## Section B Table of Contents

Federal Title X Regulations and Requirements Introduction ........................................B1

**Program Guidelines for Project Grants for Family Planning Services** ......................B1-1

**Title X Program Priorities** ......................................................................................B2-1
  - OPA Program Priorities ..............................................................................................B2-1
  - Federal Legislative Mandates ....................................................................................B2-2
  - Other Key Federal Issues ...........................................................................................B2-3

**Title X Abortion Restrictions** ..................................................................................B3-1
  - The Federal Regulation ..............................................................................................B3-1
  - The Federal Interpretation .........................................................................................B3-1
  - Options Counseling ....................................................................................................B3-2

**Sterilization Regulations** ........................................................................................B4-1
  - Federal Requirements ................................................................................................B4-1
  - Informed Consent ......................................................................................................B4-1
  - Status after Sterilization ............................................................................................B4-2

**Infertility Services** ..................................................................................................B5-1
  - Federal Requirements ...............................................................................................B5-1

**Other Requirements** ..............................................................................................B6-1
  - Federal Assurances ....................................................................................................B6-1
  - Program Instructions ..................................................................................................B6-1

**Application and Funding** ......................................................................................B7-1
  - LPHA Contracts ........................................................................................................B7-1
  - Supplemental Funding ...............................................................................................B7-2
  - Expenditure Reports ..................................................................................................B7-2
  - Family Planning Funding Formula ..........................................................................B7-3
  - Guiding Principles .....................................................................................................B7-3

**Fee Collection** .......................................................................................................B8-1
  - Establishing Fee Collection Policies ......................................................................B8-1
  - Clients Who Are Unable to Pay ..............................................................................B8-1
  - Family Planning Fees Must Be Kept Separate .......................................................B8-2
  - Donations Must Be Voluntary ................................................................................B8-2
  - Sliding Fee Scale ........................................................................................................B8-3
Reporting Requirements..................................................................................................................B9-1
  Clinic Visit Record ..................................................................................................................B9-1
  Other Important Reports and Dates .........................................................................................B9-1

Agency Reviews..........................................................................................................................B10-1

Exhibits
  Exhibit 1: Program Element #41
  Exhibit 2: OHA Revenue and Expenditure Report
  Exhibit 3: Title X Service and Supply Discount Schedule
  Exhibit 4: Reproductive Health Program Sliding Fee Scale
  Exhibit 5: Reproductive Health Program Review Schedule
  Exhibit 6: Agency Review Tools
  Exhibit 7: Budget Projection Worksheet and Instructions
  Exhibit 8: Title X Program Instructions
  Exhibit 9: Guidance on Protocol Development
Federal Title X Regulations and Requirements

This section describes the federal regulations and requirements for Title X reproductive health grant programs. Agencies and clinics that do not receive Title X grant funds are not subject to Title X rules. However, these regulations still provide good direction for delivering high quality, comprehensive reproductive health services.

Section B contains material directly from the Office of Population Affairs (OPA), followed by Oregon-specific information.

OPA’s Program Guidelines require Title X clinics to have written clinical reproductive health protocols and client education plans on all services provided. See Exhibit 9 of this section for clarification of this Title X requirement.

Title X Definitions

**Family Planning:** When an individual can determine freely the number and spacing of children.

**Reproductive Health Services:** Clinical, informational, educational, social, and referral services offered to anyone of reproductive age requesting family planning and reproductive health care.
PROGRAM GUIDELINES
For Project Grants
For Family Planning Services

United States Department of Health and Human Services
Office of Public Health and Science
Office of Population Affairs
Office of Family Planning
4350 East West Highway, Suite 200
Bethesda, Maryland 20814
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Program Guidelines for Family Planning Services

Table of Contents

PART I .........................................................................................................................1

1.0 Introduction to the Program Guidelines ................................................ 1
  1.1 Definitions .................................................................................................1

2.0 The Law, Regulations, and Guidelines .................................................. 2

3.0 The Application Process ......................................................................... 2
  3.1 Eligibility ....................................................................................................2
  3.2 Needs Assessment ....................................................................................3
  3.3 The Application ........................................................................................3
  3.4 Project Requirements .............................................................................4
  3.5 Notice of Grant Award ...........................................................................5

4.0 Grant Administration .............................................................................. 5

5.0 Legal Issues .............................................................................................. 5
  5.1 Voluntary Participation ..........................................................................5
  5.2 Confidentiality .........................................................................................5
  5.3 Conflict of Interest ..................................................................................6
  5.4 Liability Coverage ..................................................................................6
  5.5 Human Subjects Clearance (Research) ..................................................6

6.0 Project Management ................................................................................ 6
  6.1 Structure of the Grantee .........................................................................6
  6.2 Planning and Evaluation .......................................................................7
  6.3 Financial Management ..........................................................................7
  6.4 Facilities and Accessibility of Services .................................................9
  6.5 Personnel ...............................................................................................9
  6.6 Training and Technical Assistance .....................................................10
  6.7 Reporting Requirements ....................................................................10
  6.8 Review and Approval of Informational Educational Materials .......10
  6.9 Community Participation, Education, and Project Promotion .........11
  6.10 Publications and Copyright ................................................................12
  6.11 Inventions or Discoveries .................................................................12

PART II ...................................................................................................................13

7.0 Client Services .........................................................................................13
  7.1 Service Plans and Protocols ...............................................................13
  7.2 Procedural Outline ...............................................................................14
  7.3 Emergencies .........................................................................................15
  7.4 Referrals and Follow-up ....................................................................16
## Program Guidelines for Family Planning Services

### Table of Contents (Cont’d)

#### 8.0 Required Services
- 8.1 Client Education .......................................................... 17
- 8.2 Counseling ............................................................................. 18
- 8.3 History, Physical Assessment, and Laboratory Testing .......... 19
- 8.4 Fertility Regulation .............................................................. 23
- 8.5 Infertility Services ............................................................... 24
- 8.6 Pregnancy Diagnosis and Counseling .................................. 24
- 8.7 Adolescent Services ........................................................... 25
- 8.8 Identification of Estrogen-Exposed Offspring ....................... 26

#### 9.0 Related Services
- 9.1 Gynecologic Services .......................................................... 26
- 9.2 Sexually Transmitted Diseases (STD) and HIV/AIDS ......... 26
- 9.3 Special Counseling ............................................................. 27
- 9.4 Genetic Information and Referral ......................................... 27
- 9.5 Health Promotion/Disease Prevention ................................. 27
- 9.6 Postpartum Care ................................................................. 27

#### 10.0 Clinic Management
- 10.1 Equipment and Supplies .................................................. 28
- 10.2 Pharmaceuticals ............................................................... 28
- 10.3 Medical Records .............................................................. 28
- 10.4 Quality Assurance and Audit ............................................. 30

### Attachments

A. The Law: Title X Population Research and Voluntary Family Planning Programs

B. Regulations: Grants for Family Planning Services under Title X of the Public Health Service Act

C. Sterilization of Persons in Federally Assisted Family Planning Projects

D. DHHS Regional Offices – Regional Program Consultants for Family Planning Resource Documents
PART I

1.0 Introduction to the Program Guidelines

This document, Program Guidelines for Project Grants for Family Planning Services (Guidelines), has been developed by the Office of Population Affairs (OPA), U.S. Department of Health and Human Services (DHHS), to assist current and prospective grantees in understanding and utilizing the family planning services grants program authorized by Title X of the Public Health Service Act, 42 U.S.C. 300, et seq. The Office of Population Affairs also provides more detailed guidance, updated clinical information and clarification of specific program issues in the form of periodic Program Instructions to the Regional Offices.

This document is organized into two parts. Part I (sections 1–6) covers project management and administration, including the grant application and award process. Part II (sections 7–11) covers client services and clinic management.

Reference is made throughout the document to specific sections of the Title X law and implementing regulations, which are contained in Attachments A and B, respectively. (Reference to specific sections of the regulations will appear in brackets, e.g., [45 CFR Part 74, Subpart C].) Federal sterilization regulations are contained in Attachment C. The DHHS regional offices are listed in Attachment D. Selected other materials that provide additional guidance in specific areas are classified as Resource Documents.

1.1 Definitions

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

The “grantee” is the entity that receives a Federal grant and assumes legal and financial responsibility and accountability for the awarded funds and for the performance of the activities approved for funding. The “project” consists of those activities described in the grant application and supported under the approved budget. “Delegate/contract agencies” are those entities that provide family planning services with Title X funds under a negotiated, written agreement with a grantee. “Service sites” are those locations where services actually are provided by the grantee or delegate/contract agency.
2.0 The Law, Regulations, and Guidelines

To enable persons who want to obtain family planning care to have access to such services, Congress enacted the Family Planning Services and Population Research Act of 1970 (Public Law 91-572), which added Title X, “Population Research and Voluntary Family Planning Programs” to the Public Health Service Act. Section 1001 of the Act (as amended) 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)” (see Attachment A). The mission of Title X is to provide individuals the information and means to exercise personal choice in determining the number and spacing of their children.

The regulations governing Title X [42 CFR Part 59, Subpart A] set out the requirements of the Secretary, Department of Health and Human Services, for the provision of family planning services funded under Title X and implement the statute as authorized under Section 1001 of the Public Health Service Act. Prospective applicants and grantees should refer to the regulations (see Attachment B). This document, Program Guidelines for Project Grants for Family Planning Services, interprets the law and regulations in operational terms and provides a general orientation to the Federal perspective on family planning.

3.0 The Application Process

3.1 Eligibility

Any public or nonprofit private entity located in a state (which, by definition, includes the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands [Midway, 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 [59.2, 59.3].

To promote the purposes of Section 1001 of the Act in the most cost effective and efficient manner, grants will be made to public and non-profit private entities to foster projects most responsive to local needs. A non-profit private agency, institution, or organization must furnish evidence of its non-profit status in accordance with instructions accompanying the project grant application form. Under the law, grants cannot be made to entities that propose to offer only a single method or an unduly limited number of family planning methods. A facility or entity offering a single method can receive assistance under Title X by participating as a delegate/contract agency in an approvable project that offers a broad range of acceptable and effective medically approved family planning methods and services [59.5(a)(1)].
3.2 Needs Assessment

A n assessment of the need for family planning services must be conducted prior to applying for a competitive grant award. The needs assessment documents the need for family planning services for persons in the service area and should include:

- Description of the geographic area including a discussion of potential geographic, topographic, and other related barriers to service;
- Demographic description of the service area including objective data pertaining to individuals in need of family planning services, maternal and infant morbidity/mortality rates, birth rates and rates of unintended pregnancies by age groups, poverty status of the populations to be served, cultural and linguistic barriers to services, etc.;
- Description of existing services and need for additional family planning services to meet community/cultural needs;
- Need indicators that include rates of STDs and HIV prevalence (including perinatal infection rates) in the grantee area;
- Identification and descriptions of linkages with other resources related to reproductive health; and
- Identification and discussion of high priority populations and target areas.

