Program Requirements for Title X Funded Family Planning Projects

Version 1.0 April 2014

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Links

Title X Statute http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/statutes-and-regulations/

Title X Regulations http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/statutes-and-regulations/

Appropriations Language/Legislative Mandates http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/legislative-mandates/

Sterilization of Persons in Federally Assisted Family Planning Projects Regulations http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/statutes-and-regulations/

Department of Health and Human Services Regions http://www.hhs.gov/opa/regional-contacts/

ACRONYMS

The following is a list of acronyms and abbreviations used throughout this document.

ACRONYM/ ABBREVIATION	
CFR	Code of Federal Regulations
FDA	U.S. Food and Drug Administration
FPL	Federal Poverty Level
HHS	U.S. Department of Health and Human Services
HIV	Human Immunodeficiency Virus
I&E	Information and Education
NOA	Notice of Award
OASH	Office of the Assistant Secretary for Health
OGM	Office of Grants Management
OMB	Office of Management and Budget
OPA	Office of Population Affairs
OSHA	Occupational Safety and Health Administration
PHS	U.S. Public Health Service
STD	Sexually Transmitted Disease

COMMONLY USED REFERENCES

As a Federal grant program, requirements for the Title X Family Planning Program are established by Federal law and regulations. For ease of reference, the law and regulations most cited in this document are listed below. Other applicable regulations and laws are cited throughout the document.

Law	Title X Public Law (“Family Planning Services and Population Research Act of 1970”)	Public Law 91-572
Law	Title X Statute (“Title X of the Public Health Service Act”)	42 U.S.C.300, *et seq.*
Regulation	Sterilization Regulations (“Sterilization of persons in Federally Assisted Family Planning Projects”)	42 CFR part 50, subpart B
Regulation	Title X Regulations (“Project Grants for Family Planning Services”) (	42 CFR part 59, subpart A
Regulation	HHS Grants Administration Regulations	45 CFR parts 74

	("Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations" (part 74) and "Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments" (part 92))	and 92
Regulation	"Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-profit Organizations"	2 CFR 215 (OMB Circular A-110)
OMB Circular	"Grants and Cooperative Agreements with State and Local Governments"	OMB Circular A-102

INTRODUCTION

To assist individuals in determining the number and spacing of their children through the provision of affordable, voluntary family planning services, Congress enacted the Family Planning Services and Population Research Act of 1970 (Public Law 91-572). The law amended the Public Health Service (PHS) Act to add Title X, "Population Research and Voluntary Family Planning Programs." Section 1001 of the PHS Act (as amended) authorizes grants "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)."

The Title X Family Planning Program is the only Federal program dedicated solely to the provision of family planning and related preventive health services. The program is designed to provide contraceptive supplies and information to all who want and need them, with priority given to persons from low-income families. All Title X-funded projects are required to offer a broad range of acceptable and effective medically (U.S. Food and Drug Administration (FDA)) approved contraceptive methods and related services on a voluntary and confidential basis. Title X services include the delivery of related preventive health services, including patient education and counseling; cervical and breast cancer screening; sexually transmitted disease (STD) and human immunodeficiency virus (HIV) prevention education, testing, and referral; and pregnancy diagnosis and counseling. By law, Title X funds may not be used in programs where abortion is a method of family planning.

The Title X Family Planning Program is administered by the Office of Population Affairs (OPA), Office of the Assistant Secretary for Health (OASH), within the U.S. Department of Health and Human Services (HHS). OASH is responsible for facilitating the process of evaluating applications and setting funding levels according to the criteria set forth in 42 CFR 59.7(a). 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 and the Assistant Secretary for Health or their designees. The HHS Regional Offices monitor program performance of Title X grantees in each respective region.

The Title X Family Planning Guidelines consist of two parts, 1) *Program Requirements for Title X Funded Family Planning Projects* (hereafter referred to as *Title X Program Requirements*) and 2) *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*.

These documents have been developed to assist current and prospective grantees in understanding and implementing the family planning services grants program authorized by Title

X of the PHS Act (42 U.S.C. 300 *et seq.*). These documents also form the basis for monitoring projects under the Title X program.

