Advancing Quality Family Planning Practices: A Guide For Health Centers

Prepared by Feldesman Tucker Leifer Fidell LLP for the National Association of Community Health Centers



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Disclaimer

Advancing Quality Family Planning Practices: A Guide for Health Centers is a resource to support health centers in their efforts to improve access to high quality and comprehensive family planning services.

This Guide was prepared for the National Association of Community Health Centers, Inc. (NACHC) by attorneys with the law firm of Feldesman Tucker Leifer Fidell LLP, with funding from the Office of Population Affairs and the Centers for Disease Control and Prevention within the Department of Health and Human Services. It is designed to provide accurate and authoritative information in regard to the subject matter covered. While based on the principles of federal law, this Guide is published with the understanding that it does not constitute, and is not a substitute for, legal, financial, or other professional advice. Health centers should consult knowledgeable legal counsel and financial experts to pursue a particular Title X strategy.

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$Table \ of \ Contents$

| Introduction | 6 |
|--|---|
| Chapter 1: The Health Center Program and Family Planning Services | 9 |
| Required Services | 10 |
| Recent Studies Evaluating Family Planning Services in the Health Center Setting | 11 |
| Chapter 2: Quality in Family Planning Service Delivery: OPA/CDC Recommendations | 12 |
| Quality Family Planning Recommendations | 13 |
| Clinical Settings and QFP Recommendations | 14 |
| Achieving QFP Recommendations | 14 |
| Chapter 3: Payment and Reimbursement Considerations | 17 |
| Medicaid and "Family Planning Services and Supplies" | 18 |
| Family Planning under Federal Law | 18 |
| Long-Acting Reversible Contraceptives | 19 |
| Medicaid Family Planning Services in Federally Qualified Health Centers (FQHCs) | 19 |
| Examples from the Field | 20 |
| Chapter 4: Title X Family Planning Program | 23 |
| History and Overview | 24 |
| Title X Funding | 25 |
| Key Title X Requirements | 26 |
| Chapter 5: Key Considerations in Including a Title X Project within Your Health Center Project Managing Multiple Funding Streams Schedule of Discounts Reporting Operational Considerations Training | 30 31 32 33 35 36 |
| Chapter 6: Becoming a Title X Grantee or Subrecipient | 38 |
| Applying as a Direct Grantee | 39 |
| Program Priorities and Key Issues | 40 |
| Review and Selection Process | 42 |
| Project Period | 42 |
| Establishing a Subrecipient Relationship | 43 |

$Table \ of \ Contents$

| Chapter 6: continued | |
|--|----|
| Uniform Guidance | 43 |
| Subawards Generally | 43 |
| Making Subawards | 44 |
| Terms and Conditions Specific to a Subrecipient Agreement | 44 |
| Monitoring the Subrecipient's Performance | 46 |
| Subrecipient Perspective and Health Centers | 46 |
| Chapter 7: Collaboration Models | 47 |
| Collaboration as a Health Center Program Priority | 48 |
| Planning Process: Laying the Foundation for a Successful Collaboration | 49 |
| Scope of Project Considerations | 49 |
| Chapter 8: Referral Arrangements | 51 |
| Fundamentals of Referral Relationships | 52 |
| Establishing a Coordinated and Defined Referral Relationship | 52 |
| Referrals and Scope of Project | 53 |
| Key Features of a Referral Relationship | 55 |
| Referral Agreement Checklist | 57 |
| Chapter 9: Purchase of Clinical Services Arrangements | 60 |
| Fundamentals of Referral Arrangements | 61 |
| Purchase of Clinical Services and Scope of Project | 62 |
| Key Features of a Purchase of Clinical Services Arrangement | 62 |
| Purchase of Clinical Services Agreement Checklist | 64 |
| Chapter 10: Corporate Integration Models | 67 |
| Fundamentals of Corporate Integration | 68 |
| Merger | 68 |
| Partial Consolidation | 68 |
| Key Features of a Consolidation Strategy | 70 |
| Consolidation Checklist | 71 |

Prologue

Family planning and reproductive health services are integral to primary health care. The lack of convenient access to these services drives up rates of unintended pregnancies, sexually transmitted diseases, and late stage cancer diagnoses. Family planning and reproductive health services have proven to be a sound investment for our communities. For every \$1 spent on family planning, there is an estimated \$7.09 saved in Medicaid spending.

Health centers can be leaders in expanding and improving community access to family planning and reproductive health services. Health centers are highly accessible, patient-centered, and serve as the primary medical home for over 25 million people in 9,800 rural and urban communities across America. For our patients, access to quality family planning and reproductive health services can make the difference between finishing high school and dropping out. It can enable a woman who has never had a pap smear to finally get the cervical cancer screening she needs.

Advancing Quality Family Planning Practices: A Guide for Health Centers provides guidance to health centers wishing to expand and improve access to quality family planning and reproductive health services in their community. The Guide highlights requirements and considerations for health centers interested in improving their provision of quality family planning and reproductive health services, including becoming a Title X grantee or subrecipient. This Guide also summarizes various models to collaborate with existing family planning providers in order to leverage the organizations' respective strengths, ranging from referral relationships to corporate consolidation. We hope this Guide can advance the critical role of health centers in delivering quality family planning and reproductive health services.

Introduction

- Highlights:• The HRSA Technical Assistance Resource, *Family Planning and Related*
Services in Health Centers, indicates that quality family planning services
are an important part of reproductive health care for women and families
and summarizes the applicable Health Center Program requirements.
 - The report, *Providing Quality Family Planning Services—Recommendations* of *CDC and the U.S. Office of Population Affairs*, provides evidence-based recommendations for furnishing quality family planning services.
 - Multidirectional care coordination is a critical strategy to advance the provision of quality family planning services within a health center setting.

In its June 2016 Technical Assistance Resource, Family Planning and Related Services in Health *Centers,* the Health Resources and Services Administration (HRSA) indicates that "[q]uality family planning services are an important part of reproductive health care for women and families. Family planning services include patient-centered counseling, contraceptive services, pregnancy testing and counseling, assisting patients who want to conceive, basic infertility services, preventive services to improve overall health, and screening and treatment for sexually transmitted diseases."1 The report further notes that "[e]nsuring access to family planning services, including access to the full range of [Food and Drug Administration] approved contraceptive methods, is an important strategy to help reduce unplanned pregnancy."²

Health centers should aim to provide quality family planning services as defined in the HRSA Technical Assistance Resource, *Family Planning and Related Services in Health Centers.*

Family Planning Achievements and the Need for Continued Progress

Family planning is one of the ten greatest public health achievements of the 20th century.³ According to an April 2016 report issued by the Centers for Disease Control and Prevention (CDC), births to all American teenagers have dropped more than 40% within the past decade.⁴

Despite these accomplishments, access to quality family planning services continues to be an area of significant need.

 There is a disproportionate burden of unintended pregnancy, breast and cervical cancer, and sexually transmitted diseases (STDs) among minority groups, teens, and young adults in the United States.⁵ The HRSA Technical Assistance Resource, *Family Planning and Related Services in Health Centers*, includes links to several resources that address various topics to support health centers to provide quality family planning services and address potential barriers to providing the full-range of Food and Drug Administration (FDA)-approved contraceptive methods, including billing and reimbursement, provider and team training needs, and patient awareness about the availability of a chosen contraceptive method.

Investing in Family Planning: Dollars and Sense

In 2010, unintended pregnancy cost U.S. taxpayers an estimated \$21 billion each year in direct medical care.⁹

According to a 2014 study, for every \$1 spent on family planning, there is an estimated \$7.09 saved in Medicaid spending.¹⁰

- Almost half of all pregnancies in the United States are unintended.⁶
- One in eight pregnancies in the United States results in preterm birth, and infant mortality rates remain high compared with those of other developed countries.⁷
- Although regular Pap testing has contributed to decreasing cervical cancer incidence and mortality, half of women diagnosed with cervical cancer have never had a Pap test.⁸ Research has shown

that factors associated with not receiving a Pap test include, but are not limited to, being low income and uninsured.¹¹

- At some point in their lives, most sexually active people will contract a STD, the most common of which are human papilloma virus (HPV), chlamydia, and gonorrhea.¹²
- More than 1.1 million people in the United States are living with HIV and almost 1 in 6 are unaware of their HIV status.¹³ Although women only represent approximately 25% of people living with a diagnosis of HIV, women of color are disproportionately represented.¹⁴

These alarming data underscore the need for improved family planning services, particularly in medically underserved communities.

Quality Family Planning

In 2014, the CDC and the Office of Population Affairs (OPA) released evidence-based recommendations for providing quality family planning services.¹⁵ The recommendations are set forth in a report, *Providing Quality Family Planning Services—Recommendations of CDC and the U.S. Office of Population Affairs* and described more in depth in Chapter 2.¹⁶

While the recommendations are core to the Title X Family Planning Program, a central goal of the OPA/ CDC report is to assist primary care providers, like health centers, to offer family planning services that will help individuals achieve their desired number and spacing of children, increase the chances that a baby will be born healthy, and improve their health even if they choose to not have children. Establishing a family planning strategy can be an effective way to ensure patients have access to quality family planning services, as set forth in the recommendations.

Care Coordination to Ensure Access to Family Planning Services

As the United States health care system evolves in response to increased efforts to contain costs and emphasize preventive care, providers of family planning services will face new challenges and opportunities in care delivery. For example, as noted in the report <u>Providing Quality Family Planning Services</u>— <u>Recommendations of CDC and the U.S. Office of</u> <u>Population Affairs</u>, family planning providers will have increased opportunities to serve new patients and to serve as gateways to other essential health care services for existing patients. This latter role is particularly relevant for health centers given their comprehensive scope of services and medical home model of care.

The report also highlights the importance of multidirectional care coordination in efforts to improve health outcomes.

Care coordination is particularly critical in the context of family planning services within a health center setting. Some health centers may prefer not to provide family planning services directly, but rather opt to make family planning services available to its patient population through collaborative referral relationships with providers in the community. In addition, even if a health center directly furnishes comprehensive and quality family planning services, some patients may prefer to receive such services in a separate clinical setting, such as a Title X service site, given the sensitive nature of such care.

It helps to build in planning time to improve family planning services at your health center.
—Health Center Administrator

Chapter 1: *The Health Center Program and Family Planning Services*

Chapter Highlights: • By law, health centers are required to provide or arrange for voluntary family planning and reproductive health services such as gynecologic and obstetric care and screening for cancer and STDs.

- Voluntary family planning services are defined in HRSA's Technical Assistance Resource, <u>Family Planning and Related Services in</u> <u>Health Centers</u>.
- All <u>FDA-approved contraceptive services</u> can be found on the FDA website.
- Research has shown that while virtually all health centers furnish some level of family planning services consistent with Section 330 requirements, there is an identified need to improve the scope and quality of such care.
- Providing quality family planning services offers a great opportunity to increase the number of patients served and improve patient care.

Health centers, as one the nation's largest safety net systems of primary and preventive care, are uniquely poised to play a critical role in expanding access to quality family planning services. The vast majority of health centers directly provide some level of family planning services. However, the scope and quality of such services varies extensively.

The federal law that authorizes the Health Center Program, Section 330 of the Public Health Service Act (Section 330), requires that health centers provide, either directly or through an established arrangement, a broad range of primary and preventive health care services.¹⁷ The list of required services includes "voluntary family planning services."

Voluntary family planning: Services include appropriate counseling on available family planning options, consistent with federal, state, and local laws and regulations. These services may include management/treatment as appropriate for a patient's chosen method, (e.g., vasectomy, tubal ligation, and placement of long-acting reversible contraception [LARC]). More information on the full range of FDA-approved contraceptive methods is available on the FDA website page, Birth Control: Medicines to Help You.

G I have been fortunate to work in a community health center that supports the full integration of family planning services into our primary care. Since our first Title X grant in 2004, we expanded our services from 1,000 family planning users to now over 12,000. *>*

> -Lucy Loomis, MD, MSPH Denver Health's Community Health Services

Health centers are also **required by law to provide**, or arrange for the provision of, additional services related to reproductive health, including:¹⁸

Gynecological care: Services include the regular preventive assessment and appropriate treatment of conditions or disorders of the female reproductive system (with the exception of obstetrical services). At a minimum, these services must include pelvic and breast exams and the review of menstrual and reproductive history and gynecological symptoms. Services may also include common gynecological procedures (e.g., colposcopy, hysterectomy, and fibroid removal).

Obstetrical care: Services include the clinical assessment, management/treatment, and coordination of services and referrals for the mother and fetus to maximize the outcome of the pregnancy. Such services extend from the mother's diagnosis of pregnancy through the approximately six-week period following the delivery and can be divided into three components: 1) prenatal; 2) intrapartum (labor & delivery); and 3) postpartum. Services include progressive risk assessments of mother, fetus, and the newborn.

Cancer screenings: At a minimum, such services must include screening for breast, cervix, and colorectal cancers (e.g., mammography, Pap test, fecal occult blood test, sigmoidoscopy, and colonoscopy).

Communicable disease screenings: At a minimum, health centers must test for HIV, Hepatitis B and C, and other STDs based on a patient's identified risk factors and established guidelines.

Recent Studies Evaluating Family Planning Services in the Health Center Setting

A 2013 study of health centers' provision of family planning services, which was published through the Milken Institute School of Public Health at George Washington University (GWSPH), found that although virtually all health centers furnish some level of family planning services consistent with Section 330 requirements, there is an identified need to improve the scope and quality of such care.¹⁹

Of the surveyed health centers, 87% of all service sites delivered what could be characterized as a "typical" package of care, defined as testing and treatment for STDs, prescription, and/or delivery of oral contraceptives plus one additional contraceptive method (e.g., injectables, IUDs, emergency contraception pills, condoms or hormonal implants).²⁰ However, the scope of care and approach to service delivery varied widely:

- Only 19% of survey respondents reported that their largest sites both prescribe and dispense all forms of contraception onsite. Injectable and barrier method contraceptives represented the methods most commonly available onsite.²¹
- Some of the most common types of contraceptive services, such as birth control pills, were frequently unavailable for onsite dispensing, despite their low cost and the importance of immediate availability in promoting access to care.²²
- Virtually all surveyed health centers maintained referral arrangements for services they did not offer onsite, such as vasectomies and tubal ligation, yet the formality of such relationships varied across the health centers. Some, but not all, referral arrangements included explicit agreements to make referrals available on a sliding fee basis.²³

The 2013 GWSPH study found that "Title X participation was the single strongest predictor of onsite, comprehensive family planning services (outreach, counseling, and a broad range of methods) at the largest service site for each reporting health center."²⁴

A subsequent 2015 GWSPH study surveyed almost 2,000 women of childbearing age who received care at health centers. Only 10% of the women surveyed affirmatively desired to get pregnant in the coming year, and yet among women who were not actively seeking pregnancy, nearly one in three were not using contraceptives.²⁵ The report concluded that greater efforts should be made to ensure that women of childbearing age who receive care at health centers are routinely screened for pregnancy intentions and are assured full access to the most effective forms of family planning furnished in accordance with confidentiality standards.²⁶

According to the 2013 GWSPH study, major factors contributing to the challenge for health centers to maintain the scope and quality of family planning services include the following:²⁷

- The cost of care coupled with the financial realities associated with serving low-income populations;
- Difficulties attracting and retaining specialized clinical and counseling staff;
- The unique considerations associated with serving adolescents; and
- Issues associated with how best to communicate the value and importance of family planning services to patients and communities.

It's important to learn how to 'sell' the value of family planning services especially to the young patients and communities who will benefit the most.
—Health Center Administrator

Chapter 2: *Quality in Family Planning Service Delivery: OPA/CDC Recommendations*

Chapter Highlights: The report, <u>Providing Quality Family Planning Services—Recommendations</u> of <u>CDC and the U.S. Office of Population Affairs</u>, describes evidence-based guidance for delivering family planning services in health care settings and provides steps providers can take to assess the needs of a client and decide which family planning services to offer.

- The Quality Family Planning recommendations can serve as a tool to help health centers evaluate and improve upon their provision of family planning services.
- Clinical performance measures can be used to inform quality improvement efforts within Family Planning Programs.
- Resources from the <u>Family Planning National Training Center (FPNTC)</u> are available to help health centers implement the Quality Family Planning recommendations.

Quality Family Planning Guidelines

In April 2014, the CDC and OPA released a CDC Morbidity & Mortality Weekly Report (MMWR) entitled Providing Quality Family Planning Services-Recommendations of CDC and the U.S. Office of *Population Affairs.*²⁸ Aimed at existing or potential providers of family planning services, the report sets forth the Quality Family Planning (QFP) recommendations, which describe evidence-based guidance for delivering family planning services in health care settings. At the heart of the report's recommendations is the idea that improving the quality of family planning services will lead to improved reproductive health outcomes. Specifically, by applying the QFP recommendations, providers can effectively assist persons and couples to achieve their desired number and spacing of children and increase the likelihood that those children are born healthy.

The report provides an overview of steps providers can take to assess the needs of a client and decide which family planning service(s) to offer. In addition, it describes how to provide quality family planning services, with specific recommendations regarding each of the following:

- Providing contraception to help women and men plan and space births, prevent unintended pregnancies, and reduce the number of abortions;
- Offering pregnancy testing and counseling;
- Helping clients who want to conceive;
- Providing basic infertility services;
- Providing preconception health services to improve infant and maternal outcomes and improve women's and men's health; and
- Providing STD screening and treatment services to prevent tubal infertility and improve the health of women, men, and infants.

Recommended questions to ask when assessing a client's reproductive life plan

Providers should discuss a reproductive life plan with clients receiving contraceptive, pregnancy testing and counseling, basic infertility, STD, and preconception health services in accordance with CDC's recommendation that all persons capable of having a child should have a reproductive life plan.*

Providers should assess the client's reproductive life plan by asking the client questions such as:

- Do you have any children now?
- Do you want to have (more) children?
- How many (more) children would you like to have and when?

* Source: CDC. Recommendations to improve preconception health and health care—United States: a report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care. MMWR 2006; 55 (No. RR-6).

We learned quickly that collaborating and forging strong relationships with partnering agencies is vital to the delivery of comprehensive family planning services.

-Jane Lose, CNM, ANP, MSN, Metro Community Provider Network The QFP recommendations synthesize existing clinical recommendations from CDC, other federal agencies, and professional medical associations. Of particular importance are: (1) CDC's <u>US Medical</u> <u>Eligibility Criteria for Contraceptive Care</u>, 2016, which describes safety considerations related to contraceptive use for women and men who have certain characteristics or medical conditions; and (2) CDC's <u>US Selected</u> <u>Practice Recommendations</u>, 2016, which describes how to manage a group of common, yet sometimes controversial or complex, issues regarding initiation and use of specific contraceptive methods.

