# Republic of Palau
# Title X Family Planning Program
# Policy and Procedures Manual


Bureau of Public Health
Ministry of Health

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# Purpose

This Manual contains information necessary for providing family planning and reproductive health services as part of the Bureau of Public Health  services. It is intended for use by all Ministry of Health sites providing services funded under Title X Family Planning. The manual outlines federal and state policies and procedures applicable to Title X Family Planning.

The manual contains sections dealing with program administration, clinical protocols, quality assurance, and an appendix. In order for it to fulfill its purpose, the Manual must be properly maintained. The manual is reviewed and revised annually and changes are made to reflect changes in federal or state requirements.

# Title X Laws and Regulations

## Legislative Mandates

The following legislative mandates have been part of the Title X appropriations language for each of the last several years. Title X family planning services 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.

## Title X Statutes and Regulations

Requirements regarding the provision of family planning services under Title X can be found in the statute (Title X of the Public Health Service Act, 42 U.S.C. 300, et seq.) and in the implementing regulations which govern project grants for family planning services (42 CFR part 59, subpart A . Regulations that apply to grants for training to support family planning service delivery can be found at 42 CFR part 59, Subpart B ("Grants for Family Planning Service Training"). In addition, sterilization of clients as part of the Title X program must be consistent with 42 CFR part 50 subpart B, ("Sterilization of Persons in Federally Assisted Family Planning Projects"). Title X of the Public Health Service Act authorizes the Secretary of Health and Human Services (HHS) to award grants for projects to provide family planning services to any person desiring such services, with priority given to individuals from low–income families.

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)." Title X regulations further specify "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" (42 CFR 59.1). In addition, section 1001 of the statute requires that, to the extent practicable, Title X service providers shall encourage family participation in family planning services projects. Section 1008 of the Act, as amended, stipulates, "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning."

**Title X Key Issues**

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. The use of electronic technologies, such as electronic health record 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 individuals as the best protection against influenza.

**Title X Family Planning Program Priorities**

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, including adolescent abstinence counseling. 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 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.

## Palau State Legislation

### Child Abuse and Reporting

*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.*

The Bureau of Public Health, Ministry of Health adheres to and complies with the Palau National Code (PNC) that addresses child abuse, reporting of child abuse, child molestation, incest, or rape. The parts of PNC that apply to this requirement are sections:

§ 601. Declaration of policy.
§ 602. Definitions.
§ 603. Reporting procedure.
§ 604. Immunity of reporting persons from liability.

### 601. Declaration of Policy

It is the policy of the National Government to provide for the protection of children who are subject to abuse, sexual abuse, or neglect and who, in the absence of appropriate reports concerning their conditions and circumstances, may be further abused, sexually abused or neglected by the conduct of those responsible for their care and protection.

### 602. Definitions.

(a) "Abuse" means any willful or negligent act or punishment which results in harm or threat of harm to the physical or mental health of a child which leads to consequences including, but not limited to, death, fractures, burns, bleeding, disfigurement, severe bruises, severe psychological or emotional trauma, or illness not explainable on the basis of a disorder or natural occurrence.
(b) "Child" means any person under 18 years of age.
(c) "Neglect" means any willful or negligent act, which results in the failure to provide a child who is in the person's custody, with adequate nutrition, medical care, clothing, shelter, proper supervision or other basic needs, which results in the child's physical or mental health being threatened or harmed.
(d) "Responsible official" means any physician, dentist, intern, health assistant, medex, nurse or practical nurse, any school teacher or other school official, any day care worker, and any peace officer or law enforcement official.
(e) "Sexual Abuse" means any willful or negligent sexually related activity for the purpose of sexual gratification, pleasure or profit by any person, with a child under the age of 16 who is not the spouse of the perpetrator including but not limited to sexual intercourse, sodomy, masturbation, cunnilingus, fellatio, and fondling.

**603. Reporting procedure.**

(a) Every responsible official examining, attending, teaching or treating a child and having reason to believe that such child has had serious injury or injuries, inflicted upon him or her as a result of abuse, sexual abuse or neglect, shall report the matter within 48 hours to the Director of the Bureau of Public Safety, except when the report is to be made to a different person under subsection (c) or (d).

(b) If the report is not made in writing in the first instance, it shall be reduced to writing by the maker within 48 hours thereof. The report shall contain the name and address of the child and his or her parents or other persons responsible for his or her care if known, the child's age, the nature and extent of the child's injuries, including any evidence of previous injuries, and any other information that the maker of the report believes might be helpful in establishing the cause of the injuries and the identity of the person or persons responsible therefore.

(c) When attendance with respect to a child is pursuant to the performance of services as a member of the staff of a hospital or a government medical facility, such staff member shall immediately notify the Director of the Bureau of Health Services or another person in charge who shall make the report forthwith.

(d) If the person attending a child is a school teacher or other school official he shall report such abuse, sexual abuse, or neglect to supervisor or other person in charge of' the school and such matter shall then promptly reported by the latter to the Director of the Bureau of Public Safety within 48 when the supervisor or other person in charge received initial report.'

(e) Promptly and not later than 48 hours after receiving a report of child abuse, sexual abuse or neglect the Director of the Bureau of Public Safety shall investigate, prepare and submit a report to the Office of the Attorney General and to the Division of Social Services indicating the nature of abuse, sexual "abuse or neglect along with other information pertinent to the case.

**604. Immunity of reporting persons from liability**.

Anyone participating in good faith in the making of a report pursuant to this chapter shall have immunity from any liability, civil or criminal, that might otherwise be incurred or imposed. Likewise, any such participant shall have full immunity with respect to any evidence, oral or written or any other testimony, which he or she might provide in any judicial proceeding resulting from such report.

# Human Trafficking

## Anti-People Smuggling and Trafficking



### 3902. Definitions.

(a) "Child" means a person who is less than 18 years of age.
(b) "Commercial carrier" means a company, or the owner, operator or master of any means of transport, any vessel or aircraft, that engages in the transportation of cargo or passengers for commercial gain.
(c) "Company" means a corporation, partnership, or other entity that is not an individual.
(d) "Exploitation" means sexual servitude, exploitation of another person by and through prostitution, forced labor or services, or slavery.
(e) "Fraudulent passport and/or travel or identity document" means a passport, travel and/or any other identity document that:
(1) has been made or altered in a material way, by a person other than a person or agency lawfully authorized to make or issue the passport, travel and/or any other identity document on behalf of the country that issued the document; or
(2) has been issued or obtained through misrepresentation, bribery, corruption, duress, or in any other unlawful manner; or "
(3) is being improperly used by a person other than the rightful holder.
(f) "Illegal entry" means crossing the border of the Republic of Palau or any other country without complying with the requirements for lawful entry of that country.
(g) "People smuggling" means arranging or assisting a person's illegal entry into any country of which the person is not a citizen, including the Republic of Palau, either knowing or being reckless as to the fact that the person's entry is illegal.
(h) "People trafficking" means the recruitment, transportation, transfer, harboring or receipt of a person for the purposes of exploitation as described in sections 3905 or 3906 .
(i) "Receiving country" means any country into which a trafficked person is brought as part of an act of people trafficking.

(j) "Smuggled person" means any person who is a victim or object of an act of people smuggling, regardless of whether that person participated in the people smuggling.
(k) "Trafficked person" means any person who is the victim or object of an act of people trafficking.

**3903. Offense of people smuggling.**

Every person who engages in people smuggling shall be guilty of people smuggling regardless of whether the smuggled person arrives in the receiving country and upon conviction thereof shall be fined not more than $25,000, or imprisoned not more than 10 years or both.

**3904. Offense of aggravated people smuggling.**

Every person who engages in people smuggling under circumstances in which the life or safety of the smuggled person is, or is likely to be, endangered shall be guilty of aggravated people smuggling regardless of whether the smuggled person arrives in the receiving country, and upon conviction thereof shall be fined not more than $50,000 or imprisoned not more than 15 years or both.