OVERVIEW OF PROGRAM REQUIREMENTS

This document is organized into 16 sections that describe the various requirements applicable to the Title X program, as set out in the Title X statute and implementing regulations (42 CFR part 59, subpart A), and in other applicable Federal statutes, regulations, and policies. Links to the Title X statute and implementing regulations, other statutory provisions that are applicable to the Title X program, regulations related to sterilization, and additional resources to maximize the quality of services offered by Title X projects are provided on page 2 of this document.

The concise explanation of general program requirements that follows can be used to help prepare a grant application or monitor funded programs for compliance with Title X requirements. In addition, prospective applicants and grantees should consult all of the resources and references identified in this document for more complete information and to ensure that the project application and program operations comply with these and other Federal requirements.

Additional documents, including the annual *Announcement of Anticipated Availability of Funds for Family Planning Services Grants* (Title X Funding Opportunity Announcement), other Funding Opportunity Announcements for OPA priority areas, and relevant language in Federal appropriations laws, contain the most current information about Title X program requirements and are generally updated annually. The Title X Funding Opportunity Announcement includes the most recent list of program priorities and key issues, and identifies geographic areas where there will be a grant competition for the applicable fiscal year. Subject to the availability of funds, the funding announcement is published annually and posted on the HHS Grants.gov Website Portal. The *Program Requirements for Title X Funded Family Planning Projects* is posted on the OPA website (http://www.hhs.gov/opa). In general, the requirements that apply to the direct recipients of Title X funds also apply to sub-recipients and contractors (HHS Grants Policy Statement, 2007).

1. APPLICABILITY

As stated above, the requirements set forth in this document apply to the award of grants under section 1001 of the PHS Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children (42 CFR 59.1).

2. DEFINITIONS

Terms used throughout this document include:

TERM	DEFINITION
The Act or Law	Title X of the Public Health Service Act, as amended
Family	A social unit composed of one person, or two or more persons living together, as a household
Low-income family	A family whose total annual income does not exceed 100% of the most recent Federal Poverty Guidelines; also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. Unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources
Grantee	The entity that receives 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
Nonprofit	Any private agency, institution, or organization for which no part of the entity's net earnings benefit, or may lawfully benefit, any private stakeholder or individual.
Project	Activities described in the 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.
Secretary	The Secretary of Health and Human Services and any other officer or employee of the U.S. Department of Health and Human Services to whom the authority involved has been delegated.
Service Site	The clinics or other locations where services are provided by the grantee or sub-recipient.
Sub-recipients	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.
State	Includes the 50 United States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Mid-way, Wake, et. al), the Marshall Islands, the Federated States of Micronesia and the Republic of Palau.

3. ELIGIBILITY

Any public or nonprofit private entity located in a state (which includes the 50 United States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Mid-way, Wake, et. al), the Marshall Islands, the Federated States of Micronesia and the Republic of Palau) is eligible to apply for a Title X family planning services project grant (42 CFR 59.2, 42 CFR 59.3).

Even where states apply for a family planning services grant, local and regional entities may also apply directly to the Secretary for a family planning services grant. Faith-based organizations and American Indian/Alaska Native/Native American organizations are eligible to apply for Title X family planning services grants. Private nonprofit entities must provide proof of nonprofit status during the application process.

Although State agencies are eligible for funding, the Title X statute specifically protects the right of local and regional entities to apply directly to the Secretary for a family planning services grant (Section 1001(b), PHS Act).

4. APPLICATION

The Office of Population Affairs publishes, at a minimum, an annual announcement of the availability of Title X family planning services grant funds that sets forth specific application requirements and evaluation criteria. Applications must be submitted to OASH, Office of Grants Management (OGM) on the forms required by HHS, in the manner required, and approved by an individual authorized to act for the applicant. The application process is conducted through an electronic grants system.

If an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential sub-

recipients that have previously provided or propose to provide family planning services to the area to be served by the applicant (42 CFR 59.5 (a)(10)(i)).

Unless otherwise instructed, applicants should respond to the standard instructions contained in the grant application package as well as any HHS supplemental instructions.

