

Maryland Family Planning and Reproductive Health Program

Administrative Guidelines

**Maryland Department of Health and Mental Hygiene
Center for Maternal and Child Health**

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Table of Contents

I. Maryland Family Planning and Reproductive Health Program Information

A. Family Planning in Maryland _____	2
B. Maryland Health Codes and Other Rules _____	3
C. Maryland Family Planning and Reproductive Health Minimum Program Requirements _____	4
1. Definition _____	4
2. Minimum Program Requirements _____	4
D. Maryland Family Planning and Reproductive Health Minimum Reporting Requirements _____	7
E. Needs Assessment and Annual Plan Instructions _____	8
1. Program Specific Assurances and Requirements _____	8
2. Needs Assessment _____	8

II. Program Standards and Guidelines

A. Introduction to Program Guidelines _____	10
1. Definitions _____	10
B. The Law, Regulations and Guidelines _____	11
C. Application Process _____	12
1. Needs Assessment _____	12
2. Project Requirements _____	12
D. Grant Administration _____	15
E. Legal Issues _____	16
1. Voluntary Participation _____	16
2. Confidentiality _____	16
3. Conflict of Interest _____	17
4. Liability Coverage _____	17
5. Human Subjects Clearance (Research) _____	17
6. Limited English Proficiency (LEP) _____	18
F. Project Management _____	19
1. Overview _____	19
2. Planning and Evaluation _____	19
3. Financial Management _____	19
4. Charges, Billing and Collections _____	20
5. Facilities and Accessibility of Services _____	22
6. Personnel _____	23

7. Training and Technical Assistance _____	24
8. Reporting Requirements _____	25
9. Review and Approval of Informational and Educational Materials _____	25
10. Community Participation, Education and Project Promotion _____	26
11. Community Education _____	26
12. Project Promotion _____	27

III. Client Services, Required Services and Clinic Management

A. Client Services _____	29
1. Overview _____	29
2. Service Plans and Protocols _____	30
3. Procedural Outline _____	31
4. Emergencies _____	32
5. Referrals and Follow-Up _____	33
B. Required Services _____	35
1. Overview _____	35
2. Client Education _____	35
3. Informed Consent _____	36
4. Counseling _____	36
5. History, Physical Assessment and Laboratory Testing _____	38
6. Fertility Regulation (Contraception) _____	41
7. Emergency Contraception _____	42
8. Permanent Contraception (Sterilization) _____	43
9. Tubal Ligation Referral _____	44
10. Infertility Services _____	44
11. Pregnancy Diagnosis and Counseling _____	44
12. Adolescent Services _____	46
13. Identification of Estrogen-Exposed Offspring _____	47
C. Related Services _____	47
1. Gynecological Services _____	47
2. Sexually Transmitted Infections (STIs) and HIV/AIDS _____	47
3. Genetic Information and Referral _____	48
4. Health Promotion/Disease Prevention _____	49
5. Postpartum Care _____	49
6. Family and Intimate Partner Violence _____	50
7. Mandated Reporting of Child Abuse and Neglect _____	52
8. Human Trafficking _____	53
9. Reproductive Life Plan _____	54
D. Clinic Management _____	55
1. Equipment and Supplies _____	55
2. Pharmaceuticals _____	55
3. Medical Records _____	56
4. Quality Assurance And Audit _____	57
5. Maryland Family Planning Customer Satisfaction Survey _____	60

IV. Program Monitoring Site Reviews

A. Program Monitoring Site Reviews	62
1. Methodology	62
2. Process	62
B. Monitoring and Technical Assistance	64
1. Monitoring Visits	64
2. Technical Assistance (Consultation Visits)	64

I. Maryland Family Planning and Reproductive Health Program Information

A. Family Planning in Maryland

The mission of the Maryland State Family Planning and Reproductive Health Program is to reduce unintended pregnancies and to improve pregnancy outcomes by assuring that comprehensive, quality family planning services are available and accessible to Maryland citizens in need. This is consistent with the Title X Federal Family Planning Program mission "to provide individuals the information and means to exercise personal choice in determining the number and spacing of their children."

Family Planning is a preventive health measure which positively impacts on the health and well-being of women, children and families. Effective family planning programs are essential health care delivery interventions that correlate with decreased high risk pregnancy and decreased maternal and infant mortality and morbidity. Services provided through family planning clinics allow women and men to make well-informed reproductive health choices. Maryland Title X funded family planning clinics are specifically created to address the unmet family planning needs of women and men below poverty, and those slightly above poverty, but still considered low income, and to provide access to those with special needs. No one is denied services because of inability to pay.

The Center for Maternal and Child Health is responsible for carrying out federal and state mandates for improving the health of women, newborns, children, and adolescents. A major goal is to reduce maternal, infant, and child mortality and morbidity, with a focus on low income populations. Integral to this process is the development and implementation of a plan to assure statewide availability and accessibility to high quality comprehensive reproductive health care.

The fundamental belief underlying the Maryland State Family Planning and Reproductive Health Program is that every pregnancy should be a planned and wanted one. The guiding principle of the Program is that all men and women should be able to have the number of children they want, when they want to have them. Consistent with this principle are the following expectations:

- No one is denied family planning services because of the inability to pay and that priority is given to individuals who are below 250% of the federal poverty level.
- Services are provided to individuals regardless of religion, race, color, national origin, disabling condition, age, sex, number of pregnancies, or marital status
- Family planning counseling includes all methods of contraception and is conducted in a supportive and non-coercive manner that protects the dignity of the individual.
- Counseling specifically includes information on the prevention of HIV/AIDS and other sexually transmitted infections.
- Adolescents are specifically provided counseled on abstinence and resisting sexual coercion and encouragement of parental involvement.
- Health care providers from both the public and private sectors work in partnership to address the reproductive health and family planning issues within their community.
- Community members are consulted in the design and implementation of the local family planning and reproductive health program.

B. Maryland Health Codes and Other Rules

The following health codes and other rules that provide crucial information to Title X program implementation can be found in Appendix A.

Domestic Violence

Annotated Code of Maryland, Family Law Article, §4-501 to § 4-530
Md. FAMILY LAW Code Ann. § 4-501

Mandated Child Abuse Reporter Legislation

Family Law Article:
Md. FAMILY LAW Code Ann. § 5-704

Criminal Law Article:

Md. CRIMINAL LAW Code Ann. § 3-304
Md. CRIMINAL LAW Code Ann. § 3-306
Md. CRIMINAL LAW Code Ann. § 3-307
Md. CRIMINAL LAW Code Ann. § 3-308

Minor Consent:

Md. HEALTH-GENERAL Code Ann. § 20-102

Nurse Dispensing in Local Health Departments

C. Maryland Family Planning and Reproductive Health Minimum Program Requirements

1. DEFINITION

Family Planning services offer comprehensive preventive reproductive health care that includes: general health assessment and examination; screening and treatment for sexually transmitted diseases, HIV infections, cervical and breast cancer, high blood pressure, anemia, infertility problems and selected infections; contraception, pregnancy testing and counseling services; client and community educations; and follow-up and referrals for medical or socioeconomic problems. The primary mission is to provide individuals the information and means to exercise personal choice in determining the number and spacing of their children.

2. MINIMUM PROGRAM REQUIREMENTS

- a. 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). **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (a)(1).
- b. 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 participate in any other program. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (a)(2).
- c. Provide services in a manner which protects the dignity of the individual. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (a)(3).
- d. Provide services without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (a)(4).
- e. Not provide abortion as a method of family planning. 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. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (a)(5) and (i).
- f. Provide that priority in the provision of services will be given to persons from low-income families. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (a)(6).
- g. Provide that no charge will be made for services provided to any persons from a low income family (at or below 100% of the Federal Poverty Level) 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. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (a)(7).

- h. 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 person from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (a)(8).
- i. 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 agency is required. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (a)(9).
- j. Provide for an advisory committee. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (a)(11).
- k. 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. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (b)(1).
- l. 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. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (b)(2).
- m. Provide for informational and educational programs designed to: achieve community understanding of the objectives of the program; inform the community of the availability of services; and promote continued participation in the project by persons to whom family planning services may be beneficial. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (b)(3).
- n. Provide for orientation and in-service training for all project personnel. **Reference:** 42 CFR CH.1 (10-1-00 Edition) §59.5 (b)(4).
- o. Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (b)(5).
- p. Provide that the family planning medical services will be performed under the direction of a physician with special training or experience in family planning. **Reference:** 42 CFR CH.1(10-1-00 Edition) §59.5 (b)(6).

- q. Provide that all services purchased for project participants will be authorized by the project director or his/her designee on the project staff. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (b)(7).
- r. 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 support by other federal programs. **Reference:** 42 CFR CH. 1 (10-1-00 Edition)§59.5 (b)(8).
- s. Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payments procedures maintained by the agency. The agency must be prepared to substantiate that these rates are reasonable and necessary. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (b)(9).
- t. Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services. **Reference:** 42 CFR CH. 1(10-1-00 Edition) §59.5 (b)(10).
- u. Any funds granted shall be expended solely for the purpose of delivering Title X Family Planning Services in accordance with an approved plan & budget, regulations, terms & conditions and applicable cost principles prescribed in 45 CFR Part 74 or Part 92, as applicable. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.9.

These Minimum Program Requirements (MPR's) are used as indicators for the Maryland Family Planning and Reproductive Health Program site review process to determine program compliance. They are based on the Title X Family Planning Program statute (Appendix B), the Office of Population Affairs (OPA) Family Planning Standards and Guidelines (Appendix B), and the Maryland Family Planning and Reproductive Health Guidelines.

The Site Review Tool identifies the minimum program requirements and references to the above documents in the review tool. Each indicator refers to a minimum standard that must be in place to be in compliance with the Maryland Family Planning and Reproductive Health Program for grant status as a Family Planning Delegate Agency.

The Site Review Tool identifies the measurements used to determine compliance with each MPR indicator. These indicators are used in the site review process to evaluate compliance with grant requirements. Any indicator determined to be out of compliance must to be corrected.

Minimum Program Requirements and site review tool are reviewed annually as part of an ongoing quality improvement process, working toward optimal clarity and objective measurement of required program components and compliance to those components.

D. Maryland Family Planning and Reproductive Health Minimum Reporting Requirements (MPR)

The federally mandated minimum program reporting requirements for delegate agencies are explained here. It is mandatory that agencies submit these documents and do so by the deadlines set forth within. These requirements are subject to change as legislative, fiduciary and other aspects of the program change.

These documents include the:

- Family Planning Data Requirement
- Family Planning Needs Assessment

The Center for Maternal and Child Health, Family Planning and Reproductive Health Program also requires that delegate agencies report performance measures (unduplicated number of clinic users and number of clinic visits).

It is crucial that these reports are submitted accurately and timely. The information is used for essential activities not limited to legislative reporting, federal reporting requirements for the State, budgeting, funding, and other aspects of financial management. In addition, this data provides statistical information needed for program evaluation, assessment of need, and other activities required of Title X Family Planning Projects.

E. Needs Assessment and Annual Plan Instructions

The Center for Maternal and Child Health, Family Planning and Reproductive Health Program must have every delegate agency develop and submit a needs assessment and annual grant as described below:

1. PROGRAM SPECIFIC ASSURANCES AND REQUIREMENTS

- a. Each delegate agency annual performance measure is determined by taking 90% of the most recent three years.
- b. Each delegate agency will be required to adhere to Maryland Family Planning and Reproductive Health Program Minimum Program Requirements (MPRs). The MPRs are written based on the Federal Regulations for Title X Family Planning Programs (the law) and the Office of Population Affairs (OPA) Family Planning Standards and Guidelines.

2. NEEDS ASSESSMENT

- a. Demographic description of the service delivery area including objective data pertaining to individuals in need of family planning services (Examples include but are not limited to maternal and infant mortality/morbidity rates, estimates of women/teens in need of services,, teen birth rates and pregnancy rates, rates of unintended pregnancy, STI and HIV rates/prevalence and indicators of the poverty status of the populations to be served). Also discuss cultural and linguistic barriers to service.
- b. Geographic description of the service area including any geographic, topographic, and other barriers to service.
- c. Identification and discussion of high priority populations and target areas, with special emphasis on low-income women and men.
- d. Identify other major health care providers and agencies providing similar services in your service delivery area, and the existing need for additional services.
- e. Describe linkages or possible linkages with other health and social agencies related to reproductive health.