Grantees should perform periodic reassessment of service needs. Competitive grant applications must include a full and updated needs assessment.

3.3 The Application

T he Department of Health and Human Services’ Office of Population Affairs administers the Title X Family Planning Program through the DHHS Regional Offices. An annual announcement of the availability of Title X service grant funds sets forth specific application requirements and evaluation criteria. Applications must be submitted to the Office of Grants Management for Family Planning Services on the form required by the Department. The application forms are available from the Office of Grants Management for Family Planning Services. Assistance regarding programmatic aspects of proposal preparation is available from the Regional Office. For assistance with administrative and budgeting aspects of proposal preparation, contact the Office of Grants Management for Family Planning Services.
Unless otherwise instructed, applicants are to respond to the standard instructions contained in the application kit and to the PHS supplemental instructions. An application must contain:

- a needs assessment
- a narrative description of the project and the manner in which the applicant intends to conduct it in order to carry out the requirements of the law and regulations;
- a budget that includes an estimate of project income and costs, with justification for the amount of grant funds requested [59.4(c)(2)] and which is consistent with the terms of Section 1006 of the Act, as implemented by regulation [59.7(b)];
- a description of the standards and qualifications that will be required for all personnel and facilities to be used by the project;
- project objectives that are specific, realistic, and measurable; and
- other pertinent information as required [59.4(c)(4)].

The application must address all points contained in section 59.7(a) of the regulations, which are the criteria DHHS Regional Offices will use to decide which family planning projects to fund and in what amount. The application shall not include activities that cannot be funded under Title X, such as abortion, fundraising, or lobbying activities.

3.4 Project Requirements

Projects must adhere to:

- Section 59.5 and all other applicable provisions of the regulations, which list the requirements to be met by each project supported by Title X.

- The applicable requirements of these Program Guidelines for Project Grants for Family Planning Services.

- Other Federal regulations which apply to grants made under Title X [59.10]. For assistance in identifying other relevant regulations, contact the Regional Office.
3.5 Notice of Grant Award

The notice of grant award will inform the grantee how long DHHS intends to support the project without requiring it to recompete for funds [59.8]. This period of funding is called the “project period.” The project will be funded in increments called “budget periods.” The budget period is normally twelve months, although shorter or longer budget periods may be established for compelling administrative or programmatic reasons.

4.0 Grant Administration

All grantees must comply with the applicable legislative, regulatory and administrative requirements described in the Public Health Service Grants Policy Statement. A copy of the Public Health Service Grants Policy Statement may be obtained from the Office of Grants Management for Family Planning Services.

5.0 Legal Issues

5.1 Voluntary Participation

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

Project personnel must be informed that they may be subject to prosecution under Federal law if they coerce or endeavor to coerce any person to undergo an abortion or sterilization procedure.

5.2 Confidentiality

Every project must assure client confidentiality and provide safeguards for individuals against the invasion of personal privacy, as required by the Privacy Act. No information obtained by the project staff about individuals receiving services may be disclosed without the individual’s written consent, except as required by law or as 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 [59.11].
5.3 Conflict of Interest

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

5.4 Liability Coverage

Grantees and/or delegates/contractors should ensure the existence of adequate liability coverage for all segments of the project funded under the grant, including all individuals providing services. Governing boards should obtain liability coverage for their members.

5.5 Human Subjects Clearance (Research)

Grantees considering clinical or sociological research using Title X clients as subjects must adhere to the legal requirements governing human subjects research at 45 CFR Part 46, as applicable. A copy of these regulations may be obtained from the Regional Office. Grantees must advise the Regional Office in writing of research projects involving Title X clients or resources in any segment of the project.

6.0 Project Management

6.1 Structure of the Grantee

Family planning services under Title X grant authority may be offered by grantees directly and/or by delegate/contract agencies operating under the umbrella of the grantee. However, the grantee is responsible for the quality, cost, accessibility, acceptability, reporting, and performance of the grant-funded activities provided by delegate/contract agencies. Grantees must therefore have a negotiated, written agreement with each delegate/contract agency and establish written standards and guidelines for all delegated project activities consistent with the appropriate section(s) of the Program Guidelines for Project Grants for Family Planning Services, as well as other applicable requirements such as Subpart C of 45 CFR Part 74, or Subpart C of 45 CFR Part 92. If a delegate/contract agency wishes to subcontract any of its responsibilities or services, a written negotiated agreement that is consistent with Title X requirements and approved by the grantee must be maintained by the delegate/contractor. Delegate/contract agencies should be invited to participate in the establishment of grantee standards and guidelines.
6.2 Planning and Evaluation

All projects receiving Title X funds must provide services of high quality and be competently and efficiently administered. To meet these requirements, each competitive application must include a plan which identifies overall goals and specific measurable objectives for the project period. The objectives may be directed to all clients or to specific groups of clients and must be consistent with Title X objectives. The plan must include an evaluation component that addresses and defines indicators by which the project intends to evaluate itself.

6.3 Financial Management

Grantees must maintain a financial management system that meets the standards specified in Subpart C of 45 CFR Part 74 or Subpart C of 45 CFR Part 92, as applicable, as well as any other requirements imposed by the Notice of Grant Award, and which complies with Federal standards to safeguard the use of funds. Documentation and records of all income and expenditures must be maintained as required.

- Charges, Billing, and Collections

A grantee is responsible for the implementation of policies and procedures for charging, billing, and collecting funds for the services provided by the project. The policies and procedures should be approved by the governing authority or board of the grantee and the Regional Office.

Clients must not be denied project services or be subjected to any variation in quality of services because of the inability to pay. Billing and collection procedures must have the following characteristics:

1. Charges must be based on a cost analysis of all services provided by the project. At the time of services, clients who are responsible for paying any fee for their services must be given bills directly. In cases where a third party is responsible, bills must be submitted to that party.

2. A schedule of discounts must be developed and implemented with sufficient proportional increments so that inability to pay is never a barrier to service. A schedule of discounts is required for individuals with family incomes between 101% and 250% of the Federal poverty level. Fees must be waived for individuals with family incomes above this amount who, as determined by the service site project director, are unable, for good cause, to pay for family planning services.

3. Clients whose documented income is at or below 100% of the Federal poverty level must not be charged, although projects must bill all third parties authorized or legally obligated to pay for services.
Individual eligibility for a discount must be documented in the client’s financial record.

4. Bills to third parties must show total charges without applying any discount.

5. 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 delegate/contract agency level is required.

6. Bills to clients must show total charges less any allowable discounts.

7. Eligibility for discounts for minors who receive confidential services must be based on the income of the minor.

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

9. A method for the “aging” of outstanding accounts must be established.

10. *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. Donations from clients do not waive the billing/charging requirements set out above.

11. Client income should be re-evaluated at least annually.

Effective financial management will assure the short and long term viability of the project, including the efficient use of grant funds. Technical assistance in achieving this objective is available from the Regional Office. Title X projects offering services that are not required by the statute, regulations or these Guidelines should whenever possible seek other sources of funding for such services before applying Title X funds to those activities.

- **Financial Audit**

Audits of grantees and delegate/contract agencies must be conducted in accordance with the provisions of 45 CFR Part 74, Subpart C, and 45 CFR Part 92, Subpart C, as applicable. The audits must be conducted by auditors meeting established criteria for qualifications and independence.
6.4 Facilities and Accessibility of Services

Facilities in which project services are provided should be geographically accessible to the population served and should be available at times convenient to those seeking services, i.e., they should have evening and/or weekend hours in addition to daytime hours. The facilities should be adequate to provide the necessary services and should be designed to ensure comfort and privacy for clients and to expedite the work of the staff. Facilities must meet applicable standards established by the Federal, state and local governments (e.g., local fire, building and licensing codes).

Projects must comply with 45 CFR Part 84, which prohibits discrimination on the basis of handicap in Federally assisted programs and activities, and which requires, among other things, that recipients of Federal funds operate their Federally assisted programs so that, when viewed in their entirety, they are readily accessible to people with disabilities. A copy of Part 84 may be obtained from the Regional office. Projects must also comply with any applicable provisions of the Americans With Disabilities Act (Public Law 101-336).

Emergency situations may occur at any time. All projects must therefore have written plans and procedures for the management of emergencies.

6.5 Personnel

Grantees and delegate/contract agencies are reminded of their obligation 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, and Title I of the Americans With Disabilities Act. These policies should include, but need not be limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, and grievance procedures. 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 [59.5 (b)(10)].

Grantees must also ensure that:

- Projects are administered by a qualified project director;

- The clinical care component of the project operates under the responsibility of a medical director who is a licensed and qualified physician with special training or experience in family planning;

- Protocols exist that provide all project personnel with guidelines for client care;
• Personnel records are kept confidential;
• Licenses of applicants for positions requiring licensure are verified prior to employment and that there is documentation that licenses are kept current.

6.6 Training and Technical Assistance

Projects must provide for the orientation and in-service training of all project personnel, including the staffs of delegate agencies and service sites. All project personnel should participate in continuing education related to their activities. Documentation of continuing education should be maintained and used in evaluating the scope and effectiveness of the staff training program.

Training through regional training centers is available to all projects under the Title X program. In addition to training, grantees may receive technical assistance for specific project activities. Technical assistance is provided by contract from the OPA and administered through the Regional Office. Information on training and technical assistance is available from the Regional Office.

6.7 Reporting Requirements

Grantees must:

1. comply with the financial and other reporting requirements of 45 CFR Part 74 or 45 CFR Part 92, as applicable; and

2. comply with other reporting requirements as required by DHHS.

6.8 Review and Approval of Informational and Educational Materials

An advisory committee of five to nine members (the size of the committee can differ from these limits with written documentation and approval from the Regional Office) who are broadly representative of the community 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. Oversight responsibility for the I&E committee(s) rests with the grantee. The grantee may delegate the I & E operations for the review and approval of materials to delegate/contract agencies.
The I&E 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 [59.6].

The committee(s) may delegate responsibility for the review of the factual, technical, and clinical accuracy to appropriate project staff. However, final approval of the I &E material rests with the committee(s).

6.9 Community Participation, Education, and Project Promotion

Boards and advisory committees for family planning services should be broadly representative of the population served.

- Community Participation

Title X grantees and delegate/contract agencies must provide an opportunity for participation in the development, implementation, and evaluation of the project (1) by persons broadly representative of all significant elements of the population to be served, and (2) by persons in the community knowledgeable about the community’s needs for family planning services [59.5(b)(10)].