Successful applications must include:

- a narrative description of the project and the manner in which the applicant intends to conduct the project and comply with all requirements of the law and regulations;
- a budget that includes an estimate of project income and costs, with justification of the amount of grant funds requested (42 CFR 59.4(c)(2)) and which is consistent with the terms of Section 1006(a) of the Act, as implemented by regulation (42 CFR 59.7(b));
- a description of the standards and qualifications the project will use for all personnel and facilities; and
- other pertinent information as may be required by the Secretary (42 CFR 59.4(c)(4)).

Title X grant funds cannot constitute 100% of a project's estimated costs; therefore, applicants must clearly specify all other sources of funding that will be used to support the Title X project (42 CFR 59.7(c)).

5. CRITERIA FOR FUNDING

Within the limits of funds available for these purposes, grants are awarded for the establishment and operation of projects that will best promote the purposes of Section 1001 of Title X of the PHS Act. The application must address all seven points contained in section 59.7(a) of the regulations. These are the criteria HHS uses to determine which family planning projects to fund and in what amount.

In making funding decisions, HHS takes into account:

- the number of patients, and, in particular, the number of low-income patients to be served;
- the extent to which family planning services are needed locally;
- the relative need of the applicant;
- the capacity of the applicant to make rapid and effective use of the Federal assistance;
- the adequacy of the applicant's facilities and staff;
- the relative availability of non-Federal resources within the community to be served and the degree to which those resources are committed to the project; and
- the degree to which the project plan adequately provides for the requirements set forth in the Title X regulations.

Funding of applications that propose to rely on other entities to provide services will take into

consideration the extent to which the applicant indicates it will be inclusive in considering all entities that are eligible to receive Federal funds to best serve individuals in need throughout the anticipated service areas.

6. NOTICE OF AWARD

The Notice of Award (NOA) is the document that informs the grantee of the duration of HHS support for the project without requiring it to recompete for funds (42 CFR 59.8 (a)). This period of funding is called the "project period." The project is generally funded in increments known as "budget periods." Each budget period is typically 12 months, although shorter or longer budget periods may be established for compelling administrative or programmatic reasons.
Decisions regarding whether and at what level to continue awards are based on factors such as the adequacy of the grantee's programmatic progress, management practices, compliance with the terms and conditions of the previous award, program priorities, and the availability of appropriations. In all cases, subsequent budget periods, also known as non-completing continuation awards, require a determination by HHS that continued funding is in the best interest of the government.

The U.S. government is not obligated to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application (42 CFR 59.8(c)).

Grantees must provide the awarding agency with timely and unrestricted access to examine all records, books, papers, and documents related to the award (45 CFR 74.53 and 92.42). Records must be maintained generally for 3 years from submission of the final federal financial report (45 CFR 74.53)

7. USE OF GRANT FUNDS

All funds granted for Title X family planning services projects must be expended only for the purpose for which the funds were awarded and in accordance with the approved application and budget. Funds may not be used for prohibited activities, such as abortion as a method of family planning, or lobbying. The Notice of Award (NOA) provides other stipulations regarding the use of funds. Funds must be used in accordance with the Title X family planning services projects regulations, the terms and conditions of the award, and the HHS grants administration regulations set out at 45 CFR parts 74 and 92.

8. PROJECT MANAGEMENT AND ADMINISTRATION

All projects receiving Title X funds must provide services of high quality and be competently and efficiently administered.

8.1 Voluntary Participation

Family planning services are to be provided solely on a voluntary basis (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a)(2)). Clients cannot be coerced to accept services or to use or not use any particular method of family planning (42 CFR 59.5 (a)(2)).

A client's acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other services, assistance from, or participation in any other program that is offered by the grantee or sub-recipient (Section 1007, PHS Act; 42 CFR 59.5 (a)(2)).

Personnel working within the family planning project must be informed that they may be subject to prosecution if they coerce or try to coerce any person to undergo an abortion or sterilization procedure (Section 205, Public Law 94-63, as set out in 42 CFR 59.5(a)(2) footnote 1).