The final section of the QFP recommendations examines quality improvement initiatives, describing actions that all providers of family planning services should implement to ensure high quality.

OPA and CDC intend to revisit the key criteria to achieving quality family planning and, as necessary, revise the QFP recommendations over time to meet that standard and stay current with the evidence base as it evolves.

Clinical Settings and QFP Recommendations

The intended audience for the QFP recommendations is not limited to organizations that receive Title X funding. Rather, the intended audience is broad, including private and public providers of comprehensive primary care, such as health centers.

Indeed, health centers are obvious candidates to implement the QFP recommendations because of their patient-centered medical home model of care, broad scope of primary and preventive health care services, and focus on serving low income populations. Using the QFP recommendations as a tool will help health centers to evaluate and improve upon their provision of family planning services.

Achieving QFP Recommendations

HRSA's June 2016 Technical Assistance Resource, <u>Family Planning and Related Services in Health</u> <u>Centers</u>, highlights the Health Center Program requirement that health centers provide, or arrange for the provision of, obstetrics, gynecology, and voluntary family planning services to their patients. It further notes that ensuring access to family planning services, including access to the full range of FDA-approved contraceptive methods, is an important strategy to help reduce unplanned pregnancy.

Below is a summary of key points from the QFP recommendations that should be considered when health centers are planning how to implement the recommendations:

- All female and male patients of reproductive age should be screened for their pregnancy intention on a routine (i.e., annual) basis. See page 16 for more information about how to screen patients for their pregnancy intention.
- A primary focus of the QFP recommendations is to determine and meet the needs of each patient. All services, including contraceptive care, should be offered in a fully client-centered manner, which respects the patient's preferences. The QFP recommendations identify numerous factors that providers should address when assisting patients in selecting a contraceptive method (e.g., method effectiveness, correct use of the method, non-contraceptive benefits, side effects, social-behavior factors, risk of intimate partner violence, mental health and substance use behaviors).
- Patients should be offered a full range of FDAapproved contraceptive methods, preferably on a same-day, onsite basis. If this is not possible, then a robust referral network should be in place

so that the client's contraceptive care can be provided on a timely and accessible basis.

- Adolescents should be offered family planning services, with some additional considerations:
 - Adolescents should be provided comprehensive information about how to prevent pregnancy and STDs, including information about contraception and abstinence as an effective approach;
 - Confidential family planning services should be made available to adolescents, while observing applicable federal and state laws and any legal obligations for reporting;
 - Adolescents should be encouraged to talk with their parents/guardians about sexual and reproductive health;
 - Adolescents should be informed that LARC methods are safe and effective for adolescents; and
 - Pregnant/parenting adolescents should be referred to local home visiting programs that have been shown to provide needed support and reduce rates of repeat teen pregnancy.
- Clients should be offered preconception health services, with priority on those clients who are seeking pregnancy or at high risk of unintended pregnancy. Preconception health services include counseling about folic acid and screening for intimate partner violence, alcohol and other drug use, tobacco use, immunizations, depression, obesity, blood pressure, diabetes, and STDs.
- Health centers should consider integrating clinical performance measures of contraceptive care into their quality improvement programs. Information about measures of contraceptive care endorsed

by the National Quality Forum is available on the <u>OPA's website page</u> that highlights performance measures.

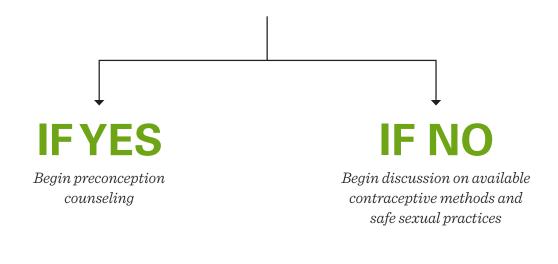
OPA supports an online <u>Family Planning National</u> <u>Training Center (FPNTC)</u> that provides many resources (e.g., job aids, patient education materials, elearning courses, learning collaboratives) to help implement the QFP recommendations.

ONE KEY QUESTION®

As part of broader efforts to expand and improve family planning services, many family planning providers are implementing a new initiative called **ONE KEY QUESTION**[®]. Developed by <u>Oregon</u> <u>Foundation for Reproductive Health</u>, ONE KEY QUESTION[®] (OKQ) is an initiative created specifically to better integrate family planning into primary care. The approach is simple — primary care providers ask all women of reproductive-age one screening question:

"Would you like to become pregnant in the next year?"

Depending on the answer, the clinician will then provide appropriate services.



The goal is to make family planning part of the primary care discussion through OKQ, instead of waiting for patients to ask their provider about contraception or preconception care.

While the overall effectiveness of OKQ still needs to be studied, initial pilot programs have been successful in both decreasing unintended pregnancies and improving the health of women and children during pregnancies.

For more information on ONE KEY QUESTION®, including OKQ patient brochures, provider resources, and related articles, visit <u>www.orfrh.org</u> or <u>www.onekeyquestion.org</u>, email <u>info@onekeyquestion.org</u>, or call: 503-223-4510.

Chapter 3: *Payment and Reimbursement Considerations*

| Chapter Highlights: | • The HRSA Technical Assistance Resource, <i>Family Planning and</i> <u>Related Services in Health Centers</u> , lists several documents that can assist health centers address potential reimbursement challenges. |
|---------------------|---|
| | • Since 1976, federal law has provided enhanced (90%) federal financial participation (FFP) in state expenditures for family planning services and supplies. |
| | • In its 2010 amendment to the Medicaid statute, Congress created a new optional Medicaid eligibility group that includes low-income individuals who receive family planning services as a standalone Medicaid benefit. |
| | • In 2016, the Centers for Medicare & Medicaid Services (CMS) acknowledged that LARCs are an effective form of contraception and encouraged states to improve access to LARCs by overcoming adminis- trative and logistical barriers. Some states are making such efforts. |
| | • Family planning services between an eligible provider and a Medicaid recipient should be identified as billable Federally Qualified Health Center (FQHC) "visits", triggering a <i>Prospective Payment System</i> |

(PPS) payment by the state.

• This Chapter highlights several state policies that reflect "best practices" for facilitating the provision of family planning services in health centers.

Health centers contemplating expanding the provision of family planning services must consider the costs of such expansion (e.g., additional staff and supplies) compared to anticipated grant support and revenue. In particular, health centers should pay close attention to Medicaid coverage of LARCs as well as other services related to family planning counseling and contraception. As noted below, HRSA's June 2016 Technical Assistance Resource, *Family Planning and Related Services in Health Centers*, lists several documents that can help address potential billing and reimbursement challenges.

Medicaid and "Family Planning Services and Supplies"

Family planning services and supplies have been a covered Medicaid benefit under federal law since 1972. Since 1976, states have been required to provide family planning services and supplies under Medicaid to categorically needy individuals of childbearing age who request them.²⁹

Even though "family planning services and supplies" is listed as a mandatory benefit in the Medicaid statute, the scope of such services and supplies is not specifically defined; the only two categories clearly included are family planning counseling and contraception.³⁰ Guidance from the CMS noted that states are "free to determine the specific services and supplies which will be covered as Medicaid family planning services," so long as the services and supplies are sufficient in amount, duration, and scope to achieve their purpose.³¹

Family Planning under Federal Law

Congress has repeatedly signaled the importance of family planning services in the Medicaid program. Since 1976, federal law has provided for enhanced (90%) federal financial participation (FFP) in state expenditures for family planning services and supplies.³² Moreover, federal policy prohibits patient cost sharing for family planning services.

In 2010, the Medicaid statute was amended to provide for a leaner Medicaid "alternative benefit" package for members of a new "adult group"—i.e., low-income non-elderly adults who are not otherwise eligible for Medicaid.³³ Nonetheless, the law required states that choose to cover the adult group to include family planning services and supplies in the alternative benefit package.³⁴

More than half of states have created programs that extend Medicaid eligibility for family planning services to people who were not otherwise Medicaid-eligible. Fourteen states had adopted family planning state plan amendments as of January 2016.³⁵

Before the enactment of this provision, many states had provided standalone Medicaid family planning benefits to individuals not otherwise eligible for Medicaid by creating a Medicaid family planning waiver program through Section 1115 waivers and through state plan amendments, which resulted in permanent changes to a state's Medicaid program. Some family planning waiver programs and state plan amendments continue to exist, especially in states that opted not to expand their full Medicaid programs.³⁶

Long-Acting Reversible Contraceptives

In recent years, as part of a policy effort at the federal level to ensure more effective coverage of family planning services and supplies under Medicaid, CMS has urged states to cover a comprehensive Medicaid family planning benefit.

The coverage of LARCs, which have been shown to be a highly effective form of contraception, has emerged as a key Medicaid family planning policy issue in recent years.³⁷ A 2016 survey by the Kaiser Family Foundation found that coverage of IUDs and implants was "widespread" and that no states reported they limited access to LARCs by requiring prior authorizations, although some states apply utilization limits under their fee-for-service programs, such as by limiting coverage to certain brands.³⁸

Even where LARCs are covered, some state Medicaid agencies impose onerous limitations on their use. For example, some states incorporate "step therapy," which is a type of policy under which a LARC may be used only after other forms of birth control have failed, while others structure payment in a disadvantageous manner, such as by refusing to provide for a separate payment to providers for a LARC insertion procedure.³⁹

In a June 2016 State Health Official Letter, <u>Medicaid</u> <u>Family Planning Services and Supplies</u>, CMS recommended that states "*cover all FDA-identified contraceptive methods for beneficiaries, including both prescription and non-prescription methods.*"⁴⁰ In this letter, CMS encouraged states to explore and pursue certain models to improve access to LARCs by overcoming "*administrative and logistical barriers*" to the provision of LARCs. CMS noted that some of the models were already being used by certain states. CMS' letter builds upon an April 2016 memorandum to state Medicaid agencies, highlighting practices implemented in several states to improve the availability of LARCs.⁴¹ Some of these promising practices focus on removing the logistical barriers that providers face in managing LARC supplies, while others aim to remove administrative barriers to the use of LARCs, such as lack of reasonable reimbursement for clinicians' professional services in inserting, removing, or re-inserting a LARC.

Additional information regarding the April and June 2016 resources is set forth on page 22.

Medicaid Family Planning Services in Federally Qualified Health Centers (FQHCs)

States must pay FQHCs on a per-visit basis using a cost-related reimbursement methodology often referred to as the *Prospective Payment System (PPS)*.⁴² Each FQHC's per-visit rate takes into account the costs associated with both (1) FQHC services, as defined in federal law; and (2) *"any other ambulatory services offered by a [FQHC] and which are otherwise included in the plan."*⁴³

Federally Qualified Health Center (FQHC)

The terms "FQHC" and "Health Center" are often used interchangeably. FQHC status is a designation under the Medicaid and Medicare statutes that enables the designated entity to obtain cost-based payment for Medicaid, Medicare, and CHIP services.

Given that this Chapter specifically focuses on health centers as FQHCs, the acronym FQHC is used throughout. "FQHC services" includes the services of physicians, midlevel clinicians (including nurse practitioners and physician assistants), licensed clinical social workers, and clinical psychologists, as well as services incident to those services.⁴⁴ These are sometimes referred to as the "core" FQHC services. The term "any other ambulatory services" refers to any outpatient Medicaid services that are both listed in the Medicaid State Plan and currently provided by a given FQHC.⁴⁵

The inclusion of "any other ambulatory services" in the Medicaid FQHC benefit is a key concept for purposes of health centers' role as Medicaid family planning providers. Because family planning services are a mandatory outpatient Medicaid benefit, this service must be encompassed in a state's Medicaid FQHC payment methodology, and importantly, this is true even when the services are furnished by clinical personnel other than the "core" FQHC providers.

In order for family planning services to be included meaningfully in the PPS methodology, the costs associated with performing these services should have been included as allowable costs on any FQHC cost report that was used to set the PPS rate. Generally, family planning services between an eligible provider and a Medicaid recipient should be identified as billable FQHC "visits" triggering a PPS payment.

G It's important to include all of the departments at the health center in planning meetings (front desk staff, providers, clinic managers, IT, billing). Bring them to the table at the beginning. We didn't include billing at first and lots of questions came up.

 $-Health \, Center \, Administrator$

Examples from the Field

Below are several examples of "best practices" that would facilitate the provision of Medicaid family planning services in FQHCs. A growing number of states are moving to implement these types of policies.

First, the provision of family planning counseling should qualify as a billable FQHC "visit," and Medicaid agencies should pay for such visits even when they occur on the same day as another (non-family planning) encounter. Generally, where a beneficiary is entitled to both full Medicaid benefits and another form of coverage, such as Medicare, Medicaid serves as the secondary payer. This means that after Medicare or any other primary form of coverage pays, the provider bills the Medicaid agency and it is obligated to make an additional payment to the provider to the extent that the PPS-level payment exceeds the Medicare payment.

Example: Arkansas

Arkansas Medicaid recognizes the "periodic family planning visit" as an FQHC billable visit. The visit includes a follow-up medical history, counseling regarding contraceptives, evaluating the patient's contraceptive program, renewing or changing the contraceptive prescription, and giving the patient opportunities for additional counseling regarding reproductive health and family planning.⁴⁶

Importantly, the periodic family planning visit is a billable visit even if no medical service (e.g. pelvic exam, laboratory services, LARC insertion) other than counseling is performed. In addition, health centers may bill for a periodic family planning visit and for a medical visit (non-family-planning-related) on the same day. Second, the insertion, re-insertion, or removal of a contraceptive device by a qualified clinician should qualify as a billable FQHC "visit."

Example: Maryland and Alabama

The Maryland and Alabama Medicaid agencies have revised their FQHC reimbursement rules to ensure that when an FQHC clinician inserts a LARC, the FQHC both receives an encounter payment for the office visit, and also is reimbursed for the LARC. The Maryland policy guidance provided for reimbursement for the LARC at actual acquisition cost.⁴⁷

Third, Medicaid programs should mitigate FQHCs' logistical burdens associated with acquisition of and billing for LARCs, by providing at least for payment at acquisition cost.

Example: South Carolina

Several states in recent years have revised their reimbursement policies regarding LARCs in order to ensure that providers, including health centers, are reimbursed for the cost of the device. This change, while an improvement over existing policy in many states, does not fully address the logistical obstacles associated with making LARCs available. Those obstacles include the difficulty of keeping adequate supply of LARCs available to meet patients' needs, and the costs that providers incur when a device that they order is not used in the patient for whom it was ordered.

In March 2014, the South Carolina Medicaid agency revised its policies to address these issues.⁴⁸ Specifically, for outpatient utilization of LARCs (including within FQHCs), South Carolina will pay for the LARC through its pharmacy program. Specialty pharmacies bill Medicaid for the LARC on behalf of a provider and ship it to the provider overnight for insertion. The provider, in turn, bills Medicaid only for insertion of the LARC.

CMS has also recently indicated in guidance that it hopes to support states in other types of policy interventions that would make LARCs more readily available under Medicaid, such as the use of the demonstration authority under Section 1115(a) of the Social Security Act to make available administrative funding for states to maintain an inventory of LARCs for Medicaid providers. Under such a demonstration, the state would incur an administrative cost to purchase a stock of LARCs for use by the Medicaid provider, and the agency would re-stock the provider once the stock is depleted. While such a policy has yet to be implemented in any state, it would be particularly helpful for health centers, which as safety net providers, are uniquely impacted by the logistical burdens of furnishing high-cost services and supplies.

Additional Resources

According to HRSA's June 2016 Technical Assistance Resource, *Family Planning and Related Services in Health Centers*, health centers are encouraged to use the following resources to enhance access to quality family planning services among the populations served:

- A <u>State Health Official Letter on Family</u> <u>Planning</u>, released on June 14, 2016 regarding the delivery of family planning services. The guidance clarifies policies that apply in both fee-for-service (FFS) and Medicaid Managed Care regarding contraceptive coverage, including the use of all FDA-approved methods of contraception, examples of appropriate and inappropriate utilization management methods, and guidance on advance purchasing of family planning methods, including LARCs.
- An Informational Bulletin, released on April 8, 2016, describing emerging payment approaches several state Medicaid agencies have used to optimize access and use of LARC methods as part of the Center for Medicaid and CHIP Services (CMCS) Maternal and Infant Health Initiative.
- The Medicaid Managed Care Final Rule, released on April 25, 2016, includes clarifications about family planning policies within managed care including: choice of family planning provider, including ability to receive services from family planning provider without a referral; free choice of family planning method, including the prohibition of utilization management methods that restrict a beneficiary's free choice of family planning method; and demonstration of a sufficient number of family planning providers within a Managed Care Organization to ensure timely access.

Chapter 4: *Title X Family Planning Program*

Chapter Highlights: The Title X Family Planning Program is the only federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services. The Title X Family Planning Program is administered by the Office of Population Affairs (OPA) in the Department of Health and Human Services (HHS).

- The Title X Family Planning Program network includes more than 4,000 service sites, covering every state, the District of Columbia, and eight United States territories.
- Approximately 20% of the current Title X service sites identify as health centers.
- Each Title X project must provide a broad range of acceptable and effective contraceptive methods approved by the FDA (including natural family planning methods) and services (including infertility services and services for adolescents). In addition, each Title X project must provide for medical services for family planning, social services for family planning, and informational and educational programs.
- Title X projects must provide contraceptive methods and supplies and information to all who want and need them, with priority given to persons from low-income families. Similar to the Health Center Program, there are corresponding requirements to waive or reduce charges in accordance with a patient's ability to pay.
- This Chapter highlights key requirements applicable to Title X projects. Copies of the Title X statute, regulations, legislative mandates, Program Guidelines, and Program Policy Notices may be downloaded from <u>OPA's website</u>.

History and Overview

For more than 40 years, Title X family planning clinics have provided high quality and cost-effective family planning and related preventive health services for low-income women and men, playing a critical role in ensuring access to voluntary family planning information and services.⁴⁹ The Title X Family Planning Program provides federal funds to public and private nonprofit organizations for the provision of family planning information and services—services which improve maternal and infant health, lower the incidence of unintended pregnancy, reduce the incidence of abortion, and lower rates of STDs.⁵⁰ While these services are available to all, the Title X Family Planning Program's priority population is low-income individuals and families. Many of the individuals served by organizations that receive Title X funding are also health center patients.