**3905. Offense relating to fraudulent passport, travel and/or any other identity documents.**

Every person who makes, obtains, gives, sells, or possesses a fraudulent passport, travel and/or any other identity document for the purpose of facilitating people smuggling or facilitating the continued presence of a smuggled person in a receiving country shall be guilty of travel document fraud, and upon conviction thereof shall be fined not more than $25,000, or imprisoned not more than 10 years or both.

**3906. Offense of trafficking people**

Every person who knowingly or recklessly recruits, transports, transfers, harbors or receives any person or persons for the purpose of exploitation by threat, use of force, abduction, fraud, deception, abuse of power, or the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, shall be guilty of people trafficking, and upon conviction thereof shall be fined not more than $250,000, or imprisoned not more than 25 years or both.

**3907. Offense of trafficking in children.**

Every person who knowingly or recklessly recruits, transports, transfers, harbors or receives a child by any means for the purposes of exploitation shall be guilty of trafficking in children and upon conviction thereof, shall be fined not more than $500,000, or imprisoned for not more than 50 years or both. Every person who knowingly or recklessly engages in, participates in, or profits from the exploitation of a trafficked person shall be guilty of exploitation of a trafficked person and, upon conviction thereof, shall be fined not more than $50,000, or imprisoned for not more than 10 years or both.

**3909. Consent of trafficked person irrelevant.**

For sections 3905, 3906 and 3907 of this chapter, it is not a defense that the trafficked person consented to the people trafficking or to the exploitation.

**3910**. **Immunity of trafficked person.**

A trafficked person shall not be subject to criminal prosecution with respect to:
(a) The act of people trafficking;
(b) That person's period of unlawful residence in the receiving country; and
(c) That person's procurement or possession of any fraudulent travel or identity documents which he or she obtained, or with which he or she was supplied, for the purpose of entering the receiving country; and
(d) That person's illegal entry into the receiving country.

**3911. Penalty for non-citizen.**

Every non-citizen convicted under anyone of sections 3903, 3904, 3905, 3906, 3907, and or 3908 of this chapter shall have his or her entry permit revoked and shall be deported upon completion of any sentence imposed by this section. The Minister of Justice shall promulgate regulations for the deportation of persons pursuant to this chapter.

**3912. Scope of application.**

The offenses described in sections 3902,3903,3904,3905,3906, and 3907 of this chapter apply, regardless of whether the conduct constituting the offense took place inside or outside the Republic of Palau if:
(a) the Republic of Palau is the receiving country or the exploitation occurs in the Republic of Palau;
(b) the receiving country is a foreign country but the people smuggling or people trafficking started in the Republic of Palau or transits the Republic of Palau; or
(c) the person who engages in the people smuggling or people trafficking is a citizen of the Republic of Palau.

**3913. Obligation of commercial carriers.**

If a commercial carrier carries a person into the Republic of Palau and, upon entry into the Republic of Palau, the person does not have the passport and/or travel documents required for lawful entry, the commercial carrier shall be liable to pay the costs of the person's detention in, and removal from, the Republic of Palau unless:
(a) the carrier had reasonable grounds to believe that the documents that the person had were the travel documents required for lawful entry of that person into the Republic of Palau; or

(b) the person possessed the passport and/or travel documents required for lawful entry into the Republic of Palau when that person boarded, or last boarded, the means of transport to travel to the Republic of Palau; or
(c) entry into the Republic of Palau occurred only because of illness of or injury to person on board, stress of weather, or other circumstances beyond the control of the commercial.

## Abortion *Section 1008 of Title X Statute Abortion Prohibition*

*"None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning."*

Title 17 of the Palau National Code states that every person who shall unlawfully causes the miscarriage or premature delivery of a woman, with intent to do so, is guilty of the crime of abortion and upon conviction thereof shall be imprisoned for a period of not more than five years.

# Program Administration

### Policy 101. *Family Planning Organizational Structure*

The Title X Family Planning Program is administered by the Ministry of Health, Bureau of Public Health, Division of Primary and Preventive Health, Family Health Unit pursuant to an agreement with the United States Department of Health and Human Services, Office of Population Affairs.

Family Health Unit is responsible for administering the portion of the Title X grant in Palau that comes to the Bureau of Public Health, Ministry of Health. The unit has multiple programs focusing on the health of men, women, children and families including: Maternal and Child Health Title V programs, Family Planning Title X programs, Early Childhood Comprehensive System, Universal Newborn Hearing Screening, school health programs, and newborn metabolic screening program. The unit works closely with the HIV/STD program and the Cancer Program as well as other public health programs within the bureau.

### Policy 102. *Program Description*

Family Planning is a basic health service essential for the promotion of optimal family health throughout the life cycle. Family Planning consists of the educational, comprehensive medical and social services necessary to aid individuals to determine freely the number and spacing of their children. The program strives to improve the health of families through education, health

promotion, health screening and the advantageous timing and spacing of pregnancies. The overall goal of the program is to provide information and means whereby individuals can exercise personal choices in determining the number and spacing of their children. This is accomplished through provisions of a broad range of acceptable and effective Family Planning methods and services.

**Policy 103.** ***Eligibility***

Any client requesting family planning services. No person shall be denied services due to inability to pay. Family Planning program must assure that priority is given to persons from low income families. Clients from low income families may not be charged for services, including the provisions of contraceptives or related medical services.

**Policy 104.** ***Non Discrimination***

Services are provided without regard to religion, race, color, national origin, creed, handicap, gender, number of pregnancies, marital status, age, sexual orientation or contraceptive preference.

**Policy 105.** ***Confidentiality***

Every effort is made to assure client confidentiality and provide safeguards for individuals against the invasion of their personal privacy. Information about clients that receive services may not be disclosed without 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 be disclosed in summary, statistical or other form that does not identify the individual.

**Policy 106.** ***Adolescent and Confidentiality***

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 sites may not require written consent of parents or guardians for the provision of services to minors. Nor can the sites notify parents or a guardian before or after a minor has requested and received Title X family planning services.

**Policy 107.** ***Confidentiality and Release of records***

A 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. 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 that 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.

**Policy 108.** ***Voluntary Participation***

Services are provided solely on voluntary basis. Individuals are not subjected to coercion or discrimination in the delivery of services, or to use any particular method of family planning. Acceptance of family planning services is not a prerequisite to eligibility of any other services, assistance, or participation in any other program. Clients are encouraged to ask questions, and may refuse a service or stop services at any time.

Family planning staff 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.

**Policy 109.** ***Conflict of Interest***

Project employees and consultants must not use their positions to influence a decision that may result in personal gain for themselves or a relative as a result of business dealings.

**Policy 110.** ***Prohibited Activities***

Activities that cannot be funded under the project include abortion, fund-raising, and lobbying activities. All Ministry of Health sites providing family planning services adheres to program mandates and regulations.

**Policy 111.** ***Human Subjects Clearance (Research)***

Programs 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. The Bureau of Public Health will advise the Regional Office in writing of research projects involving Title X clients or resources.

**Policy 112.** ***PUBLICATION 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. Publications developed under Title X must 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 an irrevocable right of the Government to reproduce, publishes, or otherwise uses such materials for Federal purposes and to authorize others to do so.

**Policy 113.** ***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.

**Policy 114.** ***Reporting***

**A**. Palau Family Planning program annually reports aggregate characteristics of family planning users to the DHHS and Region IX Title X Office of Family Planning as required by the Office of Population Affairs. This information is obtained from the Family Health Unit Family Planning Encounter Database. All Ministry of Health service sites providing family planning services must provide data through the FHUFP database for the completion of this report.