The I & E advisory committee may serve the community participation function if it meets the above requirements, or a separate group may be identified. In either case, the grantee project plan must include a plan for community participation. The community participation committee must meet annually or more often as appropriate.
Community Education

Each family planning project must provide for community education programs [59.5(b)(3)]. This should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.

Community education 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.

Project Promotion

To facilitate community awareness of and access to family planning services, projects must establish and implement planned activities whereby their services are made known to the community [59.5(b)(3)]. Projects should review a range of strategies and assess the availability of existing resources and materials. Promotion activities should be reviewed annually and be responsive to the changing needs of the community. For more information, contact the Regional Offices.

6.10 Publications and Copyright

Unless otherwise stipulated, publications resulting from activities conducted under the grant need not be submitted to DHHS for prior approval. The word “publication” is defined to include computer software. Grantees should ensure that publications developed under Title X do not contain information which is contrary to program requirements or to accepted clinical practice. Federal grant support must be acknowledged in any publication. Except as otherwise provided in the conditions of the grant award, the author is free to arrange for copyright without DHHS approval of publications, films, or similar materials developed from work supported by DHHS. Restrictions on motion picture film production are outlined in the Public Health Service Grants Policy Statement. Any such copyrighted materials shall be subject to a royalty-free, non-exclusive, and irrevocable right of the Government to reproduce, publish, or otherwise use such materials for Federal purposes and to authorize others to do so [45 CFR 74.36][45 CFR 92.34].

6.11 Inventions or Discoveries

Family planning projects must comply with Government-wide regulations, 37 CFR Part 401, which apply to the rights to inventions made under government grants, contracts and cooperative agreements.
PART II

7.0 Client Services

Projects funded under Title X must provide clinical, informational, educational, social and referral services relating to family planning to clients who want such services. All projects must offer a broad range of acceptable and effective medically approved family planning methods and services either on-site or by referral [59.5(a)(1)]. Projects should make available to clients all methods of contraception approved by the Federal Food and Drug Administration.

Part II of this document has been developed to assist grantees in determining those services which will be provided to fulfill the mission of Title X.

- Projects must provide services stipulated in the law or regulations, or which are required by these Guidelines for the provision of high-quality family planning services.
- Projects may also provide those services that are intended to promote the reproductive and general health care of the family planning client population.

7.1 Service Plans and Protocols

The service plan is the component of the grantee’s project plan, as set forth in the competitive application, which identifies those services to be provided to clients under Title X by the project. As part of the project plan, all grantees must assure that delegate/contractors have written clinical protocols and plans for client education, approved by the grantee and signed by the service site Medical Director, which outline procedures for the provision of each service offered and which are in accordance with state laws. Clinical protocols must be consistent with the requirements of these Guidelines.

Under exceptional circumstances, a waiver from a particular requirement may be obtained from the Regional Office upon written request from a grantee. In submitting a request for an exception, the grantee must provide epidemiologic, clinical, and other supportive data to justify the request and the duration of the waiver.
7.2 Procedural Outline

The services provided to family planning clients, and the sequence in which they are provided, will depend upon the type of visit and the nature of the service requested. However, the following components must be offered to and documented on all clients at the initial visit:

**Education**
- Presentation of relevant information and educational materials, based upon client needs and knowledge;

**Counseling**
- Interactive process in which a client is assisted in making an informed choice;

**Informed Consent**
- Explanation of all procedures and obtaining a general consent covering examination and treatment and, where applicable, a method-specific informed consent form;

**History**
- Obtaining of a personal and family medical and social history;

**Examination**
- Performance of a physical examination and any necessary clinical procedures, as indicated;

**Laboratory Testing**
- Performance of routine and other indicated laboratory tests;

**Follow-up & Referrals**
- Planned mechanism for client follow-up;
- Performance of any necessary clinical procedures;
- Provision of medications and/or supplies as needed; and
- Provision of referrals as needed.
Return visits, with the exception of routine supply visits, should include an assessment of the client’s health status, current complaints, and evaluation of birth control method, as well as an opportunity to change methods. The following components must be offered to and documented on all clients at the return visit:

**History**
- Updating a personal and family medical and social history;

**Examination**
- Performance of a physical examination and any necessary clinical procedures, as indicated;

**Laboratory Testing**
- Performance of routine and other indicated laboratory tests;

**Follow-up & Referrals**
- Planned mechanism for client follow-up;
- Performance of any necessary clinical procedures;
- Provision of medications and/or supplies as needed; and
- Provision of referrals as needed.

### 7.3 Emergencies

Emergency situations involving clients and/or staff may occur at any time. All projects must therefore have written plans for the management of on-site medical emergencies. At a minimum, written protocols must address vaso-vagal reactions, anaphylaxis, syncope, cardiac arrest, shock, hemorrhage, and respiratory difficulties. Protocols must also be in place for emergencies requiring transport, after-hours management of contraceptive emergencies, and clinic emergencies. All project staff must be familiar with these plans. Appropriate training, including training in CPR, should be available to staff.
7.4 Referrals and Follow-up

Grantees must assure that delegate/contract agencies provide all family planning services listed in Section 8.0 under “Required Services,” either on-site or by referral. When required services are to be provided by referral, the grantee must establish formal arrangements with a referral agency for the provision of services and reimbursement of costs, as appropriate.

Agencies must have written policies/procedures for follow-up on referrals that are made as a result of abnormal physical examination or laboratory test findings. These policies must be sensitive to clients’ concerns for confidentiality and privacy.

For services determined to be necessary but which are beyond the scope of the project, clients must be referred to other providers for care. When a client is referred for non-family planning or emergency clinical care, agencies must:

- Make arrangements for the provision of pertinent client information to the referral provider. Agencies must obtain client’s consent to such arrangements, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality;
- Advise client on their responsibility in complying with the referral; and
- Counsel client on the importance of such referral and the agreed upon method of follow-up.

Efforts may be made to aid the client in identifying potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of this care. Agencies must maintain a current list of health care providers, local health and human services departments, hospitals, voluntary agencies, and health services projects supported by other Federal programs to be used for referral purposes. Whenever possible, clients should be given a choice of providers from which to select.

8.0 Required Services

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

The client’s written informed voluntary consent to receive services must be obtained prior to the client receiving any clinical services. In addition, if a client chooses a prescription method of contraception, a method-specific consent form must be obtained and updated routinely at subsequent visits to reflect current information about that method.
8.1 Client Education

Grantees and/or delegate/contract agencies must have written plans for client education that include goals and content outlines to ensure consistency and accuracy of information provided. Client education must be documented in the client record. The education provided should be appropriate to the client’s age, level of knowledge, language, and socio-cultural background and be presented in an unbiased manner. A mechanism to determine that the information provided has been understood should be established.

Education services must provide clients with the information needed to:

- Make informed decisions about family planning;
- Use specific methods of contraception and identify adverse effects;
- Perform breast/testicular self examination;
- Reduce risk of transmission of sexually transmitted diseases and Human Immunodeficiency Virus (HIV);
- Understand the range of available services and the purpose and sequence of clinic procedures; and
- Understand the importance of recommended screening tests and other procedures involved in the family planning visit.

Clients should be offered information about basic female and male reproductive anatomy and physiology, and the value of fertility regulation in maintaining individual and family health. Additional education should include information on reproductive health and health promotion/disease prevention, including nutrition, exercise, smoking cessation, alcohol and drug abuse, domestic violence and sexual abuse.

- Method-Specific Informed Consent

Written informed consent, specific to the contraceptive method, must be signed before a prescription contraceptive method is provided. Prior to implementation, informed consent forms should be approved by the service site Medical Director.

The consent forms must be written in a language understood by the client or translated and witnessed by an interpreter. To provide informed consent for contraception, the client must receive information on the benefits and risks, effectiveness, potential side effects, complications, discontinuation issues and danger signs of the contraceptive method chosen. Specific education and consent forms for the contraceptive method provided must be part of the project’s service plan.
The signed informed consent form must be a part of the client’s record. All consent forms should contain a statement that the client has been counseled, provided with the appropriate informational material, and understands the content of both. The method-specific consent form should be renewed and updated when there is a major change in the client’s health status or a change to a different prescriptive contraceptive method.

Federal sterilization regulations [42 CFR Part 50, Subpart B], which address informed consent requirements, must be complied with when a sterilization procedure is performed or arranged for by the project (see Attachment C).

### 8.2 Counseling

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

The counseling process involves mutual sharing of information. Persons who provide counseling should be knowledgeable, objective, nonjudgmental, sensitive to the rights and differences of clients as individuals, culturally aware and able to create an environment in which the client feels comfortable discussing personal information. The counselor must be sufficiently knowledgeable to provide accurate information regarding the benefits and risk, safety, effectiveness, potential side effects, complications, discontinuation issues and danger signs of the various contraceptive methods. Additionally, the counselor should be knowledgeable about the other services offered by the agency. Documentation of counseling must be included in the client’s record.

- **Method Counseling**

  Method counseling refers to an individualized dialogue with a client that covers the following:

  - Results of physical exam and lab studies;
  - Effective use of contraceptive methods, including natural family planning (NFP), and the benefit and efficacy of the methods;
  - Possible side effects/complications;
  - How to discontinue the method selected and information regarding back-up method use, including the use of certain oral contraceptives as post-coital emergency contraception;
• Planned return schedule;
• Emergency 24-hour telephone number;
• Location where emergency services can be obtained; and
• Appropriate referral for additional services as needed.

Sexually Transmitted Disease (STD) and HIV Counseling

All clients must receive thorough and accurate counseling on STDs and HIV. STD/HIV counseling refers to an individualized dialogue with a client in which there is discussion of personal risks for STDs/HIV, and the steps to be taken by the individual to reduce risk, if necessary. Persons found to have behaviors which currently put them at risk for STD/HIV must be given advice regarding risk reduction and must be advised whether clinical evaluation is indicated. All projects must offer, at a minimum, education about HIV infection and AIDS, information on risks and infection prevention, and referral services. On an optional basis, clinics may also provide HIV risk assessment, counseling and testing by specially trained staff. When the project does not offer these optional services, the project must provide the client with a list of health care providers who can provide these services.

8.3 History, Physical Assessment, and Laboratory Testing

History

At the initial comprehensive clinical visit, a complete medical history must be obtained on all female and male clients. Pertinent history must be updated at subsequent clinical visits. The comprehensive medical history must address at least the following areas:

• Significant illnesses; hospitalizations; surgery; blood transfusion or exposure to blood products; and chronic or acute medical conditions;
• Allergies;
• Current use of prescription and over-the-counter medications;
• Extent of use of tobacco, alcohol, and other drugs;
• Immunization and Rubella status;
• Review of systems;
• Pertinent history of immediate family members; and
• Partner history
  o injectable drug use
  o multiple partners
  o risk history for STDs and HIV
  o bisexuality.