The Title X Family Planning Program is the only federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services.

Created in 1970 and authorized under Title X of the Public Health Service Act,⁵¹ the Title X Family Planning Program is funded through monies appropriated as a line item to the Health Resources and Services Administration (HRSA) and administered by the Office of Population Affairs (OPA), both of which are within the United States Department of Health and Human Services (HHS).

Title X in Your Community

The Title X Family Planning Program network includes more than 4,000 service sites, covering every state, the District of Columbia, and eight United States territories, and serving over 4 million patients annually.⁵² Organizations that receive Title X funding, either as direct grantees or as subrecipients, include state,

Key Title X Family Planning Program Definitions⁵³

Grantee: The entity that receives direct federal financial assistance via a grant and assumes legal and financial responsibility and accountability for the awarded funds and for the performance of the activities approved for funding.

Project: Activities described in the competitive grant application and any incorporated documents supported under the approved budget. The "scope of the project" as defined in the funded application consists of activities that the total approved grant-related project budget supports.

Subrecipient: Those entities that provide family planning services with Title X funds under a written agreement with a grantee. May also be referred to as "delegates" or "contract agencies."

Service Site: The clinics or other locations where services are provided by the grantee or subrecipient.

Understanding the Grantee, Subrecipient and Service Site Relationship

While only 94 organizations received Title X Family Planning Services Grants in 2014, Title X funding supported a larger service network that included 1,134 subrecipients. The subrecipient relationship, while relatively uncommon in the Health Center Program, is prevalent in the Title X Family Planning Program. For more information regarding the subrecipient relationship, see Chapter 6. county, and local health departments as well as private nonprofit organizations, such as health centers. Currently, approximately 20% of the Title X service sites identify as Health Center Program grantees.

Title X Project

Each Title X grant has an established **Title X project**. The project encompasses the activities described in the competitive application for a Title X Family Planning Services Grant, and any incorporated documents supported under the approved budget. As with the Health Center Program, an organization that is a Title X grantee or subrecipient may operate multiple service sites within the federally-approved Title X project.

An organization that receives Title X funding, either directly or as a subrecipient, may have activities outside of its Title X project (customarily referred to as "other lines of business") as long as such activities are properly distinguished and operationally separate from the Title X project and are not reflected in the total approved Title X budget.

Title X Funding

In fiscal year 2016, the Title X Family Planning Program received approximately \$286,500,000 in funding.⁵⁴ In 2015, 91 competitive Title X grants were awarded: 46 (51%) to state and local health departments and 45 (49%) to non-profit family planning and community health agencies.⁵⁵

How can my health center become a recipient of Title X grant funds?

As described in Chapter 6, health centers seeking to obtain Title X Family Planning Services Grant funds may do so by:

(1) applying through a competitive grantprocess to become a direct grantee of TitleX Family Planning Services Grant funds; or

(2) becoming a subrecipient to an organization that receives Title X Family Planning Services Grant funds.

Supporting Contraceptive Services Yields Cost Savings

The Title X Family Planning Program and additional publicly-supported Family Planning Programs serve approximately 9 million women in the U.S. each year and provide significant cost savings to taxpayers. In 2010, every public dollar invested in Family Planning Programs and providers yielded an estimated \$7.09 in government savings. These Family Planning Programs helped women avoid unintended pregnancy as well as potential reproductive-related diseases and infertility as a result of screening and testing services provided by such programs.⁵⁶

A directory of Title X grantees, subrecipients, and service sites is available on <u>OPA's website</u>.

Title X Requirements and Guidelines

Title X of the Public Health Service Act provides authority to make grants and enter into contracts under the following Sections:

1001—Project Grants and Contracts for Family Planning Services;

1003—Training Grants and Contracts;

1004—Research; and

1005—Informational and Educational Materials.57

This Guide focuses exclusively on Section 1001: Project Grants and Contracts for Family Planning Services.

The Title X statute⁵⁸ and its implementing regulations⁵⁹ establish the framework of the Title X Family Planning Program. From the statutory and regulatory framework, OPA developed additional operational guidance for projects funded under Title X. This guidance, referred to collectively as the Title X guidelines, consists of the following two documents:

- 1. the Program Requirements for Title X Funded Family Planning Projects; and
- the April 25, 2014 report, Providing Quality Family Planning Services—Recommendations of CDC and the U.S. Office of Population Affairs, as discussed in greater detail in Chapter 2 of this Guide.⁶⁰

In addition, OPA issues guidance through Program Policy Notices, which are posted on <u>OPA's website</u>.

A summary of key Title X requirements is set forth below. Note that this summary does not address all requirements of the Title X Family Planning Program. **Services:** Each Title X project must provide a broad range of acceptable and effective contraceptive methods approved by the FDA (including natural family planning methods) and services (including infertility services and services for adolescents).⁶¹ If an organization offers only a single method of family planning, it may nonetheless participate as part of a Title X project as long as the entire project offers a broad range of family planning services.⁶²

In addition, each Title X project must provide:

- Medical services related to family planning (including physician's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated;⁶³
- Social services related to family planning, including counseling, referral to and from other social and medical service agencies, and any ancillary services which may be necessary to facilitate clinic attendance;⁶⁴ and
- Informational and educational programs.65

The *Program Requirements for Title X Funded Family Planning Projects* 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 human immunodeficiency virus (HIV) prevention education, testing and referral; and pregnancy diagnosis and counseling.⁶⁶ In regard to pregnancy diagnosis and counseling, Title X projects must offer pregnant women the opportunity to receive information and counseling regarding each of the following options:⁶⁷

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

If a woman requests such information and counseling, the Title X project must provide neutral, medically accurate, factual information and nondirectional counseling on each option, 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.⁶⁸

Title X funds may not support the provision of abortion as a method of family planning.

Voluntary Participation: A cornerstone of the Title X Family Planning Program is voluntary participation: all services must be voluntary in nature and individuals may not be coerced into choosing (or not choosing) a specific service or method of family planning. Additionally, no one service may be a prerequisite for another.⁷²

Confidentiality: Due to the sensitive nature of family planning services, Title X projects must set up adequate safeguards to protect each patient's privacy. Information obtained by Title X project staff about an individual receiving services may not be disclosed without the individual's documented consent, except as required by law or as may be necessary to provide services to the individual, with appropriate safeguards for confidentiality.⁷³ Information may otherwise be disclosed only in summary, statistical, or other aggregate form that does not identify the individual.⁷⁴

Access to Services: Services furnished through Title X projects must be provided in a manner that protects the dignity of the individual and without regard to their religion, race, color, national origin, residency, handicapping condition, age, sex, number of pregnancies, or marital status.⁷⁵ Title X projects may not limit access to services, for example, by requiring physician referrals or imposing residency requirements (i.e., requiring that an individual reside in any specific county, state, or country for any length of time) in order to receive services.⁷⁶

Provision of Required Family Planning Services by Referral or Contract

Title X projects may furnish required family planning services directly, by contract, or by referral. If required services are provided by referral, the Title X grantee is expected to have written agreements for the provision of such services and reimbursement of costs as appropriate.⁶⁹ In addition, the Title X grantee must ensure that services provided through a contract or other similar arrangement are paid for under agreements that include a schedule of rates and payment procedures maintained by the Title X grantee.⁷⁰ The Title X grantee must be prepared to substantiate that these rates are reasonable and necessary.⁷¹

More Information

For more information regarding the confidentiality requirements applicable to the provision of services to minors, see OPA's Program Policy Notice 2014-01, <u>Clarification</u> <u>regarding "Program Requirements for Title</u> <u>X Family Planning Projects" Confidential</u> <u>Services to Adolescents</u> and Program Policy Notice 2016-11, <u>Integrating with Primary</u> <u>Care Providers</u>. **Charges, Discounts and Collections:** Title X projects must provide contraceptive methods and supplies and information to all who want and need them, with priority given to persons from low-income families.⁷⁷ Similar to the Health Center Program, there are corresponding requirements to waive or reduce charges in accordance with a patient's ability to pay, which is assessed based on family income, as measured by the federal poverty level (FPL).⁷⁸ There are, however, some notable differences between the fee discount requirements under Title X and Section 330.⁷⁹

Specifically, Title X projects must apply discounts in the following manner:

Under 100% FPL: No charge for services provided to patients from families at or under 100% FPL, except to the extent that payment will be made by a third party (e.g., Medicare, Medicaid, third party insurance)⁸⁰

Between 101–250% FPL: Provide a schedule of discounts for patients from families between 101–250% FPL⁸¹

Above 250% FPL: Charge patients from families above 250% in accordance with a schedule of fees designed to cover the organization's reasonable cost of providing services, without discounts.⁸²

In individual circumstances, fees may be waived for good cause, regardless of income.⁸³

Title X projects have a large measure of discretion in determining the extent of income verification activity that is appropriate for their client population. Although not required to do so, Title X projects that have lawful access to other valid means of income verification because of the patient's participation in another program may use those data rather than re-verify income or rely solely on the patient's self-report.⁸⁴

Title X projects must make reasonable efforts to collect charges, but must do so without jeopardizing client confidentiality, when confidential services are requested.

How does OPA define "family"?

OPA defines family as "a social unit composed of one person, or two or more persons living together, as a household."⁸⁵

The Special Case for Minors

Unemancipated minors seeking confidential family planning services must be billed according to the individual income of the minor. An emancipated minor is not subject to the control, authority, and supervision of his or her parents or guardians.

See the <u>OPA Program Policy Notice 2016-11</u> for more information.

Training: Title X includes a significant training component, supported in part by OPA's National Training Centers. Specifically, Title X projects must arrange for project staff to have an initial orientation as well as ongoing routine education.⁸⁹ While there is flexibility in the training content, OPA expects that the following topics will be included:

- Requirements for reporting or notification of child abuse, child molestation, sexual abuse, rape or incest, and/or human trafficking;⁹⁰
- Counseling minors on how to resist being coerced into engaging in sexual activities;⁹¹ and
- Strategies to engage family members in the decision of minors to seek family planning services.⁹²

Advisory Committee: Title X projects must establish a committee to review and approve any educational materials created or provided to patients related to the provision of family planning services.⁹³ Similar to health center boards of directors, the Advisory Committee is expected to be broadly representative of the population or community for which the educational materials are intended, which is often accomplished by including community members on the Advisory Committee (although such participation by community members is not required by OPA). OPA sets forth expectations related to the Advisory Committee and its proscribed authorities.⁹⁴ Specifically, the Advisory Committee must:

- Have between five to nine members;
- Consider the educational and cultural backgrounds of the individuals to whom the materials are addressed;
- Consider the standards of the population or community to be served with respect to such materials;
- Review the content of the material to assure that the information is factually correct or delegate such review to an appropriate program staff member;
- Determine whether the material is suitable for the population or community to which it is to be made available; and
- Establish a written record of its determinations.

Staffing: Family planning medical services furnished through a Title X project must be performed under the direction of a physician with special training or experience in family planning.⁹⁵ In addition, Title X project staff should broadly represent the population to be served by the project, and be able to provide services in a culturally sensitive manner.⁹⁶

Reporting: Title X grantees must report certain data to OPA. Such reports include performance reports,⁹⁷ the Family Planning Annual Report (FPAR),⁹⁸ data on outreach and enrollment related to health insurance enrollment efforts, as well as key sustainability indicators for each service site, and financial reports.⁹⁹ Many of these reports must be submitted annually and at the end of the project period, and are uploaded to OPA's grants management system (https:/Grantsolutions.gov).

- <u>Family Planning Annual Report (FPAR)</u>: Annually, Title X grantees submit the FPAR, which contains questions regarding a brief organizational profile and tables to report data on family planning users, service use, and revenue for the reporting year.¹⁰⁰
- Data on Sustainability Indicators: Title X grantees collect and report data using an OMB-approved form to report on key sustainability indicators to assist OPA in assessing the need for additional resources to improve the sustainability of the Title X network. This data is collected annually or biennially, at the discretion of OPA. Data elements for this reporting effort include: site information, health insurance enrollment activities, whether the site also provides primary care services, what types of health information technology are used at the site, how the site monitors quality of services provided, and more. This data is reported at the service site level and at the grantee level.¹⁰¹
- <u>Financial Reports</u>: Much like health centers, Title X grantees submit quarterly, annual, and final Federal Financial Reports (FFR) (SF-425) on a reporting schedule specified in the grant award. Grantees also submit quarterly cash reports to the HHS Payment Management System on the FFR.

For More Information... Copies of the Title X statute, regulations, legislative mandates, Program Guidelines, and Program Policy Notices may be downloaded from <u>OPA's website</u>.

Chapter 5: *Key Considerations in Including a Title X Project within Your Health Center Project*

| Chapter Highlights: | • Coordinating Section 330 and Title X funding streams within a health center takes planning. The health center must satisfy each grant pro- gram's requirements, and track the separate funding streams. |
|---------------------|--|
| | • Health centers must consider the various Title X requirements prior to pursuing an expansion to become a Title X grantee or subrecipient. Key considerations include: |
| | • Addressing Title X's more expansive confidentiality requirements; |
| | • Establishing sliding fee discount schedules that satisfy both Title X and Section 330 requirements; |
| | Establishing systems to distinguish Title X family planning services for billing purposes; and |
| | ° Identifying the impact on scheduling and patient flow. |
| | For additional considerations, please refer to the questions listed in this Chapter. |
| | • Health centers considering becoming a Title X grantee or subrecipient should review the <u>Family Planning Annual Report (FPAR)</u> reporting obligations to plan for proper tracking and reporting. |
| | • Title X regulations require that projects provide in-service training for |

 Title X regulations require that projects provide in-service training for all project staff. <u>The FPAR system</u> offers <u>training services</u> for grantees to support Title X project operations and reporting requirements. This Chapter explores some of the considerations unique to health centers evaluating whether to become Title X funded, either through a subrecipient relationship or through a competitive grant process. Throughout this Chapter, key questions are listed to help the health center assess Title X readiness. Above all, health centers looking to participate in Title X must achieve a balance between the two programs: coordinating the integration and, as appropriate, separation of the health center project and the Title X project activities.

Managing Multiple Funding Streams

For health centers that receive a Section 330 grant, the health center project budget must reflect the full cost of operations, expenses, and revenues supporting the Section 330 project. Outlined by HRSA in PIN 2013-01, this "total budget" concept includes Section 330 grant funds *and all other sources of revenue* (e.g., program income or "other revenue sources" such as other federal grants) supporting the Section 330 project.¹⁰²

The same is true for Title X: in its funding application, OPA notes that the "proposed project budget should reflect financial support in addition to Title X funds. The amount and source(s) of these funds must be clearly identified separately from the requested Title X support."¹⁰³

Despite the inclusion of all revenue sources in the total budget, the grant programs must be tracked separately. Consequently, health centers participating in Title X must be able to identify which sources of revenue support, and result from, the provision of Title X family planning services, to the extent possible.¹⁰⁴

Identifying and allocating programmatic costs becomes more nuanced with each additional funding stream and the degree of integration. For example, for a "standalone" Title X funded organization that only provides family planning services, all revenue likely supports the provision of family planning services. In contrast, if Title X family planning activities are integrated into a health center, family planning is one subset of a wide range of services that the health center's costs must cover. The health center must use appropriate internal controls and cost allocation methods to distinguish between each source of funding and the eventual allocation of each funding stream.

There are also *indirect costs* (e.g., rent, utilities, and front desk staff) that are applicable to both the health center and Title X projects. Since it is challenging to accurately capture the precise proportional benefit of these costs, they are not "readily assignable" to a particular program and may be charged in accordance with an indirect cost rate agreement or as part of a *de minimus* rate (10% of modified total direct costs).¹⁰⁵

Questions to consider:

- What updates need to be made to internal controls, accounting processes, and billing and collections policies and systems to properly manage the multiple funding streams?
- How will the health center identify costs specific to the Title X project?
- How will the health center address Title X's heightened confidentiality requirements from the billing perspective (e.g., how will the billing department know not to bill an insurer if the patient has requested not to use insurance out of privacy concerns)?¹⁰⁶
- Are clinical and billing staff appropriately trained to identify visits that should be recorded under the Title X project so that the Title X-specific costs may be identified?

Schedule of Discounts

The Health Center Program and the Title X Family Planning Program both require that services provided within their respective projects are discounted based on a patient's ability to pay. There are a few notable differences between Health Center Program and Title X Program requirements for discounting services, as reflected below:¹⁰⁷ Distinguishing Title X family planning services for billing purposes can be difficult. One effective solution to distinguish Title X family planning services from other health center services is to establish codes specific to the family planning services that are within the Title X scope of project, as identified within the Title X project agreement. This process, which may require changes to the health center's coding processes, enables providers

| HEALTH CENTER PROGRAM ¹⁰⁸ | TITLE X FAMILY PLANNING PROGRAM |
|--|---|
| Full discount or only a nominal charge for services furnished to individuals and families with annual incomes at or below 100% of the Federal Poverty Level (FPL) | Full discount for individuals and families with annual incomes at or below 100% of the FPL |
| Schedule of discounts for individuals and families with incomes above 100% and at or below 200% of the FPL | Schedule of discounts for individuals and families with incomes above 100% and at or below 250% of the FPL. |
| No sliding fee discounts for individuals and families with annual incomes above 200% of the FPL | No sliding fee discounts for individuals and families with annual incomes above 250% of the FPL |
| As noted above, the Health Center Program and Title X Program requirements have differing upper limits for their Sliding Fee Discount Schedules (SFDS). Health | and staff responsible for billing and collecting fees from patients to distinguish patients who received only Title X family planning services from patients who received |

X family planning services from patients who received both Title X and non-Title X health center services, and accordingly apply the appropriate SFDS.