**B**. Beginning January 1, 2005, the Family Planning Annual Report (FPAR) requirements include:

1. Number of clients at or below 100% of Federal Poverty Level (FPL)
2. Number of clients between 100% and 150% of FPL
3. Number of clients between 150% and 200% of FPL
4. Number of clients between 200% and 250% of FPL
5. Number of clients above 250% of FPL
6. Number of clients by race, ethnicity, gender, and age
7. Number of clients with Limited English Proficiency (LEP)
8. Program income sources
9. Male and female contraceptive users by age and primary method when they leave clinic
10. Unduplicated number of family planning users by principal health insurance coverage status
11. Number of clients receiving cervical cytology screening and number with positive cervical cytology screenings

12. Number of clients receiving clinical breast exams and referred for further evaluation.
13. Number of sexually transmitted infection (STI) and human immunodeficiency virus (HIV) tests and number of positive confidential HIV tests.
14. Family Planning encounters by clinical service providers (e.g. physician, nurse practitioner, physician's assistant) and non-clinical service providers (e.g. registered nurse, health educator, social worker and clinic aides).

**Policy 115.** ***Staff Development and Trainings***

The Family Planning Program collaborates with a variety of agencies and programs to develop and provide training and educational opportunities for all personnel providing family planning services throughout the year. The Region IX Title X Office of Family Planning provides training and technical assistance to the program.

**Policy 116.** ***PERSONNEL POLICIES***

Project must 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 1 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.

1. Personnel records must be kept confidential.

2. An organizational chart and personnel policies must be available to all personnel.

3. Job descriptions must be available for all positions, reviewed annually or as specified by agency policy and updated when necessary to reflect changes in duties.

4. An evaluation and review of the job performance of all project personnel must be conducted annually.

5. Licenses of applicants for positions requiring licensure are verified prior to employment and documentation of licenses is kept current.

6. Protocols exist that provide all project personnel with guidelines for client care.

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**Policy 117.** ***Information and Education Materials***

The Bureau of Public Health Community Advocacy Program must review and approve all information and education materials developed or made available for use in service sites. This includes billboards, banners, brochures, pamphlets, etc. Written materials and community presentations must acknowledge support of Title X funding.

**Policy 118.** ***Client Education***

Program must have plans for client education. The education provided should be appropriate to the client's age, language, and socio-cultural background and be presented in an unbiased manner. Education must be provided to the clients on information on:

1. Informed decision on family planning.

2. Available methods of contraception and adverse effects.

3. Self examination for breast and testicular.

4. Risk reduction for HIV/STI

5. Available services and clinic procedures

6. Importance of screening/test and other procedures involved in a family planning visit.

Clients should be offered information on basic reproductive anatomy and physiology. Education should include information on reproductive health, health promotion/disease prevention. Information on preconception health and reproductive health plan should be provided to all clients. Additional information should include exercise, nutrition, alcohol and drug abuse, tobacco and betel nut use, domestic violence, and sexual abuse.

**Policy 119.** ***COMMUNITY EDUCATION AND PROJECT PROMOTION***

Project must provide for community education programs. 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.

To facilitate community awareness of and access to family planning services, project must establish and implement planned activities whereby their services are made known to the community. Project should review a range of strategies and assess the availability of existing resources and materials.

**A.** A variety of strategies should be used for community education based on the objectives of the program and the intended audience. These may include:

1. Distribution of educational materials
2. Educational sessions to:
a. Schools
b. Community groups
c. Professionals;
3. Assisting community schools and groups in the development of family life and human sexuality curricula.
4. System for handling telephone requests for information

**B**.Community education activities should be directed toward target groups:

1. Teens
2. Parents
3. Teachers, school counselors, school nurses, school principals and school board members
4. Clergy
5. Medical professionals and workers in health settings
6. Members of minority populations
7. Members of the media
8. Community leaders in business and/or government
9. Workers in youth service agencies, community service offices, drug rehabilitation centers, crisis centers and mental health centers.

**Policy 120.** ***Provisions of Services***

**42 CFR 59.5**

Each project supported 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.
(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 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 sub grantees 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 sub grantees in the ongoing policy decision making of the project.
(11). 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.
(12). 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.
(13). Provide for informational and educational programs designed to inform the community on the availability of the services.
(14). Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(15). 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.

**Policy 121.** ***Priority for Services***

All Family Planning service sites must ensure that clients with income at or below 100% of the Federal Poverty Level receive priority for services.

**Policy 122.** ***Income Determination***

1. Income information are obtained from all family planning users, documented and updated annually. All Title X users are placed on a sliding fee scale regardless of whether or not they have a third party payer.

2. Income determination for minor users are based solely on the minors' income.

3. Users who report no income are not required to prove absence of income.

**Policy 123.** ***Billing and Collection***

Project 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.

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

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.

3. Clients whose documented income is at or below 100% of the Federal poverty level must not be charged.

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

5. Client income are to be re-evaluated at least annually.

6. For clients from families whose income exceeds 250% of the poverty level, charges are set to recover the reasonable cost of providing services.

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

8. Individual financial circumstances will be considered in billing and collecting of outstanding accounts.

**Policy 124.** ***Financial Audits***

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.

**Policy 125.** ***Limited English Proficiency Population***

Title VI of the Civil Rights Act of 1964 prohibits recipients of federal financial assistance from discriminating against or otherwise excluding individuals on the basis of race, color, or national origin in any of their activities. Section 601 of Title VI, 42 U.S.C. 200d provides no person in the United States shall, on the ground 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.

Program must develop and implement a plan to ensure meaningful access to services by Limited English Proficient (LEP) persons. Program must provide language assistance to LEP clients at no cost to the client. Assistance may be in the forms of educational materials in languages other than English or Palauan. Bilingual MOH staff may be used as interpreters. Program may also use community volunteers who are competent in interpreting.

**Policy 126.** ***Accessibility***

Program complies to 45 CFR Part 84 which require all programs and activities of those receiving federal funds to provide accessibility to individuals with disabilities. Facilities providing services should be geographically accessible to clients and should be available at times convenient to the population served. Clinics should have evening or weekend hours in addition to day time hours. Clinic facilities should be adequate to provide the necessary services and ensure comfort and privacy for clients.

**Policy 127.** ***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.

1. Equipment and supplies shall be safe, adequate, and appropriate to the type of care offered by the project.

2. It is the responsibility of the project to assure proper selection and maintenance of equipment and supplies.
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3. Appropriate procedures are followed for purchase and disposition of equipment costing $5,000 or more.

**Policy 128.** ***PHARMACEUTICALS***

Project must be operated in accordance with Federal and Palau laws relating to security and record keeping for drugs and devices. The inventory, supply, and provision of pharmaceuticals must be conducted in accordance with Palau 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.

**Policy 129.** ***Scheduling and Appointments***

1. Appointments should be scheduled based on the type of visit (initial, annual, or follow-up).

2. Appointments should be staggered to match client arrival to staff availability.

3. Client should be seen based on the order of the appointment.

4. Clients who do not show up for their scheduled appointments should be contacted and rescheduled for another appointment.

5. Emergencies are exception to these policies and are treated on walk-in basis.

6. Contraceptive refills do not require a scheduled appointment.

7. All referrals, lab works, and other required services should be accomplished at the time of the client appointment.

8. Clients are surveyed annually to evaluate the acceptability and accessibility of services.

**Policy 130.** ***Medical Records***

All clients who obtain clinical services must have a medical record. Records should be maintained and comply with accepted medical standards and state statues. Service sites are responsible to maintain complete and total confidentiality of all client information collected, filed or stored. All medical records should be:

1. Confidential

2. Complete, legible and accurate.

3. Signed by a clinician or an appropriate health professional making entries including, name, title, and date.

4. Organized to facilitate prompt retrieval and compilation of information.

5. Secured and locked when not in use.

6. Safeguard against loss or use by unauthorized person.

7. Information may be disclosed only in summary or other forms that do not identify the individual client.

**Policy 131.** ***Chart***

A client's chart must contain sufficient information to identify the client including contact information, clinical diagnosis, and treatment information. The chart should include the following:

1. Personal data
2. Medical history, physical exam, laboratory test orders, results, and follow-up
3. Treatment and special instructions
4. Scheduled revisits
5. Informed consents – initial and annual updates
6. Refusal of services
7. Allergies and untoward reactions to drug(s) recorded

**Policy 132.** ***Method Specific Consent Forms***

1. Each method specific consent form serves to document the provision of information about the risks, benefits, and side effects of the specific method of contraception chosen by the client.
2. Before a client may be given a method of contraception, all information contained on the form for her/his chosen method must be discussed with the client. The method specific consent form must be signed by the client and by the person providing the method counseling prior to the provision of any method.
3. The original of the form(s) must be filed in the client's record.
4. If a manufacturer requires a special consent form it must also be signed (i.e., IUD) and placed with other method specific consent forms.
5. The method specific consent form must be updated annually, or when there is a three-month break in use, a change in client's risk status for the prescribed method, or a change to a different method of contraception.