Histories of reproductive function in female clients must include at least the following:
• Contraceptive use past and current (including adverse effects);
• Menstrual history;
• Sexual history;
• Obstetrical history;
• Gynecological conditions;
• Sexually transmitted diseases, including HBV;
• HIV;
• Pap smear history (date of last Pap, any abnormal Pap, treatment); and
• In utero exposure to diethylstilbestrol (DES).

Histories of reproductive function in male clients must include at least the following:
• Sexual history;
• Sexually transmitted diseases (including HBV);
• HIV; and
• Urological conditions.

• Physical Assessment (female)

For many clients, family planning programs are their only continuing source of health information and clinical care. Therefore, an initial complete physical examination, including height and weight, examination of the thyroid, heart, lungs, extremities, breasts, abdomen, pelvis, and rectum, should be performed.
While most client services will necessarily relate to fertility regulation, family planning clinics must provide and encourage clients to use health maintenance screening procedures, initially and as indicated. Clinics must provide and stress the importance of the following to all clients:

- Blood pressure evaluation;
- Breast exam;
- Pelvic examination which includes vulvar evaluation and bimanual exam;
- Pap smear;
- Colorectal cancer screening in individuals over 40; and
- STD and HIV screening, as indicated.

Following counseling about the importance of the above preventive services, if a client chooses to decline or defer a service, this should be documented in their record. Counseling must include information about the possible health risks associated with declining or delaying preventive screening tests or procedures.

All physical examination and laboratory test requirements stipulated in the prescribing information for specific methods of contraception must be followed. Physical examination and related prevention services should not be deferred beyond 3 months after the initial visit, and in no case may be deferred beyond 6 months, unless if in the clinician’s judgment there is a compelling reason for extending the deferral. All deferrals, including the reason(s) for deferral, must be documented in the client record. Project protocols should be developed accordingly.

- Physical Assessment (male)

Family planning clinics also may be an important source of reproductive health care for male clients. Physical examination should be made available to male clients, including height and weight, examination of the thyroid, heart, lungs, breasts, abdomen, extremities, genitals and rectum. Examination should also include palpation of the prostate, as appropriate, and instructions in self-examination of the testes. Clinics should stress the importance of the following to male clients:

- Blood pressure evaluation;
- Colorectal cancer screening in individuals over 40; and
- STD and HIV screening, as indicated.
• Laboratory Testing

Specific laboratory tests are required for the provision of specific methods of contraception. Laboratory tests can also be important indicators of client health status and useful for diagnostic purposes. Pregnancy testing must be provided onsite. The following laboratory procedures must be provided to clients if required in the provision of a contraceptive method, and may be provided for the maintenance of health status and/or diagnostic purposes, either on-site or by referral:

- Anemia assessment
- Gonorrhea and Chlamydia test
- Vaginal wetmount
- Diabetes testing
- Cholesterol and lipids
- Hepatitis B testing
- Syphilis serology (VDRL, RPR)
- Rubella titer
- Urinalysis
- HIV testing

• Notification of Abnormal Lab Results

A procedure which addresses client confidentiality must be established to allow for client notification and adequate follow-up of abnormal laboratory results.

• Other Laboratory Services or Procedures

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

Revisit schedules must be individualized based upon the client’s need for education, counseling, and clinical care beyond that provided at the initial and annual visit.

Clients selecting hormonal contraceptives, intrauterine devices (IUDs), cervical caps, or diaphragms for the first time should be scheduled for a revisit as appropriate after initiation of the method to reinforce its proper use, to check for possible side effects, and to provide additional information or clarification. A new or established client who chooses to continue a method already in use need not return for this early revisit unless a need for reevaluation is determined on the basis of the findings at the initial visit.

8.4 Fertility Regulation

Reversible Contraception

Currently, the reversible methods of contraception include barrier methods (female and male), IUDs, fertility awareness methods, natural family planning, and hormonal methods (injectables, implants, orals). Certain oral contraceptive regimens have been found by the Federal Food and Drug Administration to be safe and effective for use as postcoital emergency contraception when initiated within 72 hours after unprotected intercourse. More than one method of contraception can be used simultaneously by a client and may be particularly indicated to minimize the risks of STDs/HIV and pregnancy. Consistent and correct use of condoms should be encouraged for all persons at risk for STDs/HIV.

Permanent Contraception

The counseling and consent process must assure that the client’s decision to undergo sterilization is completely voluntary and made with full knowledge of the permanence, risks, and benefits associated with female and male sterilization procedures. Federal sterilization regulations, which address informed consent requirements, must be complied with when a sterilization procedure is performed or arranged for by the project (see Attachment C).
8.5 Infertility Services

Grantees must make basic infertility services available to women and men desiring such services. Infertility services are categorized as follows:

- **Level I** Includes initial infertility interview, education, physical examination, counseling, and appropriate referral.
- **Level II** Includes such testing as semen analysis, assessment of ovulatory function and postcoital testing.
- **Level III** More sophisticated and complex than Level I and Level II services.

Grantees must provide Level I infertility services as a minimum. Level II infertility services may be offered in projects with clinicians who have special training in infertility. Level III services are considered to be beyond the scope of Title X program.

8.6 Pregnancy Diagnosis and Counseling

Projects must provide pregnancy diagnosis and counseling to all clients in need of this service. Pregnancy testing is one of the most common reasons for a first visit to the family planning facility. It is therefore important to use this occasion as an entry point for providing education and counseling about family planning.

Pregnancy cannot be accurately diagnosed and staged through laboratory testing alone. Pregnancy diagnosis consists of a history, pregnancy test, and physical assessment, including pelvic examination. Projects should have available a pregnancy test of high sensitivity. If the medical examination cannot be performed in conjunction with the laboratory testing, the client must be counseled as to the importance of receiving a physical assessment as soon as possible, preferably within 15 days. This can be done on-site, by a provider selected by the client, or by a provider to which the client has been referred by the project. For those clients with positive pregnancy test results who elect to continue the pregnancy, referral for early initiation of prenatal care should be made. Clients planning to carry their pregnancies to term should be given information about good health practices during early pregnancy, especially those which serve to protect the fetus during the first three months (e.g., good nutrition, avoidance of smoking, drugs, and exposure to x-rays). For clients with a negative pregnancy diagnosis, the cause of delayed menses should be investigated. If ectopic pregnancy is suspected, the client must be referred for immediate diagnosis and therapy.
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 option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling [59.5(a)(5)].

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

### 8.7 Adolescent Services

Adolescent clients require skilled counseling and age-appropriate information. Appointments should be available to them for counseling and clinical services as soon as possible.

Adolescents seeking contraceptive services must be informed about all methods of contraception. Abstinence as well as contraceptive and safer sex practice options to reduce risks for STD/HIV and pregnancy must be discussed with all adolescents. It is important not to assume that adolescents are sexually active simply because they have come for family planning services. As the contraceptive needs of adolescents frequently change, counseling should prepare them to use a variety of methods effectively.

Adolescents must be assured that the counseling sessions are confidential and, if follow-up is necessary, every attempt will be made to assure the privacy of the individual. However, counselors should encourage family participation in the decision of minors to seek family planning services and provide counseling to minors on resisting attempts to coerce minors into engaging in sexual activities. Title X projects may not require written consent of parents or guardians for the provision of services to minors. Nor can the project notify parents or guardians before or after a minor has requested and received Title X family planning services.
8.8 Identification of Estrogen-Exposed Offspring

The children of women who received DES or similar hormones during pregnancy may have abnormalities of their reproductive systems or other fertility related risks. As part of the medical history, clients born between 1940 and 1970 should be asked if their mothers took estrogens during pregnancy. Clients prenatally exposed to exogenous estrogens should receive information/education and special screening either on-site or by referral.

9.0 Related Services

The following related health services, which can improve quality of care, may be offered if skilled personnel and equipment are available.

9.1 Gynecologic Services

Family planning programs should provide for the diagnosis and treatment of minor gynecologic problems so as to avoid fragmentation or lack of health care for clients with these conditions. Problems such as vaginitis or urinary tract infection may be amenable to on-the-spot diagnosis and treatment, following microscopic examination of vaginal secretions or urine. More complex procedures, such as colposcopy, may be offered, provided that clinicians performing these services have specialized training.

9.2 Sexually Transmitted Diseases (STD) and HIV/AIDS

The increasing incidence and prevalence of STDs, particularly among adolescents, requires that family planning projects increase their efforts to provide education and information about the more common STDs and HIV/AIDS. Projects should make available detection and treatment of the more common STDs. At-risk clients should be urged to undergo examination and treatment as indicated, either directly or by referral. When treatment is provided on-site, appropriate follow-up measures must be undertaken.

Gonorrhea and Chlamydia tests must be available for clients requesting IUD insertion. Tests for gonorrhea, syphilis, chlamydia and HIV should be provided as indicated by client request or evidence of increased risk for infection.

Grantees and/or delegate contract agencies must comply with state and local STD reporting requirements.
9.3 Special Counseling

Clients should be offered appropriate counseling and referral as indicated regarding future planned pregnancies, management of a current pregnancy, and other individual concerns (e.g., substance use and abuse, sexual abuse, domestic violence, genetic issues, nutrition, sexual concerns, etc.) as indicated. Preconceptional counseling should be provided if the client’s history indicates a desired pregnancy in the future.

9.4 Genetic Information and Referral

Basic information regarding genetic conditions should be offered to family planning clients who request or are in need of such services. Extensive genetic counseling and evaluation is beyond the scope of the Title X program. Referral systems should be in place for those who require further genetic counseling and evaluation.

9.5 Health Promotion/Disease Prevention

Family planning programs should, whenever possible, provide or coordinate access to services intended to promote health and prevent disease. Programs are encouraged to assess the health problems prevalent in the populations they serve and to develop strategies to address them.

9.6 Postpartum Care

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

10.0 Clinic Management

10.1 Equipment and Supplies

Equipment and supplies must be appropriate to the type of care offered by the project. Projects are expected to follow applicable Federal and state regulations regarding infection control.
10.2 Pharmaceuticals

A gencies must be operated in accordance with Federal and state laws relating to security and record keeping for drugs and devices. The inventory, supply, and provision of pharmaceuticals must be conducted in accordance with state pharmacy laws and professional practice regulations.

It is essential that each facility maintain an adequate supply and variety of drugs and devices to effectively manage the contraceptive needs of its clients. Projects should also ensure access to other drugs or devices that are necessary for the provision of other medical services included within the scope of the Title X project.