Questions to consider:

- How will the health center maintain SFDSs to comply with the differing upper limits required under each program?
- How will the health center ensure that billing staff will be able to identify patients who received only Title X family planning services directly related to preventing or achieving pregnancy? How will the health center establish systems to ensure that Section 330 grant funds are not used to provide discounts to patients between 200% and 250% of FPL?
- What staff training is necessary to ensure that Title X family planning services are appropriately identified, and that patients are charged in accordance with the correct schedule of discounts?
- How can the health center modify its signage, website, and/or patient brochures to describe the availability of Title X services?

| Program requirements have differing upper limits for |
|--|
| their Sliding Fee Discount Schedules (SFDS). Health |
| centers that have integrated Title X projects may have |
| two SFDSs: one that ranges from 101% to 200% |
| FPL for all health center services (i.e., the Section |
| 330 SFDS), and one that ranges from 101% to 250% |
| for Title X family planning services directly related to |
| preventing or achieving pregnancy, as defined in the |
| organization's approved Title X project (i.e., the Title X |
| SFDS). ¹⁰⁹ It is important to note that a health center |
| would apply the Title X SFDS if, during the course |
| of a single visit, a patient only receives one or more |
| family planning services directly related to preventing |
| or achieving pregnancy. For example, a patient who |
| receives an STD test alone, without receiving a |
| service related to preventing or achieving pregnancy, |
| would be charged in accordance with the Section |
| 330 SFDS. In addition, a health center would apply the |
| Section 330 SFDS if a patient receives a family planning |
| service directly related to preventing or achieving |
| pregnancy, in addition to another service (e.g., vision or |
| hearing test, behavioral health counseling). See OPA's |
| Program Policy Notice, Integrating with Primary Care |
| Providers, for further information. |
| |

Reporting

Health centers considering becoming Title X grantees or subrecipients should review the Family Planning Annual Report (FPAR) reporting obligations and assess how the health center's current system must be modified to ensure that it can accurately capture the information necessary for the FPAR.

When submitting data for the annual FPAR, every "family planning user" must be accounted for, even if Title X funds were not used to pay for the family planning services.

Some health centers that receive Title X funding have noted that identifying family planning users for the FPAR is not always a simple task. A client visit that may have been scheduled as a regular health center visit (such as a hearing or vision test) may also become a family planning visit if the patient asks the provider a question about contraception methods and the provider engaged the patient in a conversation around preventing or achieving pregnancy, or if the provider brings in an educator during the visit for further counseling around family planning, contraceptive method options, or related reproductive health services. Providers may document such family planning discussions in a notes section of an electronic medical record, which would make it difficult for health centers to know that the client received both regular health center and Title X services during that visit. For this reason, it is important to train all providers (or whomever assigns codes in electronic health records after each client encounter) on how to code services appropriately. Using free text boxes or notes fields in electronic health records can often lead to misreporting.

To comply with mandatory program reporting requirements for both the Title X Program and the Health Center Program, health centers that receive Title X funding must provide data on services provided through FPAR and UDS, as appropriate. In cases where a data element is applicable to both FPAR and UDS, reporting such data to each report does not result in "double" credit for services provided; rather, it ensures that both Title X and HRSA receive accurate information on services provided to patients during the given reporting period.¹¹²

The FPAR Forms & Instructions document provides Title X grantees with specific guidance, definitions, and instructions for reporting data correctly to OPA through the annual FPAR reporting process.¹¹³ Additional resources are available to get new Title X grantees up-to-speed on annual reporting requirements, including on-demand <u>training courses for FPAR</u>, and a <u>National Training Center</u> with participatory communities of practice that give grantees direct access to OPA and Title X experts.

Questions to consider:

- Can the health center readily identify family planning users? If not, what system changes could be implemented to ease the data reporting burden on the health center providers and billing staff?
- Does the EMR system currently capture, or can it be updated to capture, Title X data elements for FPAR?
- What staff training is necessary to ensure that staff accurately capture family planning users?
- Are required Title X data elements integrated into the workflow?
- Are there ways to streamline data collection from the EMR?

Title X Annual Reporting – Key Definitions

The FPAR Forms & Instructions¹¹⁰ guidance document provides the following definitions:

Family Planning User: An individual who has at least one family planning encounter at a Title X service site during the reporting period.

Family Planning Encounter: A documented, face-to-face contact between an individual and a family planning provider¹¹¹ that takes place in a Title X service site. The purpose of a family planning encounter is to provide family planning and related preventive health services to female and male clients who want to avoid unintended pregnancies or achieve intended pregnancies. To be counted for purposes of the FPAR, a written record of the services provided during the family planning encounter must be documented in the client record. There are two types of family planning encounters at Title X service sites: (1) family planning encounters with a "Clinical Services Provider" and (2) family planning encounters with an "Other Services Provider." The type of family planning provider who renders the care,

regardless of the services rendered, determines the type of family planning encounter. Lab tests and related counseling and education, in and of themselves, do not constitute a family planning encounter without face-to-face contact between the client and provider, documentation of the encounter in the record, and accompanying family planning counseling or education.

According to the FPAR's definition, "Other Service Providers" include registered nurses, public health nurses, licensed vocational or licensed practical nurses, certified nurse assistants, health educators, social workers, or clinic aides that offer [among other services] client education, counseling, referral, or follow-up services relating to the client's proposed or adopted method of contraception, general reproductive health, or infertility treatment.

Operational Considerations

Although most health centers already provide family planning services, participating in the Title X Family Planning Program is nonetheless likely to result in a service expansion. For some health centers, this expansion may not meaningfully impact operations. However, if the health center does not offer comprehensive family planning services currently, then participation in the Title X Family Planning Program is likely to necessitate several operational changes.

Health centers evaluating whether to participate in the Title X Family Planning Program should review their current staffing model, including the capacity of counselors, educators, and providers. The health center should consider whether additional staff will be necessary, as well as how it may handle potential staff recruitment. In addition, the health center may need to adjust patient flow, expand facility space, or expand hours of operation to prepare for increased demand of family planning services.

Note that Title X entities are eligible to participate in the 340B Drug Discount Program by applying through the Office of Pharmacy Affairs within HRSA. Once registered, the covered entity may purchase 340B-eligible drugs at a discounted price. 340B eligible drugs include all drugs that (1) meet the definition of a covered outpatient drug, as defined by the Medicaid statute; and (2) are prescribed to an eligible patient, as defined by the 340B program.¹¹⁴

Implementation Tip: According to a health center that receives Title X funding, utilizing family planning educators and medical assistants is an effective means to provide patients with information around preventing or achieving pregnancy. This staffing model helps to ensure that patients receive thorough information and counseling, in accordance with a patient-centered approach, while ensuring that clinician time is spent on the medical issues that require their time and expertise.

Questions to consider:

What will be the financial impact of integrating Title X family planning operations into the health center's current model? Health centers should consider staffing, training costs, and overhead costs, as well as synergies that could be leveraged between the two programs.

- Are existing staff appropriately licensed and credentialed to provide any new services added by the Title X scope of project (e.g., LARC insertion)?
- How will the expanded services impact scheduling and patient flow?
- If the health center has multiple sites, will all sites be written into the Title X grant, or will Title X services be offered at specific sites only?
- Do the facilities effectively protect patient confidentiality (e.g., are there private rooms for education and counseling sessions)?
- Does the health center have clinical protocols in place for all required family planning services? Do they meet the expectations outlined in the Title X requirements and clinical guidelines described in the QFP recommendations?

Training

Unlike the Health Center Program, Title X Family Planning Program regulations require that projects provide orientation and in-service training for *all* project staff.¹¹⁵

The <u>*Title X Family Planning Program Requirements*</u> identifies a number of specific routine training topics that must be covered in the project's training plan, including the following:

- Information on the federal and state requirements for reporting or notification of child abuse, child molestation, sexual abuse, rape or incest, as well as on human trafficking.¹¹⁶
- Involving family members in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities.¹¹⁷

The role of cultural competency is significant when it comes to developing family planning educational materials and staff training.¹¹⁸ One health center observed a significant impact in immigrant communities with access to Title X services, finding that many individuals were initially unfamiliar with, or uncomfortable discussing, family planning topics such as contraception options. Given the stigma surrounding family planning topics in some communities, staff explained that simply broaching the subject required careful consideration, and having training to help understand the cultural beliefs at play enabled providers to advise patients successfully without offending them or deterring them from accessing care in the future.

Implementation Tip: A health center that receives Title X funding as a direct grantee developed a documented training curricula and calendar, and recorded and monitored when staff received the requisite training.

In addition, the health center took advantage of trainings offered through <u>OPA's National Training Centers</u>, an online platform with a range of resources targeted to provide technical assistance to the Title X network. The organization ensured that its Title X subrecipients participated in and complied with the training plan.

Questions to consider:

- > How will staff be oriented to the Title X program?
- How often do staff currently receive training (beyond informal mentoring)?
- Does the health center currently track and document staff member training?
- Are staff adequately trained in furnishing the full range of family planning services? If not, are there reasonable opportunities for development (onsite or offsite)?
- Does the health center currently serve a sizeable adolescent population in the community? Are staff trained to work with teens (e.g., outreach staff, counselors, etc.)?
- How does the health center incorporate cultural competency into training topics?

Despite the additional considerations involved in Title X Family Planning Program participation, many health centers would like to expand family planning services. One health center staff member noted:

Family planning is an area that touches the lives of each individual of reproductive age and it really impacts their health. Whether it's a teen you're talking to about preconception health or someone who wants to get pregnant, or a diabetic for whom it would be dangerous to have an unplanned pregnancy, family planning is of critical importance. Family planning impacts our patients' lives across a huge age range: adolescents to very old ages for men and well into middle ages for women.

Chapter 6: Becoming a Title X Grantee or Subrecipient

Chapter Highlights: • At least annually, OPA publishes <u>an announcement for available Title X</u> <u>family planning service grants</u> to fund specific geographic areas. Any public or private non-profit entity may apply. The announcement lists all eligibility criteria.

- An organization applying to become a Title X grantee often identifies a network of subrecipients or service sites that will provide family planning services as part of the Title X project.
- Health centers may apply for and become direct Title X grantees. It is far more common, however, for health centers to establish a subrecipient relationship with an organization that receives Title X funding.
- Health centers applying for Title X funds (or that seek to become subrecipients) should review the funding opportunity announcement and the OPA Program Priorities.
- The Uniform Guidance defines the fundamental requirements and rights of parties in a subrecipient relationship. A subreceipient relationship must be established in a written Subrecipient Agreement with standards and guidelines for all delegated project activities per the <u>Title X Family</u> <u>Planning Program Requirements</u> and other applicable requirements.

There are two options for a health center to become a recipient of Title X funding: (1) directly apply to OPA to receive a Title X grant or (2) establish a subrecipient relationship with an organization that receives Title X funding. Each option is described below.

Applying as a Direct Grantee

Any public or private nonprofit entity located in a state, including health centers, may apply for a competitive Title X family planning services grant.¹¹⁹

At least annually, OPA publishes an announcement for available Title X family planning services grant funds for specific geographic areas. Many are statewide, yet some grants are for a subset of counties within a state. All Title X grants are typically re-competed every three years, but at any given time, only certain areas (usually states) are up for competition.

An organization applying to become a Title X grantee often identifies a network of subrecipients or service sites that will provide family planning services as part of the Title X project. A 2016 Title X funding announcement sets forth the following:

Funding of applications that propose to rely on other entities to provide services must take into consideration the extent to which the applicant indicates that it can provide the required services and best serve individuals in need throughout the anticipated service area. For applicants that will not provide all required services directly, the applicant must document the process it will use for providing an opportunity to receive subawards to qualified entities eligible to receive federal funds in providing services throughout the service area to meet the needs of project beneficiaries.¹²⁰

Health centers have been successful in being awarded direct Title X funding. In August 2016, five of 91 total Title X grantees were also Health Center Program grantees. It is more common, however, for health centers to receive Title X funds as a subgrantee. In August 2016, nearly 21% of Title X service sites identified as Health Center Program grantees.¹²¹

Title X Application Elements

Title X funding opportunity announcements (FOAs) stipulate specific application element requirements, eligibility criteria, and evaluation criteria. Although each Title X FOA may include unique requirements, application packages generally include a project narrative describing how the applicant will meet the Title X requirements, a budget that outlines estimated costs, and a work plan identifying the specific services and clinical operations that the project will support. Funding opportunity announcements are posted on grants.gov; search CFDA 93.217 to find open and archived grants.

Program Priorities and Key Issues

Each year OPA establishes **program priorities** that represent overarching goals for the Title X Family Planning Program. These priorities derive from Healthy People 2020 Objectives and from HHS priorities. Title X project plans, which are included in the grant application, should be developed to address the program priorities and should provide evidence of the Title X project's capacity to address program priorities as they evolve in future years.

The 2017 program priorities include the following:

- Assuring the delivery of quality family planning and related preventive health services, with priority for services to individuals from low-income families. This includes ensuring that grantees have the capacity to support implementation (e.g., through staff training and related systems changes) of the Title X program guidelines throughout their Title X services projects, and that project staff have received training on Title X program requirements;
- Assessing clients' reproductive life plan/reproductive intentions as part of determining the need for family planning services, and providing preconception services as stipulated in QFP;
- Providing access to a broad range of acceptable and effective family planning methods and related preventive health services in accordance with the Title X program requirements and the QFP. These services include, but are not limited to, contraceptive services, pregnancy testing and counseling, services to help clients achieve pregnancy, basic infertility services, STD services, preconception health services, and breast and cervical cancer screening. The broad range of services does not include abortion as a method of family planning;

- Ensuring that all clients receive contraceptive and other services in a voluntary, client-centered and non-coercive manner in accordance with QFP and Title X requirements;
- Identifying individuals, families, and communities in need, but not currently receiving family planning services through outreach to hard-to-reach and/or vulnerable populations, and partnering with other community-based health and social service providers that provide needed services; and
- Demonstrating that the project's infrastructure and management practices ensure sustainability of family planning and reproductive health services delivery throughout the proposed service area including:
 - Incorporation of certified Electronic Health Record (EHR) systems that have the ability to capture family planning data within structured fields;
 - Evidence of contracts with insurance plans and systems for third party billing as well as the ability to facilitate the enrollment of clients into private insurance and Medicaid, optimally onsite; and to report on numbers of clients assisted and enrolled; and
 - Addressing the comprehensive health care needs of clients through formal, robust linkages or integration with comprehensive primary care providers.

In addition to program priorities, OPA has indicated that the following **key issues** have implications for Title X projects and should be considered in developing the project plan:

- Incorporation of the 2014 Title X Program Guidelines throughout the proposed service area as demonstrated by written clinical protocols that are in accordance with Title X Requirements and QFP;
- Efficiency and effectiveness in program management and operations;
- Patient access to a broad range of contraceptive options, including LARCs, other pharmaceuticals, and laboratory tests preferably on site;
- Establishment and use of performance measures to regularly perform quality assurance and quality improvement activities, including the use of measures to monitor contraceptive use;
- Establishment of formal linkages and documented partnerships with comprehensive primary care providers, HIV care and treatment providers, and mental health, drug and alcohol treatment providers;
- Incorporation of the National HIV/AIDS Strategy (NHAS) and CDC's "Revised Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women in Health Care Settings"; and
- Efficient and streamlined electronic data collection (such as for the FPAR), reporting, and analysis for internal use in monitoring staff or program performance, program efficiency, and staff productivity in order to improve the quality and delivery of family planning services.

If a health center is applying for a Title X grant, it is critical to review the funding opportunity announcement closely; the program priorities and/or key issues may differ from those set forth above.

Family Participation

Title X applications require that the applicant include a written statement in the application certifying that, if funded, their Title X Family Planning Services project will encourage family participation in the decision of minors to seek family planning services, and that they will provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.

Subrecipients should be aware that they must make the same certification, pursuant to the terms of the Subrecipient Agreement.

Review and Selection Process

Independent review panels evaluate Title X grant applications. Based on the Application Review Criteria in each FOA, the reviewers comment on and score the applications. In addition to the independent review panel, federal HHS staff review each application for programmatic, budgetary, and grants management compliance. Final award decisions are made by the Regional Health Administrator for the applicable Public Health Service Region, in consultation with the Deputy Assistant Secretary for Population Affairs (or his/her designee) and the Assistant Secretary for Health.

Title X grants are awarded for the establishment and operation of projects that will best promote the purposes of the Title X Family Planning Program. According to a recent 2016 Title X funding announcement, OPA takes into account the following in making funding decisions:

- The adequacy of the applicant's facilities and staff, including evidence of an infrastructure that is sustainable in ensuring continued access to services for the target population. For applicants that will not provide all services directly, the extent to which the applicant has documented the process it will use for providing an opportunity to receive subawards to qualified entities eligible to receive federal funds in providing services throughout the service area to meet the needs of project beneficiaries.
- The degree to which the project plan adequately provides for the requirements set forth in the Title X regulations.
- The extent to which the applicant substantiates and/or justifies that family planning services are needed within the proposed service area.

- The capacity of the applicant to make rapid and effective use of the federal assistance.
- The number of patients to be served, particularly low-income.
- The relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project.
- The relative need of the applicant.

Project Period

Successful applicants will receive a Notice of Award (NoA) that informs the grantee of the amount and duration of funding for the Title X project (the "project period"), typically broken up into shorter budget periods, usually 12 months. Annually, each Title X grantee, with at least one full grant year remaining in their project period, must complete a non-competing, continuation application, which includes a progress report for the current budget year and before work plan, budget, and budget justification for the upcoming year.

At the end of each project and budget period, each Title X grantee that wishes to continue participation in the Title X program must re-compete for funds and becomes a "new" grantee if successful. These re-compete applicants undergo the same review process as all other applicants, regardless of whether they had previous Title X awards.

Establishing a Subrecipient Relationship

As noted above and in Chapter 4, health centers may receive Title X funding directly from OPA or through a Title X "subaward" from an organization that receives Title X funding. The Title X grantee that subgrants a portion of its Title X grant is customarily referred to as the **"grantee," "prime grantee,"** or **"recipient,"** and the organization that receives the subaward is customarily referred to as the **"subrecipient."**¹²² An entity that provides the Title X family planning services onsite is referred to as a **"service site."** Grantees, subrecipients, and service sites may all provide Title X services onsite.

The Title X grantee is accountable for the quality, cost, accessibility, acceptability, reporting, and performance of the grant-funded activities provided by subrecipients within the Title X project. According to the Title X regulations, subrecipients must be given an opportunity to participate in the development of the Title X application and in the ongoing policy decision making of the Title X project.¹²³

This section describes subrecipient relationships generally, key terms for Subrecipient Agreements, terms and conditions specific to Title X programmatic requirements, and key considerations applicable to monitoring a subrecipient's performance.

Uniform Guidance

As a federal grant program under HHS, funds awarded through the Title X Family Planning Program are governed by the *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards,* implemented at 45 C.F.R. Part 75. The Uniform Guidance, which is also referred to as "Part 75" and the "Supercircular," sets forth certain fundamental requirements and rights of parties in subrecipient relationships (e.g., administrative requirements and oversight authority).¹²⁴ Health centers that receive grant funding under Section 330 should be familiar with Uniform Guidance principles because such requirements apply to their Section 330-funded health center project.