II. Program Standards and Guidelines

A. Introduction to Program Guidelines

Reference is made throughout the document to specific sections of the Title X law and implementing regulations. (Reference to specific sections of the regulations will appear in brackets, e.g. [45 CFR Part 74, Subpart C].). Selected materials that provide additional guidance are classified as Resource Documents.

The format used in this document follows the *Program Guidelines for Project Grants for Family Planning Services*, 2001, U.S. Department of Health and Human Services.

1. DEFINITIONS

Throughout this document, the words **required** or **must** indicate mandatory program requirements. Standards refer to **minimally required** services.

The word **should** indicates recommended program guidelines and policies. These guidelines and policies reflect current acceptable medical or professional practices and are highly recommended by the Maryland Family Planning and Reproductive Health Program in order to fulfill the intent of Title X. The words **can** and **may** indicate suggestions for consideration by individual projects.

MFPRH refers to the Maryland Family Planning and Reproductive Health Program as the entity that receives a Federal grant and assumes legal and financial responsibility and accountability for the awarded funds and for the performance of the activities approved for funding.

The *project* consists of those statewide activities described in the Center for Maternal and Child's Health, Family Planning and Reproductive Health Program grant application submitted to the Office of Population Affairs (OPA), Family Planning Program and supported under the approved budget. For more information about the OPA Family Planning Program, go to www.hhs.gov/opa .

Delegate agencies are those entities that provide family planning services with Federal Title X funds under.

Service sites are those locations where Title X family planning services are provided by the delegate agency.

References made throughout this document to Title X law and Federal policy can be explored in Appendix B and Appendix C.

B. The Law, Regulations and Guidelines

The philosophy of the Maryland Family Planning and Reproductive Health (MFPRH) Program is consistent with that of Title X. Family planning is a preventive health measure which positively impacts on the health and wellbeing of women, children and families. Effective family planning programs are essential health care delivery interventions that correlate with decreased high risk pregnancy and decreased maternal and infant morbidity and mortality. Services provided through family planning clinics allow women and men to make well-informed reproductive health choices. Title X family planning clinics are specifically created to address the unmet family planning needs of women and men living below or slightly above poverty, but still considered low income, and to provide access to those with special needs (including teens). No one is denied services because of inability to pay.

1. To enable persons voluntary access to family planning services, Congress enacted the Family Planning Services and Population Research Act of 1970 (Public Law 91-571), which added Title X, "Population Research and Voluntary Family Planning Program," to the Public Health Services Act. Section 1001 of the Act (as amended by Public Laws 94-63 and 95-613), "The Secretary is authorized to make grants to and enter into contracts with public and 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 to 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), published in the Federal Register on June 3, 1980, amended on February 2, 1988, and on July 3, 2000 are 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 Services Act.

2. The Maryland Department of Health and Mental Hygiene, Center for Maternal and Child Health is the Title X Program Grantee and has the primary responsibility in Maryland to receive and administer State and Federal funds for family planning services. Guidelines for MFPRH Program administration of the federal program are based on requirements as cited in the document *Program Guidelines for Project Grants for Family Planning Services* available at the following website: <http://www.hhs.gov/opa/>. Additional guidelines may be required through either the federal or state annual funding process, or as MFPRH Program deems necessary.
3. The program guidelines found in this document interpret the law and regulations in the form of standards and provide a general orientation to the federal and state perspective on family planning. This manual is written to define minimum standards (requirements) and give recommendations for quality care. This manual is designed to be used for the:
 - a. Orientation of all new family planning staff members
 - b. Annual quality assurance review procedures required of all delegate agencies

C. Application Process

1. NEEDS ASSESSMENT

An assessment of the need for family planning services in the service area **must** be conducted prior to applying for a grant award and supplied in the annual plan thereafter. The information will be used to ensure that services are being delivered in areas under-served by other medical and/or social welfare facilities. At a minimum, the needs assessment **must** include the following:

- a. Description of the geographic area including a discussion of potential geographic, topographic, and other related barriers to service;
- b. Demographic description of the service delivery area including objective data pertaining to individuals in need of family planning services (Examples include but are not limited to maternal and infant mortality/morbidity rates, estimates of women/teenagers in need of services, teen birth rates and teen pregnancy rates, rates of unintended pregnancy by age groups, and indicators of the poverty status of the populations to be served). Also discuss cultural and linguistic barriers to services;
- c. Description of existing services and the need for additional family planning services to meet community/cultural needs;
- d. Rates and/or prevalence of STIs and HIV (including perinatal infection rates) in the service delivery area;
- e. Identification and description of linkages with other resources related to reproductive health; and
- f. Identification and discussion of high priority populations and target areas and an estimate of the number of clients to be served, with special emphasis on low-income women and men.

2. PROJECT REQUIREMENTS

All delegate agencies providing family planning services **must** assure the following requirements.

- a. Provision of a broad range of effective medically approved family planning methods and services including natural family planning methods, infertility services and services for adolescents. (Sections 8.4, 8.5 and 8.7)
- b. Services will be provided to clients (Section 5.1):
 - 1.) On a voluntary basis
 - 2.) Without coercion to accept services or any particular method of family planning
 - 3.) Without making acceptance of services a prerequisite to eligibility for any other service or assistance in other programs

- c. Provide services in a manner that will protect each individual's dignity and will respect the diverse cultural and social practices of the service area population. (Section 5.0)
- d. Provide services impartially to all without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies or marital status in accordance with Title VI of the Civil rights Act of 1996. (Section 5.0) In addition, all delegate agencies **must** have a policy that assures meaningful access to family planning services for persons with limited English proficiency. This means that language assistance **must** be provided that results in accurate and effective communication at no cost to the client. (Section 5.6)
- e. Not provide abortions as a method of family planning. A project **must** offer pregnant women the opportunity to be provided information and counseling on prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination. Information on any of these options **must** be factual, neutral and nondirective. (Section 8.6)
- f. Persons from low-income families are given priority in the provision of services. Agencies **must** strive to increase use of services by historically under-served segments of the population (people of color, non-English speaking persons, persons abusing substances, homeless persons, etc.).
- g. Low-income individuals (below 100% of poverty) are not charged except where third party payment is authorized (Section 6.3.1).
- h. Clients **must** not be denied services or be subjected to any variation in quality of service because of inability to pay. Charges will be made to persons other than low-income individuals (at or below 100% poverty) based on the following (Section 6.3.1):
 - 1.) Current Federal Department of Health and Human Services (DHHS) Poverty Guidelines
 - 2.) Sliding fee scale schedule
 - 3.) Periodic cost analysis of all services provided
- i. Individuals from families with an annual income above 250% poverty will be charged to recover the reasonable cost of providing services (Section 6.3.1).
- j. Reasonable effort is made to recover third party payment from all sources (Section 6.3.1).
- k. Provide for medical services related to family planning including (Sections 7 and 8):
 - 1.) Physician's consultation
 - 2.) Examination
 - 3.) Prescription
 - 4.) Continuing supervision of clients
 - 5.) Laboratory examination
 - 6.) Contraceptive supplies
 - 7.) Referral to other medical facilities when medically indicated
 - 8.) Effective usage of contraceptive devices and practices

- l. Provide for social services related to family planning including (Sections 7 and 8):
 - 1.) Counseling
 - 2.) Referral to and from other social and medical services agencies
 - 3.) Referral to any ancillary services which may be necessary to facilitate clinic attendance

- m. Provide informational and educational programs designed to (Sections 6.9.2 and 6.9.3):
 - 1.) Achieve community understanding of program objectives
 - 2.) Inform community of availability of services
 - 3.) Promote continued participation in the project by persons to whom family planning services may be beneficial

- n. Orientation and in-service training are provided for all project personnel (Section 6.6).

- o. Services are provided without residency requirement or physician referral.

- p. Medical services that are provided by delegate agencies are done so under the direction of a physician.

- q. All services purchased for the project participants are authorized by the project director or director's designee.

- r. Provide for coordination and use of referral arrangements with other appropriate providers supported by other federal programs (Section 7.4).

- s. Agreements on methods and rates of payments for medical care by contracted or referral providers are in place and are reasonable and necessary.

- t. Provide an opportunity for a broadly based representation from the service population and those in the community knowledgeable about family planning needs, to participate in the development, implementation and evaluation of the project (Section 6.9).

D. Grant Administration

1. All delegate agencies **must** comply with MFPRH Program and federal grants administration requirements, including the following:
 - a. All Family Planning Directors **must** be familiar with the MFPRH Program Administrative Guidelines and the Title X law and regulations.
 - b. All delegate agencies receiving Title X funds **must** provide services of high quality which meet minimum program standards.
 - c. Delegate agencies **must** have an Information and Education Committee which reviews all educational materials.

E. Legal Issues

Written protocols and operating procedures are required to meet the standards of the legal issues described in section 2.1.5.

Services **must** be provided without regard to religion, race, color, national origin, creed, handicap, sex, number of pregnancies, marital status, age, sexual orientation, and contraceptive preference in a manner that protects the dignity of the individual.

1. VOLUNTARY PARTICIPATION

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

Personnel **must** be informed that they may be subject to prosecution under Federal law if they coerce or endeavor to coerce any person to undergo an abortion or sterilization procedure. A statement acknowledging the staff member's awareness and understanding of the voluntary participation policy **must** be maintained in his or her personnel file.

2. CONFIDENTIALITY

Every delegate agency **must** assure client confidentiality and provide safeguards for individuals against the invasion of personal privacy, as required by the Privacy Act. No information obtained by the project staff about individuals receiving services may be disclosed without the individual's written consent, except as required by law or as necessary to provide services to the individual, with appropriate safeguards for confidentiality. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual [59.11]. Confidentiality under Title X cannot be invoked to circumvent Maryland mandated reporting requirements for Child Abuse and Neglect. Health care providers are required to report suspected child abuse or neglect. When they make a report of suspected maltreatment in good faith, they are protected under the law from civil or criminal liability pertaining to abrogation of confidentiality

- a. Under Maryland law, an individual under the age of 18 may consent on his or her own behalf to confidential family planning services and certain other medical treatment; however, a doctor providing the treatment, or his or her designee, may notify the minor's parents. For example, a doctor in a family planning clinic may decide it is necessary to notify a minor's parents when the minor has been found to have a serious health problem and the minor does not return to the clinic for treatment.
- b. When serving an adolescent or adult client who does not wish to be contacted by phone or by mail at home or at other stipulated locations, providers should ask the client to sign an *Individualized Contact Plan* found in the MFPRH Program Clinical Guidelines or an equivalent local form. This form, provides a space where the client can identify a special contact plan. The client **must** be informed that, in the event that a serious health problem

is identified, the clinic will make every attempt possible to contact the client, which could mean abrogating confidentiality.

- c. Every effort should be made to have all written and verbal exchanges between clients and office/clerical staff kept private, so that other clients in the waiting room or other uninvolved staff do not know who is visiting the clinic or the reason for the visit. An example would be keeping the sign-in sheet from being inappropriately read by other people.

3. CONFLICT OF INTEREST

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

4. LIABILITY COVERAGE

Liability insurance coverage **must** be assured for all segments of the program funded under the Title X grant, including all personnel providing direct patient services.

5. HUMAN SUBJECTS CLEARANCE (RESEARCH)

- a. Delegates 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.
- b. All DHMH facilities must comply with DHMH requirements for research. Information on DHMH requirements can be found at <http://www.dhmh.state.md.us/oig/irb>.
- c. Delegate must send written notification of any planned research activities to the MFPRH Program, State Family Planning Administrator prior to the initiation of activities. This notification must include the following:
 - 1.) A description of the project, including plans to comply with legal requirements pertaining to human subjects of research, especially the method for obtaining informed consent;
 - 2.) Documentation of approval by an Institutional Review Board (IRB); and/or Indication of when the researcher(s) plan to submit an application to the DHMH IRB. All applications to the DHMH IRB must be processed through the Center for Maternal and Child Health.
- d. The State Family Planning Administrator will inform the federal Region III office in writing of all planned research with IRB approval.
- e. Information concerning rights of people who participate in research and federal regulations on using humans in medical or behavioral research may be obtained by calling 1-866-447-4777 or by writing: Office for Human Research Protections (OHRP), 1101 Wootton Parkway, Room 200, Rockville, MD 20852

- f. Any provider planning to publish materials based upon activities conducted under funding from the Center for Maternal and Child Health should contact the State Family Planning Administrator or his/her designee to ensure that the publication complies with all relevant federal and DHMH requirements.