8.2 Prohibition of Abortion

Title X grantees and sub-recipients must be in full compliance with Section 1008 of the Title X statute and 42 CFR 59.5(a)(5), which prohibit abortion as a method of family planning. Grantees and sub-recipients must have written policies that clearly indicate that none of the funds will be used in programs where abortion is a method of family planning. Additional guidance on this topic can be found in the July 3, 2000, Federal Register Notice entitled *Provision of Abortion-Related Services in Family Planning Services Projects*, which is available at 65 Fed. Reg. 41281, and the final rule entitled *Standards of Compliance for Abortion-Related Services in Family Planning Services Projects*, which is available at 65 Fed. Reg. 41270.

Grantees are also responsible for monitoring sub-recipients' compliance with this section.

8.3 Structure and Management

Family planning services under a Title X grant may be offered by grantees directly and/or by sub-recipient agencies operating under the umbrella of a grantee. However, the grantee is accountable for the quality, cost, accessibility, acceptability, reporting, and performance of the grant-funded activities provided by sub-recipients. Where required services are provided by referral, the grantee is expected to have written agreements for the provision of services and reimbursement of costs as appropriate.

8.3.1 The grantee must have a written agreement with each sub-recipient and establish written standards and guidelines for all delegated project activities consistent with the appropriate section(s) of the Title X Program Requirements, as well as other applicable requirements (45 CFR parts 74 and 92).

8.3.2 If a sub-recipient wishes to subcontract any of its responsibilities or services, a written agreement that is consistent with Title X Program Requirements and approved by the grantee must be maintained by the sub-recipient (45 CFR parts 74 and 92).

8.3.3 The grantee must ensure that all services purchased for project participants will be authorized by the project director or his designee on the project staff (42 CFR 59.5(b)(7)).

8.3.4 The 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 grantee. The grantee must be prepared to substantiate that these rates are reasonable and necessary (42 CFR 59.5(b)(9)).

8.3.5 Sub-recipient agencies must be given an opportunity to participate in the establishment of ongoing grantee policies and guidelines (42 CFR 59.5 (a)(10)).

8.3.6 The grantee and each sub-recipient must maintain a financial management system that meets Federal standards, as applicable, as well as any other requirements imposed by the Notice of Award, and which complies with Federal standards that will support effective control and accountability of funds. Documentation and records of all income and expenditures must be maintained as required (45 CFR parts 74.20 and 92.20).

8.4 Charges, Billing, and Collections

The grantee is responsible for the implementation of policies and procedures for charging, billing, and collecting funds for the services provided by the projects. Clients must not be denied project services or be subjected to any variation in quality of services because of inability to pay.

Projects should not have a general policy of no fee or flat fees for the provision of services to minors, or a schedule of fees for minors that is different from other populations receiving family planning services

8.4.1 Clients whose documented income is at or below 100% of the Federal Poverty Level (FPL) must not be charged, although projects must bill all third parties authorized or legally obligated to pay for services (Section 1006(c)(2), PHS Act; 42 CFR 59.5(a)(7)).

Within the parameters set out by the Title X statute and regulations, Title X grantees have a large measure of discretion in determining the extent of income verification activity that they believe is appropriate for their client population Although not required to do so, grantees that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients self-report.

8.4.2 A schedule of discounts, based on ability to pay, is required for individuals with family

incomes between 101% and 250% of the FPL (42 CFR 59.5(a)(8)).

8.4.3 Fees must be waived for individuals with family incomes above 100% of the FPL who, as determined by the service site project director, are unable, for good cause, to pay for family planning services (42 CFR 59.2).

8.4.4 For persons from families whose income exceeds 250% of the FPL, charges must be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services. (42 CFR 59.5(a)(8)).

8.4.5 Eligibility for discounts for unemancipated minors who receive confidential services must be based on the income of the minor (42 CFR 59.2).

8.4.6 Where there is legal obligation or authorization for third party reimbursement, including public or private sources, all reasonable efforts must be made to obtain third party payment without the application of any discounts(42 CFR 59.5(a)(9)).

Family income should be assessed before determining whether copayments or additional fees are charged. With regard to insured clients, clients whose family income is at or below 250% FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.