10.3 Medical Records

P rojects must establish a medical record for every client who obtains clinical services. These records must be maintained in accordance with accepted medical standards and State laws with regard to record retention. Records must be:

• Complete, legible and accurate, including documentation of telephone encounters of a clinical nature;
• Signed by the clinician and other appropriately trained health professionals making entries, including name, title and date;
• Readily accessible;
• Systematically organized to facilitate prompt retrieval and compilation of information;
• Confidential;
• Safeguarded against loss or use by unauthorized persons;
• Secured by lock when not in use; and
• Available upon request to the client.
• Content of the Client Record

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

- Personal data;
- Medical history, physical exam, laboratory test orders, results, and follow-up;
- Treatment and special instructions;
- Scheduled revisits;
- Informed consents;
- Refusal of services; and
- Allergies and untoward reactions to drug(s) recorded in a prominent and specific location.

The record must also contain reports of clinical findings, diagnostic and therapeutic orders, and documentation of continuing care, referral, and follow-up. The record must allow for entries by counseling and social service staff. Projects should maintain a problem list at the front of each chart listing identified problems to facilitate continuing evaluation and follow-up. Client financial information should be kept separate from the client medical record. If included in the medical record, client financial information should not be a barrier to client services.

• Confidentiality and Release of Records

A confidentiality assurance statement must appear in the client’s record. The written consent of the client is required for the release of personally identifiable information, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality [59.11]. HIV information should be handled according to law, and kept separate whenever possible. When information is requested, agencies should release only the specific information requested. Information collected for reporting purposes may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Upon request, clients transferring to other providers must be provided with a copy or summary of their record to expedite continuity of care.
10.4 Quality Assurance and Audit

A quality assurance system must be in place that provides for ongoing evaluation of project personnel and services. The quality assurance system should include:

- An established set of clinical, administrative and programmatic standards by which conformity would be maintained;
- A tracking system to identify clients in need of follow-up and/or continuing care;
- Ongoing medical audits to determine conformity with agency protocols;
- Peer review procedures to evaluate individual clinician performance, to provide feedback to providers, and to initiate corrective action when deficiencies are noted;
- Periodic review of medical protocols to insure maintenance of current standards of care;
- A process to elicit consumer feedback; and
- Ongoing and systematic documentation of quality assurance activities.
**Federal Guidelines Attachments**

Attachment A: Title X – Population Research and Voluntary Family Planning Programs

Attachment B: Title X Family Planning Program Regulations

Attachment C: Sterilization of Persons in Federally Assisted Family Planning Projects

Attachment D: Regional Office Program Consultants for Family Planning Regional Health Administrators, U.S. Public Health Service

Resources for Title X Family Planning Programs

- The Law, Regulations, and Guidelines
- Application, Grants Administration, and Legal Issues
- Project Management and Reporting Requirements
- Client Services
- Health Promotion/Disease Prevention
TITLE X - POPULATION RESEARCH AND VOLUNTARY FAMILY PLANNING PROGRAMS (Title X Statute)

PROJECT GRANTS AND CONTRACTS FOR FAMILY PLANNING SERVICES
SEC. 1001 [300]
(a) The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents). To the extent practicable, entities which receive grants or contracts under this subsection shall encourage family participation in projects assisted under this subsection.

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

(c) The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by the fair market value of any supplies or equipment furnished the grant recipient by the Secretary. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment on which the reduction of such grant is based. Such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(d) For the purpose of making grants and contracts under this section, there are authorized to be appropriated $30,000,000 for the fiscal year ending June 30, 1971; $60,000,000 for the fiscal year ending June 30, 1972; $111,500,000 for the fiscal year ending June 30, 1973; $111,500,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $115,000,000 for fiscal year 1976; $115,000,000 for the fiscal year ending September 30, 1977; $136,400,000 for the fiscal year ending September 30, 1978; $200,000,000 for the fiscal year ending September 30, 1979; $230,000,000 for the fiscal year ending September 30, 1980; $264,500,000 for the fiscal year ending September 30, 1981; $126,510,000 for the fiscal year ending September 30, 1982; $139,200,000 for the fiscal year ending September 30, 1983; $150,030,000 for the fiscal year ending September 30, 1984; and $158,400,000 for the fiscal year ending September 30, 1985.

1So in law. See section 931(b)(1) of Public Law 97-35 (95 Stat. 570). Probably should be “family.”
FORMULA GRANTS TO STATES FOR FAMILY PLANNING SERVICES
SEC. 1002 [300a]
(a) The Secretary is authorized to make grants, from allotments made under subsection (b), to State health authorities to assist in planning, establishing, maintaining, coordinating, and evaluating family planning services. No grant may be made to a State health authority under this section unless such authority has submitted, and had approved by the Secretary, a State plan for a coordinated and comprehensive program of family planning services.
(b) The sums appropriated to carry out the provisions of this section shall be allotted to the States by the Secretary on the basis of the population and the financial need of the respective States.
(c) For the purposes of this section, the term "State" includes the Commonwealth of Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, the District of Columbia, and the Trust Territory of the Pacific Islands.
(d) For the purpose of making grants under this section, there are authorized to be appropriated $10,000,000 for the fiscal year ending June 30, 1971; $15,000,000 for the fiscal year ending June 30, 1972; and $20,000,000 for the fiscal year ending June 30, 1973.

TRAINING GRANTS AND CONTRACTS; AUTHORIZATION OF APPROPRIATIONS
SEC. 1003 [300a-1]
(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to provide the training for personnel to carry out family planning service programs described in section 1001 or 1002 of this title.
(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $2,000,000 for the fiscal year ending June 30, 1971; $3,000,000 for the fiscal year ending June 30, 1972; $4,000,000 for the fiscal year ending June 30, 1973; $3,000,000 each for the fiscal years ending June 30, 1974 and June 30, 1975; $4,000,000 for fiscal year ending 1976; $5,000,000 for the fiscal year ending September 30, 1977; $3,000,000 for the fiscal year ending September 30, 1978; $3,100,000 for the fiscal year ending September 30, 1979; $3,600,000 for the fiscal year ending September 30, 1980; $4,100,000 for the fiscal year ending September 30, 1981; $2,920,000 for the fiscal year ending September 30, 1982; $3,200,000 for the fiscal year ending September 30, 1983; $3,500,000 for the fiscal year ending September 30, 1984; and $3,500,000 for the fiscal year ending September 30, 1985.

RESEARCH
SEC. 1004 [300a-2]
The Secretary may –
(1) conduct, and
(2) make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for, research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.
INFORMATIONAL AND EDUCATIONAL MATERIALS

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

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $750,000 for the fiscal year ending June 30, 1971; $1,000,000 for the fiscal year ending June 30, 1972; $1,250,000 for the fiscal year ending June 30, 1973; $909,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $2,000,000 for fiscal year 1976; $2,500,000 for the fiscal year ending September 30, 1977; $600,000 for the fiscal year ending September 30, 1978; $700,000 for the fiscal year ending September 30, 1979; $805,000 for the fiscal year ending September 30, 1980; $926,000 for the fiscal year ending September 30, 1981; $570,000 for the fiscal year ending September 30, 1982; $600,000 for the fiscal year ending September 30, 1983; $670,000 for the fiscal year ending September 30, 1984; and $700,000 for the fiscal year ending September 30, 1985.

REGULATIONS AND PAYMENTS

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

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

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

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

(2) no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge.
For purposes of this subsection, the term “low-income family” shall be defined by the Secretary in accordance with such criteria as he may prescribe so as to insure that economic status shall not be a deterrent to participation in the programs assisted under this title.

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

(2) In the case of any grant or contract under section 1001, such assurances shall provide for the review and approval of the suitability of such materials, prior to their distribution, by an advisory committee established by the grantee or contractor in accordance with the Secretary's regulations. Such a committee shall include individuals broadly representative of the population or community to which the materials are to be made available.

**VOLUNTARY PARTICIPATION**

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

**PROHIBITION OF ABORTION**

SEC. 1008[1] [300a-6]
None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.

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[1]Section 1009 was repealed by section 601(a)(1)(G) of Public Law 105-362 (112 Stat. 3285).
Title X Family Planning Program Regulations

Subpart A—Project Grants for Family Planning Services

Sec.
59.1 To what programs do these regulations apply?
59.2 Definitions.
59.3 Who is eligible to apply for a family planning services grant?
59.4 How does one apply for a family planning services grant?
59.5 What requirements must be met by a family planning project?
59.6 What procedures apply to assure the suitability of informational and educational material?
59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?
59.8 How is a grant awarded?
59.9 For what purposes may grant funds be used?
59.10 What other HHS regulations apply to grants under this subpart?
59.11 Confidentiality.
59.12 Additional conditions.

Subpart B [Reserved]

Subpart C—Grants for Family Planning Service Training

59.201 Applicability.
59.202 Definitions.
59.203 Eligibility.
59.204 Application for a grant.
59.205 Project requirements.
59.206 Evaluation and grant award.
59.207 Payments.
59.208 Use of project funds.
59.209 Civil rights.
59.210 Inventions or discoveries.
59.211 Publications and copyright.
59.212 Grantee accountability.
59.213 [Reserved]
59.214 Additional conditions.
59.215 Applicability of 45 CFR part 74.

Subpart A—Project Grants for Family Planning Services

Authority: 42 U.S.C. 300a-4.

Source: 65 FR 41278, July 3, 2000, unless otherwise noted.

Sec. 59.1 To what programs do these regulations apply?

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

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

Sec. 59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

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

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

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

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

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

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

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

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

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

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

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

(c) The application shall contain:

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

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

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

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

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

(a) Each project supported under this part must:

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

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

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

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

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

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

      A. Prenatal care and delivery;
      B. Infant care, foster care, or adoption; and
      C. Pregnancy termination.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

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

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

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

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

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

(3) Function. In reviewing materials, the Advisory Committee shall:
   (i) Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;
   (ii) Consider the standards of the population or community to be served with respect to such materials;
   (iii) Review the content of the material to assure that the information is factually correct;
   (iv) Determine whether the material is suitable for the population or community to which it is to be made available; and
   (v) Establish a written record of its determinations.

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

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:
   (1) The number of patients, and, in particular, the number of low-income patients to be served;
   (2) The extent to which family planning services are needed locally;
   (3) The relative need of the applicant;
   (4) The capacity of the applicant to make rapid and effective use of the federal assistance;
   (5) The adequacy of the applicant's facilities and staff;
   (6) The relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project; and
   (7) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

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

Sec. 59.8 How is a grant awarded?

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

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

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

Sec. 59.9 For what purpose may grant funds be used?