6. LIMITED ENGLISH PROFICIENCY (LEP)

- a. All delegate agencies **must** ensure meaningful access to services for persons with limited English proficiency.
- b. All delegate agencies **must** develop and implement a written plan regarding the process for providing language assistance to LEP clients. Guidance can be found in Federal Register/Vol. 67, No 22/Friday 1, 2002/Notices and Federal Register/Vol 68, No. 153/Friday, August 8, 2003/Notices.
- c. The scope and complexity of the plan **must** consider:
 - 1.) Size of the LEP population eligible to be served or likely to be encountered.
 - 2.) Frequency of contact with the LEP population.
- d. All LEP plans **must** include:
 - 1.) Statement of the agency's commitment to provide meaningful access for LEP persons.
 - 2.) Statement that services will not be denied to a client because s/he is limited English proficient.
 - 3.) Statement that clients will not be asked or required to provide their own interpreter. Because of the concerns for confidentiality and the sensitive nature of the information that clients may disclose during services, the use of family and friends as interpreters is strongly discouraged. If the client chooses to use family or friends, first inform the client of the right to receive free interpreter services and permit the use of family/friends only after the offer has been declined and documented.
- e. At minimum, delegate agencies **must** include and address the following within their LEP Plans:
 - 1.) Identify LEP individuals who need language assistance
 - 2.) Language assistance measures
 - 3.) Oral interpretation
 - 4.) Written translation
 - 5.) Training staff
 - 6.) Providing notice to LEP persons
 - 7.) Monitoring and updating the LEP plan.
- f. MFPRH will provide technical assistance for the development of the LEP plan.

- g. MFPRH will review delegate agencies' LEP practices and policies during site review.

F. Project Management

1. OVERVIEW

Structure of the Maryland Family Planning and Reproductive Health Program

Family planning services under Title X grant authority are offered by delegate/contract agencies, however MFPRH is responsible for the quality, cost, accessibility, acceptability, reporting, and performance of the grant-funded activities provided by delegate/contract agencies. MFPRH **must** therefore have a negotiated, written agreement with each delegate/contract agency and establish written standards and guidelines for all delegated project activities consistent with the appropriate section(s) of the Program Guidelines for Project Grants for Family Planning Services, as well as other applicable requirements such as Subpart C of 45 CFR Part 74, or Subpart C of 45 CFR Part 92.

If a delegate/contract agency wishes to subcontract any of its responsibilities or services, a written negotiated agreement that is consistent with Title X requirements **must** be established. It is the responsibility of the delegate to ensure that, given the necessary information, every effort is directed to total compliance with regulations.

- a. MFPRH **must** provide each delegate agency with an updated MFPRH Program Administrative manual. This manual will be routinely provided online through the MFPRH website. A hard copy will be provided upon request.
- b. MFPRH **must** perform a program review on individual delegate agencies a minimum of every three years.
- c. MFPRH is responsible for providing technical assistance and consultation as needed to ensure that the delegate agencies are in compliance with all applicable state/federal regulations and laws.

All requests for technical assistance should be forwarded to MFPRH Program in writing.

2. PLANNING AND EVALUATION

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

3. FINANCIAL MANAGEMENT

Delegates **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.

4. CHARGES, BILLING AND COLLECTIONS

A delegate is responsible for the implementation of policies and procedures for charging, billing, and collecting funds for the services provided by the project.

- a. Clients **must** not be denied family planning services or be subjected to any variation in quality of services because of the inability to pay.
- b. Charges **must** be based on a cost analysis of all services provided by the project. At the time of services, clients who are responsible for paying any fee for their services **must** be given bills directly. In cases where a third party is responsible, bills **must** be submitted to that party.
- c. A schedule of discounts **must** be developed and implemented with sufficient proportional increments so that inability to pay is never a barrier to service. A schedule of discounts is required for individuals with family incomes between 101% and 250% of the Federal poverty level. Fees may be waived for individuals with family incomes above this amount who, as determined by the service site project director, are unable, for good cause, to pay for family planning services.
- d. Clients whose documented income is at or below 100% of the Federal poverty level **must** not be charged, although projects **must** bill all third parties authorized or legally obligated to pay for services.
- e. Along with these Guidelines, refer to the current DHMH *Non-Chargeable Services List* (updated each fiscal year) at <http://dhmh.maryland.gov/dca> for information on family planning services that are non-chargeable except, in certain cases, to Medicaid or other third party insurers.
- f. Individual eligibility for a discount **must** be documented in the client's record/file.
- g. Bills to third parties **must** show total charges without applying any discount.
- h. Bills to clients **must** show total charges less any allowable discounts.
- i. Eligibility for discounts for minors who receive confidential services **must** be based on the income of the minor.
- j. Reasonable efforts to collect charges without jeopardizing client confidentiality **must** be made.
- k. A method for the "aging" of outstanding accounts **must** be established.

1. DHMH Policy 3205 establishes certain requirements for collection by local health departments of accounts declared by the Health Officer to be delinquent. Once an account has been designated delinquent, it must be transferred to the Central Collection Unit, Department of Budget and Fiscal Planning (CCU). However, Title X precludes any practice that may constitute a barrier to the receipt of services, such as the assignment of the account of a service recipient to a collection agency.

- m. In order to refer an account to Central Collection Unit the following procedures must be in place:
 - 1.) The Family Planning Clinic must make the expectation of payment known to the client when the client schedules the appointment.
 - 2.) The Family Planning Clinic must bill all third party payors (medical assistance and private insurance) as well as self-pay.
 - 3.) The Family Planning Clinic must be able to accept cash, credit/debit and checks at time service is provided.
 - 4.) The Family Planning Clinic must be able to provide a payment plan to the client at the time of the fee assessment.
 - 5.) An invoice must be given to every client at the time of service showing the actual charge of the visit, the discount based on the approved sliding fee schedule, and the amount the client owes for the services performed that day and any previous unpaid balance.
 - 6.) A client can not be sent to the Central Collection Unit if a partial payment has been made towards the outstanding charge within 90 days.
 - 7.) A client, excluding confidential clients, must be sent three (3) invoices at least 30 days apart before a client can be sent to the Central Collection Unit. Each invoice must include the following:
 - a) A statement stating the Clinic accepts cash, credit/debit and check payments.
 - b) A copy of the payment plan and details on how the client can participate in the payment plan.
 - c) A notice that states after the third invoice a client will be referred to the Central Collection Unit if payment or partial payment is not received.
 - 8.) A quarterly summary will be sent to the Family Planning Fiscal Coordinator at the Maryland Department of Health and Mental Hygiene's Family Planning Program. A worksheet developed by the Family Planning Fiscal Coordinator will be used to capture the following information:
 - a) Client ID#
 - b) Client's Age
 - c) Type of birth control method used by client.

- d) Amount due
- n. Voluntary donations from clients are permissible. However, clients **must** not be pressured to make donations, and donations **must** not be a prerequisite to the provision of services or supplies. Donations from clients do not waive the billing/charging requirements set out above.
- o. Client income should be re-evaluated at least annually.

5. FACILITIES AND ACCESSIBILITY OF SERVICES

- a. Facilities in which project services are provided should be geographically accessible to the population served and should be available at times convenient to those seeking services, i.e., they should have evening and/or weekend hours in addition to daytime hours.
- b. The facilities should be adequate to provide the necessary services and should be designed to ensure comfort and privacy for clients and to expedite the work of the staff. Facilities **must** meet applicable standards established by the Federal, state and local governments (e.g., local fire, building and licensing codes).
- c. Projects **must** comply with [45 CFR Part 84], which prohibits discrimination on the basis of handicap in Federally assisted programs and activities, and which requires, among other things, that recipients of Federal funds operate their Federally assisted programs so that, when viewed in their entirety, they are readily accessible to people with disabilities. A copy of Part 84 may be obtained from the Regional office. Projects **must** also comply with any applicable provisions of the Americans with Disabilities Act (Public Law 101-336).
- d. All delegate agencies **must** have a written policy and plan pertaining to services for disabled clients. The plan should include information on referral to the closest facility offering the necessary accommodation when a clinic cannot serve a particular individual for any reason. At a minimum, the plan should address service delivery to the following clients:
 - 1.) Clients who are wheelchair dependant or who have any special needs due to physical disability.
 - 2.) Clients who are hearing impaired: Clinics should make an effort to provide interpreters who know sign language. Another source of help may be the Maryland Relay Service (MRS), which is a telephone service that gives people with hearing and/or speech impairments the ability to communicate by telephone. The number is 1-800-735-2258. There is no additional fee for local calls and long distance calls are billed at reduced rates. For more information call the Customer Service Center at 1-800-676-3777.

- e. Questions about services for the disabled may be addressed to the DHMH Office of Equal Opportunity Programs (OEOP) OEOP information may be found on-line at <http://dhmh.state.md.us/oeop/> or by calling 410-767-6600.
- f. If sterilizations are performed on-site by the delegate, they **must** conform to facility standards as established by federal Title X guidelines.
- g. In an effort to assure accessible and acceptable client services, it is **strongly** encouraged that each delegate agency offer late afternoon, evening, and/or weekend clinic hours. Emergency situations may occur at any time. All projects **must** therefore have written plans and procedures for the management of medical and non medical emergencies. (Section 7.3)

6. PERSONNEL

Delegates, or their organizing body, **must** establish and maintain written personnel policies that comply with federal and state requirements and Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, and Title 1 of Americans with Disabilities Act (Public Law 101-336).

- a. These policies **must** cover the following items: [59.5(b)(10)].
 - 1.) Staff recruitment and selection methods.
 - 2.) Methodology for performance evaluation.
 - 3.) Staff promotion.
 - 4.) Staff termination.
 - 5.) Compensation and benefits.
 - 6.) Grievance procedures.
 - 7.) Staff orientation.
 - 8.) Nondiscrimination in hiring employees.
 - 9.) Patient confidentiality issues.
 - 10.) Duties, responsibilities, and qualifications of each staff position.
 - 11.) Licenses for those positions requiring licensure.
- b. Policies should cover the following items as appropriate:
 - 1.) A system for replacing key staff members in case of illness, vacation or unexpected absence.
 - 2.) Use of volunteer employees.
 - 3.) Use of contractual consultants in providing service.
 - 4.) Project personnel should reflect racial and ethnic diversity of population being served and be sensitive to the cultural needs of the client population.
- c. Delegates must ensure that:
 - 1.) The medical care component of the project operates under the supervision of a medical director who is a licensed and qualified physician. It is recommended that the medical director has training or experience in family planning. If colposcopy and related services are provided the supervising physician **must** be trained in

- OB/GYN residency or provide documentation of a minimum two-day training course or its equivalent.
- 2.) Clinicians other than physicians performing medical functions do so under protocols and/or standing orders approved by the delegate medical director.
- d. Personnel records **must** be kept confidential.
 - e. Organizational chart and personnel policies **must** be available to all personnel.
 - f. Job descriptions **must** be available for all positions, reviewed annually, and updated as needed.
 - g. Annual evaluation of all project personnel **must** be conducted.
 - 1.) The written evaluations are discussed with the employee and are kept in the employee's personnel files.
 - 2.) Annual peer reviews **must** be conducted of all project clinicians/providers.
 - h. All clinicians employed in the family planning program **must** agree to follow the clinic protocols and procedures and/or standing orders.
 - i. Personnel policies should be reviewed and updated as needed.
 - j. The agency **must** have written policies and procedures to ensure compliance with OSHA regulations regarding transmission of blood borne disease (e.g. HIV, Hepatitis B, etc.).

7. TRAINING AND TECHNICAL ASSISTANCE

- a. Delegates **must** provide for orientation and in-service training for all project personnel.
 - 1.) The agency should document attendance at training and continuing education programs.
 - 2.) All staff should be offered the opportunity to attend training programs, particularly Region III training programs, MFPRH training programs, and the annual family planning update at least once per year.
 - 3.) All staff, including administrative and support staff, as well as direct service providers, **must** be trained regarding prevention, transmission and infection control in the health care setting of sexually transmitted infections including HIV (See Section 8.8).
 - 4.) Funding for training and continuing education should be included in each year's operating budget.
 - 5.) Staff **must** be trained in the unique social practices, customs and beliefs of underserved populations of their service area.
- b. Delegates should conduct an annual assessment of the training needs of their staff; and an evaluation of the scope and effectiveness of all educational programs offered.
 - 1.) Educational opportunities should be developed to assist in meeting identified needs.
 - 2.) Regular training topics should include Mandated Reported and Human Trafficking.
 - 3.) These training needs should be shared with MFRPH.