8.4.7 Where reimbursement is available from Title XIX or Title XX of the Social Security Act, a written agreement with the Title XIX or the Title XX state agency at either the grantee level or sub-recipient agency is required (42 CFR 59.5(a)(9)]

8.4.8 Reasonable efforts to collect charges without jeopardizing client confidentiality must be made.

8.4.9 Voluntary donations from clients are permissible; however, clients must not be pressured to make donations, and donations must not be a prerequisite to the provision of services or supplies.

8.5 Project Personnel

Title X grantees must have approved personnel policies and procedures.

8.5.1 Grantees and sub-recipients are obligated to establish and maintain personnel policies that comply with applicable Federal and State requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, Title I of the Americans with Disabilities Act, and the annual appropriations language. These policies should include,

but are not to be limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, and grievance procedures.

8.5.2 Project staff should be broadly representative of all significant elements of the population to be served by the project, and should be sensitive to, and able to deal effectively with, the cultural and other characteristics of the client population (42 CFR 59.5 (b)(10)).

8.5.3 Projects must be administered by a qualified project director. Change in Status, including Absence, of Principal Investigator/Project Director and Other Key Personnel requires pre-approval by the Office of Grants Management. For more information, see HHS Grants Policy Statement, 2007 Section II-54.

8.5.4 Projects must provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning (42 CFR 59.5 (b)(6).

8.5.5 Appropriate salary limits will apply as required by law.

8.6 Staff Training and Project Technical Assistance

Title X grantees are responsible for the training of all project staff. Technical assistance may be provided by OPA or the Regional Office.

8.6.1 Projects must provide for the orientation and in-service training of all project personnel, including the staff of sub-recipient agencies and service sites (42 CFR 59.5(b)(4)).

8.6.2 The project's training plan should provide for routine training of staff on Federal/State requirements for reporting or notification of child abuse, child molestation, sexual abuse, rape or incest, as well as on human trafficking

8.6.3 The project's training plan should provide for routine training on 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.

8.7 Planning and Evaluation

Grantees must ensure that the project is competently and efficiently administered (42 CFR 59.5 (b) (6) and (7)). In order to adequately plan and evaluate program activities, grantees should develop written goals and objectives for the project period that are specific, measurable, achievable, realistic, time-framed, and which are consistent with Title X Program Requirements. The program plan should be based on a needs assessment. Grantee project plans must include an evaluation component that identifies indicators by which the program measures the

achievement of its objectives. For more information on quality improvement, see *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs.*

9. PROJECT SERVICES AND CLIENTS

Projects funded under Title X are intended to enable all persons who want to obtain family planning care to have access to such services. Projects must provide for comprehensive medical, informational, educational, social, and referral services related to family planning for clients who want such services.

9.1 Priority for project services is to persons from low- income families (Section 1006(c)(1), PHS Act; 42 CFR 59.5(a)(6)).

9.2 Services must be provided in a manner which protects the dignity of the individual (42 CFR 59.5 (a)(3)).

9.3 Services must be provided without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status (42 CFR 59.5 (a)(4)).

9.4 Projects must provide for social services related to family planning including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance (42 CFR 59.5 (b)(2)).

9.5 Projects must provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs (42 CFR 59.5 (b)(8).

9.6 All grantees should assure services provided within their projects operate within written clinical protocols that are in accordance with nationally recognized standards of care, approved by the grantee, and signed by the physician responsible for the service site.

9.7 All projects must provide for medical services related to family planning and the effective usage of contraceptive devices and practices (including physician's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) as well as necessary referrals to other medical facilities when medically indicated (42 CFR 59.5(b)(1)). This includes, but is not limited to emergencies that require referral. Efforts may be made to aid the client in finding potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of

this care.

9.8 All projects must provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services. (42 CFR 59.5(a)(1)).

9.9 Services must be provided without the imposition of any durational residency requirement or requirement that the client be referred by a physician (42 CFR 59.5(b)(5)).

9.10 Projects must provide pregnancy diagnosis and counseling to all clients in need of this service (42 CFR 59.5(a)(5)).