**Policy 133.** ***Minor Consents***

Minors (under age 18) seeking family planning services may self-consent for comprehensive family planning services.

***Does not include sterilization procedures or hormonal implants***

**Policy 134.** ***MEDICAL EMERGENCIES and NON-MEDICAL 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 and non-medical emergencies.

# Clinical Services

**Policy 201.** ***Service Plan and Protocols***

Medical policies and protocols shall be reviewed and approved by the Medical Director and the Director of the Bureau of Public Health. Policies and protocols should be consistent with Title X Guidelines and be based on current standards of care or recommendations from nationally recognized standards.

All Title X service sites must have a service plan that identifies those services to be provided to clients under Title X. The plan must be written in accordance to Title X program guidelines, state laws and current medical practices, and must cover services provided at the initial visit, annual visits, and other revisits including contraceptive supply and other problem revisits. All clinical protocols are documented in the provider's manual. The provider manual must be reviewed and updated annually.

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

Patients shall be afforded access to a comprehensive, age-appropriate reproductive health/family planning education and services. The program shall meet their particular and individual health needs and include information about his/her current health status, family planning information, sexually transmitted diseases and prevention, and general health education. Clinicians shall attend to the special health needs of females including, but not limited to, their unique developmental and reproductive health needs.

Services provided to a client at a family planning visit 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, counseling, consent, history, physical assessment, appropriate laboratory testing, necessary referral and follow-up.

**Policy 202.** ***Initial Visit (New Clients)***

At a minimum, the initial history must cover the following areas:

## A. Education and Counseling

1. Client education, including use of relevant educational materials (pamphlets, audiovisual, brochures, etc.).
2. Education includes information about all contraceptive methods including common side effects.
3. Information about basic male and female reproductive anatomy and physiology.
4. Information on health promotion and disease prevention including nutrition, exercise, alcohol, tobacco and drug use, domestic violence, sexual abuse.
5. Education and counseling on developing a reproductive life plan.
6. Information on fertility regulation in maintaining individual and family health.
7. HIV/AIDS and STI education and information must be offered to clients.
8. For adolescent clients, information on the importance of parental involvement.
9. Client education should be individualized as much as possible based upon client needs and knowledge.
10. Explanation of all procedures and range of available services.
11. Information on consent covering examination and treatment and where applicable a method specific informed consent form.
12.Emergency phone number.
13. Information on available clinic services and what to expect during the clinic appointment.
14. Information about routine screening test and what to expect on a family planning visit.

## B. Personal, Family, Social History

1.Chronic or acute medical conditions
2. Previous hospitalizations
3. Sexual risk behavior
4. Drug/substance abuse
5. Pregnancies
6. Current or previous methods of birth control
7. Major illnesses including STIs
8.Hepatitis
9. OB/GYN problems
10.Diabetes
11.Hypertension
12. Sexual History
13. Partner history
14. Smoking
15. Cancer
16. Heart Disease
17. Immunization

**C. Physical Examination**

A physician or a nurse practitioner should perform all initial and annual physical examination. A physical examination includes:

1. Blood Pressure Reading
2. Assessment of Height/Weight/BMI
3. Heart
4. Lungs
5. Clinical breast exam including instructions on self examination
6. Abdomen
7. Extremities
8. Rectum
9. Pelvic Exam/Pap Smear
10. Testicular exam for male
11. Cancer screening –Age appropriate
12. STI and HIV screening

Clients must be counseled about the importance of the above preventive services, and the dangers and health risks involved if they defer or decline them. If the client decides to decline or defer a service, both the counseling that took place and the reason for the deferral must be documented in the client record.

**D. Laboratory Testing**

Service site must provide the following laboratory procedures.

1. Anemia Assessment
2. Gonorrhea and Chlamydia test
3. Diabetes Screening
4. Lipids Profile
5. Hepatitis B test
6. Syphilis
7. Urinalysis
8. HIV test
9. Vaginal wet mount
10. Pregnancy test
11. Colo-rectal screening

**E. Initiate appropriate referrals**

1. Mechanism of client follow-up
2. Provisions of referrals as needed

**Policy 202.** ***ANNUAL VISIT (established clients)***

An annual visit must include an update from the initial visit including the following:

**A.History**

1. Obstetrical history
2. LMP
3. Medical history
4. Gynecologic history
5. Family history
6. Allergy history
7. Contraceptive history
8. Sexual history
9. Psycho-social history
10. Miscellaneous Information:

a. Review current medication intake
b. Review smoking/alcohol/drug abuse

**B. Physical Assessment**

Same as initial visit

**C. Education and counseling**

Contraceptive assessment
Counseling and education covered in initial visit

**D. Appropriate laboratory testing**

Routine testing and others as needed

**E. Initiate appropriate referrals**

1. Mechanism of client follow-up
2. Provisions of referrals as needed

**Policy 204.** ***New clients electing non-prescription methods of contraception***

1. Clients must be counseled about the importance of preventive services, and the dangers and health risks involved if they defer or decline them. If the client decides to decline or defer a service, both the counseling that took place and the reason for the deferral must be documented in the client record.
2. Clients should be encouraged to have a routine exam and appropriate laboratory testing performed.

**Policy 205.** ***Contraceptive Follow-up***

1. Clients should be seen after initiating a prescription method of contraception:
   A. Hormonal Contraceptives
   B. IUD Copper Bearing
   C. Diaphragm
2. This type of visit should also apply to clients who need additional contraceptive supplies but do not need other services. For routine refills with no reported problems, a clinical judgment based on the client information should be utilized to determine additional services provided.
3. Service provided includes:
   A. Method specific history
   B. Method specific exam
   C. Weight and blood pressure measurement
   D. Lab as necessary
4. Other services may be provided based on the clinicians' judgment.

**P***olicy 206. ORAL CONTRACEPTIVE (OCP) REFILL VISIT*

**New Clients**

Should be monitored after 3 months. A new client who chooses to continue a method already in use may choose not to return for this early revisit unless a need for re-evaluation is determined based on the findings of the initial visit. Oral contraceptive refill counseling is provided in a structured interview session. It incorporates the following areas routinely but is not necessarily limited to:

1. A brief update of LMP, obstetrical, contraceptive, gynecological and medical histories, and current use of medications, or changes in smoking habits.
2. An assessment of the client's correct utilization of the method, satisfaction with the method, and knowledge of how to make up missed OCP's.
3. A review of minor side effects and provisions of counseling appropriate to resolution/relief if a problem is identified.

4. Screening for symptoms of serious, possibly life threatening complications and appropriate referral of the identified problem including:
a. Shortness of breath
b. Severe chest pain
c. Severe, persistent headaches
d. Visual disturbances (double vision-blurring)
e. Severe pain, redness or numbness in extremity
f. Hypertension
g. Acute abdominal pain

**Policy 207. *Problem Visit***

1. Clients with problems related to contraceptive use should be scheduled for a problem visit.
2. Emergencies are treated as walk-ins and do not require a schedule.
3. Client history must be obtained.
4. Symptoms must be analyzed
5. Physical assessment as needed
6. Reassess current contraceptive status
7. Provide needed treatment using clinical protocols as identified in the provider's manual.
8. Initiate appropriate referrals.