Although the Uniform Guidance requirements are applicable to all HHS grants, this section specifically refers to Title X.

Subawards Generally

The key features of a Title X subaward are that the prime grantee passes Title X funds to the subrecipient and delegates a substantial degree of programmatic decision-making authority to the subrecipient.¹²⁵ In return, the subrecipient agrees to comply with all of the terms and conditions of the prime grantee's Title X award, which are deemed to **flow down** to the subrecipient.¹²⁶

The prime grantee remains responsible to OPA for the proper use of the Title X funds by the subrecipient. The subrecipient relationship is distinguishable from one in which the prime grantee is merely purchasing clinical or administrative services from another party (referred to in contracting situations as the "contractor" or "vendor"). While such service contracts may contain terms and conditions designed to ensure that the providing contractor performs the contracted services in a manner consistent with the prime grantee's obligations under its Title X award, the grantee would not delegate any programmatic decision-making authority to the contractor.¹²⁷

Making Subawards

A prime grantee may only make a Title X subaward with the prior approval of OPA. Since, as noted above, subawards are not contracts to purchase services, they may be made without adhering to the competition requirements of the Uniform Guidance procurement standards. Rather, in selecting a subrecipient, the key administrative obligation of the prime grantee is to evaluate the candidate subrecipient's *"risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward…" ¹²⁸* Prime grantees are specifically encouraged to consider:¹²⁹

- The candidate subrecipient's experience with similar awards,
- Prior audit results of the candidate subrecipient, 130
- Whether the candidate subrecipient has new personnel or systems, and
- The extent to which the candidate subrecipient is subject to direct federal monitoring as a result of other awards.

While not expressly required by the Uniform Guidance, prime grantees are encouraged to visit the candidate subrecipient's site(s) and examine its systems necessary to successfully perform under the Title X subaward. For example, the prime grantee may examine how the candidate subrecipient will document the time and effort of its employees in working on the activities funded by the Title X subaward, and how the candidate subrecipient will account for uses of Title X funds in its financial management systems. In addition, prior to award, a prime grantee also customarily examines the extent to which the candidate subrecipient understands, and the mechanisms by which it intends to comply with, the Title X statute, implementing regulations, and OPA guidance.¹³¹

Terms and Conditions Specific to a Subrecipient Agreement

According to the OPA Guidelines, *Program Requirements* for Title X Funded Family Planning Projects, all Title X subrecipient relationships must be documented in a written agreement that establishes written standards and guidelines for all delegated project activities consistent with the <u>Title X Family Planning Program</u> <u>Requirements</u>, as well as other applicable requirements, including the Uniform Guidance.¹³²

Fundamental to establishing the terms and conditions in the Subrecipient Agreement is the fact that all of the terms and conditions of the prime grantee's Title X award flow down to the subrecipient.¹³³ The Subrecipient Agreement must reflect this flow down, or the prime grantee is at great risk of the subrecipient failing to abide by such terms and conditions. Moreover, any relationship in which the prime grantee failed to flow down the requirements of its Title X award may be deemed by OPA to be inadequate safeguarding of federal funds.¹³⁴

Accordingly, the Subrecipient Agreement should include the various terms and conditions of the Title X grant. In addition to including that the subrecipient must comply with the terms and condition of the grant award, the Subrecipient Agreement should also include a clear statement that the subrecipient must comply with applicable statutes, regulations, and guidance, including but not limited to the following:

- Title X of the Public Health Service Act (42 U.S.C. § 300 et seq.);
- Title X implementing regulations (42 C.F.R. Part 59);
- Sterilization of Persons in Federally Assisted Family Planning Projects regulations (42 C.F.R. Part 50);
- Abortion-related services guidance (65 Fed. Reg. 41281 (Jul. 3, 2000);

- Uniform Guidance (45 C.F.R. Part 75);
- HHS Grants Policy Statement (2007); and
- Any applicable restrictions on expenditures of federal funds in the HHS Appropriation Act for the year in which the "prime" grant award was made.

In addition, the Uniform Guidance lists basic information that must be included in Subrecipient Agreements, including most notably:

- A statement that the relationship is a "subaward";
- The grant program's Catalog of Federal Domestic Assistance (CFDA) number;
- The period of performance;
- The total amount of the subaward; and
- The indirect cost rate (if any) agreed for the subaward.

Additionally, where a subrecipient has a federally-approved indirect cost rate, the Subrecipient Agreement should specify that the rate must be applied to the subaward unless waived by the subrecipient.¹³⁵

Subrecipient Agreements should also include terms that address:

- Payment;
- Beneficiary eligibility;
- Subrecipient's maintenance of a discount schedule that complies with Title X requirements;
- Record retention and access to records and personnel;
- Process by which the subrecipient provides the prime grantee with information necessary for prime grantee to submit the requisite forms to OPA (e.g., data regarding patient encounters, revenues, costs, and charges);

- Prohibition on contracting with suspended or debarred entities;
- Disallowance remedies;
- Process to resolve disputes;
- Corrective action process upon discovering the subrecipient's non-compliance with the terms of the subaward;
- Causes for suspension and termination of the subaward;
- Closeout procedures and post-closeout rights;
- Specific references to pertinent national policy requirements, as defined in the Uniform Guidance, including statutory, executive order, other Presidential directive, or regulatory requirements that are not specific to the Title X program;
- Requirement that subrecipient will encourage family participation in the decision of minors to seek family planning services, and that they will provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities; and
- Assertion that Title X funds may not support the provision of abortion as a method of family planning.

Question:

My health center is interested in becoming a Title X subrecipient. How do I identify the Title X recipients in my community?

Answer:

Consult OPA's Title X Grantee Directory.

Monitoring the Subrecipient's Performance

The Uniform Guidance requires prime grantees to include at least the following elements in their monitoring of a subrecipient's performance:

- Review of periodic financial and performance reports required under the Subrecipient Agreement;
- Follow-up to ensure corrective action on any identified deficiency in the subrecipient's performance; and
- Issuance of a "management decision," as defined in the Uniform Guidance, for any audit findings issued by A-133/Subpart F auditors.¹³⁶

Beyond these minimum requirements, the Uniform Guidance encourages prime grantees to:

- Conduct their own onsite visits of the subrecipient;
- Hire independent auditors to conduct reviews of the subrecipient's operations; and
- Provide technical assistance to subrecipients.¹³⁷

The Subrecipient Agreement should describe the prime grantee's oversight functions. For example, it may set forth that the subrecipient agrees to permit the prime grantee and HHS, or any of their duly authorized representatives, to evaluate, through inspection or other means, the quality, appropriateness, and timeliness of services delivered under the Subrecipient Agreement, the proper expenditure of federal funds, as well as the proper allocation of funds awarded to the subrecipient. The parties may also agree to include that the subrecipient must perform an annual self-assessment of its compliance with <u>Title X Family Planning Program Requirements</u>, which must be submitted to the prime grantee.

Subrecipient Perspective and Health Centers

Health centers that are funded under Section 330 are well-positioned to serve as successful Title X subrecipients. They already receive direct federal awards from HHS in a complex health care program, and, as such, generally have substantial experience implementing HHS grant management requirements. In fact, Section 330-funded health centers typically have policies and procedures in place to comply with many of the same requirements applicable to Title X grantees, and undergo an onsite Operational Site Visit (OSV) conducted by HRSA at least once every project period.

Chapter 7: *Collaboration Models*

| Chapter Highlights: | • HRSA encourages health centers to work collaboratively with other safety net providers. |
|---------------------|--|
| | • A health center may identify potential collaborators through locating Title X clinics in the health center's geographic service area. |
| | • Collaboration can be an effective means to maximize limited resources, avoid duplication of services, and expand access to high quality family planning services. |
| | • To establish a coordinated planning process to identify collaborative opportunities, consider executing a non-binding Memorandum of Agreement that defines the parties' joint goals and shared responsibilities. |

• Consider whether the collaboration may result in a change to a health center's scope of project.

Collaboration as a Health Center Program Priority

HRSA has reiterated its emphasis on the importance of working cooperatively with other community-based providers, such as Title X clinics, particularly in rural areas. In Program Assistance Letter (PAL) 2011-02, HRSA wrote: "[c]ollaboration among safety-net providers is critical to maximizing resources and efficiencies in the health care system in the underserved areas. As health centers seek new opportunities to create access to high-quality, coordinated care for patients, this collaboration will become even more important."138 The PAL further indicates that "[b]ecause other safety net providers often play a key role in serving these medically underserved populations, it is imperative that health centers thoroughly research as part of any expansion plan where these other safety net providers are located and the services they are providing."139

Before a health center expands its provision of family planning services and/or pursues becoming a Title X grantee or subrecipient, it should identify the existing Title X clinics in its service area to explore potential collaborative opportunities. Becoming familiar with the Title X clinics' operations, including their scope of services and target population, and identifying options to work together to leverage the organizations' strengths, can enable the health center to maximize its limited resources, avoid duplication of services, and expand access to high quality family planning services for its patient population. Collaboration benefits not only the health center, but the broader safety net.

The collaboration models described in this guide include:

- Referral arrangements (Chapter 8);
- Purchase of clinical services arrangements (Chapter 9); and
- Corporate integration models (Chapter 10).

Beginning the Collaboration Process

A long-standing, successful collaborative relationship, ranging from a subrecipient to a referral model, often begins with discussions regarding the organizations' respective needs assessment findings, target populations, and short and long-term goals. In addition to implementing a formal relationship to coordinate services, the organizations often pursue additional initiatives, such as joint outreach efforts and conducting a comprehensive community needs assessment with additional safety net providers.

Population health has been defined as "the health of a population, including the distribution of health outcomes and disparities in the population."¹⁴⁰

One method to improve population health is **population health management**, which has been defined as "a set of interventions that can improve people's health across the full continuum of care..."¹⁴¹

Planning Process: Laying the Foundation for a Successful Collaboration

Identifying Title X clinics in a health center's service area is a critical first step to exploring strategies to increase access to family planning services.

To establish a coordinated planning process to identify, evaluate, and implement a collaboration, the health center and Title X clinic are advised to execute a non-binding agreement, often referred to as a "Memorandum of Agreement." Key topics that may be addressed in the Memorandum of Agreement include the following:

- Overarching goal of the collaboration;
- Mutually agreed upon collaboration models that will be the focus of the planning process;
- Management and other staff from both organizations who will be involved in the planning process;
- Requirement that the parties will agree on any publicity, press releases, and/or third party disclosure regarding the collaboration;
- Timeline for establishing the collaboration, including the frequency of periodic meetings throughout the planning process;
- Understanding that the implementation of any collaboration is subject to the approval of state and/or federal agencies, as applicable, and the organizations' respective governing bodies; and
- Consultants (if any) to be hired, by which party, and the sharing of fees, as applicable.

In addition, the organizations are advised to execute a Confidentiality Agreement if the planning process necessitates the exchange of financial or other confidential and/or proprietary organizational information.

Opportunities in the Evolving Health Care Landscape

As the health care landscape evolves, with the emphasis on meaningful use, population health management, and health care homes, health centers and their Title X neighbors can support one another in their efforts to respond to, and prepare for, the changing environment. For example, joint quality improvement initiatives and health information exchange systems are effective approaches to create a more integrated network of care.

Scope of Project Considerations

Certain Title X collaborations may result in a change to a health center's scope of project. Regardless of which collaboration approach is adopted, a health center's scope of project (notably its scope of services, as set forth in Form 5A, and its service sites, as set forth in Form 5B) must accurately reflect the health center's operations.

For certain scope of project changes, health centers must obtain HRSA's approval prior to implementation. Such change in scope requests are submitted on-line through the HRSA Electronic Handbook (EHB) at least 60 days before a health center intends to implement a change that would:

- Add a new service or service delivery site,
- Terminate an existing service or service delivery site, or
- Add a new target population.

Identifying whether a Title X collaboration will trigger the need to obtain HRSA's prior approval for a change in scope of project is a critical planning step. Failure to obtain such approval may jeopardize a health center's eligibility for grant funding under Section 330 (or certification as an FQHC look-alike¹⁴²), and may result in grant conditions.

For more information about service delivery and site changes that require HRSA approval, see the HRSA resource, <u>Allowable Form 5A Updates and Allowable</u> <u>Form 5B Updates</u>.

Q&A for HRSA Scope Change

Q: My health center is entering into a formal referral relationship with a local family planning provider to increase access to certain screening services, including mammography and communicable disease screening. The health center also furnishes such services directly, and will continue to do so. Does the health center need to submit a formal change in scope request to HRSA in order to add a check under column III of Form 5A for the screening services?

A: No.

A formal change in scope request is not required if a health center furnishes a required service directly, and seeks to add the provision of such service by formal referral. The change may be achieved through a "Monitored 5A Attributes" change in scope request.

Q: My health center provides contraceptive counseling services by contract. The health center plans to terminate the contractual relationship and establish a referral relationship with a nearby family planning provider. Does the health center need to submit a formal change in scope request to HRSA?

A:Yes.

As set forth in the Allowable Form 5A Updates, changing the mode of delivery for a required service from contract (i.e., column II) to formal referral (i.e., column III) must be made through a formal change in scope request.

Q: My health center provides voluntary family planning services directly and is becoming a Title X subrecipient. This relationship will not impact the sites or services (including mode of delivery) within the health center's scope of project. Does the health center need to submit a formal change in scope request to HRSA?

A: No.

A formal change in scope request is not required because the subrecipient relationship will not modify the sites and services within the health center's scope of project.

Q: My health center is becoming a subrecipient of a Title X grantee. The health center intends to use Title X funds to directly provide cervical cancer screening and mammography. Such services, as well as other required screenings, have historically been furnished by formal referral. Does the health center need to submit a formal change in scope request to HRSA?

A:Yes.

According to the Allowable Form 5A Updates, changing the mode of delivery for a required service from referral (i.e., column III) to direct (i.e., column I) must be made through a formal change in scope request.

Chapter 8: *Referral Arrangements*

Chapter Highlights: • Referral relationships are an effective way to deliver patient-centered care. They provide patients with access to a broader range of family planning services.

- Referral relationships allow a health center and a Title X clinic to become more familiar with one another and support a more clinically coordinated relationship.
- An effective referral relationship between a health center and Title X clinic requires well-defined care coordination steps to schedule appointments, arrange for follow-up care, and exchange medical records.
- HRSA requires a formal written arrangement to document in-scope services furnished via referral. The written arrangement is often set forth in the form of a Memorandum of Understanding (MOU). Formal referral arrangements are reflected in the health center's Form 5A under Column III. (Informal relationships for out-of-scope services do not need satisfy the formal written arrangement requirements.)
- Tips on how to create a formal written referral arrangement that satisfies HRSA requirements are set forth in this Chapter.
- Use the referral agreement Checklist on page 57 to help establish referral relationships for the provision of comprehensive family planning services.

Fundamentals of Referral Relationships

Under a referral relationship, a Title X clinic agrees to furnish family planning services to patients who are referred by the health center. The referral relationship is typically reciprocal, with the health center simultaneously agreeing to furnish primary care services (and/or other in-scope services) to patients who are referred by the Title X clinic. Referrals between the two organizations are always subject to the provider's independent clinical judgment and the patient's freedom of choice.

A key feature of referral relationships is that the organizations operate autonomously: each is financially, clinically, and legally responsible for the services it directly provides and neither oversees or otherwise directs the services furnished by the other. Referral relationships can be an effective means to coordinate care and furnish services in a patient-centered manner.

Establishing referral relationships is particularly important in the context of family planning because, as noted previously in this Guide, patients may opt to receive family planning services outside of the health center setting. In addition, Title X clinics often provide a more expansive scope of family planning services than health centers, and are particularly qualified to provide effective counseling, particularly with youth.

Referral relationships also allow the health center and the Title X clinic to become more familiar with one another's operations and service lines, often serving as a useful precursor to a more integrated relationship in the future, such as a subrecipient relationship or a corporate consolidation.

Establishing a Coordinated and Defined Referral Relationship

As stated in Chapter 1, GWSPH's 2013 study of health centers' provision of family planning services found that virtually all surveyed health centers maintained referral arrangements for services they did not offer onsite, such as vasectomies and tubal ligation, yet the formality of such relationships varied across the health centers.¹⁴³

It is important to note that an effective referral relationship is not passive. Rather, an effective referral relationship is contingent on the health center and Title X clinic establishing a well-defined care coordination process to:

- Schedule appointments,
- Arrange for appropriate follow-up services, and
- Exchange medical records, as clinically necessary.

Before establishing a referral relationship with a Title X clinic, the organizations should convene their key management to discuss their respective clinical services, clinical needs, scheduling processes, and available capacity. It is also important to include clinical staff and scheduling staff in the discussions and planning process.

This Chapter provides tips to establish a referral relationship with a Title X clinic that is both effective and consistent with HRSA guidance.

BENEFITS OF REFERRAL RELATIONSHIPS

- Expands patients' access to a broader scope of services
- Reduces loss of clinical information as patients transition between health center to Title X clinic for care
- Reaches additional individuals from the target population who don't have a regular source of primary care
- Improves quality of clinical care through convening providers to share best practices
- Reduces clinical redundancies
- Allows the organizations to retain their autonomy

Referrals and Scope of Project

Before embarking on a referral relationship with a Title X clinic, a health center should review the fundamentals of HRSA's scope of project requirements applicable to service delivery.

Formal Written Referral Arrangements

Required FQHC services that are provided by referral to another entity must be coordinated through a formal written referral arrangement (e.g., a memorandum of understanding, memorandum of agreement, or other formal written arrangement), and reflected in a health center's Form 5A under Column III. Services provided via formal written referral arrangement are not technically included in the health center's scope of project. Rather, the establishment of the referral arrangement and any follow-up care provided by the health center after the referral are included in the health center's scope of project.

HRSA requires that agreements for formal written referral arrangements under which health center patients receive services include provisions addressing:

- The manner by which the referral will be made and managed;
- The process for tracking and referring patients back to the health center for appropriate follow-up care;
- An assurance that the referral provider will furnish services on a sliding fee scale to health center patients eligible for discounted services (i.e., patients with incomes less than or equal to 200% of FPL) consistent with the requirements of HRSA's sliding fee discount program PIN 2014-02 (see the "Myth Buster" on page 56 for more information);
- An assurance that the referral provider will furnish services to health center patients at or below 100% of the FPL at no charge (or will impose, at most, a nominal charge that meets the criteria for nominal charges set forth in PIN 2014-02); and
- An assurance that the services furnished by the referral provider will be available equally to all health center patients regardless of their ability to pay.¹⁴⁴

CHALLENGES OF REFERRAL RELATIONSHIPS

- Establishing a referral protocol may be time consuming and requires input from multiple staff
- Exchanging medical records requires coordination and consideration of applicable state and federal patient confidentiality laws
- Not the preferred mode of delivery for patients who seek to receive their comprehensive family planning services at the health center

Failure to have an adequate formal referral agreement for in-scope services furnished via referral may result in a grant condition.

