, or suspicion of abuse, in order to rule out victimization of the minor. Records must be maintained that would identify, among other things, the age of any minor clients served, the age of their sexual partner(s) where required by State law, and what reports or notifications were made to appropriate State agencies.

**My organization is a Title X subrecipient, meaning that the organization receives Title X funds from a Title X grantee, rather than directly from HHS. Do the March 4, 2019, Title X regulations impact how the Title X grantee will monitor and oversee our Title X activities?**

Yes. The March 4, 2019, Title X regulations note that HHS believes there has been insufficient transparency and accountability in the use of taxpayer funds because Title X grantees have not been required to provide HHS with sufficient information about subrecipients. The March 4, 2019, Title X regulations accordingly require Title X grantees to include, as part of their applications, a list of all subrecipients, detailed descriptions of the extent of services and collaboration with subrecipients, and a clear explanation of how the applicant would ensure that the subrecipients comply with Title X requirements.

#### **IV. Effective Date of the March 4, 2019, Title X Regulations**

**Where are the March 4, 2019, Title X regulations being challenged and what impact do the challenges have on the implementation of the amended regulations?**

In March 2019, several States and other Title X grantees filed lawsuits to block HHS' implementation of the March 4, 2019, Title X regulations. These cases were filed in federal courts in Washington State, Oregon, California, Maryland and Maine. In April 2019, federal courts in Washington and Oregon issued nationwide preliminary injunctions preventing HHS from implementing and enforcing the March 4, 2019,

Title X regulations.<sup>3</sup> A federal court in California issued a similar preliminary injunction, but limited its effect to California. In May 2019, a federal court in Maryland issued a preliminary injunction, prohibiting HHS from implementing the March 4, 2019, Title X regulations in Maryland. In July 2019, the Maine federal court ruled in favor of HHS and denied the preliminary injunction.

HHS appealed the rulings of the federal courts in Oregon, Washington State, and California to the U.S. Court of Appeals for the Ninth Circuit (“Ninth Circuit”) and the decision of the Maryland federal court to the U.S. Court of Appeals for the Fourth Circuit (“Fourth Circuit”). Concurrently, HHS asked that the Fourth and Ninth Circuits stay (or put on hold) the preliminary injunctions pending appeal. On June 20, 2019, the Ninth Circuit granted HHS’ request to stay the injunctions. Similarly, on July 2, 2019 the Fourth Circuit also granted HHS’ request to stay the effects of the Maryland preliminary injunction. *As such, as of the publication of these FAQs, HHS has the authority to implement the Title X regulations nationwide.*

The current situation could very well change. For instance, on July 3, 2019, the Ninth Circuit agreed to rehear arguments regarding the decision to stay the preliminary injunctions (issued by the Oregon, Washington, and California courts) with an en banc panel (i.e., before eleven judges of the Ninth Circuit). Similarly, the Fourth Circuit is currently considering whether to rehear its decision to stay the effects of the appeal en banc. In either case, the en banc panel could allow the preliminary injunctions to take effect again.

Regardless of how the en banc panel (potentially panels) rules with respect to the preliminary injunctions, these challenges to the March 4, 2019, Title X regulations will continue for the foreseeable future. A preliminary injunction is not a “ruling on the merits” (i.e., a final decision) by a federal district court. As such, the cases will return to the lower federal courts until those courts decide whether to issue permanent injunctions. When those decisions are made, the defeated party will again have the opportunity to appeal to their respective court of appeals. Any one of these courts, or the circuits over them, may rule against HHS at some point in the future. Further, due to the importance of the subject matter and the breadth of the challenges, an ultimate decision by the Supreme Court is feasible.

### **Updated: Are the March 4, 2019, Title X regulations currently in effect?**

As described below, several lawsuits challenging the March 4, 2019, Title X regulations temporarily prevented HHS from implementing the such regulations on May 3, 2019. However, recent litigation ended such delays, granting HHS with authority to implement and enforce the March 4, 2019, Title X regulations. On July 15, 2019, HHS sent an email stating that “Compliance with the requirements of the Final Rule, except for the physical-separation requirements, is therefore required as of Monday, July 15, 2019.”<sup>4</sup>

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<sup>3</sup> An injunction is a court order that prevents or stops a person or organization from taking certain actions. Injunctions may also compel an individual or organization to take certain actions. In this case, the federal courts had prevented HHS from implementing or enforcing the March 4, 2019, Title X regulations, finding that the plaintiffs (various States and Planned Parenthood) were likely to succeed in their claims against HHS.

<sup>4</sup> See <https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/statutes-and-regulations/compliance-with-statutory-program-integrity-requirements/index.html>

## V. Complying with the March 4, 2019, Title X Regulations – Added 8/13/19

### **New: What guidance has HHS provided about compliance with the new regulations?**

On July 20, HHS issued a [Grantee Guidance document](#) outlining steps that Title X **grantees** (not sub-recipients) are expected to take to demonstrate “good faith efforts” to come into compliance. These include:

- Submitting an “Assurance and Action Plan Documenting Steps to Come Into Compliance” to HHS by August 19, 2019
- Submitting a “Statement and Supporting Evidence with Compliance Requirements” to HHS by September 18, 2019

HHS has also published sample plans for meeting these requirements:

- [Part 1:](#) 2019 Title X Regulations Sample Compliance Plan (due August 19, 2019)
- [Part 2:](#) 2019 Title X Regulations Sample Compliance Plan (due September 18, 2019)

To date, HHS has not issued any requirements for Title X **subrecipients** to submit information directly to HHS. However, each Title X subrecipient should remain in close contact with its Title X grantee to ensure coordination on any changes that may be needed to ensure compliance with the new rules. This should include discussing and reviewing any potential revisions to the Subrecipient Agreement.

### **New: Has HHS published other documents explaining the new rules or how to comply with them?**

The following documents are available on the HHS website:

- [Title X Guidance: Frequently Asked Questions](#)
- [Fact Sheet:](#) Final Title X Rule Detailing Family Planning Grant Program
- [Title X Final Rule Compliance and Enforcement: Myth vs. Fact](#)

### **New: What other actions should health centers that receive Title X funding take at this time?**

***All health centers that receive Title X funding – either as grantees or subrecipients -- are strongly advised to update their Policy and Procedure (P&P) on Women’s Reproductive Health Services promptly, to ensure that it reflects the new Title X rules.*** (Note that the previous template P&P provided by NACHC reflected the outdated Title X requirements.) NACHC will provide an updated template for this P&P on its [Women’s Health webpage](#) not later than Friday August 16, 2019.

Health Centers that do not receive Title X funding may also choose to update this P&P, as the previous version referred to Title X requirements which have been superseded by the recent Final Rule. However, there is less urgency for them to make these updates than for health centers that receive Title X funds.