- c. Delegates should have appropriate clinical resource books available for staff such as:
 - 1.) Family Planning Perspectives (AGI)
 - 2.) The most current annual edition of Contraceptive Technology and monthly editions of Contraceptive Technology Update.
 - 3.) Drug Facts and Comparisons, or current PDR

8. REPORTING REQUIREMENTS

- a. All delegate agencies **must** comply with MFRPH minimum reporting requirements,
- b. Sterilization reporting requirements **must** be met. All projects **must** be in compliance with Title X regulations on minimum age, waiting period between signing of consent and surgical procedure and informed consent. Documentation that these requirements have been met should be found in the client's chart and/or the sterilization log (See Attachment C of the federal Program Guidelines, Jan. 2001 and Section 8.4 of this manual for specific guidance.)

9. REVIEW AND APPROVAL OF INFORMATIONAL AND EDUCATIONAL MATERIALS

An advisory committee of five to nine members who are broadly representative of the community **must** review and approve all informational and educational materials developed or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X. Whether materials have been obtained from an outside source or created in-house, they are subject to informational and educational review procedures established under Title X.

- a. When reviewing educational materials the I&E Committee should consider the following:
 - 1.) The educational and cultural backgrounds of the individuals to whom the materials are addressed;
 - 2.) The standards of the population or community to be served with respect to such materials;
 - 3.) The content of the material to assure that the information is factually correct;
 - 4.) Whether the material is suitable for the population or community to which it is to be made available; and
 - 5.) Establish a written record of its determinations [59.6]. The *Informational & Educational Materials Review Evaluation Worksheet* should be used for this purpose. The *Worksheet* is available on the Family Planning and Reproductive Health, Administrative Guidelines section of the CMCH website at <http://fha.dhmh.maryland.gov/mch/> .

- b. The committee(s) may delegate responsibility for the review of the factual, technical, and clinical accuracy to appropriate project staff. However, final approval of information and education materials rests with the committee(s).
- c. After the local I&E Review Committee has completed its work, a packet containing the following items must be submitted to the MFPRH Program I&E Program Coordinator:
 - 1.) A list of local committee members;
 - 2.) A copy of each of the print materials reviewed and a listing of any videos and/or DVDs;
 - 3.) Photocopies of each *Informational & Educational Materials Review Evaluation Worksheet* completed by committee members during the review; and
 - 4.) A copy of the sign-in sheet for the review.
- d. Packets containing materials reviewed during the previous 12 month period should be submitted to the MFPRH Coordinator of Special Projects, CMCH, 201 West Preston Street, Baltimore, MD 21201. no later than March 31.

10. COMMUNITY PARTICIPATION, EDUCATION AND PROJECT PROMOTION

Agencies typically have diverse ways of connecting within their communities to assess needs and promote family planning services. Delegate agencies must convene an informational and educational (I&E) materials review committee at least annually consisting of diverse members of the community to advise family planning staff on the suitability of materials provided to or viewed by clients. Ideally, these committees link the agency with others who are knowledgeable about the needs of the community for affordable family planning and reproductive health services.

A record should be kept of all community education and outreach efforts. Staff should evaluate the effectiveness of the efforts. Delegate agencies must submit a Health Education Report to MFPRH Coordinator of Special Projects, CMCH, 201 West Preston Street, Baltimore, MD 21201 no later than March 31 each year describing education and outreach activities for the preceding 12 months. Reports should follow the Community Health Education Annual Report Format, which can be found in the Family Planning and Reproductive Health, Administrative Guidelines section of the CMCH website at <http://fha.dhmh.maryland.gov/mch/>.

11. COMMUNITY EDUCATION

- a. Each family planning project **must** provide for community education programs [59.5(b)(3)]. This should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.
- b. Community education program should enhance community understanding of the family planning project, make known the availability of services to potential clients, and encourage participation by persons to whom family planning may be beneficial.

- c. A written plan inclusive of goals, objectives, and measurement criteria **must** be submitted with the agency's annual grant application. The plan should be based on an assessment of the needs of the service delivery area.
- d. A variety of strategies used in community education programming may include:
 - 1.) Distribution of educational materials
 - 2.) Educational sessions to schools, community groups, agencies and professionals
 - 3.) Assisting community groups in the development of family health related curricula
 - 4.) A system for handling community requests for information and materials

12. PROJECT PROMOTION

- a. To facilitate community acceptance of and access to the delegate's family planning services, delegates **must** establish and implement planned activities whereby their services are made known to the community. [59.5(b)(3)]. Projects should review a range of strategies and assess the availability of existing resources and materials.
- b. Delegates **must** have a formal, written plan for program promotion. This plan **must** be submitted with the annual needs assessment and health care plan.
 - 1.) Low income women and teens **must** be included in the target groups the agency has identified for program promotion activities.
 - 2.) Promotional activities should be reviewed annually and updated in response to the changing needs of the community.
- c. A variety of approaches may be used for promotional activities based on the goals of the program and the intended audience, such as:
 - 1.) Distribution of posters and brochures
 - 2.) Distribution of a newsletter to clients, board members, community leaders, etc.
 - 3.) Providing information to the public through mass media
 - 4.) Participation in community fairs, speakers bureaus, community organizations
 - 5.) Assisting community schools and groups in developing curricula in family life and human sexuality, reproductive health, pregnancy prevention, etc.

III. Client Services, Required Services and Clinic Management

A. Client Services

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

Section III of this document has been developed to assist delegate agencies in determining those services which will be provided to fulfill the mission of Title X. Delegate agencies **must** provide services stipulated in the law or regulations or which are required by these guidelines for the provision of high quality family planning services. Delegate agencies may also provide those services that are intended to promote the reproductive and general health care of the family planning client population.

1. OVERVIEW

- a. Family Planning services **must** be provided under a clinical operations plan with approved protocols and procedures.
 - 1.) The clinic staff **must** use approved protocols for the provision of all family planning services.
 - 2.) Emergency arrangements **must** be available for after hours and weekend care and should be posted, given to, and/or explained to clients.
 - 3.) Clinic hours should be convenient for the target population.
 - 4.) The staffing level of providers should be appropriate for the size and complexity of the project.
 - 5.) Procedures to be followed in case of fire, disaster, or other emergency should be posted.
 - 6.) The clinic should have adequate space and lighting, and should be clean and attractive.
- b. The clinic facility **must** provide for the confidentiality and privacy of the client. The traffic flow pattern in the clinic should be organized to promote privacy and confidentiality.
- c. The agency **must** assure client confidentiality.
 - 1.) A confidentiality assurance statement **must** appear in the client's record.
 - 2.) Delegate agencies **must** assure confidentiality in policy and procedures
 - 3.) Delegate agency personnel **must** assure confidentiality, such as in a confidentiality statement.
 - 4.) Confidentiality should be assured in the following ways:
 - a) Inclusion of consent forms
 - b) Verbalized to clients
 - c) Posted in the clinic

- d. Clients should be informed of their rights and responsibilities as related to the delivery of family planning services. Suggested approaches include:
 - 1.) Use of a consent form delineating these rights and responsibilities.
 - 2.) A poster on the wall.
 - 3.) An informational brochure.
- e. Clinic scheduling should be efficient and promote the delivery of high quality services.
 - 1.) The agency should have a written procedure for scheduling client appointments.
 - 2.) Clients should be able to make appointments for specific times.
 - 3.) Clients should be able to schedule appointments within two weeks.
 - 4.) Teens should be able to schedule appointments within 2-4 days.
 - 5.) The agency should make supply visits available at various times of the day and week for convenience to the client and clinic efficiency.
 - 6.) Where possible, clients should be scheduled for all needed services in one visit.
- f. The agency should have written procedures for handling service delivery to walk-ins, urgent problems and emergencies.
- g. The no-show and walk-in rates should not exceed 30% of total appointments.

2. SERVICE PLANS AND PROTOCOLS

The service plan is the component of the delegate agency's health care plan which is developed by staff and the medical director and which identifies those services to be provided to clients under Title X.

All delegate agencies **must** have written clinical protocols and client education plans, signed by the agencies Medical Director, which outline procedures for the provision of each service offered. Delegate agencies **must** have the written protocols available at each clinical site. Clinical protocols **must** be written in accordance with Title X program requirements, Maryland Family Planning and Reproductive Health Program requirements, State of Maryland laws and nationally recognized standards for medical care. Clinical Protocols **must** be reviewed and signed annually by the medical director. The MFPRH Program Administrative and Clinical Guidelines Manual **must** be available at each clinical site.

According to the Office of Population Affairs Program Instruction, OPA 09-01, acceptable recommendations and standards of care include those of the following nationally recognized health agencies or professional organizations:

- American Cancer Society
- Agency for Health Care Policy and Research, U.S. Preventive Services Task Force
- Centers for Disease Control and Prevention
- American College of Obstetricians and Gynecologists
- North American Society of Pediatric and Adolescent Gynecology
- American Society for Colposcopy and Cervical Pathology
- Agency for Healthcare Research and Quality
- Partners in Information Access for Public Health Resources (Department of Health and Human Services)

Protocols should outline the services provided at initial visits, annual revisits, and other revisits, including supply and problem revisits.

3. PROCEDURAL OUTLINE

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

- a. Service delivery to all clients **must** include the following:
 - 1.) Assuring clients are treated courteously and with dignity and respect.
 - 2.) Assurance of confidentiality.
 - 3.) The opportunity to participate in planning their own medical treatment.
 - 4.) Encouraging clients to voice any questions or concerns they may have.
 - 5.) Materials and/or interpreter available for those with limited ability to read or understand English and for those who may be blind or hearing impaired.
 - 6.) Explanation of all procedures, range of available services, and agency fees and financial arrangements.
- b. Client education, including use of relevant educational materials such as pamphlets, audiovisuals, and brochures, **must** be offered.
 - 1.) Education **must** include information about all contraceptive methods and may include information about basic male and female reproductive anatomy and physiology.
 - 2.) HIV/STI education and information **must** be offered to clients.
 - 3.) Client education should be individualized as much as possible based upon client needs and knowledge.
- c. Individual counseling, an interactive process to assist the client in making an informed choice **must** be offered.
 - 1.) **Must** be done prior to client making informed choice regarding a contraceptive method.
 - 2.) Clients **must** be provided HIV/STI risk assessment, counseling regarding risk reduction and offered testing or referral for testing.
- d. A signed general consent covering examination and treatment, and where applicable a method specific informed consent, **must** be obtained.
- e. A personal, family medical and social history **must** be obtained.
- f. A physical examination, including necessary clinical procedures, **must** be provided.
 - 1.) New clients may defer the required initial physical exam:
 - 2.) Clients **must** be counseled about the importance of preventive services, and the dangers and health risks involved if they defer or decline them.
 - 3.) Physical exam and other related prevention services should not be deferred more than 3 months and **must** not be deferred beyond 6 months, unless the clinician documents a compelling reason.

- 4.) 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.
 - 5.) On future visits, these clients should be encouraged to have a physical exam and appropriate laboratory testing performed.
- g. Laboratory testing **must** be provided, as indicated.
- h. Medications and/or supplies **must** be provided, as indicated/requested.
- 1.) **Must** provide written specific instructions on how to use chosen birth control method
 - 2.) **Must** include danger signs and when, where, and how to obtain emergency care, return schedule and follow-up
- i. Follow-up and Referral **must** be provided, as indicated.
- 1.) Planned mechanism of client follow-up
 - a) Suggested return visit date
 - b) Contact information for emergencies after hours
 - 2.) Performance of any necessary clinical procedures
 - 3.) Provision of referrals as needed

Return visits, with the exception of routine supply visits, should include an assessment of the client's health status, current complaints, and evaluation of the birth control method as well as an opportunity to change methods.

4. EMERGENCIES

Emergency situations involving clients and/or staff may occur any time; therefore, all agencies **must** have written plans and protocols/ operating procedures for the management of on-site medical and non-medical emergencies.

- a. At a minimum, written protocols **must** address:
 - 1.) Vaso-vagal reactions/Syncope (fainting)
 - 2.) Anaphylaxis
 - 3.) Cardiac arrest
 - 4.) Shock
 - 5.) Hemorrhage
 - 6.) Respiratory difficulties
- b. Protocols **must** also be in place for emergencies requiring EMS transport, after hour's management of contraceptive emergencies and clinic emergencies.
- c. All staff should be trained in emergency procedures and **must** be familiar with the plans. Licensed medical staff providing direct patient care services **must** be trained in CPR and hold current certification.
- d. There **must** be a procedure in place for maintenance of emergency resuscitative drugs, supplies, and equipment.