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

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

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

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

Sec. 59.11 Confidentiality.

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

Sec. 59.12 Additional conditions.

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

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

Subpart B [Reserved]

Subpart C--Grants for Family Planning Service Training

Authority: Sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a-4; sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a-1.

Source: 37 FR 7093, Apr. 8, 1972, unless otherwise noted.

Sec. 59.201 Applicability.

The regulations in this subpart are applicable to the award of grants pursuant to section 1003 of the Public Health Service Act (42 U.S.C. 300a-1) to provide the training for personnel to carry out family planning service programs described in sections 1001 and 1002 of the Public Health Service Act (42 U.S.C. 300, 300a).

Sec. 59.202 Definitions.

As used in this subpart:
(a) Act means the Public Health Service Act.
(b) State means one of the 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, or the Trust Territory of the Pacific Islands.
(c) Nonprofit private entity means a private entity no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.
(d) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.
(e) Training means job-specific skill development, the purpose of which is to promote and improve the delivery of family planning services.

Sec. 59.203 Eligibility.

(a) Eligible applicants. Any public or nonprofit private entity located in a State is eligible to apply for a grant under this subpart.
(b) Eligible projects. Grants pursuant to section 1003 of the Act and this subpart may be made to eligible applicants for the purpose of providing programs, not to exceed three months in duration, for training family planning or other health services delivery personnel in the skills, knowledge, and attitudes necessary for the effective delivery of family planning services: Provided, That the Secretary may in particular cases approve support of a program whose duration is longer than three months where he determines (1) that such program is consistent with the purposes of this subpart and (2) that the program's objectives cannot be accomplished within three months because of the unusually complex or specialized nature of the training to be undertaken.

[37 FR 7093, Apr. 8, 1972, as amended at 40 FR 17991, Apr. 24, 1975]

Sec. 59.204 Application for a grant.
(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe. The application shall contain a full and adequate description of the project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart, and a budget and justification of the amount of grant funds requested, and such other pertinent information as the Secretary may require.

(b) The application shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the regulations of this subpart and any additional conditions of the grant.

(Sec. 6(c), Public Health Service Act, 84 Stat. 1506 and 1507 (42 U.S.C. 300, 300a-1, and 300a-4))

[37 FR 7093, Apr. 8, 1972, as amended at 49 FR 38116, Sept. 27, 1984]

An approvable application must contain each of the following unless the Secretary determines that the applicant has established good cause for its omission:

(a) Assurances that:
   (1) No portion of the Federal funds will be used to train personnel for programs where abortion is a method of family planning.
   (2) No portion of the Federal funds will be used to provide professional training to any student as part of his education in pursuit of an academic degree.
   (3) No project personnel or trainees shall on the grounds of sex, religion, or creed be excluded from participation in, be denied the benefits of, or be subjected to discrimination under the project.

(b) Provision of a methodology to assess the particular training (e.g., skills, attitudes, or knowledge) that prospective trainees in the area to be served need to improve their delivery of family planning services.

(c) Provision of a methodology to define the objectives of the training program in light of the particular needs of trainees defined pursuant to paragraph (b) of this section.

Sec. 59.205 Project requirements.

(d) Provision of a method for development of the training curriculum and any attendant training materials and resources.

(e) Provision of a method for implementation of the needed training.

(f) Provision of an evaluation methodology, including the manner in which such methodology will be employed, to measure the achievement of the objectives of the training program.

Sec. 59.206 Evaluation and grant award.

(a) Within the limits of funds available for such purpose, the Secretary may award grants to assist in the establishment and operation of those projects which will in his judgment best promote the purposes of section 1003 of the Act, taking into account:
   (1) The extent to which a training program will increase the delivery of services to people, particularly low-income groups, with a high percentage of unmet need for family planning services;
   (2) The extent to which the training program promises to fulfill the family planning services delivery needs of the area to be served, which may include, among other things:
      (i) Development of a capability within family planning service projects to provide pre- and in-service training to their own staffs;
      (ii) Improvement of the family planning services delivery skills of family planning and health services personnel;
      (iii) Improvement in the utilization and career development of paraprofessional and paramedical manpower in family planning services;
      (iv) Expansion of family planning services, particularly in rural areas, through new or improved approaches to program planning and deployment of resources;
   (3) The capacity of the applicant to make rapid and effective use of such assistance;
   (4) The administrative and management capability and competence of the applicant;
   (5) The competence of the project staff in relation to the services to be provided; and
   (6) The degree to which the project plan adequately provides for the requirements set forth in Sec. 59.205.

(b) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either: (1) On the basis of his estimate of

1 Applications and instructions may be obtained from the Program Director, Family Planning Services, at the Regional Office of the Department of Health and Human Services for the region in which the project is to be conducted, or the Office of Family Planning, Office of the Assistant Secretary for Health, Washington, DC 20201.
the actual indirect costs reasonably related to the project, or (2) on the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as travel or supply costs) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(c) Allowability of costs shall be in conformance with the applicable cost principles prescribed by Subpart Q of 35 CFR part 74.

(d) All grant awards shall be in writing, shall set forth the amount of funds granted and the period for which support is recommended.

(e) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application annually at such times and in such form as the Secretary may direct.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

Sec. 59.207 Payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred in the performance of the project to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

Sec. 59.208 Use of project funds.

(a) Any funds granted pursuant to this subpart as well as other funds to be used in performance of the approved project shall be expended solely for carrying out the approved project in accordance with the statute, the regulations of this subpart, the terms and conditions of the award, and, except as may otherwise be provided in this subpart, the applicable cost principles prescribed by subpart Q of 45 CFR part 74.

(b) Prior approval by the Secretary of revision of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.

(c) The Secretary may approve the payment of grant funds to trainees for:

1. Return travel to the trainee's point of origin.
2. Per diem during the training program, and during travel to and from the program, at the prevailing institutional or governmental rate, whichever is lower.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

Sec. 59.209 Civil rights.

Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) and in particular section 601 of such Act which provides that no person in the United States shall, on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR part 80).

Sec. 59.210 Inventions or discoveries.

Any grant award pursuant to Sec. 59.206 is subject to the regulations of the Department of Health and Human Services as set forth in 45 CFR parts 6 and 8, as amended. Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries shall be maintained for such periods, and filed with or otherwise made available to the Secretary, or those he may designate at such times and in such manner, as he may determine necessary to carry out such Department regulations.

Sec. 59.211 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications,
films or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

**Sec. 59.212 Grantee accountability.**

(a) Accounting for grant award payments. All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this part: Provided, however, That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) [Reserved]

(c) Accounting for grant-related income—(1) Interest. Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the governments of the political subdivisions of the State. All grantees other than a State, as defined in this subsection, must return all interest earned on grant funds to the Federal Government.

(d) Grant closeout—(1) Date of final accounting. A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) Final settlement. There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section;

(ii) Any credits for earned interest pursuant to paragraph (c)(1) of this section;

(iii) Any other amounts due pursuant to subparts F, M, and O of 45 CFR part 74.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assignees by setoff or other action as provided by law.


**Sec. 59.213 [Reserved]**

**Sec. 59.214 Additional conditions.**

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

**Sec. 59.215 Applicability of 45 CFR part 74.**

The provisions of 45 CFR part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to State and local governments as those terms are defined in subpart A of that part 74. The relevant provisions of the following subparts of part 74 shall also apply to grants to all other grantee organizations under this subpart.

45 CFR Part 74

Subpart:

A General.
B Cash Depositories.
C Bonding and Insurance.
D Retention and Custodial Requirements for Records.
F Grant-Related Income.
G Matching and Cost Sharing.
K Grant Payment Requirements.
L Budget Revision Procedures.
M Grant Closeout, Suspension, and Termination.
O Property.
Q Cost Principles.

[38 FR 26199, Sept. 19, 1973]
Sterilization of Persons in Federally Assisted Family Planning Projects

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

Sec. 50.201 Applicability.

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

Sec. 50.202 Definitions.

As used in this subpart:

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

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

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

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

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

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

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

[43 FR 52165, Nov. 8, 1978, as amended at 49 FR 38109, Sept. 27, 1984]

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

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

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

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

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

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

Sec. 50.204 Informed consent requirement.

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

(a) A person who obtains informed consent for a sterilization procedure must offer to answer any questions the individual to be sterilized may have concerning the procedure, provide a copy of the consent form, and provide orally all of the following information or advice to the individual who is to be sterilized:

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

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

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

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

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

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

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

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

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

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

(1) In labor or childbirth;
(2) Seeking to obtain or obtaining an abortion; or
(3) Under the influence of alcohol or other substances that affect the individual's state of awareness.

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

Sec. 50.205 Consent form requirements.

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

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

(1) The individual to be sterilized; and
(2) The interpreter, if one is provided; and
(3) The person who obtains the consent; and
(4) The physician who will perform the sterilization procedure.

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

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

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

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

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

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

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

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized. Except in the case of premature delivery or emergency abdominal surgery, the physician must further certify that at least 30 days have passed between the date of the individual's signature on the consent form and the date upon which the sterilization was performed. If premature delivery occurs or emergency abdominal surgery is required within the 30-day period, the physician must certify that the sterilization was performed less than 30 days but not less than 72 hours after the date of the individual's signature on the consent form because of premature delivery or emergency abdominal surgery, as applicable. In the case of premature delivery, the physician must also state the expected date of delivery. In the case of emergency abdominal surgery, the physician must describe the emergency.

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

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

Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any mentally incompetent individual or institutionalized individual.
Sec. 50.207 Sterilization by hysterectomy.

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

(b) Except as provided in paragraph (c) of this section, programs or projects to which this subpart applies may perform or arrange for the performance of a hysterectomy not covered by paragraph (a) of this section only if:

1. The person who secures the authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing, that the hysterectomy will make her permanently incapable of reproducing; and
2. The individual or her representative, if any, has signed a written acknowledgment of receipt of that information.

(c)(1) A program or project is not required to follow the procedures of paragraph (b) of this section if either of the following circumstances exists:

i. The individual is already sterile at the time of the hysterectomy.
ii. The individual requires a hysterectomy because of a life-threatening emergency in which the physician determines that prior acknowledgment is not possible.

(2) If the procedures of paragraph (b) of this section are not followed because one or more of the circumstances of paragraph (c)(1) exist, the physician who performs the hysterectomy must certify in writing:

i. That the woman was already sterile, stating the cause of that sterility; or
ii. That the hysterectomy was performed under a life-threatening emergency situation in which he or she determined prior acknowledgment was not possible. He or she must also include a description of the nature of the emergency.

Sec. 50.208 Program or project requirements.

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

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

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

Sec. 50.209 Use of Federal financial assistance.