Informal Referral Arrangements

HRSA does not require that out-of-scope services furnished via referral be memorialized in writing and/ or otherwise satisfy the above criteria. Such referral arrangements are not reflected on Form 5A as neither the service nor the referral relationship is part of the health center's scope of project.

Although health centers are not required to establish written referral agreements for out-of-scope services, it is nonetheless beneficial to memorialize in writing all referral relationships, including those covering out-of-scope family planning services. In addition, such agreements are helpful insofar as HRSA generally requires evidence of affiliation relationships with other safety net providers, such as Title X clinics, as part of all grant applications (e.g., New Access Point, Expanded Medical Capacity, and Services Expansion).

Intersection of Family Planning and Scope of Project As described in Chapter 1, health centers are required by law to provide "voluntary family planning services."¹⁴⁵ HRSA indicated that "voluntary family planning" includes "appropriate counseling on available reproductive options consistent with Federal, state, local laws and regulations" and "may include management/treatment and procedures for a patient's chosen method (e.g., vasectomy, subdermal contraceptive placement, IUD placement, tubal ligation)." ¹⁴⁶

If a health center does not furnish voluntary family planning services directly, but rather by referral to a Title X clinic, then the health center *must* enter into a formal written referral arrangement with the Title X clinic.

On the other hand, optional family planning services, such as management/treatment and procedures for a patient's chosen method (e.g., vasectomy,

Tips to Identify How the Referral will be "Made and Managed"

Written agreements for formal referral arrangements must establish the manner by which the referral will be "made and managed." This phrase refers to a health center's documented referral process (including tracking and sharing of information), which may be included in the body of the referral agreement or in a separate protocol attached to the agreement.

To identify whether your agreement satisfies the "made and managed" criteria, consider whether your documented referral process addresses the following:

- What is the process for scheduling appointments through referral? Are particular staff designated to assist the patient?
- How do the organizations exchange appropriate patient health information prior to and following the scheduled appointment?
 Do the organizations participate in a health information exchange?
- If appropriate, how would the health center be informed if the patient missed their scheduled appointment?
- How will the organizations communicate information regarding a referred patient's linguistic and/or cultural needs that may impact care delivery?

subdermal contraceptive placement, IUD placement, tubal ligation) do not require a formal referral agreement if provided solely by referral. However, as noted above there are many benefits to establishing a documented referral arrangement with a Title X clinic for such services, even if a formal referral agreement is not required by HRSA policy.

Key Features of a Referral Relationship

Although each arrangement will look different, there are several common features in every referral relationship. The following section provides a brief synopsis of these common features that health centers should consider when developing a referral relationship with a Title X clinic.

Financial Systems, Fees and Discounts

Under a referral relationship, the health center and Title X clinic separately bill and collect payment for services from applicable payors and patients, in accordance with their respective fee and discount schedules and applicable policies and procedures. There is no compensation or other exchange of anything of value between the two organizations. The billing and coding functions of the organizations remain separate.

Medical Records

Under a referral arrangement, the health center and the Title X clinic maintain separate medical records and exchange applicable diagnosis and treatment notes and information for purposes of continuity of care. As such, the referral agreement should include provisions specifying the process for sharing such notes and information, as well as a statement that the organizations will comply with federal and state patient confidentiality requirements, as well as the organizations' respective patient privacy policies.

Exclusive Referral Relationships

HRSA has expressed concern regarding exclusive arrangements that limit a health center's ability to establish relationships with providers in the community.¹⁴⁷ Accordingly, referral arrangements should not preclude either party from entering into arrangements with other providers, whether for the same or for similar services.

Federal Tort Claims Act

If the health center is deemed under the Federal Tort Claims Act (FTCA), then FTCA coverage would extend to the health center for purposes of its provision of in-scope services to its patients (including patients who were referred to the health center by the Title X clinic). Under a referral relationship, FTCA coverage is not available to the Title X clinic or its contracted or employed health care professionals furnishing family planning services.

Myth Buster: Separate Sliding Fee Discount Schedules are NOT a Barrier to Referral Relationships

A common misperception is that if a Title X clinic furnishes services to health center patients under a formal referral arrangement, the Title X clinic must apply a schedule of fees that mirrors HRSA's requirements. This is not true.

As noted above, services furnished by formal referral arrangements must be reasonably available to all health center patients, regardless of their ability to pay and in accordance with health center requirements.

In PIN 2014-02, HRSA clarified that at a minimum, a referral provider's sliding fee discount scale must comply with the requirements of PIN 2014-02; however, a health center may enter into a formal written referral arrangement with another provider that results in greater discounts to patients than they would receive under the health center's sliding fee discount schedule policy if it were applied to the referral provider's fee schedule, so long as:

- All health center patients at or below 200% FPL receive the same or greater discount for the services rendered by the referral provider than if the health center's sliding fee discount schedule had been applied in the same care scenario; and
- Patients at or below 100% of the FPL receive no charge or only a nominal charge for the services provided by the referral entity.¹⁴⁸

Because the Title X Program includes sliding fee discount requirements that are broader than the Health Center Program requirements, as set forth in Chapter 4, there is no barrier to establishing a referral relationship with a Title X clinic. In fact, such relationships guarantee that health center patients have access to comprehensive family planning services, regardless of their ability to pay.

Referral Agreement Checklist

The following key considerations and terms are *recommended* for all referral relationships with Title X clinics. Items identified with a * are *required* terms for formal written referral arrangements.

For clarity, the checklist only includes provisions specific to the referral of patients from the health center to the Title X clinic. Note that the terms of the referral agreement are typically bilateral, such that the Title X clinic utilizes the health center as a referral source for primary care and other services within the health center's scope of project.

Before entering into the Referral Agreement, have you confirmed that:

- The health center understands the range of services furnished by the Title X clinic?
- Providers from both the health center and the Title X clinic reviewed and approved the referral methodology from a clinical perspective?
- Scheduling staff from both the health center and the Title X clinic reviewed and approved the referral methodology from an operational perspective?
- ✓ The Title X clinic has capacity to see additional patients?
- The proposed protocol for sharing medical notes and information satisfies federal and state patient confidentiality laws and the organizations' respective policies and procedures?
- ✓ If the relationship constitutes a formal referral arrangement, the referral relationship is accurately reflected in the health center's Form 5A and, if necessary, HRSA approval has been obtained?

Key terms to a Referral Agreement with a Title X clinic should include the following:

Availability of Referral Services:

- Title X clinic agrees to furnish voluntary family planning services, including [insert description of specific services] to all patients referred by health center, regardless of the patient's ability to pay.*
- The availability of the voluntary family planning services to patients referred by health center will be subject to Title X clinic's capacity limitations. The Title X clinic will inform the health center if it does not have capacity to serve additional patients referred by health center.

Charges and Discounts:

- ✓ Title X clinic agrees to be solely responsible for billing and collecting all payments from appropriate third party payors, and, as applicable, patients for the services it furnishes to patients referred by the health center.
- Title X clinic agrees to bill self-pay patients referred by health center consistent with the Title X Family Planning Program regulations set forth at 42 C.F.R. § 59.5(a), which require no charge for patients with incomes at or below 100% of FPL, and a schedule of discounts for patients with incomes between 101% and 250% of the FPL.*
- Title X clinic is solely liable for all family planning services provided by it and its health care professionals.

Referral Process:

- ✓ Title X clinic and health center have established a process to make and manage referrals. [Include key elements of referral process in the body of the agreement or a separate protocol. Referral process should address: (1) how timely and orderly referrals of patients will be made; (2) patient tracking; (3) the exchange of patient medical notes and information; and (4) coordination for follow-up care.]*
- ✓ Health center retains responsibility for the referred patients' overall primary care treatment plans and will be responsible for billing payors and patients for follow-up care provided by health center.*
- ✓ Title X clinic agrees to refer patients back to health center for the provision of preventive and primary services, as clinically appropriate and determined on a case-by-case basis, as well as for necessary follow-up care within health center's scope of practice.*
- ✓Title X clinic agrees to provide health center with a written diagnosis (as applicable) and specific recommendations for appropriate follow-up care to be furnished by health center (if this is not included in the referral protocol discussed above).

$Compliance, Autonomy, and {\it Freedom} of {\it Choice}:$

- The health center and Title X clinic agree to comply with all federal and state laws governing the privacy and confidentiality of patient health information, including but not limited to the Health Information Portability and Accountability Act (HIPAA). To assure the continuity of care of health center patients, health center and Title X clinic agree to cooperate in developing a method by which records and other clinical notes can be shared between the parties, subject to applicable federal and state laws and regulations and the policies and procedures of each party.
- ✓ The health center and Title X clinic agree that each shall maintain the right to enter into referral arrangements with other providers, whether for the same or for similar services. [Note that while not required, this reflects HRSA affiliation policy.]

While HRSA does not require the following provisions, it is advisable to include them for anti-kickback purposes:

- ✓ Nothing in the arrangement requires, or is intended to require, or provides payment or benefit of any kind (directly or indirectly), for the referral of patients or business to either party by the other party. Neither health center nor Title X clinic shall (1) require their professionals to refer patients to one another (or to any other entity or person); or (2) track such referrals for purposes relating to setting the compensation of their employed or contracted staff.
- Nothing in the arrangement will, or is intended to, impair the exercise of professional judgment by any and all health care professionals employed by or contracted to either health center or Title X clinic when making referrals.
- ✓ Nothing in the arrangement will, or is intended to, impair the exercise of freedom of choice of provider by any and all patients served by health center and Title X clinic.

Insurance:

✓ The Title X clinic and its employees and contractors providing services pursuant to the referral are covered by a professional liability insurance policy (malpractice, errors, and omissions) that provides sufficient coverage against professional liabilities which may occur as a result of furnishing services to patients referred to the Title X clinic by the health center. [The referral agreement may include greater specificity regarding the required malpractice insurance. Note that a parallel provision for the health center should reference FTCA coverage, if the health center is FTCA deemed.]

Chapter 9: *Purchase of Clinical Services Arrangements*

Chapter Highlights: • Under a purchase of clinical services arrangement, the health center contracts with a Title X clinic to provide family planning services on the health center's behalf. The health center is responsible (financially, clinically, and legally) for the contracted services.

- The Purchase of Services Agreement must include information about the health center's authority to bill and collect for the contracted family planning services, compensation to the family planning organization, expectations and qualifications in regard to the contracted family planning providers, the health center's oversight authority, ownership of medical records, non-exclusivity, and medical malpractice coverage (including FTCA, if applicable).
- Health centers should consult with local legal counsel before executing a Purchase of Services Agreement.
- Use the checklist on page 64 of this Chapter to structure a purchase of services relationship.

Fundamentals of Referral Arrangements

Under a purchase of clinical services arrangement, the health center contracts with a Title X clinic to purchase the capacity of certain Title X clinic staff to furnish family planning services on the health center's behalf.¹⁴⁹ The contracted staff furnishes services in accordance with the health center's policies and procedures.

The health center is financially, clinically, and legally responsible for the services furnished by the contracted Title X clinic staff. As the provider of record, the health center maintains the applicable patient medical records and bills and collects payments from patients and third party payors for services furnished by the contracted Title X staff.

Alternative Approaches to Purchase Services

While this Chapter is specific to purchase of clinical service arrangements between Title X clinics and health centers, similar relationships may be entered into between health centers and other providers of family planning services.

In addition, this Guide does not address an arrangement where a Title X clinic purchases clinical services from a health center. While this alternative model is feasible, and many of the key considerations and provisions noted below are relevant, if a health center provider is contracted by another organization, then key Health Center Program benefits (namely FTCA and cost-based reimbursement under Medicare, Medicaid, and CHIP) are not available for the provision of the services provided by contract.

BENEFITS OF PURCHASE OF SERVICES RELATIONSHIPS

- Leverages the organizations' existing staffing capacity, particularly given that recruiting licensed providers with experience and expertise furnishing family planning services is challenging in many communities
- Improves care coordination between family planning services and other primary and preventive care furnished by the health center
- Minimizes transportation barriers for patients if the Title X clinic is not located in the health center's community and the contracted Title X staff come to the health center site
- Enables the health center to maintain control over the manner by which services are provided and the standard of care

CHALLENGES OF PURCHASE OF SERVICES RELATIONSHIPS

- Patients may opt to receive family planning services in a non-health center setting
- Title X clinic may not have excess capacity to lease to the health center
- Does not reduce clinical redundancies
- Contracted Title X staff are not protected under the health center's FTCA coverage; the Title X clinic must ensure it maintains malpractice insurance that extends to the contracted staff furnishing services on the health center's behalf
- Health center may have difficulty getting buy-in from the Title X staff regarding providing services consistent with the health center's policies and procedures and standards

Purchase of Clinical Services and Scope of Project

Services within a health center's scope of project provided via contract must be coordinated through a **formal written agreement** (hereinafter, a "Purchase of Services Agreement"), and reflected in a health center's Form 5A under Column II.

HRSA requires that Purchase of Services Agreements for in-scope services include provisions addressing:

- How the service will be documented in the health center's patient records;
- How the health center will pay and/or bill for the service;
- How the health center will oversee, monitor, and evaluate the provision of purchased services by the contracted providers; and
- How the health center's policies and procedures will apply to the provision of the contracted services.

Failure to have an adequate agreement for in-scope services furnished via contract may result in a grant condition.

Key Features of a Purchase of Clinical Services Arrangement

Each Purchase of Services Agreement must be tailored to fit the circumstances of the health center and the providers it is contracting to provide services. However, similar to referral arrangements, there are several common features in every purchase of clinical services. The following section provides a brief synopsis of these key components that health centers should discuss in order to purchase clinical services from a Title X clinic.

Financial Systems, Fees and Discounts

The patients served by the contracted Title X providers are considered health center patients. As such, the health center (and not the Title X provider) bills and collects payment for services from applicable payors and patients for services furnished by the contracted Title X providers. The health center furnishes the contracted services in accordance with the health center's fee and discount schedule.

Although the health center is not required to furnish the contracted family planning services at each of its sites, it must ensure that the family planning services are reasonably available across its patient population.

Compensation to Title X Clinic

The health center compensates the Title X clinic based on a fair market, arm's length negotiated rate. This rate would not be based on the rates the health center receives for services it provides to Medicare, Medicaid, and CHIP beneficiaries, but rather would take into account the amount the health center would pay similarly qualified employees or, in the absence of such arrangements, what it would pay in a comparable marketplace.¹⁵⁰

Procurement Considerations

If the health center intends to purchase services from the Title X clinic using Section 330 grant funds, such procurement must be consistent with the uniform administrative requirements, cost principles, and audit requirements for federal awards as set forth in the Uniform Guidance (which is also referred to as "Part 75" and the "Supercircular").

Expectations and Qualifications

Contracted Title X providers must be licensed and/or certified as is necessary to furnish the applicable family planning services. In addition, all contracted Title X providers who qualify as "licensed independent practitioners" or "other licensed or certified practitioners" under PIN 2002-22 must be credentialed and privileged by the health center in accordance with the health center's applicable policies and procedures prior to their provision of clinical services on the health center's behalf.

In addition to listing the required qualifications, the Purchase of Services Agreement should describe any additional expectations for contracted Title X providers. For example, the Purchase of Services Agreement should specify if the contracted staff are expected to participate in the health center's quality improvement and/or peer review activities.

Assurances and Oversight

The Purchase of Services Agreement should set forth that the contracted Title X providers will furnish services in accordance with federal and state laws and regulations and health center's policies and procedures.

The health center should maintain certain rights in order to fulfill its oversight responsibilities, including approval of all providers from the Title X clinic assigned to the health center; evaluation of their performance; and, as necessary, authority to terminate or suspend the contracted Title X providers from furnishing services on the health center's behalf.

Medical Records

Under a contract arrangement, the health center is the provider of record. All services furnished by the contracted Title X providers on behalf of the health center should be set forth in the health center's medical records system, in accordance with the health center's applicable policies and procedures. As such, the Purchase of Services Agreement should include provisions specifying that the health center maintains ownership of the records, and that the contracted Title X providers will comply with federal and state patient confidentiality requirements, as well as the health center's applicable policies and procedures.

Exclusive Referral Relationships

HRSA has expressed concern regarding exclusive arrangements that limit a health center's ability to establish relationships with providers in the community.¹⁵¹ Accordingly, contract arrangements should not preclude either party from entering into arrangements with other providers, whether for the same or for similar services.

Federal Tort Claims Act

If the health center is deemed under FTCA, then FTCA coverage would extend to the health center for purposes of its provision of in-scope services to its patients. Under a purchase of services relationship, FTCA coverage is *not available* to the Title X clinic or its health care professionals who furnish services on the health center's behalf, unless the professionals contract with the health center individually and meet certain requirements.¹⁵² Accordingly, under such contractual arrangements the Title X clinic should obtain and carry professional liability for both itself and its providers who are contracted to the health center.

Purchase of Clinical Services Agreement Checklist

The following key considerations and terms are recommended for Purchase of Services Agreements with Title X clinics.

Note that the list of terms does not provide an exhaustive summary of all recommended provisions, nor does it take into consideration state-specific requirements. In addition, the sample terms are written in a shorthand manner and are not intended to serve as template provisions. Health centers should consult knowledgeable local counsel before entering into a Purchase of Services Agreement.

Before entering into the Purchase of Services Agreement, have you confirmed that:

- The purchased services will be reasonably available to all of the health center's patients?
- The purchased services are currently within the health center's HRSA-approved scope of project or, if necessary, HRSA approval is obtained?
- The mode of delivery for the purchased services is accurately reflected in the health center's scope of project (i.e., Form 5A under column II)?
- The purchased services will be provided at a site that is within the health center's HRSA-approved scope of project or, if necessary, HRSA approval is obtained?

- ✓ If the health center intends to use its Section 330 funds to compensate the other party, the procurement process satisfied the HHS requirements set forth in the Uniform Guidance?
- The identified compensation amount is commercially reasonable and based on a fair market, arm's length negotiated rate (unless the arrangement is structured to comply with the safe harbor under the Anti-Kickback Statute for federally-funded health centers)?