- e. Protocols **must** also be in place for non-medical emergencies including:
 - 1.) Fire
 - 2.) Natural disaster
 - 3.) Robbery
 - 4.) Power failure
 - 5.) Harassment

5. REFERRALS AND FOLLOW-UP

Written protocols and operating procedures for referrals and follow-up **must** be in place for the following: referrals that are made as result of abnormal physical exam or laboratory findings, referrals for required services, and referrals for services determined to be necessary but beyond the scope of family planning.

- a. Referral procedures **must** be sensitive to clients' concerns for confidentiality and privacy.
- b. Client consent for release of information to providers **must** be obtained, except as may be necessary to provide care or as required by law
- c. Protocols and operating procedures for referrals and follow-up made as a result of abnormal physical examination or laboratory test findings within the scope of Title X that impact contraceptive management **must** include the following:
 - 1.) A system to document referrals and follow up procedures **must** be in place.
 - 2.) Follow-up procedures **must** include the following:
 - a) A method to identify clients needing follow-up
 - b) A method to track follow-up results on necessary referrals (such as, Pap and breast follow-up)
 - c) Documentation in the client record of contact and follow-up.
 - d) Documentation of reasons, actions and follow-up where recommendations were not followed and/or protocols not acted upon.
 - 3.) Referral procedures should include that the client be given an explanation of the referral and need for follow-up including:
 - a) Reason and importance of the referral
 - b) Services to be received from the referral agency
 - c) Address of the referral provider/agency
 - d) Any instructions needed to follow through with the referral
 - e) When to return to the family planning clinic
- d. Delegate agencies **must** provide all family planning services listed in Section 8.0 of the Federal Title X *Program Guidelines for Project Grants for Family Planning Services* under "Required Services" either on-site or by referral. When required services are provided by referral, the agency **must** have in place formal arrangements with a referral provider that includes a description of the services provided and includes cost reimbursement information.
- e. For services determined to be necessary but which are beyond the scope of the project (such as thyroid abnormalities), clients **must** be referred to other providers for care.

When a client is referred for non family planning or emergency clinical care, agencies **must**:

- 1.) Make arrangements for the provision of pertinent client information to the referral provider (client may hand carry referral information).
 - 2.) Obtain the client consent for referral arrangements, except as necessary to provide care or as required by law.
 - 3.) Document that the client was advised of the referral and the importance of follow-up.
 - 4.) Document that the client was advised of their responsibility to comply with the referral.
 - 5.) Maintain appropriate safeguards for confidentiality.
- f. Agencies **must** maintain a current list of providers including health care providers, local health and human service departments, hospitals, voluntary agencies, and health service projects supported by other federal programs to be used for referral purposes.
- 1.) Referral lists **must** be current and updated annually.
 - 2.) Providers should be selected by procedures which assure fairness in selection and identify providers of acceptable quality.
 - 3.) When possible, clients should be given a choice of providers.

B. REQUIRED SERVICES

1. OVERVIEW

The services contained in this section **must** be provided by all Title X funded projects. The client's written informed voluntary general consent **must** be obtained prior to receiving any clinical services. In addition, if a client chooses a prescription method of contraception, a method-specific consent **must** be obtained and updated at subsequent visits to reflect a change to a different method or significant changes in information regarding the method.

2. CLIENT EDUCATION

a. Delegate agencies **must** have written client education plans that include goals and content outlines to ensure the consistency and accuracy of the education. The education **must** provide clients with the information needed to make informed decisions about their reproductive health. Client education **must** be documented in the client record. The education provided **must** be appropriate to the client's age, level of knowledge, language, socio-cultural background and be presented in an unbiased manner. The education plan should include content on the educational focus for initial, annual, other revisits and supply visits.

b. Following are educational topic areas that **must** be provided:

1.) Birth control methods:

- a) Hormonal Contraceptives (oral, injectable, implant, patch, ring)
- b) Abstinence
- c) Natural family planning
- d) Barrier Methods (male & female condoms, diaphragm, sponge, cervical cap, spermicide)
- e) Intrauterine Devices
- f) Sterilization (tubal surgery, tubal implant, vasectomy)
- g) Emergency Contraception

2.) Instruction in breast self awareness and testicular self-exam

3.) Education on reducing the risk of Sexually Transmitted Infections (STIs), including Human Immunodeficiency Virus (HIV)

4.) Information on the range of available services, purpose and sequence of clinic procedures.

5.) Information on the importance of recommended screening tests and other procedures involved in the family planning visit.

c. Following educational topic areas should be provided as indicated:

1.) Clients should be offered information about basic male and female anatomy and physiology and the value of fertility regulation in maintaining individual and family health.

2.) Information on reproductive health and health promotion, disease prevention, including nutrition, exercise, smoking cessation and alcohol and drug abuse, domestic violence and sexual abuse.

- 3.) Education should include information on clinical services that are available and what to expect during clinic appointments.
- 4.) Individualized educational needs should be identified and addressed during the visit
- 5.) The client should receive information about routine screening tests and other procedures involved in the family planning visit.
- 6.) A variety of teaching methods may be used, for example:
 - (i) One-on-one instruction with the client
 - (ii) Videotape or DVD
 - (iii) Pamphlets or other written media
 - (iv) Group education.

3. INFORMED CONSENT

Delegate agencies may need to obtain multiple types of written informed consent, depending on the services a client will receive: a general consent **must** be obtained prior to receiving clinical services; a second, method-specific informed consent **must** be obtained for prescription birth control; and a third federally required consent for sterilization. In addition, consent to release information may be required before client information is released.

- a. A written consent for general family planning services must be obtained at the initial visit. It should be obtained again every four years for continuing clients or if there is a break in service of one year or greater.
- b. Each consent form must be signed and dated by the client and witnessed and signed and dated by a staff member after thorough counseling and review of the information on the form.
- c. A written consent for a specific procedure (such as IUD/IUS insertion) needs to be obtained only at the time of the procedure.
- d. The FDA-approved and manufacturer-supplied pamphlet must be given to the client for all hormonal methods and the IUD. This action should be documented.
- e. The client may be given a copy of each consent, if requested.
- f. If the clinician believes that a client is unable to give informed consent (for example, because of mental disability), then written informed consent must be given by the parent or legal guardian if the client is a minor, or a legal guardian if the client is an adult.
- g. Local programs may use additional consent forms.
- h. Templates for method specific consent forms can be found on the MFPRH Program website http://fha.dhmh.maryland.gov/mch/SitePages/fp_home.aspx

4. COUNSELING

The main reason for counseling is to assist clients to reach informed choices about their reproductive health and continued use of family planning methods and services. The

counseling process should be designed to help clients resolve uncertainty, ambivalence, and anxiety about their reproductive health and increase their ability to make decisions that fit their lifestyle. The counseling process involves mutual sharing of information. It **must** be provided by someone who is knowledgeable, objective, non-judgmental, sensitive to the rights and differences of clients as individuals, culturally aware and able to make the client comfortable while sharing personal information. The counselor **must** have the knowledge to provide accurate information about the benefits and risks, safety, effectiveness, potential side effects, complications, discontinuation issues and danger signs of various contraceptive methods. The counselor should be aware of other services and referral agencies. Documentation of counseling **must** be in the client's record.

- a. Method Counseling is an individualized discussion that includes the following:
 - 1.) The results of the history, physical exam, and lab testing
 - 2.) How to use contraceptive methods, including natural family planning (NFP), and the benefit and efficacy of the methods
 - 3.) Possible side effects and complications
 - 4.) How to discontinue the method selected and information regarding back up method use
 - 5.) Protection against STI/HIV with the method selected
 - 6.) Return visit schedule
 - 7.) Emergency 24-hour telephone number
 - 8.) Location where emergency services can be obtained
 - 9.) Appropriate referral for additional services as needed.

- b. Sexually-Transmitted Infection (STI) and HIV (Human Immunodeficiency Virus) Counseling
 - 1.) All clients **must** receive accurate counseling on STIs and HIV. Counseling refers to an individualized discussion with a client that involves personal risks for STIs and HIV and the steps to be taken by the individual to reduce their risks. Clients with at risk behaviors for STIs and HIV **must** be advised about risk reduction and if clinical evaluation is needed.
 - 2.) All delegate agencies **must** offer the following HIV components:
 - 3.) Education about HIV infection and Acquired Immune Deficiency Syndrome (AIDS)
 - 4.) Individualized risk assessment and risk reduction counseling
 - 5.) If the delegate agency does not provide HIV testing on-site, they **must** provide the client with a referral list of health care providers who can provide this service.
 - 6.) All delegate agencies must follow the most current [Centers for Disease Control and Prevention \(CDC\) Sexually Transmitted Diseases Treatment Guidelines](#) (CDC Guidelines) and their local health department or Maryland Department of Health and Mental Hygiene's Infectious Disease and Environmental Health Administration.
 - 7.) Information on reportable disease is available on the Infectious Disease and Environmental Health Administration's (IDEHA) website at <http://ideha.dhmh.maryland.gov/SitePages/reportable-diseases.aspx>

5.

HISTORY, PHYSICAL ASSESSMENT AND LABORATORY TESTING

a. History

- 1.) At the initial comprehensive clinical visit, a complete medical history **must** be obtained on female and male clients. At minimum, the history **must** include the following:
 - a) Significant illnesses; hospitalizations; surgery; blood transfusion (prior to 1984) or exposure to blood products; and chronic or acute medical conditions
 - b) Allergies.
 - c) Current use of prescription and over-the-counter medications
 - d) Extent of use of tobacco, alcohol, and other drugs
 - e) Immunizations and Rubella status (use of MCIR is encouraged)
 - f) Review of systems
 - g) Pertinent history of immediate family members
 - h) Partner history of:
 - (i) injectable drug use
 - (ii) multiple partners
 - (iii) risk history for STIs and HIV
 - (iv) sex with men, sex with women or both
- 2.) Female reproductive history **must** include at least the following:
 - a) Contraceptive use, past and current (including any adverse effects); reasons for stopping past method
 - b) Menstrual history, including last menstrual period (LMP)
 - c) Sexual history
 - d) Obstetrical history
 - e) Gynecological conditions
 - f) Sexually transmitted infections, including Hepatitis B Virus (HBV)
 - (i) HIV infection
 - (ii) Pap test history (date of last Pap, abnormal Pap, treatment)
 - (iii) In-utero exposure to diethylstilbestrol (DES).
- 3.) Male reproductive history **must** include at least the following:
 - a) Sexual history
 - b) Sexually transmitted infections, including HBV
 - c) HIV infection
 - d) Urological conditions

b. Physical Assessment (female)

For many clients, Family Planning programs are the only continuing source of health information and clinical care. Therefore, an initial complete physical exam, including height and weight, examination of the thyroid, heart, lungs, extremities, breasts, abdomen, pelvis, and rectum, should be performed. The primary reason for family planning visits is fertility regulation, but other health maintenance screening is important and should be encouraged.

- 1.) Clinics **must** provide and stress the importance of the following to all clients:
 - a) Blood pressure evaluation
 - b) Clinical breast exam (CBE) as age appropriate, including instruction in breast self awareness.
 - c) Pelvic examination including vulvar evaluation and bimanual exam, beginning at age 21 and only as indicated for 13-20 years of age.
 - d) Pap testing as indicated
 - e) Colo-rectal cancer screening, beginning at age 50
 - f) STI and HIV risk assessment and screening or referral, as indicated

- 2.) 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 a service is deferred or declined, both the counseling that took place and the reason for the deferral **must** be documented in the client record.

- 3.) Delegate agencies protocols **must** be developed to ensure that:
 - a) All physical exam and laboratory tests required for specific methods of contraception **must** be followed.
 - b) Physical exam and related preventive services should not be deferred more than 3 months after the initial visit, and in no case be deferred beyond 6 months, unless in the clinician documents a compelling reason to do so.
 - c) All deferrals and reason for deferral **must** be documented in the client record.

- c. Physical Assessment (male)

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

 - 1.) Blood pressure evaluation
 - 2.) Colorectal cancer screening, beginning at age 50
 - 3.) STI and HIV risk assessment and screening or referral, as indicated

- d. Laboratory Testing

Written laboratory protocols and operating procedures **must** be in place that meets the following required standards:

 - 1.) Specific laboratory tests are required for the provision of specific methods of contraception. These tests are also indicators of health status and are useful for diagnostic reasons. These tests are provided to the client unless written results of the test done within 12 months are obtained and placed in the medical record.
 - a) Pregnancy testing **must** be provided on site as indicated.
 - b) Laboratory testing **must** be provided if indicated for a specific method of contraception.
 - c) Pap testing **must** be provided on site as indicated.