**Policy 208. *Male Client Visit***

Men may accompany their partners who are clients to the clinic, or they may come to the clinic as clients. Some existing family planning clinics are not prepared to offer men a full range of health care services; however, educational services and limited medical services including STD screening and treatment are available for men. Counseling and referral for sterilization, infertility education, and provision of birth control methods are provided if appropriate.

**A. The Major Disease History**

Provides a quick overview of the individual and family history of disease. In addition to these, the interviewer should ask about a personal history of STD or other infections involving the genitals.

The following is a list of issues that should be addressed:

1. BP, Wt as indicated
2. Urinary symptoms such dysuria, frequency, nocturia, hematuria
3. Painful ejaculation
4. Urethral discharge
5. Genital lesion, recent, past or persistent

6. Sexual history
a. Partners – male, female or both; how many partners?
b. Homosexual activities (oral and/or anal sex); how many partners?
c. Bisexual activities; how many partners?
7. Significant illnesses, recent hospitalization and previous medical care
8. History of contraceptive use
9. Instruction on self-exam for testicular cancer
10. Current medication: prescription, over the counter, drug use, alcohol, smoking, street drugs
11. History of STD/HIV (Hepatitis B)
12. Depression screen
13. Violence/rage screen
14. Tobacco, Alcohol and Drug use

**Policy 209.** ***POSTPARTUM VISIT***

Ideally, clients will have their postpartum exam done by the physician who provided prenatal care and delivery. Attempts to obtain records of prenatal care and delivery should be made.

**A.NEW -** postpartum client, initiate initial visit protocol, counseling.

**B.REVISIT -** postpartum client, initiate annual visit protocol, and counseling.

**C. Review Ob Discharge Summary (if available)**

1. Date and Method of delivery (vaginal or cesarean)
2. Infant's sex, weight, health status
3. Complication of pregnancy and/or L & D:
a. Hemorrhage
b. Infection
c. Pregnancy-induced hypertension
d. Gestational diabetes
e. Premature rupture of membranes
f. Premature delivery
g. Other
4. Length of hospital stay

**D. Other Concerns**

1. History of coitus since delivery and birth control method used.
2. Review when client may resume coitus and discuss associated fears
3. Knowledge of breast care/presence of breast engorgement
4. Infant feeding choice/concerns/immunizations/referral
5. Postpartum depression signs or symptoms
6. Bladder and bowel function

7. Support and help at home
8. Sleep patterns and rest
9. Resolution of lochia, onset of menses
10. Current medication
11. Status of episiotomy, or abdominal incision
12. Contraceptive plans

**E. Initiate Appropriate Referrals**

**Policy 210.** ***Abnormal Results***

**A.Notification and referrals**

Procedures must be established that addresses confidentiality so that clients can be notified about abnormal results and receive adequate follow up. Follow up contacts and referrals must be documented in a client's record. Client must be advised of the referral and the follow up appointment. Contact information for the client should be obtained at the initial visit, noted in the client's record and updated as needed. All attempts to contact a client should be documented in the client's record.

STI treatments must be provided on site and referred to HIV/STI program. Treatments and follow-up procedures for positive test must comply with current CDC guidelines.

Abnormal results for Pap smear and Breast Exam must be referred to the Cancer Program.

**Policy 211.** ***Contraceptive Methods***

**A.Family Planning Methods**

1. Nonhormonal methods of contraception (male and female barrier methods, intrauterine devices (IUD), fertility awareness, natural family planning) and hormonal methods (oral contraceptives, OrthoEvra patch, and Mirena intrauterine system (IUS).
2. Permanent methods of contraception include vasectomy for males and tubal ligation for females.

**B.Services and Protocols for Methods Provided**

1. **Abstinence**
    a) Follow-up annual preventive health examination
2. **Condoms**
    b) Follow-up: Annual preventive health examination
3. **Combined Oral Contraceptives**
    a) Family Planning staff may issue up to three packets of oral contraceptives at the time of the client's first visit. A return visit must be scheduled to assess for complications.

b) Instructions on when to start pills
   1) First Day Start: First day of menses
   2) Quick Start: If emergency contraception (EC) is not indicated and pregnancy can be ruled out, have client take first pill in the office, then give two weeks follow up appointment to repeat pregnancy test.
   3) If EC is indicated take two pills of Plan B or equivalent and start oral contraceptives the next day.

c) Emergency contraception (EC) is a therapeutic option for women who experience an act of unprotected sexual intercourse. It has also been called the "morning-after pill", interception, and postcoital contraception. Methods to achieve emergency contraception include use of combination oral contraceptives. The Family Planning Program authorizes only the use of oral contraceptives for emergency contraception. Oral combined hormonal contraceptives may be used if Plan B is unavailable.

d) Referrals for clients with the following conditions who desire combined oral contraceptives must be referred for management of that condition:
   a. Poorly controlled diabetes mellitus
   b. Uncontrolled hypertension
   c. AIDS
   d. Active renal disease
   e. History of internal organ cancer or melanoma
   f. Cardiovascular conditions requiring medical management
   g. Migraine or vascular headaches requiring medical management
   h. Other significant conditions requiring ongoing medical management

4. **Contraceptive Spermicide** (Foam, Film, Suppository, Jelly or Cream)
   a) Follow-up: Annual preventive health examination
5. **Diaphragm** (Vaginal Barrier Contraceptive)
   a) Refer clients with signs and symptoms of Toxic Shock Syndrome or unresolved dysplasia.
6. **Fertility Awareness/Natural Family Planning** can be a very complicated method to use requiring education of the client by a qualified instructor. This is not a method to be taught by a health care provider who does not have an adequate background and training. Clients selecting this method should be referred to a qualified instructor.
7. **IUD – Copperbearing**
   a) Required services are
      1) Gonorrhea/chlamydia test result is negative within ninety days
      2) Hemoglobin if history of severe anemia or excessive bleeding
      3) Pregnancy test if not on menses, or not on a reliable form of contraception, or as indicated by history
      4) Current normal pap (within 1year)
      5) Women who have had at least one child
      6) Women who are in a stable, mutually monogamous relationship
      7) No history of pelvic inflammatory disease (PID) in recent past

8). Insertion: IUDs should be inserted at any time during the menstrual cycle, after pregnancy has been ruled out, to prevent inconvenience to the client.

**8. Medroxyprogesterone Acetate (Depo-Provera Contraceptive Injection**)

a) Required Services are:
   1) Negative pregnancy test at initial exam unless client is currently on a reliable method of contraception.
   2) Risk Factors
   3) In women with osteoporosis risk factors, health care providers should consider individual client history in assessing the risk/benefit analysis for the use of Depo-Provera Contraceptive Injection.
   4) Osteoporosis risk factors include metabolic bone disease, chronic alcohol and/or tobacco use, anorexia nervosa, strong family history of osteoporosis, chronic use of drugs that can reduce bone mass, such as anticonvulsants, or cortocosteroids, and/or have used Depo-Provera Contraceptive Injection for greater than two years duration.
   5) Women who use Depo-Provera Contraceptive Injection may lose significant bone mineral density.
      1) Bone loss is greater with increasing duration of use and may not be completely reversible.
      2) It is unknown if use of Depo-Provera Contraceptive Injection during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass.

**9. Progestin-Only Oral Contraceptives**

1. When to Start Pills
   a. First day of menses
   b. At six weeks postpartum if breastfeeding
   c. Immediately postpartum if not breastfeeding
   d. As directed by health care provider

**10. Jadelle** -is an effective, reversible contraceptive that prevent pregnancy for up to five years. Two thin, flexible rods filled with a synthetic progestin are inserted just under the skin of your upper arm. The implants should be inserted within 7 days after the onset of menstrual bleeding. If they are inserted at any other time, a client will need to use an additional non-hormonal (barrier) method for the following 7 days.