Key terms to a Purchase of Services Agreement with a Title X clinic should include the following:

Scope of Services:

- ✓ Contracted Title X providers agree to furnish family planning services, including *[insert description of specific services]*, to all patients served by the health center, regardless of the patient's ability to pay.
- ✓All patients receiving services from contracted Title X providers will be registered as patients of the health center.

Charges and Discounts:

✓ The health center will be solely responsible for billing patients and third-party payors for services rendered to the health center patients by the contracted Title X providers. The health center will be solely responsible for the collection and retention of any and all payments.

Monitoring and Oversight of Purchased Services:

- The health center will maintain responsibility and authority for approving, monitoring, evaluating, and, as necessary, suspending or removing contracted Title X providers from providing services on behalf of the health center.
- The health center's Chief Medical Officer or his/her designee will oversee the contracted providers' day-today provision of services on the health center's behalf.
- ✓The contracted provider(s) will:
 - □ Provide services consistent with:
 - Relevant state and federal laws, regulations, and policies;
 - The health center's policies and procedures (e.g., clinical policies and procedures, patient privacy policies and procedures, standards of conduct, and provider complaint resolution procedures);
 - Generally accepted standards of practice.
 - Furnish services under the direction of the health center's management team.
 - Satisfy the health center's licensure, credentialing and other professional qualification requirements.
 - Be and remain eligible to participate in federal health care programs, including the Medicaid and Medicare programs.
 - Develop, maintain, and furnish programmatic reports and records, as required by the health center.
 - Prepare medical records consistent with the health center's standards (which records will be the property of the health center).
 - Comply with any federal or state law governing the privacy and confidentiality of individually identifiable health information.

Payment to the Title X clinic:

- ✓ All payments to the Title X clinic have been determined through good-faith and arm's length bargaining and are consistent with what the parties reasonably believe to be within fair market value for the services to be provided (unless the arrangement is structured to comply with the safe harbor under the Anti-Kickback Statute for federally-funded health centers), unrelated to the volume or value of any referrals or business generated between the parties.
- The parties agree that nothing in the agreement is intended to require, nor requires, nor provides payment or benefit of any kind (directly or indirectly) for the referral of individuals or business to either party by the other party.

Insurance:

✓ The Title X clinic will be responsible, as the employer of the contracted Title X providers, for securing and maintaining worker's compensation insurance and comprehensive professional and general liability insurance for its staff who are contracted to provide services on behalf of the health center.

Compliance, Autonomy, and Freedom of Choice:

- Nothing in the arrangement will, or is intended to, impair the exercise of professional judgment by any health care professionals employed by or contracted to either party.
- ✓Nothing in the arrangement will, or is intended to, impair the exercise of freedom of choice of provider by any and all patients served by each party.
- Each party maintains the right to enter into arrangements with other providers, whether for the same or for similar services.

Obligations of the Title X Clinic:

- ✓ The Title X clinic certifies that neither it nor any of the contracted Title X providers is listed under either the SAM Exclusion Database or the OIG Exclusion Database. The Title X clinic will check the Databases on a monthly basis and will promptly notify the health center upon receipt of any notice that it and/or any of the contracted Title X providers is listed on either Database.
- ✓ The Title X clinic agrees to provide the health center with programmatic and/or financial reports, or access to such reports, pertaining to the services provided under the agreement, as deemed necessary by the health center for monitoring and oversight.

Does the Purchase of Services Agreement:

- ✓ Specify the scope of the leased services?
- ✓ Specify the leased providers' time commitments, productivity expectations (if applicable), and schedules?
- Establish that the health center can interview and approve the Title X clinic providers who are recommended for assignment at the health center?
- Describe how the parties will resolve both scheduled and unscheduled contracted provider absences?
- Set forth a term? Do the parties want the term to renew automatically at the end of the term period? If so, does the agreement reflect such understanding?

- ✓ Include provisions for termination?
- Contain provisions that appropriately allocate the parties' obligations with respect to insurance?
- Comply with the Uniform Guidance requirements, if applicable?
- Protect the confidentiality of any business and proprietary information?
- Contain a "governing law" provision that identifies the applicable state and federal laws governing the health center?
- ✓ Include processes to resolve disputes informally?

Chapter 10: *Corporate Integration Models*

Chapter Highlights: Corporate integration models enable a health center and family planning provider to leverage their respective strengths and expand the scope of family planning services in the primary care setting. Highlighted models include partial and full corporate consolidation.

- A merger is typically achieved through a written plan of merger agreement that sets forth that the "dissolving" corporation merges into the "surviving" corporation.
- A partial consolidation is typically achieved through a written transfer agreement or asset purchase agreement. This model enables a health center to assume authority over part, but not all of, another entity's operations.
- Prior to implementing a corporate consolidation, consider whether and how the transaction will impact the health center's scope of the project, governance, and/or staffing. Also consider whether the transaction includes the transfer of property or equipment in which the government retains a federal interest, and/or the transfer of Title X funds via the "successor-in-interest" process.
- Health centers should consult with local legal counsel for assistance in structuring and implementing a corporate integration model.
- Use the consolidation checklist on page 71 to help evaluate and structure a corporate integration strategy.

Fundamentals of Corporate Integration

Under a corporate integration model, the health center would assume another organization's family planning operations and its corresponding Title X grant. Corporate integration may be achieved through a merger or partial consolidation, each of which is described below. Although outside the scope of this Guide, a corporate integration model may also include a health center transferring some or all of its operations (which may include its Section 330 grant) to a family planning provider.

Merger

Under a merger, a corporation that receives a Title X grant (the "dissolving" corporation) would merge into a health center (the "surviving" corporation). The dissolving corporation would cease to exist as a separately incorporated entity.

Post-merger, the health center would become directly responsible for the management and daily operation of the dissolving corporation. The health center would assume the Title X grant through a "successor-in-interest," as described below, and would become responsible for the dissolving corporation's Title X project.

All of the dissolving corporation's assets would transfer to, and vest in, the health center, subject to federal, state, and/or other third party property interests. In addition to acquiring all assets, the health center would assume all of the dissolving corporation's liabilities, whether known or unknown. Accordingly, assessing the other corporation's assets and liabilities is a critical step to evaluating whether to proceed with a merger.

Mergers are typically implemented through a written **plan of merger agreement** (or similar document as established by state law). The plan of merger agreement

must be approved by the governing boards of both corporations and relevant state agencies. A plan of merger typically defines, among other things:

- The effective date for the merger;
- The extent to which the dissolving corporation's staff will transfer to the health center's employment; and
- Governance strategies (e.g., granting the dissolving corporation one or more Board seats or limited representation through advisory positions and/or committee membership on the surviving health center's governing Board of Directors).

The process for executing a merger and the specific terms that must be included in a plan of merger are defined by state law.

Partial Consolidation

Under a partial consolidation, there are no "dissolving" and "surviving" corporations. Rather, the health center (as the "transferee") assumes operational authority over part, but not all, of the other corporation's (the "transferor's") operations. Specifically, the Title X project transitions to the health center, and the transferor may continue its non-family planning service operations. The parties may further seek to establish the transferor as a subsidiary to the health center.

As with a merger, the health center would assume the Title X grant through a "successor-in-interest," as described below. However, unlike the merger option, the other corporation retains its corporate existence. Accordingly, the health center can avoid assuming some or all of the other corporation's liabilities.

Partial consolidations are implemented through a written **transfer agreement** or **asset purchase agreement** (or similar document as established by state law). The agreements typically define, among other things:

- The assets transitioning to the "purchasing" health center;
- The extent to which the health center will assume liabilities, if at all;
- That the liabilities not explicitly transferring to the health center will remain liabilities of the transferor;
- The purchase price for the assets, based on fair market value, if applicable;
- The extent to which workforce will transfer to the health center's employment; and
- Governance strategies (e.g., granting the transferor corporation one or more Board seats or limited representation through advisory positions and/or committee membership on the health center's governing Board of Directors).

Health Center as the "Surviving" Corporation

This Guide only addresses corporate integration options where the health center is the surviving corporation.

HRSA has expressed grave concerns regarding any affiliation arrangement between a health center and a non-health center that could jeopardize the autonomy and integrity of the health center's Board of Directors.¹⁵³ Specifically, in its affiliation policy, HRSA indicated that it is unlikely to approve certain changes in corporate structure, stating that "[n]o sole corporate member or any other parent-subsidiary approach to corporate integration, or any approach with a different name that appears to be structurally similar, will be deemed to have met all statutory and regulatory requirements unless there is no violation of any aspect of the affiliation policy clarification."¹⁵⁴

HRSA scrutinizes proposed sole corporate member and parent-subsidiary affiliations (where the health center becomes a subsidiary to another organization) to determine whether the relationship will impact the health center's compliance with the Health Center Program requirements, especially those related to Board selection, composition, and responsibilities (e.g., autonomous decision-making of the health center Board in key areas of policy-making).

In short, an arrangement where the health center is the dissolving or subsidiary organization is not an option if the health center seeks to preserve the Health Center Program benefits.

Key Features of a Consolidation Strategy

Each corporate consolidation will be unique. However, similar to the collaborative arrangements described in Chapters 8 and 9, there are common features to any corporate consolidation model. The following section provides a brief synopsis of these key components that a health center should discuss with its potential partner when considering consolidation strategies.

Scope of Project

When a health center pursues a consolidation strategy with a Title X clinic (i.e., merger or partial consolidation), the health center typically adds sites and/or services to its health center scope of project. Since adding sites or services (or both) requires HRSA's prior approval, a health center exploring a potential consolidation should evaluate whether it can satisfy HRSA's change of scope requirements. For example, prior to adding a new site to its scope of project, the health center must ensure that it can operate the new location without additional federal grant dollars (unless the site is added through a New Access Point grant).

Federal Interest

Consistent with federal property standards that govern the transfer, sale, and disposition of property and equipment acquired or improved with federal grant funds, including but not limited to Title X funds, the parties must secure prior permission from the federal government to transfer property and equipment in which the government retains an interest.¹⁵⁵ Upon the transfer, the health center's rights in such assets would be subject to any interests retained by the federal government. Alternatively, the health center could "buy-out" the federal interests by compensating the federal government for its share of the fair market value of the assets.

Governance

The health center's Board of Directors oversees the health center's expanded operations post-consolidation. If the consolidation results in an expansion of the service area and/or a modification to the patient demographics, the composition of the Board of Directors must be reconfigured to ensure continued compliance with Health Center Program requirements (e.g., the Board must represent the patient population post-consolidation).

Staffing

The health center and the other corporation should discuss and agree upon whether some (or all) of the dissolving entity's staff will transfer to the health center's employment post-consolidation.

Successor in Interest

If the corporate consolidation includes the transfer of a Title X grant to the health center, the procedures for recognizing a "successor-in-interest" will apply. A successor-in-interest is a process whereby the rights to and obligations under an HHS grant are acquired incidental to the transfer of all of the assets of the recipient, or the transfer of that part of the assets involved in the performance of the grant.

The transfer must be implemented consistent with federal law. In addition, OPA approval is necessary to implement a successor-in-interest for a Title X grant.

In order to be recognized as the successor-in-interest, the health center, as the transferee organization, must meet the Title X Family Planning Program's eligibility requirements. Upon review and acceptance of this information, OPA, as the awarding office, will revise the NoA to show the transferee health center as the Title X grant recipient of record.

Consolidation Checklist

The following key considerations are applicable to all consolidation strategies. Note that this list does not include a list of sample terms because state law dictates what information must be included in the applicable agreement.

Have the parties to the consolidation strategy:

- ✓ Executed a Confidentiality Agreement?
- Reviewed each organization's organizational documents (e.g., Articles of Incorporation, bylaws, etc.)?
- Reviewed applicable state law requirements to (1) determine whether the desired consolidation strategy is feasible and (2) assess the implementation steps?
- Established a joint communications strategy to inform staff and the community of the consolidation strategy?
- Identified how the consolidation will impact the health center's budget?
- ✓ Compared the organizations' personnel compensation packages for purposes of addressing which staff, if any, of the other party will transition to the health center's employment?

- Completed a due diligence process to assess the other party's assets and liabilities? (Note that a partial consolidation approach may allow the health center to avoid assuming all of the other entity's liabilities.)
- Completed the successor-in-interest process to secure OPA's approval of the transfer of the Title X grant, if required?
- ✓Obtained approval from the parties' respective Boards of Directors?
- ✓ Obtained HRSA's approval if new sites and/or services will be added to the health center's scope of project by virtue of the consolidation?
- ✓ Obtained approval from the applicable state and from federal agencies (e.g., the Internal Revenue Service), as may be required?

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Endnotes:

¹Health Resources and Services Administration (HRSA) Technical Assistance Resource, *Family Planning and Related Services in Health Centers*, June 14, 2016 (citing Galvin, Loretta et al., *Providing Quality Family Planning Services—Recommendations of CDC and the U.S. Office of Population Affairs*, page 1 in 63 Morbidity and Mortality Weekly.

²ld.

³National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, *Achievements in Public Health, 1900–1999: Family Planning,* in 48 Morbidity and Mortality Weekly Report 1037, 1073-80 (1999), <u>http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4847a1.htm</u>.

⁴Romero, Lisa et al., *Reduced Disparities in Birth Rates Among Teens Aged 15–19 Years—United States, 2006–2007 and 2013–2014, in* 65 Morbidity and Mortality Weekly Report 409, (2016), <u>http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6516a1.pdf</u>.

⁵Oglesby, Willie H., *Perceptions of and Preferences for Federally-funded Family Planning Clinics*, 11 Reprod. Health Art. 115 (2014), <u>http://www.ncbi.nlm.</u> <u>nih.gov/pmc/articles/PMC4086278/</u>.

⁶Finer, Lawrence B. and Zolna, Mia R., Declines in Unintended Pregnancy in the United States, 2008–2011, *N Engl J Med* 2016; 374:843-852 March 3, 2016, DOI: 10.1056/NEJMsa1506575.

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¹⁰Frost, J.J. et al., 2014, Return on investment: a fuller assessment of the benefits and cost savings of the US publicly funded Family Planning Program, *Milbank Quarterly*, 92(4):696–749.

¹¹ Id.

¹²Chesson, Harrell W., Dunne, Eileen F., Hariri, Susan, Markowitz, Lauri E., *The estimated lifetime probability of acquiring human papillomavirus in the United States*. Sexually Transmitted Diseases 660 (2014).

¹³Centers for Disease Control and Prevention, Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 U.S. dependent areas—2011, HIV Surveillance Supplemental Report 18 (No.5) (Oct. 2013) http://www.cdc.gov/hiv/library/reports/surveillance

¹⁴Oglesby, *supra* note 7, page 2.

¹⁵Gavin, Loretta E., Moskosky, Susan B. and Barfield, Wanda D., *Introduction to the Supplement: Development of Federal Recommendations for Family Planning Services*, 49 Am. J. Preventative Med. S1, S1-S5 (2015).

¹⁶Providing Quality Family Planning Services—Recommendations of CDC and the U.S. Office of Population Affairs. Recommendations and Reports. April 25, 2014 / 63(RR04);1-29. For more information, please see Chapter 2.

1742 U.S.C. §254b(b)(1)(A).

¹⁸HRSA defines the specific services included in each of these larger categories in the resource *Service Descriptors for Form 5A: Services Provided,* available at: <u>http://bphc.hrsa.gov/about/requirements/scope/form5aservicedescriptors.pdf</u>.

¹⁹Wood, Susan F. et al., *Health Centers and Family Planning: Results of a Nationwide Study,* Geiger Gibson/RCHN Community Health Foundation Research Collaborative and the Jacobs Institute of Women's Health, George Washington University School of Public Health and Health Services, Department of Health Policy.

²⁰*Id.* at 21.

²¹*Id.* at v.

²²Id.

²³*Id.* at 41.

²⁴*Id.* at vi.

²⁵Wood, Susan F. et al., *Patient Experiences With Family Planning in Community Health Centers*, Geiger Gibson/RCHN Community Health Foundation Research Collaborative and the Jacobs Institute of Women's Health, George Washington University School of Public Health and Health Services, Department of Health Policy and Management, page 4 (July 28, 2015), <u>https://publichealth.gwu.edu/sites/default/files/Geiger_Gibson_Family_Planning_Report_2015.pdf</u>.

²⁶*Id.* at 5.

²⁷Wood, *supra* note 19, at vi.

²⁸ Providing Quality Family Planning Services—Recommendations of CDC and the U.S. Office of Population Affairs, 63, Morbidity and Mortality Weekly (April 25, 2014). For more information, please see Chapter 2.

²⁹Social Security Act, 42 U.S.C. §§ 1396a(a)(10(A), 1396d(a)(4)(C).

³⁰CMS has clarified that services such as diagnosis of and treatment for sexually transmitted infections should be considered "family planning *related*" services, which are covered by Medicaid as mandatory benefits.

³¹U.S. Dept. of Health & Human Serv., Ctr. for Medicare & Medicaid Serv., The State Medicaid Manual § 4270(B).

3242 U.S.C. § 1396b(a)(5).

³³Patient Protection and Affordable Care Act (PPACA), Pub. L. 111-148, § 2303(c) (amending 42 U.S.C. 1396u- to add subparagraph (b)(7)). Also of note, the alternative benefit packages for the newly eligible individuals must include all "essential health benefits" covered under Exchange qualified health plans, including (within the "preventive services" category) all U.S. Food and Drug Administration (FDA) approved methods of contraception prescribed for women by a health care practitioner, 42 U.S.C. § 1396u-7.

³⁴Patient Protection and Affordable Care Act (PPACA), Pub. L. 111-148, § 2303(c), (amending 42 U.S.C. 1396a(a)(10)(G)).

³⁵Ranji, U., Bair, Y., Salganicoff, A. Medicaid and Family Planning: Background and Implications of the ACA. (February 2016). The Henry J. Kaiser Family Foundation. <u>http://kff.org/report-section/medicaid-and-family-planning-medicaid-family-planning-policy/</u>.

³⁶Ranji, U., Bair, Y., Salganicoff, A. Medicaid and Family Planning: Background and Implications of the ACA. (February 2016). The Henry J. Kaiser Family Foundation. <u>http://kff.org/report-section/medicaid-and-family-planning-medicaid-family-planning-policy/</u>.

³⁷U.S. Dept. of Health & Human Serv., Ctr. for Medicare & Medicaid Serv., CMCS Info. Bull. Re: State Medicaid Payment Approaches To Improve Access To Long-Acting Reversible Contraception 1 (Apr. 8, 2016).