- d) HIV testing, or referral for testing, as indicated
- e) Colo-rectal cancer screening, beginning at age 50
- f) The following laboratory testing **must** be provided if required in the provision of a specific contraceptive method. They may be provided, either on site or by referral, for health maintenance and/or for diagnostic purposes as indicated.
 - (i) Anemia assessment
 - (ii) Gonorrhea and Chlamydia testing
 - (iii) Vaginal wet mount
 - (iv) Diabetes testing
 - (v) Cholesterol and lipids
 - (vi) Hepatitis B testing
 - (vii) Genital Herpes testing
 - (viii) Syphilis serology (VDRL, RPR)
 - (ix) Rubella titer
 - (x) Urinalysis
- g) The following testing may be provided either on site or by referral for health maintenance and/or diagnostic purposes as indicated.
 - (i) Condylomata Acuminata (HPV)
 - (ii) Trichomonas
 - (iii) Candidiasis
 - (iv) Bacterial Vaginosis
- h) Quality control, equipment maintenance and proficiency testing for on-site lab testing **must** be in place.
- i) Assurance of high quality lab testing for off-site labs **must** include:
 - (i) Compliance with Clinical Laboratory Improvement Amendments (CLIA) regulations. Following is a CLIA website for more information:
<http://www.cms.hhs.gov/clia>
 - (ii) A system for assessing credentials of contracting labs should be in place.
 - (iii) Cytology services **must** be provided by laboratories compliant with state licensure regulations
- j) A procedure **must** be established for referral and follow-up for abnormal tests that includes the following:
 - (i) Documentation of the appropriate management for abnormalities
 - (ii) Notification of the client
 - (iii) Protection of the client's confidentiality
 - (iv) Follow-up with the client of significant lab results
 - (v) Referral for necessary services if not provided on-site
 - (vi) When initial contact is not successful, a reasonable further effort should be made, consistent with the severity of the abnormality.

- e. Agencies should provide testing for a variety of STIs as indicated. If testing is provided, delegate agencies **must** have STI treatment protocols and follow-up procedures in place that are consistent with current CDC guidelines.
 - f. When indicated the following lab tests and procedures may be provided or referred:
 - 1.) Microscopic exam of vaginal smears and wet mounts.
 - 2.) Microscopic exam and/or culture and sensitivity of urine.
 - 3.) Selected blood tests including fasting and/or random blood sugar, cholesterol, and other lipid panels.
 - g. Written protocols for abnormal Pap testing follow-up **must** be in place.
 - 1.) Follow-up contact **must** be noted in the client's medical record.
 - 2.) Results of the follow-up **must** be noted in the client's medical record.
 - 3.) If unable to contact client, a certified letter should be sent to those clients who have any high grade lesions or cancer on their Pap test result.
 - h. Revisits
 - 1.) Revisit schedules **must** be individualized based on the client's need for education, counseling, and clinical care beyond that provided at the initial and annual visits.
 - 2.) Clients selecting hormonal contraceptives, implants, intrauterine devices (IUD/IUS), or diaphragms for the first time may be scheduled for a revisit, if needed, to reinforce proper use, check fit, side effects, and provide additional information.
 - 3.) A new or established client who chooses to continue a method already in use need not return for a revisit unless a need for reevaluation is determined on the basis of findings at the initial visit.
 - 4.) Pertinent history **must** be updated at subsequent physical exam visits.
6. FERTILITY REGULATION (CONTRACEPTION)
- a. Written protocols and operating procedures **must** be in place that meets the following standards:
 - 1.) A broad range of Federal Drug Administration (FDA) approved methods of contraception **must** be made available on site or through referral.
 - 2.) Current FDA guidelines as to relative and absolute contraindications should be followed when prescribing contraceptives.
 - 3.) More than one method may be used simultaneously by the client. Clients with high-risk sexual behavior patterns should be encouraged to use condoms correctly and consistently in addition to any other chosen method to reduce the risks of STIs/HIV and pregnancy.
 - b. Methods of contraception that **must** be provided and for which written protocols **must** be in place include:

- 1.) Reversible contraception
 - a) Hormonal Contraceptives
 - b) At least two delivery methods of combined hormonal contraceptives **must** be available on site
 - c) At least one delivery method of progestin-only contraceptives **must** be available on site.
 - d) At least a second type of progestin-only method **must** be made available on site within two weeks of client request.
- 2.) Condoms
 - a) At least male condoms **must** be available on site.
- 3.) Implants and Intrauterine Devices (IUD/IUS) **must** be provided, either on site or by paid referral.
- 4.) Education materials and information regarding all methods including, hormonal contraceptives, abstinence, natural family planning, barrier methods, intrauterine devices, sterilization, and emergency contraception.
- 5.) The agency formulary **must** indicate
 - a) Methods maintained and available on site
 - b) Methods available on site within two weeks of client request
 - c) Methods available by paid referral.
 - d) Methods available by unpaid referral.
- 6.) Agencies are encouraged to review current practice and the needs of their client population and maintain the most frequently used methods where feasible.
- 7.) Agencies are strongly encouraged to provide emergency contraception and maintain supplies on site.

7. EMERGENCY CONTRACEPTION

Certain oral contraceptive regimens have been found by the FDA to be safe and effective for use as postcoital emergency contraception when initiated after unprotected intercourse, including 1 and 2 pill formulations of progestin-only emergency contraceptive pills. Emergency Contraception education and referral **must** be provided to all female clients. The provision of pre-placement emergency contraception is strongly encouraged, but not required for delegate agencies. Where delegate agencies provide this method the following **must** occur:

- a. Written protocol **must** be in place.
- b. The client requesting emergency contraception should have a negative, highly sensitive pregnancy test to exclude a pre-existing pregnancy if indicated by the client's history.

- c. Birth control counseling should accompany or follow any method used for emergency contraception.

8. PERMANENT CONTRACEPTION (STERILIZATION)

Clinical guidance on sterilization for males and for females can be found in the *Maryland Family Planning and Reproductive Health Program Clinical Guidelines*. The guidance that follows pertains to the process of counseling and referring the client, obtaining informed consent where appropriate, processing the consent form and assisting in scheduling the procedure.

a. Vasectomy

Since 1994, the Maryland Family Planning Program has funded vasectomy procedures for a limited number of Maryland men aged 21 or older who desire this method of contraception but cannot afford it. The procedures are performed at the Planned Parenthood of Maryland. Counseling and consent, which must be completed at least 30 days prior to the procedure, may be provided either at Planned Parenthood of Maryland or at any other Maryland State Family Planning Program clinic site. To obtain information about vasectomy services offered by Planned Parenthood of Maryland and funded by the Maryland State Family Planning Program, go to www.plannedparenthoodmd.org or call 410-665-9775.

1.) Counseling

- a) The client may receive vasectomy counseling at any delegate agency. When the counseling is performed locally, the prospective vasectomy patient signs the consent form at the conclusion of the session and hand-carries the original to Planned Parenthood of Maryland on the day of the procedure.
- b) Patient education tools may be used in order to assist with vasectomy counseling. Vasectomy counseling will include information about the “no-scalpel” procedure, advantages, disadvantages, permanency, the availability of other contraceptive options for the client and his partner and the post-operative semen analysis.

2.) Consent

- a) The Federal Sterilization Consent (OMB 0937-0166) **must** be used when a client chooses sterilization through the MFPRH Program partnership with Planned Parenthood of Maryland. It is available in English or Spanish for from the OPA Clearinghouse (<http://www.opaclearinghouse.org/title.html>). It must be signed by the client and witnessed by staff. If the client signed the consent at a local clinic, he must bring the original with him to the Planned Parenthood Maryland facility on the day of the procedure.
- b) It is important to remember that vasectomies funded through federal government programs such as the Title X program and Medicaid or Medicare require that there be a **30**-day waiting period between the date the consent was signed and the date of the vasectomy. Once signed, the consent form is effective for **180** days from the date of the signature.

3.) Release of Medical Information

If the local provider wants vasectomy information returned, the provider must forward a release of information form signed by the client to Planned Parenthood of Maryland. The INDIVIDUAL'S AUTHORIZATION form which can be found by staff of local health departments on the DHMH Intranet at <http://indhmb/hipaa/html/guideandforms.html> or an alternative HIPAA-compliant release form is acceptable.

4.) Financial Eligibility Determination

The contact person at Planned Parenthood of Maryland will explain the fee assessment eligibility process when the client calls to make the vasectomy appointment.

9. TUBAL LIGATION REFERRAL

The MFPRH Program does not fund tubal ligation surgeries. However, clients seeking information about sterilization should be counseled by staff regarding the advantages and disadvantages of tubal ligation, its permanency, and the availability of other contraceptive options. Patient education tools may be used in order to assist with tubal ligation counseling. The Office of Population Affairs (OPA) Clearinghouse offers the information on female sterilization (<http://www.opaclearinghouse.org/title.html>)

Clinics should have a current list of local providers for referral. Women who are in the Maryland Medical Assistance Family Planning (Purple and White Card) Program are eligible for tubal ligation if they are 21 years or older. The women can choose any doctor or clinic that accepts Medical Assistance.

10. INFERTILITY SERVICES

All clinics must offer at least basic (Level I) infertility services, which include an initial infertility interview, education, physical examination, counseling, and appropriate referral. However, Level II and Level III infertility services are beyond the scope of services offered by the Maryland State Family Planning Program. The following centers are referral resources for infertility:

- a. University of Maryland Hospital
Gynecology, Endocrinology and Infertility Clinic
410-328-6640
- b. Johns Hopkins Hospital
Gynecologic, Infertility and Endocrine Clinic
410-955-5191

11. PREGNANCY DIAGNOSIS AND COUNSELING

Delegate agencies **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. It is therefore important to use this occasion as an entry point for providing education and counseling about family planning services.

- a. Written protocols and procedures **must** meet the following standards:
 - 1.) Pregnancy diagnosis services include:
 - a) Informed consent
 - b) History
 - c) Pregnancy testing with high sensitivity
 - d) Physical exam, including pelvic exam.
- b. When a physical exam is not performed at the time of the pregnancy test, the client **must** be counseled about the importance of a physical assessment, preferably within 15 days. This physical exam can be done on-site, by a provider of the client's choice, or through a referral.
- c. If the pregnancy test is positive, all of the following counseling options to manage the pregnancy **must** be offered, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.
 - 1.) Prenatal care and delivery
 - 2.) Infant care, foster care, or adoption
 - 3.) Pregnancy termination
- d. Pregnancy options counseling **must** be provided in a non-directive, unbiased manner. When requested to provide such information and counseling, agencies **must** provide neutral, factual information and nondirective counseling on each of the options, and referrals upon request, except with respect to any options about which the pregnant woman indicates she does not wish to receive information and counseling. [59.5(a)(5)].
- e. Clients with positive pregnancy tests who elect to continue the pregnancy should receive a referral for early prenatal care and information about the importance of early prenatal care. Clients planning to carry their pregnancies to term should be given information about good health practices during early pregnancy, especially those which serve to protect the fetus during the first three months (e.g., good nutrition, avoidance of smoking, drugs, alcohol and exposure to x-rays).
- f. Clients with a negative pregnancy diagnosis should be given information about the availability of contraceptive and infertility services and offered an appointment, as appropriate. If the pregnancy test is negative, but other indicators are present for pregnancy, the client should be encouraged to have a repeat pregnancy test within the appropriate time frame. Clients with a negative pregnancy test should have the cause of their delayed menses investigated.
- g. 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) are at high risk for ectopic pregnancies. Follow-up with these clients **must** occur and all contact **must** be documented in the medical record.
- h. Personnel involved in pregnancy diagnosis and counseling **must** have knowledge of:

- 1.) Pregnancy testing procedures
- 2.) Prenatal care and delivery
- 3.) Infant care, foster care and adoption
- 4.) Pregnancy termination
- 5.) Local availability of referral services
- 6.) Methods of contraception
- 7.) Federal and state requirements regarding mandatory reporting, options counseling, and abortion laws
- 8.) Non-directive counseling skills and techniques
- 9.) Documentation needed for the client record

12. ADOLESCENT SERVICES

Adolescent clients require skilled counseling and age-appropriate information. An atmosphere in which the adolescent is comfortable asking questions should be created. The agency **must** address in their annual plan service delivery to adolescents, including the total number of adolescents the agency anticipates serving.