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

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

[43 FR 52165, Nov. 8, 1978, as amended at 47 FR 33701, Aug. 4, 1982]

Sec. 50.210 Review of regulation.

The Secretary will request public comment on the operation of the provisions of this subpart not later than 3 years after their effective date.

Appendix to Subpart B of Part 50—
Required Consent Form

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS RECEIVING FEDERAL FUNDS.

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from ___________________________ (doctor or clinic). When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as A.F.D.C. or Medicaid that I am now getting or for which I may become eligible.

I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED PERMANENT AND NOT REVERSIBLE. I HAVE DECIDED THAT I DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN OR FATHER CHILDREN.
I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a . The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least 30 days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by federally funded programs.

I am at least 21 years of age and was born on (day), (month), (year).

I, , hereby consent of my own free will to be sterilized by a method called . My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health and Human Services or
Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form.

Signature
Date:
(Month, day, year)

You are requested to supply the following information, but it is not required:

Ethnicity and Race Designation
Ethnicity:
Hispanic or Latino
Not Hispanic or Latino

Race (mark one or more):
American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or Other Pacific Islander
White

INTERPRETER'S STATEMENT

If an interpreter is provided to assist the individual to be sterilized:

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

Interpreter
Date

STATEMENT OF PERSON OBTAINING CONSENT

Before (name of individual), signed the consent form, I explained to him/her the nature of the sterilization operation , the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it. I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequence of the procedure.

Signature of person obtaining consent
Date
Facility
Address
PHYSICIAN'S STATEMENT

Shortly before I performed a sterilization operation upon (name of individual to be sterilized), on (date of sterilization), (operation), I explained to him/her the nature of the sterilization operation (specify type of operation), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(Instructions for use of alternative final paragraphs: Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.)

1. At least 30 days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

2. This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested):

   Premature delivery
   Individual's expected date of delivery:
   Emergency abdominal surgery:
   (Describe circumstances):

Physician
Date

PAPERWORK REDUCTION ACT STATEMENT

A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays the currently valid OMB control number. Public reporting burden for this collection of information will vary; however, we estimate an average of one hour per response, including for reviewing instructions, gathering and maintaining the necessary data, and disclosing the information. Send any comment regarding the burden estimate or any other aspect of this collection of information to the OS Reports Clearance Officer, ASBTF/Budget Room 503 HHH Building, 200 Independence Avenue, SW., Washington, DC 20201.

Respondents should be informed that the collection of information requested on this form is authorized by 42 CFR part 50, subpart B, relating to the sterilization of persons in federally assisted public health programs. The purpose of requesting this information is to ensure that individuals requesting sterilization receive information regarding the risks, benefits and consequences, and to assure the voluntary and informed consent of all persons undergoing sterilization procedures in federally assisted public health programs. Although not required, respondents are requested to supply information on their race and ethnicity. Failure to provide the other information requested on this consent form, and to sign this consent form, may result in an inability to receive sterilization procedures funded through federally assisted public health programs.

All information as to personal facts and circumstances obtained through this form will be held confidential, and not disclosed without the individual's consent, pursuant to any applicable confidentiality regulations.


[Revised as of October 1, 2003]
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Resource List for Title X Family Planning Programs

The following is a list of selected resources that provide additional guidance in specific areas. It is intended to assist programs in administering their Title X grant and in providing services to clients. The list is not intended to be exhaustive, nor does it imply endorsement of any of the non-governmental resources.

The Law, Regulations, and Guidelines

The Title X Family Planning statute (42 USC 300 et. seq.) and regulations can be obtained from:

- Office of Family Planning
  Office of Population Affairs
  Office of Public Health and Science
  U.S. Department of Health and Human Services
  4350 East West Highway, Suite 200
  Bethesda, MD 20817
  (301) 594-4008
  http://www.hhs.gov/opa/
  opa@hhs.gov

Application, Grants Administration, and Legal Issues

- Grants Management
  http://www.hhs.gov/grantsnet

- Grants Process Policy Notices for Title X Family Planning Services, rev. 1999
  (Available from Title X Grants Management Office. 1301 Young Street, Ste.766, Dallas, TX 75202; 214-767-3490)
Project Management and Reporting Requirements

- Annual Report for OPA Title X Family Planning Program Grantees Forms and Instructions (Available from the Regional Office).


Client Services

- Cultural Competence [http://minorityhealth.hhs.gov](http://minorityhealth.hhs.gov)


**Health Promotion/Disease Prevention**


Title X Program Priorities

The purpose of the Title X program is to assist in the establishment and operation of voluntary family planning projects. Services consist of education, comprehensive medical services, a broad range of acceptable and effective family planning methods, and social services necessary to aid individuals to determine freely the number and spacing of their children. Agencies receiving Title X funding must make these services their primary activity. The priority is to serve those from low-income families.

In addition, the Office of Population Affairs, the federal agency that funds Title X, has established a set of national priorities, some of which they may elect to emphasize during a given Title X grant cycle. These may change over time. The current program priorities, legislative mandates, and other key issues are listed below.

OPA Program Priorities

The following priorities represent the overarching goals for the Title X program:

1. Assuring the delivery of quality family planning and related preventive health services, where evidence exists that those services should lead to improvement in the overall health of individuals, with priority for services to individuals from low-income families;

2. Expanding access to a broad range of acceptable and effective family planning methods and related preventive health services that include natural family planning methods, infertility services, and services for adolescents, emphasizing the important role Title X plays in teen pregnancy prevention. The broad range of services does not include abortion as a method of family planning;

3. Providing preventive health care services in accordance with nationally recognized standards of care. This includes, but is not limited to, breast and cervical cancer screening and prevention services; sexually transmitted disease (STD) and HIV prevention services; and prenatal care for pregnant women.
education, testing, and referral; and, other related preventive health services;

4. Emphasizing the importance of counseling family planning clients on establishing a reproductive life plan, and providing preconception counseling as a part of family planning services, as appropriate;

5. Addressing the comprehensive family planning and other health needs of individuals, families, and communities 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.

6. Identifying specific strategies for addressing the provisions of health care reform (“The Patient Protection and Affordable Care Act”), and for adapting delivery of family planning and reproductive health services to a changing health care environment, and assisting clients with navigating the changing health care system. This includes, but is not limited to, enhancing the ability of Title X clinics to bill third party payers, private insurance, and Medicaid.

**Federal Legislative Mandates**

The following legislative mandates have been part of the Title X appropriations for each of the last several years. Title X family planning projects should include administrative, clinical, counseling, and referral services necessary to ensure adherence to these requirements.

“None of the funds appropriated in this 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 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.”

**Other Key Federal Issues**

In addition to the Program Priorities and Legislative Mandates, the following key issues have implications for Title X projects and should be acknowledged in the project plan:

1. Efficiency and effectiveness in program management and operations;
2. Cost of contraceptives, including long acting reversible contraceptives (LARC), other pharmaceuticals, and laboratory tests;
3. Management and decision-making through performance measures and accountability for outcomes;
4. Linkages and partnerships with HIV care and treatment providers, and mental health, drug and alcohol treatment providers;
5. HIV prevention integration in family planning settings, incorporating CDC’s “Revised Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women in Health Care Settings;”
6. Incorporation of electronic technologies, such as electronic health records and practice management systems;
7. Data collection (such as the Family Planning Annual Report (FPAR)) for use in monitoring performance and improving family planning services;
8. Service delivery improvement through translation into practice of research outcomes that focus on family planning and related population issues;
9. Utilizing practice guidelines and recommendations, developed by recognized national professional organizations and Federal agencies, in the provision of evidence-based Title X clinical services; and,
10. Encouraging vaccination of patients and providers as the best protection against influenza.
Title X Abortion Restrictions

The Federal Regulation

Section 1008 of Title X of the Public Health Service Act (the law that established federally funded family planning programs) states that “none of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.”

The Federal Interpretation

The federal government interprets Section 1008 to mean that abortions as well as any activities that promote or encourage abortions may not be conducted by Title X family planning programs.

Activities such as the following have been found by federal officials to promote or encourage abortion:

- Providing counseling that promotes any particular option
- Making abortion appointments for clients
- Having clients sign abortion consent forms
- Providing speakers to debate in opposition to anti-abortion speakers
- Advocating the need for abortion in the community
- Producing or showing audio-visual aids which encourage or promote a favorable attitude to abortion

Every family planning program must provide non-directive pregnancy diagnosis and counseling to all clients in need of this service, even though activities related to abortion are restricted. See Options Counseling on the following page.

A number of federal documents have been published to clarify and interpret the Section 1008 abortion regulations. If you need additional information on this issue, please contact the Reproductive Health Program.
Options Counseling

Section 8.6, Pregnancy Diagnosis and Counseling, of the federal Program Guidelines for Project Grants for Family Planning Services states:

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 option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.

This nondirective counseling is also referred to as options counseling.

Due to the sensitive nature of this issue for staff and local communities, we require that clients with unintended pregnancies be given a single handout that provides referral information to local resources for all three options. If there are no local resources for a given option, indicate where a member of your community can go to receive the services. This will help fulfill the requirement for nondirective counseling, as well as serving clients who may change their minds, or who want to consider a different alternative after leaving the clinic.
Sterilization Regulations

Federal Requirements

Sterilization is one of the many contraceptive services your family planning clinic must make available to clients. You can meet this requirement by providing information and/or referrals for the procedure.

Any sterilization service provided in Title X clinics must comply with federal regulations. This includes services made available through Oregon Contraceptive Care (CCare) or the Oregon Vasectomy Project (OVP). Clients eligible for the Oregon Health Plan (OHP) may have sterilizations funded with state resources through the Division of Medical Assistance Programs (DMAP). Most, but not all, of the same federal regulations apply in these cases. See the online OHP provider guide for more information: http://www.dhs.state.or.us/policy/healthplan/main.html

If your Family Planning Program provides sterilization services, you must follow federal sterilization regulations. Federal sterilization regulations are included as Attachment C of the Program Guidelines for Project Grants for Family Planning Services (Section B.1 of this manual). See the Vasectomy section of this manual (A.7) for additional information related to participation in the Oregon Vasectomy Project.

Informed Consent

Federal funds may not be used to pay for sterilization procedures to persons under age 21.

Federal regulations require that clients must voluntarily give informed consent prior to sterilization. Exhibit 4 of this section contains the current consent forms in English and Spanish from the Office of Population Affairs (OPA) Clearinghouse, which you can photocopy for use in your program. Forms can also be downloaded from the OPA Clearinghouse website at: http://www.hhs.gov/opa/pdfs/consent-for-sterilization-english-updated.pdf
The site also includes a wide variety of publications on sterilization and other family planning issues.