**11. Voluntary Surgical Sterilization**

a) Voluntary Surgical Sterilization must be considered a permanent method of contraception and not the method of choice for the client who would consider future pregnancies under any circumstances.
b) Sterilization may be requested for a specific client by life threatening condition.
c) Contraindications
   1) Client desiring future children
   2) Client less than 21 years of age
   3) Institutionalized client
   4) Inability to give informed consent
   5) Major surgical or anesthesia risk

6) Other Considerations
    a) Age, parity or lifestyle of client that is at either end of the reproductive continuum.
    b) Contraindications to other methods

d) Mechanism of Action
    1) Tubal Ligation: Fallopian tubes are cut to prevent the sperm and egg from uniting
    2) Vasectomy: Blocks the vas deferens to prevent the passage of sperm

e) Major Risks
    1) All risks associated with surgery and anesthesia
    2) Should pregnancy occur there is an increased risk of ectopic pregnancy.
    3) Post vasectomy hydrocele or spermatocele

f) Management of Common Complaints
    1) Postoperative abdominal distention is normal
        b) Clients should be counseled to walk frequently and increase fluid intake
    2) Take medications as prescribed by contracting physician for minor discomfort.
    3) Bruising or mild hematomas are normal and will resolve without treatment

g) Long Term
    1) Changes in menstrual pattern must be assessed for causative relationship to tuballigation. If not related to tubal ligation, must be referred for evaluation
    2) Hydrocele or spermatocele: Refer to physician for assessment.

**Policy 212.** ***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 a family planning agency. This opportunity must be taken to provide education and counseling about family planning.

Written protocols and procedures must meet the following standards:

**A**. Pregnancy diagnosis services include:

1. Informed consent
2. History
3. Physical exam, including pelvic exam. If a physical exam, including pelvic cannot be performed at the time of the pregnancy test, the client must be counseled about the importance of the physical assessment and early prenatal care. This can be done on-site or through a referral.
4. Pregnancy test with high sensitivity

**B**. Pregnancy counseling services must be provided in a non-directive, unbiased manner. If requested to provide such information and counseling, provide neutral, factual information 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.

If the pregnancy test is positive, all of the following counseling options to manage the pregnancy must be offered if appropriate:

1. Prenatal care and delivery;
2. Infant care or adoption;

Clients with positive pregnancy tests who elect to continue the pregnancy must receive a referral for early prenatal care. They should also be counseled 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, alcohol and exposure to x-rays).

If the pregnancy test is negative, but other clinical indicators are present for pregnancy, client must be encouraged to have a repeat pregnancy test within the appropriate time frame. Prescriptive methods of birth control should not be given if pregnancy is suspected. Women with a negative pregnancy test should have the cause of their delayed menses investigated.

If an ectopic pregnancy is suspected, the client must be referred for immediate diagnosis and treatment. Clients with a history of pelvic inflammatory disease (PID) (due to Chlamydia and other STIs) are at high risk for ectopic pregnancies. Follow-up with these clients must occur and all contact must be documented in the medical record and initiate appropriate referral.

**Policy 213.** ***ADOLESCENT SERVICES***

Services for adolescents should follow the standard of care as outlined for initial and annual visits. They also must include:

1. Appointments- adolescent appointments for counseling and clinical services should be made as soon as possible.
2. Counseling
a. Regarding their decision to be sexually active.
b. Regarding resisting coercive sexual activity.
3. Discussion ff Contraceptive Methods-must include all methods of birth control and safer sexual practices to reduce the risk of STDs, including abstinence as the most effective method.

4. If a Contraceptive Method Is Prescribed- the adolescent must be encouraged to share that information with an adult member of the family.
5**.** Confidentiality Statement- adolescents must be assured that counseling services are confidential and if follow-up is necessary every attempt will be made to assure privacy.

Parents or guardians cannot be notified before or after a minor has requested or received Title X services without written consent. A provision for the notification of a parent in the event that a life threatening condition is identified must be included in the consent for services. This provision is exercised only if the minor is unwilling or unable to follow up on referrals.
All clients under the age of 18 must be encouraged to talk with their parents about their decision to seek family planning services.

***Does not include sterilization procedures or hormonal implants***

**Policy 214.** ***GYNECOLOGIC SERVICES***

Family planning delegate agencies should provide for the diagnosis and treatment of minor gynecologic problems 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 dipstick testing.

**A**. On the spot diagnosis and treatment should include:
1. Vaginitis/vaginosis
2. Urinary tract infections

More complex procedures, such as colposcopy, may be offered, provided that clinicians performing these services have specialized training.

Project must participate in the Breast and Cervical Cancer Control Program (BCCCP) for client cervical cancer diagnostic services unless other arrangements for payment are in place. Initiate a referral for eligible clients.

**Policy 215.** ***SEXUALLY TRANSMITTED INFECTIONS (STI) AND HIV/AIDS***

Project must make available detection and treatment of the more common STIs. 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 to all clients.

**A**. Sexually transmitted infections written protocols and operating procedures must be in place that meets the following required standards and should be in place for all other items:

1. Screening and treatment for all sexually transmitted infections must follow current Centers for Disease Control and Prevention STI Treatment Guidelines.

2. Chlamydia tests should be provided annually for high-risk clients, especially those who are ages 15-24. Positive cases should be treated on site and referred to HIV/STI for further testing and follow-up.

3. Gonorrhea testing should be offered annually to high risk clients.

4. Project must comply with State and local reporting requirements.

5. When treatment for any STI is provided on-site, the service site must ensure appropriate measures are taken with all persons treated.

6. Test for syphilis, as needed.

8. Screening for other STIs as indicated.

**B**. HIV/AIDS written protocols and operating procedures must be in place to meet the following required HIV/AIDS services:

1. Education on HIV infection and AIDS

2. HIV/AIDS risk assessment, counseling regarding risk reduction and referral services

3. Discussion of HIV infection and AIDS must be presented in all appropriate educational sessions within the community

4. Testing or referral for testing

5. All clinical staff must receive in-service training regarding:
a. HIV infection and AIDS and its prevention
b. Transmission and infection control.

**Policy 216.** ***Level I Infertility Services***

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

**A. Level I:** Includes initial infertility interview, education, physical examination, counseling, and appropriate referral.

**B.Level II**: Includes such testing as semen analysis, assessment of ovulatory function and postcoital testing.

**C. 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 services may be offered in projects with clinicians who have special training in infertility. Level III services are considered beyond the scope of Title X program.

**Policy 217.** ***SPECIAL COUNSELING***

Clients should be offered appropriate counseling and referrals 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. Preconception counseling should be provided if the client's history indicates a desired pregnancy in the future.

**A**. Service site should provide nutritional problem identification, basic nutritional information, screening and medical care to clients at high risk of nutrition problems or those requiring nutritional management of disease.
1. At a minimum, each client having a low hematocrit/hemoglobin should be interviewed to determine if the cause could be a nutritional deficiency. Information on dietary source of iron should be given as appropriate.

**B.** Preconception counseling should be provided if the client's history indicates a desired pregnancy in the future.

**Policy 218.** ***IMMUNIZATION***

1. Clinic staff should review immunization status of all clients. This review may include MMR, HPV, Tdap, Hepatitis B, Varicella, Influenza, Meningococcal Conjugate, and Pneumonia as appropriate.
2. Follow the policies and procedures of the Bureau of Public Health when administering immunizations to family planning clients.
3. Immunizations administered in the family planning clinic must be documented in the client's record. Consents for vaccines should be placed in the client's record.
4. If the client declines immunization, that should be noted in the record.
5. Clients should be provided with referral information about vaccines if they are not available in the family planning service site.

# Quality Assurance and Audit

**Policy 301.** ***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:

1. An established set of clinical, administrative and programmatic standards by which conformity would be maintained.

2. A tracking system to identify clients in need of follow-up and/or continuing care including: Pap test results and follow-up, the need for colposcopy, mammography results and necessary follow up if done, laboratory tests and radiologic studies, pathology reports and any afterhours emergencies.