Appointments should be available to them for counseling and clinical services as soon as possible. Adolescents seeking contraceptive services **must** be informed about all methods of contraception. It is important not to assume that the adolescent is sexually active because they came for family planning services. As the contraceptive needs of adolescents frequently change, counseling should prepare them to use a variety of methods effectively.

- a. The agency **must** have protocols and operating procedures that address the following requirements related to adolescent health:
 - 1.) Adolescent counseling services **must** consist of:
 - a) Assurance of confidentiality of services
 - 2.) An atmosphere in which the adolescent is comfortable in asking questions.
 - 3.) Informed on all methods of contraception, including abstinence
 - 4.) Discussion of sexually transmitted infections, including HIV infection, and safer sex practices to reduce risks for STI/HIV.
 - 5.) Encourage participation in the agency's medical services, including physical exam, laboratory testing, and treatment as indicated
 - 6.) Encourage family participation in the decision of minors to seek family planning services.
 - 7.) Provide counseling on how to resist attempts to coerce adolescents into engaging in sexual activities.
 - 8.) Inform adolescents that in special cases, (e.g. suspected child abuse) that reporting to authorities is required.
- b. The delegate should have specialized projects or services for adolescents. These may include the following:
 - 1.) Peer counselors
 - 2.) Special clinic hours for adolescents
 - 3.) School/community education programs
 - 4.) Priority appointments to schedule within 2-4 days

13. IDENTIFICATION OF ESTROGEN-EXPOSED OFFSPRING

Women born between 1940 and 1970 **must** be assessed for in-utero DES exposure. The children of women who received DES or similar hormones during pregnancy may have abnormalities of their reproductive systems or other fertility related risks. Clients exposed to exogenous estrogen **must** receive information, education and special screening either onsite or by referral.

C. Related Services

1. GYNECOLOGICAL 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 dip stick testing. These services should be provided.

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

2. SEXUALLY TRANSMITTED INFECTIONS (STIs) AND HIV/AIDS

The increasing incidence and prevalence of STIs, particularly among adolescents, requires that family planning delegate agencies increase their efforts to provide education and information about the more common STIs and HIV/AIDS. Delegate agencies should 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, if indicated. Tests for gonorrhea, chlamydia, syphilis, and HIV should be available as indicated by client request or evidence of increased risk.

a. Written protocols and operating procedures for sexually transmitted infections **must** be in place when STI services are provided by the delegate agency and must include the following:

1.) Screening should follow current Centers for Disease Control and Prevention STI Treatment Guidelines.

a) Chlamydia tests should be provided annually for sexually active females 24 and under. Clients who test positive should be re-tested 3 months following treatment for early detection of re-infection. Clients who do not present at 3 months for re-test should be re-tested the next time they present for services in the 12 months following treatment of the initial infection. Females over 24 should be tested only if other risk factors are present (infected partner, symptoms, history of STI or multiple partners in the last year.)

- b) CDC screening recommendations indicate targeted chlamydia screening for men only when resources permit and do not hinder chlamydia screening efforts in young women 24 and under.
- 2.) Gonorrhea testing should be offered annually to high risk clients 24 and under who reside in high prevalence areas. Females over 24 should be tested only if other risk factors are present (infected partner, symptoms, history of STI or multiple partners in past year.)
- 3.) Routine Gonorrhea screening of males at low risk is not recommended
- 4.) When treatment for any STI is provided on-site, the delegate **must** follow current Centers for Disease Control and Prevention STI Treatment Guidelines and ensure appropriate follow-up measures are taken with all persons treated.
- 5.) Delegate agencies **must** comply with state and local STI reporting requirements.
- 6.) Providers should encourage their clients with STIs to notify their sex partners and urge them to seek medical evaluation and treatment.
- 7.) Test for syphilis as indicated.
- 8.) Test 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 risk assessment, counseling regarding risk reduction and referral services
 - 3.) Testing or referral for testing
 - 4.) All clinical staff **must** receive in-service training regarding:
 - 5.) HIV infection and its prevention
 - 6.) Transmission and infection control in a health care setting
 - 7.) Education on HIV infection should be included in appropriate community educational sessions

3. GENETIC INFORMATION AND REFERRAL

Information gathered when completing the family planning initial record may assist in assessing the client's need for genetic counseling and evaluation. The clinician and other staff members should be alert to any indication of genetic disorders or conditions in a client that may lead to birth defects.

Extensive genetic counseling and evaluation are beyond the scope of the MFPRH Program; therefore, a referral systems should be in place for those that require such services. The Office for Genetics and Children with Special Health Care Needs at DHMH can facilitate referral for in-depth personalized counseling. You may call the Office for Genetics and Children with Special Health Care Needs at 410-767-6730 or 1-800-638-8864. Additionally, the following centers are referral resources:

- a. University of Maryland Hospital
Prenatal Diagnostic Center
410-328-3335
- b. Johns Hopkins Hospital
Prenatal Diagnostic Center
410-955-3091
- c. Sinai Hospital
Prenatal Diagnostic Center
410-601-5853

4. HEALTH PROMOTION/DISEASE PREVENTION

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

For many clients, family planning programs are their only continuing source of health information and medical care. Delegate agencies should, whenever possible, provide or coordinate access to services intended to promote health and prevent disease.

Health promotion/disease prevention information should include the following:

- a. Cancer detection - breast, cervical, testicular and colon
- b. Harmful effects of smoking and smoking cessation resources
- c. Automobile safety, including seat belt and child car seat resources
- d. Sexual risk behaviors
- e. Substance abuse
- f. Mental health problems
- g. Weight control
- h. Regular exercise
- i. Violence prevention; including domestic assault, relationship abuse, and human trafficking

5. POSTPARTUM CARE

Family planning programs may provide postpartum care in collaboration with local agencies or institutions which provide prenatal and/or intrapartum care. If a family planning program assumes responsibility for postpartum care, such care should be directed toward:

- a. Assessment of the woman's physical health
- b. Initiation of contraception, if desired
- c. Counseling and education related to
 - 1.) Parenting
 - 2.) Breast feeding
 - 3.) Infant care
 - 4.) Post-partum depression

5.) Family adjustment

6. FAMILY AND INTIMATE PARTNER VIOLENCE

Family and intimate partner violence (FIPV) includes physical, sexual and psychological assault and/or coercion within a current or past family, cohabiting or dating relationship. It is also known as domestic violence. It may be an isolated event, when the perpetrator lacks continuing access to the victim; however, more frequently it is a pattern of ongoing behavior. The goal of such behavior is achieving compliance from or control over the victim. A child or adolescent may be the actual or intended target of a violent act, or may become traumatized by witnessing abusive behavior. A high proportion of those who behave violently with an adult partner also abuse children within the family. Children may come to believe that violence is an acceptable way of dealing with problems or conflicts. They may also be more likely to enter into abusive relationships as they mature.

Most violence toward a partner is perpetrated by a male against a female; however, male-to-male, female-to-male and female-to-female violence is known to occur as well. FIPV can result in injury, death or chronic illness. Some victims are at greatest risk when they try to leave the situation or have separated from the abuser.

Healthcare providers need to view interpersonal violence as a health problem. Appropriate health care management of all women includes universal screening for family or intimate partner violence.

Many women who have been victimized are reluctant or unable to get help. Some are literally held captive, and others may not have the money or means of transportation to leave. Cultural, ethnic and/or religious influences may affect a woman's response to violent behavior and her awareness of viable options.

Maryland does not have mandatory reporting requirements for domestic violence. In Maryland, mandatory reporting is required only for abuse or neglect of a child or abuse, neglect or exploitation of a vulnerable adult. A vulnerable adult is defined as a person aged 18 or older who lacks the physical or mental capacity to provide for his or her daily needs. In other situations involving interpersonal violence, it is the responsibility of the victim to report the abuse to the proper authorities. However, whenever any health care provider treats a person for an injury that was caused by or shows evidence of having been caused by any type of gunshot, the police must be notified.

a. FIPV guidelines for providers are as follows:

- 1.) All clients should be educated to increase their awareness of violence as a health problem. This information should be part of their health care education and counseling.
- 2.) Family planning clients should be screened for current or previous FIPV during initial visits. Screening should be updated at least annually thereafter. Information about a person's prior experience of physical, psychological or sexual violence may have

bearing upon current or future health and wellbeing.

- 3.) Clients should be informed about the level of confidentiality they may expect in response to any disclosure they may make. Requirements for mandated reporting of child abuse or neglect should be clearly stated, including the requirement that maltreatment be reported even when it occurred when an adult was still a child.
 - 4.) Screening should be carried out in private. Direct, specific questions should be phrased in order to make them nonjudgmental and as non-threatening as possible.
 - 5.) Health care providers should accurately document any problems or complaints of abuse, or physical evidence of violence.
 - 6.) The possibility of FIPV should be considered when a client's explanation for an injury does not seem plausible, when there has been a delay in seeking medical care or when an individual presents with vague complaints for which there is no other plausible explanation.
 - 7.) Cultural competency is important, and questions should be asked in the client's primary language when possible.
 - 8.) Upon learning of an incident or pattern of domestic violence, a provider needs to assess the current safety of the client. If the client was victimized in the past and is no longer at risk, a referral for counseling may be indicated. If there is violence in a current relationship, a provider should attempt to establish a safety plan with the client and make referrals to community resources. Each clinic should maintain listings with contact information for local law enforcement, shelters and other agencies that serve victims of domestic violence and counselors. The Maryland Network Against Domestic Violence (MNADV) and the Maryland Coalition Against Sexual Assault (MCASA) can provide statewide information on laws as well as national and local resources. To contact MNADV, go to www.MNADV.org or call 1-800-MD HELPS. To contact MCASA, go to www.mcasa.org or call 1-800-983 RAPE. Providers should maintain respect for the right of each individual to determine his or her own course of action. If a client does not wish to seek counseling or involve the authorities, it may be helpful to promote the importance of a social support system.
- b. Women are sometimes under the mistaken impression that violence will stop during pregnancy. It is important to advise such clients that research has not shown this to be true. In fact, abusive behavior is likely to continue unabated or increase.
 - c. When a woman fears that her partner may respond violently if he discovers that she has come to the clinic, it is likely that the provider will wish to recommend an undetectable method of contraception such as injectable progestin (Depo-Provera®).
 - d. When a provider suspects or is told that an adolescent client has experienced violence,

sexual coercion and/or assault that is not reportable to Child Protective Services or law enforcement, the provider should seek to engage the young person in safety planning. Counseling may also be appropriate on ways to avoid sexual coercion. The client should be given information about ways to contact local victims' services programs, emergency medical facilities and law enforcement.

- e. Details about the laws concerning Domestic Violence can be found in the Annotated Code of Maryland, Family Law Article, §4-501 to §4-530.
- f. Details about the laws concerning sexual assault and rape can be found in the Annotated Code of Maryland, Criminal Law Article, §3-304, §3-305, §3-306, §3-307 and §3-308.

7. MANDATED REPORTING OF CHILD ABUSE AND NEGLECT

All health care workers acting in their professional capacity are mandated to report information that otherwise would be confidential when they suspect child abuse or neglect. In Maryland, reports are required even when a previously maltreated child is now an adult. All mandated reporters **must** have an updated training every two years and documentation of this training must be maintained.

Workers are protected from civil liability and criminal penalty when making a report in good faith. Alternatively, they could be subject to sanctions from their professional licensing boards if they knowingly fail to report.

A child is defined as an individual under the age of 18. Child abuse includes physical injury or mental injury under circumstances indicating that a child's health or welfare is harmed or at substantial risk of harm and sexual abuse, with or without physical injury, perpetrated upon a child by a family or household member or someone with temporary or permanent, current or past care, custody or responsibility for supervision of the child.

Child neglect means the failure to provide proper care and attention to the child under circumstances that the child's health or welfare is harmed or placed at substantial risk of harm. It includes leaving the child unattended and mental injury or substantial risk of mental injury that is caused by failure to provide proper care and attention to the child.

When the perpetrator of a physical or sexual assault is an individual **other than** a family or household member or someone with temporary or permanent, current or past care, custody or responsibility for the supervision of the child, the mandated reporting requirement does not apply. In fact, a provider could risk licensing or criminal penalties or civil liability for violating the confidentiality of a client were the provider to make a report in a situation that falls outside the mandated reporting law.