9.11 Projects must offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:

- prenatal care and delivery;
- infant care, foster care, or adoption; and
- pregnancy termination.

If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any options(s) about which the pregnant woman indicates she does not wish to receive such information and counseling (42 CFR 59.5(a)(5)).

9.12 Title X grantees must comply with applicable legislative mandates set out in the HHS appropriations act. Grantees must have written policies in place that address these legislative mandates:

"None of the funds appropriated in the Act may be made available to any entity under Title X of the Public Health Service Act unless the applicant for the award certifies to the Secretary of Health and Human Services that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities."

"Notwithstanding any other provision of law, no provider of services under Title X of the Public Health Service Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest."

10. CONFIDENTIALITY

Every project must have safeguards to ensure client confidentiality. Information obtained by the 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. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual (42 CFR 59.11).

11. COMMUNITY PARTICIPATION, EDUCATION, AND PROJECT PROMOTION

Title X grantees are expected to provide for community participation and education and to promote the activities of the project.

11.1 Title X grantees and sub-recipient agencies must provide an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served; and by persons in the community knowledgeable about the community's needs for family planning services (42 CFR 59.5(b)(10)).

11.2 Projects must establish and implement planned activities to facilitate community awareness of and access to family planning services (42 CFR 59.5(b)(3)). Each family planning project must provide for community education programs (42 CFR 59.5(b)(3)). The community education program(s) should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.

11.3 Community education should serve to enhance community understanding of the objectives of the project, make known the availability of services to potential clients, and encourage continued participation by persons to whom family planning may be beneficial (42 CFR 59.5 (b)(3).

12. INFORMATION AND EDUCATION MATERIALS APPROVAL

Every project is responsible for reviewing and approving informational and educational materials. The Information and Education (I&E) Advisory Committee may serve the community participation function if it meets the requirements, or a separate group may be identified .

12.1 Title X grantees and sub-recipient agencies are required to have a review and approval process, by an Advisory Committee, of all informational and educational materials developed or made available under the project prior to their distribution (Section 1006

(d)(2), PHS Act; 42 CFR 59.6(a)).

12.2 The committee must include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of the population or community for which the materials are intended (42 CFR 59.6 (b)(2)).

12.3 Each Title X grantee must have an Advisory Committee of five to nine members, except that the size provision may be waived by the Secretary for good cause shown (42 CFR 59.6(b)(1)). This Advisory Committee must review and approve all informational and educational (I&E) materials developed or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X (Section 1006(d)(1), PHS Act; 42 CFR 59.6(a)).

12.4 The grantee may delegate I&E functions for the review and approval of materials to sub-recipient agencies; however, the oversight of the I&E review process rests with the grantee.

12.5 The Advisory Committee(s) may delegate responsibility for the review of the factual, technical, and clinical accuracy to appropriate project staff; however, final responsibility for approval of the I&E materials rests with the Advisory Committee.

12.6 The I&E Advisory Committee(s) must:

- 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;
- 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 (Section 1006(d), PHS Act; 42 CFR 59.6(b)).

13. ADDITIONAL ADMINISTRATIVE REQUIREMENTS

This section addresses additional requirements that are applicable to the Title X program and are set out in authorities other than the Title X statute and implementing regulations.

13.1 Facilities and Accessibility of Services

Title X service sites should be geographically accessible for the population being served. Grantees should consider clients' access to transportation, clinic locations, hours of operation, and other factors that influence clients' abilities to access services.

Title X clinics must have written policies that are consistent with the HHS Office for Civil Rights policy document, *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons* (August 4, 2003) (HHS Grants Policy Statement 2007, II-23).

Projects may not discriminate on the basis of disability and, when viewed in their entirety, facilities must be readily accessible to people with disabilities (45 CFR part 84).

13.2 Emergency Management

All grantees, sub-recipients, and Title X clinics are required to have a written plan for the management of emergencies (29 CFR 1910, subpart E), and clinic facilities must meet applicable standards established by Federal, State, and local governments (e.g., local fire, building, and licensing codes).