**Status After Sterilization**

Sterilized persons remain eligible to be served in Title X family planning clinics as long as they are of reproductive age (female 10–60; male 10 and older) and they receive medical services and/or counseling related to Title X’s broad definition of family planning. However, Medicaid services for family planning (OHP or CCare) are limited to those individuals who require contraceptive care.
Infertility Services

Federal Requirements

Title X requires that clinics must make basic infertility services available to women and men desiring such services. At a minimum, Level I services must be provided.

- Level I includes initial infertility interview, education, physical examination, counseling, and appropriate referral.
- Level II includes such testing as semen analysis, assessment of ovulatory function, and postcoital testing.
- Level III is more complex than Level I and II services and is considered to be beyond the scope of a Title X program.

See Program Guidelines for Project Grants for Family Planning Services, Section 8.5, for additional information.
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Other Requirements B.6

Federal Assurances

As with other programs for which your agency receives federal funds through OHA – Public Health, your family planning program must assure compliance with federal laws relating to such issues as:

- Nondiscrimination [Title VI of the Civil Rights Act of 1964]
- Consideration of the disabled [Title II of the Americans with Disabilities Act (ADA) of 1990]
- Protection of human subjects [Code of Federal Regulations, Title 45, Part 46 (2005)]
- Restrictions on the use of federal funds for lobbying [31 USC, Section 1352 (the “Byrd Amendment”)]
- Drug-free workplace [Drug-Free Workplace Act of 1988 for federal contractors and grantees]
- HIPPA, the Health Insurance Portability and Accountability Act of 1996
- Prohibition of smoking

Program Instructions

The Office of Population Affairs periodically sends out Program Instructions and other memos that update or clarify the Program Guidelines. It is required that a paper manual be on-site and updated with the most current Program Instructions from OPA. Exhibit 8 of this section contains all Program instructions released since January, 2001.

Program Instructions and memos are also available at:
http://www.hhs.gov/opa/familyplanning/toolsdocs/xinstruction.html
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LPHA Contracts

Each year, every local public health authority (LPHA) in Oregon receives a comprehensive community assessment and annual plan packet that must be completed and returned. Several areas of the packet specifically address family planning.

All Title X family planning delegates also receive a Notice of Grant Award (NGA) and an extensive interagency agreement/contract from the OHA Contracts Office in Salem. The contract and NGA must be signed and returned to OHA prior to July 1 so that funding for the next fiscal year can begin.

Program elements: The contract contains general and specific program elements (formerly called assurances). A copy of the current program element for family planning services follows at the end of this section in Exhibit 1. Minor revisions are anticipated in a future contract amendment.

Funding: Family planning grant funding is based on a formula agreed upon by the Center for Prevention and Health Promotion (CPHP) and the Conference of Local Health Officials (CLHO). The current formula provides a small base amount and distributes the remaining funds on a per client basis. It is described in more detail on page B7-3.

The Title X funding period is July 1 through June 30. Any changes in funding throughout the year are initiated through the contract amendment process.
Supplemental Funding

Our agency occasionally makes additional funding available in the form of “directed supplement” or “special project” funds. When applying for these funds, keep in mind that consideration is often given to projects that address specific national program priorities. You’ll find a list of the current priorities in Section B.2.

We recommend developing outlines for appropriate special projects in advance, since proposal deadlines for this additional funding are often very tight.

Expenditure Reports

Title X grant payments are made to your agency monthly. You are required to submit quarterly expenditure reports to the Office of Financial Services. A sample of the current Revenue and Expenditure Report is included in this section as Exhibit 2.

Accuracy is important. Please take care to ensure that expenditure reports are accurate by line item. Personal service expenditures must be based on time activity reports where appropriate.

Final expenditure reports. Family Planning Service Grant funds may not be carried forward to the next year. Therefore, it is in your interest to spend up to the limit of your grant. We recommend spending CPHP funds before local funds so that there is no danger of funds being lost.
Family Planning Funding Formula

The Center for Prevention and Health Promotion and the Conference of Local Health Officials have approved the current version of the family planning funding formula, which went into effect beginning July 1, 2006. The formula is used to distribute Title X and Title V grant funds to serve low-income clients who do not have public or private medical insurance.

After exploring a variety of funding models during 2005, an ad hoc funding formula workgroup recommended the following formula:

1. Distribute a base amount of $5,000 to each agency.
2. Distribute the remaining funds on a per-client basis, using the total number of non-Medicaid (non-CCare and non-OHP) clients served by each agency in the prior year.

This straightforward solution, the workgroup judged, would reflect a set of critical guiding principles (see list below), while also avoiding potential problems due to subjective weighting or poor quality data.

Guiding Principles

1. Family planning services should be available in every county.
2. Title X funds should be focused on providing direct family planning services to low-income women and others who can’t access services elsewhere.
3. Title X providers are required to follow the Title X Standards of Care.
4. Some funding stability should be maintained in order to support continuity of services.
5. Some consideration should be given to equity in revenue per client.
Fee Collection

Establishing Fee Collection Policies

Title X requires every family planning project to set fees for all family planning services and supplies. Fees should be designed to recover the reasonable costs of providing services and may include clinical, support, and administrative costs. (Requirements are listed in Program Guidelines for Project Grants for Family Planning Services, Section 6.3.)

Each agency is responsible for developing its own fee collection policies to meet its own unique circumstances. The information in this section is intended to help. Please note, however, that it does not cover every situation that may arise.

Important Basic Guidelines

- The goal is to charge fees based on the client's ability to pay. Fee collection policies and practices should never be a barrier to a client receiving services.
- Clients may not be subjected to any variation in quality of services because of inability to pay.
- Employees within the same agency must deliver consistent messages to clients about fee collection.

Clients Who Are Unable to Pay

Federal regulations clearly state that clients must never be denied services because of an inability to pay. This fact should be reflected in your clinic’s fee policy, in any clinic signage addressing fees, and in any discussions with clients about fees.

Who Qualifies As “Unable to Pay”

Clients with incomes at or below 100% of the federal poverty level are assumed to be unable to pay and cannot be charged.
A client whose income is above the federal poverty level but is unable to pay for good cause (as determined by the project director) may have the fee waived, in full or in part. The project must determine, as accurately as possible, the client’s ability to pay based upon family income.

**Note:** In the case of minors seeking confidential services, just the minor’s income may be used in fee assessments.

### Family Planning

**Fees Must Be Kept Separate**

In accordance with federal rules, fees collected in all family planning clinics funded through Oregon’s Center for Prevention and Health Promotion must be kept separate from other funds and shall be used only to support the Family Planning Program. Program income collected must be fully used within the period of the LPHA contract agreement and not carried over into subsequent years. See Program Element 41 in Exhibit 1 of this section for details.

### Donations Must Be Voluntary

Voluntary donations from clients are permissible, under the following conditions:

- Clients must not be pressured to make donations, and donations must not be a prerequisite to the provision of services or supplies.
- Client donations do not waive billing/charging requirements.
- Any donation policy, including information offered about the agency's ability to accept donations, must be applied consistently across all clients, regardless of fee or payment status.
Sliding Fee Scale

Your program must base its fees on an authorized sliding fee scale that incorporates federal poverty guideline figures. The current scales issued by the federal government (“Title X Service and Supply Discount Schedule” and “Reproductive Health Program Sliding Fee Scale”) are in Exhibit 3 and Exhibit 4 of this section, respectively. If your family planning program prefers to use a different scale, it must have sufficient proportional increments so the inability to pay is never a barrier to service.

In order to apply the sliding fee scale, you must determine the client’s family size and income. Instructions for making those calculations are spelled out in the CVR Manual for Title X and CCare on page D3-9 in Section D of this manual.

Important Considerations about Fees

- Clients whose incomes are at or above 250% of the federal poverty level must be charged the full fee for services and supplies.
- Clients whose incomes are between 100% and 250% of the federal poverty level must be charged according to an approved sliding fee scale.
- Clients whose incomes are at or below 100% of the federal poverty level must not be charged.
- No flat or minimum fees of any sort (no-show fees, dispensing fees, family planning lab handling fees, etc.) may be charged. As noted previously, voluntary donations may be discussed with all clients.
- No one may be denied services based on an inability to pay.
- Proof of income is not required to receive Title X services.
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**Reporting Requirements**

**Clinic Visit Record**

The Clinic Visit Record (CVR) serves as the data collection tool for the Family Planning Information System and as the billing mechanism for services provided to CCare clients.

All agencies (Title X and CCare) must fill out a CVR for every family planning visit by a client of Oregon’s Reproductive Health Program. For complete information on filling out a CVR, see Section D.

**Other Important Reports and Dates**

Reporting deadlines and other important dates that apply specifically to recipients of federal grant funds (Title X or Title V) follow:

**Agency Reviews**
Agency reviews for Title X delegate agencies are scheduled on a rotating basis. (See Exhibit 5 of this section for a current schedule.)

**Annual Plan Request**
Each local public health authority must submit an annual plan for family planning services covering the period July 1 through June 30 of the succeeding year. The Reproductive Health Program will supply the required format, deadline and current service data for use in completing the plan.

**Annual Request for Information**
Known as “the January mailing,” this packet requests information required for the State of Oregon’s federal Title X grant application. It also provides the opportunity to update contact information and assess training needs. The request is usually sent to local agencies in early January and is due back to the state in approximately three weeks.
Budget Projection
A projected budget for Family Planning Services covering the period of July 1 through June 30 of the succeeding year is submitted to the Reproductive Health Program annually. The required format and due date are supplied by the Program, generally as part of the local agency contract process. See Exhibit 7 for a sample budget projection worksheet and instructions.

Local Agency Contracts
A contract outlining all requirements for funding must be signed annually between the State of Oregon and each local public health authority. The contract contains a specific program element for the Reproductive Health Program. This signing process takes place in May and June.

Expenditure Reports
Quarterly expenditure reports are due to the Office of Financial Services on October 25, January 25, April 25, and July 25. For more information on local agency contracts and expenditure reports, see Section B.7

Pap Smear Results
All agencies are now required to provide data about abnormal cervical cancer screening test results for the previous calendar year for purposes of the Federal Family Planning Annual Report. This information will be requested in the Annual Request for Information packet described above.
Agency Reviews

Agency reviews are part of an ongoing effort to evaluate and provide technical assistance to Title X-funded agencies. They are conducted on-site by OHA Public Health every third year, on a rotating basis. The Reproductive Health Program staff provides follow-up during the other two years.

The current on-site agency review schedule through 2015 can be found in Exhibit 5 of this section. In Exhibit 6, copies of the Reproductive Health Program Review, Reproductive Health Records Review, and Region X IPP/Family Planning Chart Audit tools are included.