³⁸Walls, Jenna et al., *Medicaid Coverage of Family Planning Services: Results from a State Survey Findings*, Kaiser Family Foundation (Sept. 2016). <u>http://kff.org/womens-health-policy/report/medicaid-coverage-of-family-planning-benefits-results-from-a-state-survey/</u>.

³⁹U.S. Dept. of Health & Human Serv., Ctr. for Medicare & Medicaid Serv., CMCS Informational Bulletin re: State Medicaid Payment Approaches to Improve Access to Long-Acting Reversible Contraception, page 1 (Apr. 8, 2016).

⁴⁰U.S. Dept. of Health & Human Serv., Ctr. for Medicare & Medicaid Serv., SHO #16-008 RE: Medicaid Family Planning Services And Supplies (June 14, 2016).

⁴¹U.S. Dept. of Health & Human Serv., Ctr. for Medicare & Medicaid Serv., CMCS Informational Bulletin re: State Medicaid Payment Approaches to Improve Access to Long-Acting Reversible Contraception (Apr. 8, 2016).

⁴²Under the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000, States were required to develop a per-visit rate for each FQHC based on an average of the FQHC's reasonable cost of providing Medicaid-covered services in 1999 and 2000. 42 U.S.C. § 1396a(bb)(2).

4342 U.S.C. §§ 1396a(bb), 1396d(l), 1396d(a)(2)(C).

4442 U.S.C. 1396d(I)(2)(A) (incorporating by reference 42 U.S.C. 1395x(aa)).

⁴⁵Memorandum from Richard Chambers to Associate Regional Administrators, HCFA (Sept. 12, 2001).

⁴⁶Arkansas Dept. of Human Serv., Div. of Med. Serv., *Federally Qualified Health Center Manual* § 216.120.

⁴⁷Maryland Dept. of Health & Mental Hygiene, Maryland Med. Assistance Program, FQHC Transmittal No. 1 RE: Reimbursement of Long Acting Reversible Contraceptives (LARCs) (June 6, 2013); Alabama Medicaid Agency, *Changes to Intrauterine Devices (IUD) and Implantable Contraceptive Coverage*, Alert (May 7, 2012).

⁴⁸South Carolina Dept. of Health & Human Serv., South Carolina Medicaid, *Physicians Provider Manual* 2-50, <u>https://www.scdhhs.gov/internet/pdf/manu-als/Physicians/Section%202.pdf</u> (updated 4/01/2016).

⁴⁹Title X: The National Family Planning Program, Off. of Population Affairs, <u>http://www.hhs.gov/opa/title-x-family-planning/</u> (last visited June 24, 2016).

⁵⁰An Act Making Appropriations for the Departments of Labor, Health and Human Services, and Education, and Related Agencies, for the Fiscal Year Ending September 30, 1996, and for Other Purposes: Hearings on H.R. 2127 Before a Subcommittee of the Committee on Appropriations United States Senate, 104th Cong. 240 (1996). ⁵¹42 U.S.C. §§ 300-300a-8 (2012), implemented in 42 C.F.R. §§ 59.1-59.12 (2015).

⁵²Fowler, Christina et al., *Family Planning Annual Report: 2014 National Summary*, Off. of Population Affairs, U.S. Dept. of Health & Human Serv., at ES-1 (Aug. 2015).

⁵³Off. of Population Affairs, Program Requirements for Title X Funded Family Planning Projects (Apr. 2014).

⁵⁴Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, 129 Stat. 2602.

⁵⁵Fowler, C.I., Gable, J., Wang, J., & Lasater, B. (2016, August). *Family Planning Annual Report: 2015 national summary*. Research Triangle Par, NC: RTI International.

⁵⁶Frost, J.J., Sonfield, A., Zolna, M.R., Finer, L.B. (2014). *Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program.* The Milbank Quarterly, Vol. 92, No. 4.

5742 U.S.C. § 300 (2012).

5842 U.S.C. §§ 300-300a-8.

⁵⁹42 C.F.R. §§ 59.1-59.12.

⁶⁰Note that Title X projects are expected to furnish services in accordance with the QFP recommendations, and applicants for Title X funding must include a project plan that addresses the organization's ability to satisfy the QFP recommendations on an ongoing basis.

6142 C.F.R. § 59.5(a)(1).

6242 C.F.R. § 59.5(1).

6342 C.F.R. § 59.5(b)(1).

6442 C.F.R. § 59.5(b)(2).

6542 C.F.R. § 59.5(b)(3).

⁶⁶Off. of Population Affairs, Program Requirements for Title X Funded Family Planning Projects, page 5 (Apr. 2014).

6742 C.F.R. § 59.5(a)(5).

6842 C.F.R. § 59.5(a)(5).

⁶⁹Program Requirements for Title X Funded Family Planning Projects. (April 2014). U.S. Department of Health & Human Services/Office of Population Affairs.

⁷⁰42 C.F.R. § 59.5(b)(9)).

7142 C.F.R. § 59.5(b)(9)).

⁷²42 C.F.R. § 59.5(a)(2); see also OPA, supra note 53, pages 10-11 (Program Requirement 8.1).

7342 C.F.R. § 59.11.

⁷⁴42 C.F.R. § 59.11.

⁷⁵42 C.F.R. § 59.5(a)(4); see also OPA, supra note 53, page 15 (Program Requirement 9.3).

⁷⁶42 C.F.R. § 59.5(b)(5); see also OPA, supra note 53, page 16 (Program Requirement 9.9).

⁷⁷42 C.F.R. § 59.5(a)(6); see also OPA, supra note 53, page 15 (Program Requirements 9.1).

⁷⁸42 C.F.R. § 59.5(a)(8). Note that the Title X Requirements refer to the Federal Poverty *Level* (FPL) while Section 330 guidance (primarily in PIN 2014-02) uses Federal Poverty *Guidelines* (FPG). Both refer to the same data measure: a simplified version of the income thresholds used by the U.S. Census Bureau to estimate the number of people living in poverty. The thresholds are annual income levels, varying by the number of family members, below which a person or family is considered to be living in poverty. For the purposes of this manual, FPL and FPG may be considered interchangeable.

⁷⁹For more information regarding how to align the schedule of discounts required under the Title X Family Planning Program with the schedule of discount requirements under the Health Center Program, see Chapter 5.

8042 C.F.R. § 59.5 (a)(7).

8142 C.F.R. § 59.5 (a)(8).

8242 C.F.R. § 59.5 (a)(8).

⁸³42 C.F.R. § 59.2; see also OPA, supra note 54, page 13 (Program Requirement 8.4.3).

⁸⁴OPA, *supra* note 53, at 12 (Program Requirement 8.4.1); *see also* Letter from Evelyn M. Kappeler, Acting Director, Office of Population Affairs to Regional Health Administrators, Department of Health & Human Services (Sept. 23, 2008).

⁸⁵OPA, *supra* note 53, page 7.

⁸⁶OPA, supra note 53, at 13 (Program Requirement 8.4.8); *see also* English, Abigail et al., *Confidentiality, Third-Party Billing, & the Health Insurance Claims Process: Implications for Title X*, National Family Planning & Reproductive Health Association (Apr. 2015), <u>http://www.confidentialandcovered.com/file/ConfidentialandCovered_WhitePaper.pdf</u>.

⁸⁷42 C.F.R. § 59.2; see also OPA, supra note 53, page 13 (Program Requirement 8.4.5).

8842 C.F.R. § 59.5(a)(12)(i)(C)(1983).

8942 C.F.R. § 59.5(b)(4).

⁹⁰OPA, supra note 53, page 14 (Program Requirement 8.6.2).

⁹¹OPA, *supra* note 53, page 14 (Program Requirement 8.6.3).

⁹²Id.

9342 C.F.R. § 59.5(a)(11).

⁹⁴42 C.F.R. § 59.6.

9542 C.F.R. § 59.5(b)(6); see also OPA, supra note 53, page 13 (Program Requirement 8.5.4).

⁹⁶OPA, supra note 53, page 14 (Program Requirements 8.5.3-8.5.4).

⁹⁷Grantees must submit to OPA the "Monitoring and Reporting Program Performance" required of federal grantees at 45 CFR § 75.342(b)(2).

⁹⁸The FPAR contains questions regarding a brief organizational profile and 14 tables to report data on family planning users, service use, and revenue for the reporting year.

⁹⁹In addition to submitting the Federal Financial Reports to OPA, Title X grantees must also upload quarterly cash reporting separately to the HHS Payment Management System. At this time, data is not transferable between the two systems and some data elements must be reported twice.

¹⁰⁰The FPAR instrument and instructions can be found on the OPA Web site at <u>http://hhs.gov/opa</u>.

¹⁰¹Title X Sustainability Assessment Tool for Grantees and Service Sites. OMB Control Number: 0990-0442. Expires 12/2018.

¹⁰²U.S. Dept. Health & Human Serv., Health Resources and Services Administration, PIN 2013-01: Health Center Budgeting and Accounting Requirements (Mar. 18, 2014), <u>http://bphc.hrsa.gov/programrequirements/pdf/pin201301.pdf</u>. In the PIN, HRSA defines "other revenue sources" as "state, local, or other federal grants or contracts."

¹⁰³ See e.g., U.S. Dept. Health & Human Serv., Announcement of Availability of Funds for Family Planning Services Grants Virginia, page 11 (PA-FPH-16-034, CFDA: 93.217), <u>https://www.hhs.gov/opa/sites/default/files/fy16-family-planning-services-grants-virginia.pdf</u>.

¹⁰⁴There is some flexibility offered by the Uniform Guidance: where a direct cost benefits both the Health Center Project and the Title X Project "in proportions that *cannot be determined because of the interrelationship of the work involved*, then...the costs may be allocated or transferred to benefitted projects on any reasonable documented basis." 45 C.F.R. § 75.405 (*emphasis added*).

¹⁰⁵For more information on indirect costs, see 45 C.F.R. § 75.414.

¹⁰⁶English, Abigail et al., *Confidential & Covered: Title X Network Perspectives on Confidentiality and Billing*, National Family Planning & Reproductive Health Association (NFPRHA) 10 (Apr. 2015), <u>http://www.confidentialandcovered.com/file/ConfidentialandCovered_ResearchReport.pdf</u> (noting that not billing third party payors "is an important failsafe for Title X patients… when the provider has ascertained that seeking reimbursement would jeopardize patient confidentiality and the patient has indicated a need for confidentiality protection").

¹⁰⁷Previously, OPA required "sufficient proportional steps" in the Title X sliding fee discount scale, similar to the payment gradations required of health centers by PIN 2014-02. Though, there is no longer a specific requirement, OPA does expect some degree of proportionality between discount classes.

¹⁰⁸According to HRSA PIN 2014-02, if a health center elects to acquire, purchase, or facilitate access to supplies and equipment, such as IUDs, they are permitted to charge patients based on a different structure for discounting than what is described above. To maximize access to IUDs, health centers may charge patients based on amounts that are less than the locally prevailing rates; however, such charges can be set to cover the reasonable costs of such items or can be further discounted to pass additional savings on to patients. The structure for these charges, if any, and associated payment options should be based on an analysis of the health center's patient/target population's needs and support patients' access to IUDs. In addition, it should include provisions to waive or reduce payments on IUDs consistent with board-approved policies and the health center's supporting operating procedures.

¹⁰⁹*Title X Program Policy Notice: 2016 -11: Integrating with Primary Care Providers.* U.S. Department of Health & Human Services Office of Population Affairs. (November 2016.) Available at: <u>https://www.hhs.gov/opa/sites/default/files/Title-X-Program-Policy-Notice-Integrating-with-Primary-Care-Providers.pdf</u>.

¹¹⁰*Title X Family Planning Annual Report: Forms & Instructions.* U.S. Department of Health & Human Services Office of Population Affairs. (October 2013). Available at http://www.hhs.gov/opa/sites/default/files/fpar-reissued-oct13_0.pdf.

¹¹¹The FPAR defines a family planning provider as the individual who assumes primary responsibility for assessing a client and documenting services in the client record, which includes any staff who exercise independent judgment as to the services rendered to the client during an encounter.

¹¹² *Title X Program Policy Notice: 2016 -11: Integrating with Primary Care Providers.* U.S. Department of Health & Human Services Office of Population Affairs. (November 2016.) Available at: <u>https://www.hhs.gov/opa/sites/default/files/Title-X-Program-Policy-Notice-Integrating-with-Primary-Care-Providers.pdf</u>.

¹¹³Available at: http://kff.org/report-section/medicaid-and-family-planning-medicaid-family-planning-policy/.

11442 U.S. Code § 256b(b)(2).

¹¹⁵42 C.F.R. § 59.5(b)(4); see also OPA, supra note 53, page 14 (Program Requirement 8.6.1).

¹¹⁶OPA, *supra* note 53, page 14 (Program Requirement 8.6.2).

¹¹⁷OPA, supra note 53, page 14 (Program Requirement 8.6.3).

¹¹⁸ Providing Quality Family Planning Services—Recommendations of CDC and the U.S. Office of Population Affairs, 63, Morbidity and Mortality Weekly (April 25, 2014). For more information, please see Chapter 2.

¹¹⁹ "State" includes one of the 50 United States, District of Columbia, Commonwealth of Puerto Rico, U.S. Virgin Islands, Commonwealth of the Northern Mariana Islands, American Samoa, Guam, Republic of Palau, Federated States of Micronesia, and the Republic of the Marshall Islands.

120 U.S. Dept. Health & Human Serv., Announcement of Availability of Funds for Family Planning Services Grants 5 (PA-FPH-16-034, CFDA Number 93.217).

¹²¹Title X Grantee and Service Site Sustainability Assessment Tool. (Data not yet published.)

12245 C.F.R. § 75.2.

¹²³42 C.F.R. § 59.5(a)(10).

¹²⁴45 C.F.R. § 75.353.

12545 C.F.R. § 75.351(a).

12645 C.F.R. §§ 75.101(b)(1), 75.352.

¹²⁷45 C.F.R. § 75.351(b).

¹²⁸45 C.F.R. § 75.352(b).

12945 C.F.R. § 75.352(b).

¹³⁰Pursuant to 45 C.F.R. § 75.512(g), full A-133 audit reports for all federal grant recipients are to be available on the Federal Audit Clearinghouse website at <u>https://harvester.census.gov/facweb</u>.

¹³¹Pursuant to 45 C.F.R. § 75.352(c), prime grantees may, where appropriate, apply special award conditions to mitigate particular risks identified in evaluating a subrecipient candidate. *See also* 45 C.F.R. § 75.207.

¹³²Off. of Population Affairs, *supra* note 53, page 11 (Program Requirement 8.3.1).

¹³³45 C.F.R. § 75.101(b)(1).

¹³⁴See 45 C.F.R. § 75.303 (setting minimum standards for internal controls).

13545 C.F.R. § 75.352(a)(4).

¹³⁶45 C.F.R. § 75.352(d).

13745 C.F.R. § 75.352(e).

¹³⁸U.S. Dept. of Health & Human Serv., Health Resources and Services Administration, PAL 2011-02: Health Center Collaboration (November 23, 2010). ¹³⁹/*d.* at 2.

¹⁴⁰National Quality Forum. Multistakeholder Input on a National Priority: Improving Population Health by Working with Communities—Action Guide 3.0. May 2016 DRAFT.

¹⁴¹Felt-Lisk, S. and Higgins, T. Exploring the Promise of Populations Health Management Programs to Improve Health. Mathematica Policy Research. August 2011.

¹⁴²FQHC look-alikes are organizations that do not receive health center funding, but meet all of the Health Center Program Requirements, including serving the same populations, being subject to the same programmatic rules and regulations, and receiving many of the same benefits as health center grantees.

¹⁴³Wood, Susan B. et al., *supra* note 19, page vi.

¹⁴⁴ See U.S. Dept. Health & Human Serv., Health Resources and Services Administration, PIN 2008-01: Defining Scope of Project and Policy for Requesting Changes, page 10-11 (Dec 31, 2007); see also the Health Center Visit Guide 4; see also U.S. Dept. Health & Human Serv., Health Resources & Serv. Admin., Policy Information Notice. (PIN) 2014-02: Sliding Fee Discount and Related Billing and Collections Program Requirements, page 12 (Sept. 22, 2014).

14542 U.S.C. §254b(b)(1)(A).

¹⁴⁶U.S. Dept. of Health & Human Serv., Health Resources and Services Administration, *Service Descriptors for Form 5A*, <u>http://bphc.hrsa.gov/archive/</u> about/requirements/scope/form5aservicedescriptors.pdf.

¹⁴⁷U.S. Dept. of Health & Human Serv., Health Resources and Services Administration, PIN 97-27: Affiliation Agreements of Community and Migrant Health Centers 9-10 (July 22, 1997).

¹⁴⁸U.S. Dept. of Health & Human Serv., Health Resources and Services Administration, PIN 2014-02: Sliding Fee Discount and Related Billing and Collections Program Requirements, page 12 (Sept. 22, 2014).

¹⁴⁹A health center could establish a purchase of family planning services arrangement with a provider that is not a Title X grantee or subrecipient.

¹⁵⁰Note that it may be possible for the health center to compensate the Title X organization at a rate that is lower than fair market value if the transaction is established in accordance with the Anti-Kickback Statute safe harbor for federally-funded health centers, as set forth in 42 U.S.C. §1320a-7b(3), implementing regulations at 42 C.F.R. §1001.952(w).

¹⁵¹U.S. Dept. of Health & Human Serv., Health Resources and Services Administration, PIN 97-27: Affiliation Agreements of Community and Migrant Health Centers 9-10 (July 22, 1997).

¹⁵²Typically, a covered entity will issue a Form 1099 to an individual who is a contractor. Licensed or certified individual health care provider contractors working full-time (on average at least 32.5 hours per week for the health center for the period of the contract) are eligible for FTCA coverage. These time requirements do not apply to individually contracted providers in the fields of family practice, general internal medicine, general pediatrics, obstetrics and gynecology, who are eligible for FTCA coverage even if they provide services to the covered entity on a part-time basis.

¹⁵³U.S. Dept. of Health & Human Serv., Health Resources and Services Administration, PIN 1997-27: Affiliation Agreements of Community and Migrant Health Centers 8-9 (July 22, 1997).

¹⁵⁴*Id.* at 10.

¹⁵⁵45 C.F.R. §§ 75.316-75.323, § 75.436, § 75.439, § 75.443.