Health and safety issues within the facility fall under the authority of the Occupational Safety and Health Administration (OSHA). Disaster plans and emergency exits are addressed under 29 CFR 1910, subpart E. The basic requirements of these regulations include, but are not limited to:

- Disaster plans (e.g. fire, bomb, terrorism, earthquake, etc.) have been developed and are available to staff.
- Staff can identify emergency evacuation routes.
- Staff has completed training and understand their role in an emergency or natural disaster.
- Exits are recognizable and free from barriers.

13.3 Standards of Conduct

Projects are required to establish policies to prevent employees, consultants, or members of governing/advisory bodies from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others (HHS Grants Policy Statement 2007, II-7).

13.4 Human Subjects Clearance (Research)

Research conducted within Title X projects may be subject to Department of Health and Human Services regulations regarding the protection of human subjects (45 CFR Part 46). The grantee/sub-recipient should advise their Regional Office in writing of any research projects that involve Title X clients (HHS Grants Policy Statement 2007, II-9).

13.5 Financial and Reporting Requirements

Audits of grantees and sub-recipients must be conducted in accordance with the HHS grants administration regulations (45 CFR parts 74.26 and 92.26), as applicable, by auditors meeting established criteria for qualifications and independence (OMB A-133).

Grantees must comply with the financial and other reporting requirements set out in the HHS grants administration regulations (45 CFR parts 74 and 92), as applicable. In addition, grantees must have program data reporting systems which accurately collect and organize data for program reporting and which support management decision making and act in accordance with other reporting requirements as required by HHS.

Grantees must demonstrate continued institutional, managerial, and financial capacity (including funds sufficient to pay the non-Federal share of the project cost) to ensure proper planning, management, and completion of the project as described in the award (42 CFR 59.7(a)).

Grantees must reconcile reports, ensuring that disbursements equal obligations and drawdowns. HHS is not liable should the recipient expenditures exceed the actual amount available for the grant.

14. ADDITIONAL CONDITIONS

With respect to any grant, HHS may impose additional conditions prior to or at the time of any award, when, in the judgment of HHS, these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds (42 CFR 59.12).

15. CLOSEOUT

Within 90 days of the end of grant support, grantees must submit:

- a final Federal Financial Report (FFR)
- a final progress report

Following closeout, the recipient remains obligated to return funds due as a result of later refunds, corrections, or other transactions, and the Federal Government may recover amounts based on the results of an audit covering any part of the period of grant support (HHS Grants Policy Statement, II-90).

For a complete list of requirements, grantees should review the HHS Grants Policy Statement, available at http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf

16. OTHER APPLICABLE HHS REGULATIONS AND STATUTES

Attention is drawn to the following HHS Department-wide regulations that apply to grants under Title X. These include:

- 37 CFR Part 401: Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements;
- 42 CFR Part 50, Subpart D: Public Health Service grant appeals procedure;
- 45 CFR Part 16: Procedures of the Departmental Grant Appeals Board;
- 45 CFR Part 74: Uniform administrative requirements for awards and sub-awards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments, and Indian tribal governments;
- 45 CFR Part 80: Nondiscrimination under programs receiving Federal assistance through HHS effectuation of Title VI of the Civil Rights Act of 1964;
- 45 CFR Part 81: Practice and procedure for hearings under Part 80 of this Title;
- 45 CFR Part 84: Nondiscrimination on the basis of disability in programs and activities receiving or benefitting from Federal financial assistance;
- 45 CFR Part 91: Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance;
- 45 CFR Part 92: Uniform administrative requirements for grants and cooperative agreements to State and local governments; and
- 45 CFR Part 100: Intergovernmental Review of Department of Health and Human Services Programs and Activities.

In addition, the following statutory and regulatory provisions may be applicable to grants under Title X:

- The Patient Protection and Affordable Care Act (Public Law 111-148);
- The Trafficking Victims Protection Act of 2000, as amended (Public Law 106-386);
- Sex Trafficking of Children or by Force, Fraud, or Coercion (18 USC 1591);
- The Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191); and
- Appropriations language that applies to the Title X program for the relevant fiscal year.