3. Ongoing medical audits to determine conformity with agency protocols.

4. Peer review procedures to evaluate individual clinician performance, to provide feedback to providers, and to initiate corrective action when deficiencies are noted.

5. Annual review of medical protocols to insure maintenance of current standards of care.

6. Periodic client satisfaction surveys for input on services provided both on-site and by referral.

7. Ongoing and systematic documentation of quality assurance activities.

8. Ongoing evaluation of outreach activities

9. Annual quality improvement projects.

10. Equipment maintenance checks and calibration of equipment on a regular basis.

11. Annual review of educational materials used in both the clinic setting and community education activities.

12. Annual review of all forms used for completeness and applicability.

13. Emergency drugs and supplies checked routinely.

14. The process for monitoring the reliability and accuracy of the local client data system assures program performance, quality care, and generating of maximum revenues. The following components should be monitored:
a. Missing user data
b. Coding error editing
c. Data outcome

**Policy 302.** ***Chart Audit***

The Bureau of Public Health Family Planning Chart Audit is to assure documentation of quality family planning services.

The chart audits must evaluate the care provided to a variety of types of family planning clients. The following chart audit requirements are provided:

1. Chart audit are to be conducted on a monthly basis.

2. Charts are to be randomly selected from all clinic sites for clients served within the past 12 months.

3. Of the charts audited the following charts are required:
A. Initial charts
B. Annual charts
- Pregnancy test charts
- Chart that required follow-up

4. Service sites must select at least one indicator as the focus of a medical audit.

5. The following are criteria for chart review:

1. Vital Signs
a. Blood pressure
b. Weight and BMI
c. Height
d. Last menstrual period
2. Lab Results - done as indicated and entered in chart
a. Pregnancy test
b. Pap smear
c. Chlamydia screen
d. Gonorrhea test
e. Wet prep
f. Hematocrit/hemoglobin
g. Urine screening (protein, sugar, leukocytes, nitrites, etc.)
h. Special chemistries
3. Appropriate Physical Exam
a. Standards for routine visits met
b. Appropriate exam for problems
4. Health Issues Addressed
5. Clinical Diagnosis/Impression/Assessment Recorded

6. Treatment Plan Outlined (excluding any birth control method)
a. Medication orders correctly written and dispensed
b. Other measures outlined - psycho-social follow-up
c. Referrals documented . Procedures described -IUD Insertion, Diaphragm Fitting, etc.
7. Follow-up Specified -Return to clinic, etc.
8. Method Noted
a. OCP/contraceptive patch/contraceptive vaginal ring prescription correctly written and dispensed
b. Diaphragm type and size written
c. IUD type and expiration date written
d. DMPA site of injection, correct prescribing regimen
e. Jadelle
f. Emergency Contraception, including specific brand and how dispensed
g. Non prescriptive method, if applicable
h. Continuation of a method noted
i. Reason for any method change or reason method deferred
9. Provider Signature (must be legible)
10. Consent forms -Appropriate consent forms related to client visit in chart
11. Education and Counseling Provided

**Policy 303.** ***Post-Clinic Conference***

**A**. Purpose - To review client records to:
1. Assure that appropriate services are provided and documented
2. Assure correction of errors or omissions is made

**B**. Process
1. A post-clinic conference follows each clinic session, or at a minimum, occurs on a monthly basis. It is recommended that nursing and clerical be actively involved in the conference.
2. Written documentation must be taken during the post-clinic conference documenting:
a. Review of clinic flow/communication and any problems or concerns
b. Conflicts or problems and resolution or discussion
c. A plan of action, decisions, and recommendations to address identified problems or issues
d. Record reviews

**Policy 304.** ***Client Evaluation of Clinic Services***

**A**. Purpose
1. To assure that clients are receiving the highest quality service
2. Identify current or potential barriers to service and gaps in service

**B.** Process

1. All Family Planning service sites and contract agencies must assess client satisfaction with services at a minimum of once per year (July 1 through June 30). At a minimum, documentation must include how the top two findings are addressed. Options for obtaining client evaluations are:

a. A client evaluation form developed by the clinic

b. Use of a suggestion box

c. Focus group

2. Disposition of a completed Client Evaluation of Clinic Services:

a. The clinic manager and staff are to review client evaluations as part of the quality improvement/quality assurance program.

# Appendix

## Title X Statute

## Federal Regulations

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 provide a broad range of acceptable and effective medically approved methods(including natural family planning methods) and services (including infertility services and services for adolescents)." 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.

**TITLE X - POPULATION RESEARCH AND VOLUNTARY FAMILY PLANNING PROGRAMS**
**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 1 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;
$158,400,000 for the fiscal year ending September 30, 1985.

**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 MDCH 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 appropriate under this title shall be used in programs where abortion is a method of family planning.

## Program Priorities, Legislative Mandates, Key Issues,

Program Priorities
1. Assuring ongoing high quality family planning and related preventive health services that will improve the overall health of individuals;
2. Assuring 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; highly effective contraceptive methods; breast and cervical cancer screening and prevention that corresponds with nationally recognized standards of care; STD and HIV prevention education, counseling, and testing; extramarital abstinence education and counseling; and other preventive health services. The broad range of services does not include abortion as a method of family planning;
3. Encouraging participation of families, parents, and/or other adults acting in the role of parents in the decision of minors to seek family planning services, including activities that promote positive family relationships;
4. Improving the health of individuals and communities by partnering with community-based organizations (CBOs), faith-based organizations (FBOs), and other public health providers that work with vulnerable or at-risk populations;
5. Promoting individual and community health by emphasizing family planning and related preventive health services for hard-to-reach populations, such as uninsured or under-insured individuals, males, persons with limited English proficiency, adolescents, and other vulnerable or at-risk populations.

### Legislative Mandates

The following legislative mandates have been part of the Title X appropriations for each of the last several years. In developing a proposal, the applicant should describe how the proposed project will address each of these legislative mandates.
"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;" and
"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 Issues**

In addition to the Program Priorities and Legislative Mandates, the following Key Issues have implications for Title X services projects and should be acknowledged in the program plan:
1. The increasing cost of providing family planning services;
2. The U.S. Department of Health and Human Service priorities and initiatives, including increasing access to health care; emphasizing preventive health measures, improving health outcomes; improving the quality of health care; and eliminating disparities in health; as well as Healthy People 2010 objectives for Family Planning (Chapter 9); Health Communication (Chapter 11); HIV (Chapter 13), and Sexually Transmitted Diseases (Chapter 25). (http://www.health.gov/healthypeople);
3. Departmental initiatives and legislative mandates, such as the Health Insurance Portability and Accountability Act (HIPAA); Infant Adoption Awareness Training Program (IAATP); providing unmarried adolescents with information, skills and support to encourage sexual abstinence; serving persons with limited English proficiency;
4. Integration of HIV/AIDS services into family planning programs; specifically, HIV/AIDS education, counseling and testing either on-site or by referral should be provided in all Title X family planning services projects. Education regarding the prevention of HIV/AIDS should incorporate the "ABC" message. That is, for adolescents and unmarried individuals, the message should include "A" for abstinence; for married individuals or those in committed relationships, the message is "B" for be faithful; and, for individuals who engage in behavior that puts them at risk for HIV, the message should include "A," "B," and "C" for correct and consistent condom use.
5. Utilization of electronic technologies, such as electronic grants management systems;
6. Data collection and reporting which is responsive to the revised Family Planning Annual Report (FPAR) and other information needs for monitoring and improving family planning services;
7. Service delivery improvement through utilization of research outcomes focusing on family planning and related population issues; and
8. Utilizing practice guidelines and recommendations developed by recognized professional organizations and Federal agencies in the provision of evidence-based Title X clinical services.

## Office of Population Affairs
## Program Instruction Series

**Safety Information for Depo-Provera Contraceptive Injection**
**(medroxyprogesterone acetate injectable suspension)**

**U.S. Public Health Service**
**DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary**
**Assistant Secretary for Health**
**Office of Public Health and Science**
**Washington, DC 20201**

Date: February 10, 2005

From: Deputy Assistant Secretary for Population Affairs

Subject: OPA Program Instruction Series, OPA 05-01:
Updated Safety Information for Depo-Provera Contraceptive Injection
(medroxyprogesterone acetate injectable suspension)

To: Regional Health Administrators, Regions I-X

On November 17, 2004, the U.S. Food and Drug Administration (FDA) announced that a "black box" warning would be added to the labeling of Depo-Provera Contraceptive Injection. This warning highlights that prolonged use of Depo-Provera may result in significant loss of bone density. The loss of bone density is greater the longer the drug is administered and may not be completely reversible after discontinuation of the drug. The "black box" warning indicates that Depo-Provera Contraceptive Injection should be used as a long-term birth control method (e.g., longer than two years) only if all other methods are inadequate. In addition, the warning states that it is unknown if the use of Depo-Provera Contraceptive Injection during adolescence or early adulthood will reduce peak bone mass and increase the risk of osteoporosis fracture in later life. On November 18, 2004, U.S. Pharmaceuticals, Pfizer Inc., the pharmaceutical company that manufactures Depo-Provera, issued letters to Healthcare Professionals and Healthcare Organization Leaders, informing them of the new "black box" warning, as well as other updated safety information included in the drug's labeling (copies of these letters are attached). Although the FDA has indicated that Depo-Provera remains a safe and effective contraceptive (see attached "FDA Talk Paper"), the "black box" warning was added to the drug's labeling to" ensure that physicians and patients have access to this important information." The addition of the "black box" warning came as a result of the FDA's and Pfizer's analysis of data from two separate studies that showed Depo-Provera's effect on bone density during prolonged use. One study began in 1994 and enrolled 540 women ages 25 to 38. The other study--which started in1997 and will continue through 2006--enrolled approximately 400 girls ages 12 to 18 who were taking the drug and is examining ways to reverse bone mineral density loss.

Depo-Provera has been authorized for use in Title X-funded projects since October 29, 1992, when the FDA announced approval of Depo-Provera for the prevention of pregnancy. Among females who received services in Title X-funded clinics during calendar year 2003, the Family Planning Annual Report (FPAR) reflected that 16 percent relied on Depo-Provera as their primary method of contraception.

As with other prescriptive contraceptive methods, Title X providers should ensure that medical protocols are developed and followed in accordance with the most current evidence-based information, accepted standards of care, and current recommendations for use. Title X providers should ensure that their medical protocols, informed consent and practice related to the use of Depo-Provera Contraceptive Injection are consistent with the November 17, 2004, “black box” warning added to the Depo-Provera package insert. Special consideration should be given to the potential impact of long term use in adolescence and early adulthood.

If you have any questions, please contact Susan Moskosky, Director of the Office of Family Planning, on 301-594-4008.

## Screening for Cervical and Colorectal Cancer and Sexually Transmitted Diseases (STD)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Assistant Secretary for Health
Office of Public Health and Science

Washington, DC 20201
DATE: October 29, 2003
TO: Regional Health Administrators, Regions I-X
FROM: Deputy Assistant Secretary for Population Affairs
SUBJECT: OPA Program Instruction Series, OPA 03-01: Screening for Cervical and Colorectal Cancer and Sexually Transmitted Diseases (STD)
In January 2001, "Program Guidelines for Project Grants for Family Planning Services" (Title X Program Guidelines) were revised and distributed to all Title X providers. The purpose of the Title X Program Guidelines is to assist current and prospective MDCH 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.
Currently, Title X Program Guidelines, Section 8.3, specify that the initial physical examination for females must include a Pap smear. In that same section, the Guidelines specify that colorectal cancer screening must be provided for individuals over the age of forty, both males and females. Since 2001, a number of professional organizations that establish national standards of care have published revised recommendations for cervical and colorectal cancer screening based on current

evidence. In particular, the American College of Obstetricians and Gynecologists (ACOG), the American Cancer Society (ACS), and the U.S. Preventive Services Task Force (USPSTF) are recognized groups that have established revised recommendations for standards of care in one or both of these areas.

With the concurrence of agency medical directors, Title X providers should ensure that their medical protocols and practice related to cervical cancer and colorectal cancer screening correspond with current recommendations issued by the formerly mentioned professional groups (ACOG, ACS, USPSTF). Individual agency protocols should note the specific standard of care being utilized in the development of said protocols, as well as the date the protocols were revised. Specifics regarding initiating screening and screening intervals for cervical and colorectal cancer should be noted in the protocol. Clinical protocols should continue to take into account individual client risk, use of specific methods of contraception, as well as current national standards of care.

Sexually transmitted diseases (STD) continue to be of concern for clients served in Title X service projects. For example, each year, young, sexually active females have the highest reported rates of Chlamydia and gonorrhea, and other STDs are common. All clients served in Title X clinics should have a thorough history and physical assessment performed that includes screening for risk of STDs.

Regardless of whether or not an annual Pap test is conducted, clinicians should screen young, sexually active women (ages 15 - 24) at least annually for Chlamydia. In high prevalence areas, gonorrhea screening should also be part of the routine annual STD screening tests for young, sexually active women. Clients who are symptomatic of other STDs should be screened according to the current Centers for Disease Control and Prevention STD Treatment Guidelines (http://www.cdc.gov/std/treatment). In addition to these screening tests, providers should inquire about sexual behaviors, assess ongoing risk for STDs, and counsel about risk avoidance and risk reduction.

If you have questions, please contact Susan Moskosky, Director of the Office of Family Planning at (301) 594-4008.

## Compliance with State Reporting Laws

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Office of Public Health and Science
Office of Population Affairs
Washington, D.C. 20201
Date: January 12, 1999
From: Deputy Assistant Secretary for Population Affairs
Subject: OPA Program Instruction Series, OPA 99-1: Compliance with State Reporting Laws
To: Regional Health Administrators, Regions I-X

The Fiscal Year 1999 Omnibus Appropriations bill (P.L. 105-277) contains new language governing the use of Title X funds. Specifically section 219 states,

*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 reporting of child abuse, child molestation, sexual abuse, rape, or incest.*

This memorandum is intended to serve as a formal notice to the regional offices, as well as Title X grantees, concerning compliance with State reporting laws. A copy of this memorandum should be provided to all Title X grantees in your region, and Title X providers should refer to this memorandum as needed, if questions in this area arise. The language of section 219 means that Title X providers must report such incidents to the appropriate State authority in accordance with requirements imposed by State laws. The reporting and notification requirements referenced in section 219 concern State laws; the authority to enforce compliance with such laws lies with the States. It is therefore important that grantees review and be familiar with the relevant reporting requirements in their individual State. Because State laws vary, it is not possible for this office to provide more specific guidance as to the requirements of particular States' laws; grantees are urged to consult with their own attorneys for specific guidance.

Identified instances of child abuse, child molestation, sexual abuse, rape, or incest present serious medical and psychological situations for patients and their families. Findings of such instances coming within the applicable State law should be documented in the medical record and reported as required by the applicable State requirements. The Office of Population Affairs encourages efforts to augment existing training programs for Title X providers to ensure optimal medical assistance in such situations. Grantees should fully understand their obligations under State law related to reporting when such acts or actions are disclosed, and they should review current protocols for responding to such reports. We also encourage enhanced counseling and education efforts targeted to the unique needs of adolescents.

Title X providers are encouraged to continue to work at the local level in an interdisciplinary manner with other local health care providers who may also have reporting obligations under State law, law enforcement officials, child protective services, social service experts and others in order to explore how best to respond to these situations. To accomplish this, regional offices and Title X grantees are encouraged to utilize resources available through the regional training centers and the technical assistance contractor, as well as other available resources.

We appreciate your continued cooperation in assuring that grantees are aware of their obligations and hope this memorandum provides clarification on this matter.