In Maryland, statutory rape is not reportable unless the perpetrator is a family or household member or someone with temporary or permanent, current or past care, custody or responsibility for the supervision of the minor. However, even when it is not reportable, a sexual relationship between an adolescent and an older adolescent or adult may raise

concerns that sexual coercion is occurring. Family planning providers are required to counsel minors about ways to resist attempts to coerce them into engaging in sexual activities. In addition to counseling, referrals to sexual assault programs or other types of assistance may be offered.

a. Guidelines for mandated reporters are as follows:

- 1.) Under Maryland's mandated reporting law, after a health care provider has learned about a suspected incident or incidents of child maltreatment, a report to the appropriate authorities is required.
- 2.) An oral report of child physical or sexual abuse must be made as soon as possible to Child Protective Services (CPS) or the appropriate law enforcement agency.
- 3.) An oral report of neglect or mental injury must be made as soon as possible to CPS.
- 4.) The head of the public health agency in which the provider is employed should be informed of an abuse or neglect report immediately.
- 5.) Within 48 hours, a written report of abuse or neglect must be sent to CPS and, if the report concerns child abuse, a copy must also be sent to the State's Attorney. Information on how to report to CPS can be found at www.dhr.state.md.us/cps.
- 6.) When the mandated reporting law does not apply in cases of statutory rape, dating violence or sexual assault, a young person may need assistance in accessing a variety of medical, including mental health, and community services. At a minimum, the client should be counseled about safety, parental involvement and ways to resist sexual coercion. The youth should be urged to take advantage of local victims' services programs. Referral to emergency medical facilities and/or local law enforcement authorities may also be appropriate.

8. HUMAN TRAFFICKING

Human trafficking is a form of modern-day slavery and is a federal crime since the passage of the Trafficking Victims Protection Act of 2000. This act applies to both U.S. citizens and foreign born nationals. All delegate agency staff must have an updated training every two years on human trafficking and documentation of this training must be maintained.

There are three categories of human trafficking:

- Those over 18 involved in commercial sex via force, fraud or coercion.
- Minors involved in commercial sex
- Adults or minors involved in forced labor services or involuntary servitude via force, fraud, or coercion.

a. Identifying Trafficking Victims

Human trafficking is a hidden industry and many clients do not self-report being victims of trafficking because of shame, fear, or distrust. When conducting an assessment to identify if someone is a victim, use the existing protocols for sexual coercion, intimate

partner violence, and child abuse. Ensure that the client is seen individually if they are accompanied by another person, including individuals that present themselves as interpreters. It is important to provide the client with interpreter services.

Human trafficking is a significant public health and human rights issue. Providers can assist victims through heightened awareness, provision of care for the health consequences of human trafficking, and client counseling, which may include referrals to government and/or assistance agencies. Providers must discuss possible options with the client, provide referral resources, help facilitate referrals (i.e. offer to make the first call, ask advocates if they can meet clients at the clinic), and assist the client with safety planning.

Maryland does not have mandatory reporting requirements for human trafficking. In Maryland, mandatory reporting is required only for abuse or neglect of a child or abuse, neglect or exploitation of a vulnerable adult. A vulnerable adult is defined as a person aged 18 or older who lacks the physical or mental capacity to provide for his or her daily needs. In other situations involving interpersonal violence, it is the responsibility of the victim to report the abuse to the proper authorities. However, if you suspect a client is a victim of trafficking, call the National Human Trafficking Resource Center (www.acf.hhs.gov/trafficking) 24 Hour National Hotline at 1-888-3737-888 for information on how to report.

9. REPRODUCTIVE LIFE PLAN

A reproductive life plan is a set of personal goals about having or not having children. It also states how to achieve those goals. All clients need to make a reproductive life plan based on their own values, goals, and resources. Clients need to think about when and under what conditions they want to become pregnant. If they do not plan to have children, they need to think about how they will prevent pregnancy.

A reproductive life plan allows for preconception counseling. Preconception counseling offers women an ideal time to plan their pregnancies and establish good health habits. Certain congenital anomalies and complications of pregnancy may be prevented if intervention occurs prior to conception. Promoting positive health behaviors and eliminating medical risks are most effective when initiated well before a woman becomes pregnant.

Since approximately 50% of all pregnancies are unintended, targeting only self-referred women who are planning their next conception will result in a significant number of missed opportunities for primary prevention. Counseling women of childbearing age allows for an identification of women with risk factors. As an example, we can educate women to avoid any teratogenic medications, to update their immunizations, and take folic acid supplements to decrease their risk of neural tube defects. The active planning of pregnancy will maximize the benefits of appropriate interventions and adherence to good health habits to help insure a reduction of maternal and perinatal morbidity and mortality.

D. Clinic Management

1. EQUIPMENT AND SUPPLIES

Equipment and supplies **must** be appropriate to the type of care offered by the project. Projects are expected to follow applicable Federal and state regulations regarding infection control. An Exposure Control Plan must be developed by each delegate agency in accordance with the OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030, the Maryland Occupational Safety and Health Act, Title 09, Subtitle 12, 09.12.31, and DHMH Policy 03.02.01, The HIV Policy for DHMH Facilities, version effective April 15, 2002.

All staff included in the Exposure Control Plan are considered to be affected staff. Affected staff should be aware of the location of the written Exposure Control Plan at each clinic site. They are required to follow Plan requirements, use personal protective equipment as directed by their employer and attend an annual Exposure Control Plan training update.

Documentation of staff attendance at the annual update must be kept on file. In addition:

- a. Equipment and supplies **must** be safe, adequate, and appropriate to the type of care offered by the project.
- b. It is the responsibility of the project coordinator, in consultation with the medical director, to assure proper selection and maintenance of equipment and supplies.
- c. Equipment maintenance and calibration **must** be performed and documented based on manufacturer instructions.

2. PHARMACEUTICALS

- a. Agencies **must** operate in accordance with Federal and state laws relating to security and record keeping for drugs and devices. The inventory, supply, and provision of pharmaceuticals **must** be conducted in accordance with state pharmacy laws and professional practice regulations.
- b. 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. Agencies are allowed to write prescriptions for Title X clients who choose and can conveniently obtain their contraceptives and medications from a pharmacy. To preserve the principle of equality, prescriptions may be written only for items on the approved formulary.
- c. The medical director of the family planning program is responsible for all policies and procedures pertaining to the general handling of pharmaceuticals.
- d. All clients **must** receive verbal and written instructions for each drug. Medication education sheets should be kept current annually reviewed and revised as needed. The nature of drug education should be documented in the medical records.

- e. There **must** be documentation that in-service education pertaining to the nature and safety aspects of pharmaceuticals is provided to staff involved in the provision of medications to clients.
- f. Safeguards **must** be in place for assuring that supplies purchased through the 340B program are provided only to clients of the family planning program.
- g. A system for silent notification in case of drug recall **must** be in place.
- h. A current formulary, listing all drugs available for Title X clients, **must** be maintained and reviewed at least annually. Formularies should be retained for three years.

3. MEDICAL RECORDS

a. General Policy

- 1) A medical record **must** be established for each client who receives clinical services, including all pregnancy testing/counseling clients and emergency contraception clients.
- 2) Medical records are maintained in accordance with the accepted medical standards and state laws with regard to record retention. Records **must** be:
 - a) Complete, legible, and accurate.
 - b) Signed and dated by the clinician health professional making each entry
 - i) Each entry includes date, name and title of the clinician/health professional
 - ii) Each entry is a permanent part of the record
 - c) Readily accessible
 - d) Systematically organized to facilitate retrieval and compilation of information
 - e) Confidential
 - f) Safeguarded against loss or use by unauthorized persons
 - g) Secured by lock when not in use
 - h) Available upon request to the client
- 3) HIPPA regulations regarding personal health information **must** be followed.

b. Record Contents

The client's medical record **must** contain sufficient information to identify the client, indicate where and how the client can be contacted, justify the clinical diagnosis, and warrant the treatment and end results. Records **must** include the following:

- 1) Personal data
 - a) Name
 - b) Address, phone number(s), and how to contact
 - c) Age
 - d) Sex
 - e) Income Assessment
 - f) Unique client number
 - g) Race and ethnicity (as required for FPAR)

- 2) Medical history
 - a) Allergies recorded in a prominent, consistent location
- 3) Physical exam
 - a) Documentation of clinical findings, diagnostic/therapeutic orders
 - i) Laboratory test results and follow-up done for abnormal results
 - ii) Treatments and special instructions
 - iii) Documentation of continuing care, referral and follow-up
 - iv) Documentation of scheduled revisits
 - b) Contraceptive method chosen by the client
 - c) Informed consents
 - d) Documentation of all counseling, education, and social services given
 - e) Documentation of deferrals, reason for deferral, and refusal of services
 - f) Date and signature of clinician or health professional for each entry, including documentation of telephone encounters of a clinical nature.
 - i) Signature includes name and title of provider
 - ii) A signature log, if full name and title are not used in medical record
 - g) A confidentiality assurance statement in the client's record.
 - h) A problem list should be maintained at the front of the chart listing identified problems to facilitate continuing evaluation and follow-up.
- c. Confidentiality and Release of Records
 - 1) A system **must** be in place to maintain confidentiality of client records.
 - 2) A confidentiality assurance statement **must** appear in the client's record.
 - 3) HIV, mental health, and substance use information **must** be handled according to state law.
 - 4) The written consent of the client is required for the release of personally identifiable information, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality.
 - a) Consent form for release of information, signed by the client, specifies to whom information may be disclosed.
 - b) Only the specific information requested may be released.
 - 5) Information collected for reporting purposes **must** be disclosed only in summary, statistical, or other form which does not identify individuals

- 6) Upon request, clients transferring to other providers **must** be provided with a copy or summary of their record to expedite continuity of care.
- 7) Upon request, clients **must** or be given access to their medical record

4. QUALITY ASSURANCE AND AUDIT

- a. Delegate agencies **must** have a quality assurance system in place that provides for the ongoing evaluation of family planning personnel and services. The quality assurance system should include an established set of clinical, administrative and programmatic standards by which conformity is maintained.
- b. Delegate agencies **must** have a quality assurance system in place that includes the following elements:
 - 1) A tracking system that identifies clients in need of follow up and/or continuing care **must** be in place (Section 7.4 Referrals and Follow-up).
 - 2) A system to assure that professional licenses and CPR certifications are current **must** be in place (Sections 6.5 Personnel & 7.3 Emergencies).
 - 3) Medical Audits to determine conformity with agency protocols, current standards, and acceptable medical practices **must** be conducted monthly by the medical director. A minimum of two to three charts per clinician **must** be reviewed by the medical director monthly.
 - 4) Chart Audits/ Record Monitoring to determine completeness and accuracy of the medical record **must** be conducted monthly by the quality assurance committee or identified personnel.
 - a) Chart audits **must** represent a minimum of three percent (3%) of the agency's monthly caseload, randomly selected and reviewed by staff.
 - b) All clinical sites should be represented in the sampling.
 - c) Topic audits are strongly suggested.
 - 5) Annual performance evaluations **must** be performed for all family planning program staff, including the medical director (Section 6.5 Personnel).
 - 6) Annual peer review of all clinician/providers **must** be conducted (Section 6.5 Personnel).
 - 7) Clinical Protocols and procedures **must** be reviewed and signed annually by the medical director (Section 7.1 Service Plans and Protocols).
 - 8) Infection control policies and procedures reflecting current CDC recommendations and OSHA regulations **must** be in place (Sections 6.5 Personnel & 6.6 Training and technical Assistance).

- 9) Laboratory audits to assure quality and CLIA compliance **must** be in place (Section 8.3. D. 8 & 9).
 - 10) Equipment maintenance and calibration **must** be documented (Section 10.1 Equipment and Supplies).
 - 11) Review and approval of all educational materials used by the delegate agency **must** be conducted by the I & E Committee prior to distribution (6.8 Education).
 - 12) A process to implement corrective actions when deficiencies are noted **must** be in place.
- c. Delegate agency quality assurance systems should include the following:
- 1) Regularly scheduled staff meetings to update and/or review medical or service delivery topics. Minutes should be kept of these meetings.
 - 2) Routine check of emergency drugs and supplies.
 - 3) A process to elicit consumer feedback should be in place.
 - 4) Periodic review of forms used by the agency for completeness and applicability.
 - 5) Routine monitoring of critical incident/occurrence reports.
 - 6) Periodic review of credentials of contracted laboratories.
 - 7) Periodic patient flow analysis.
 - 8) Periodic review of provider liability insurance coverage.
 - 9) Periodic monitoring for reliability and accuracy of the client data system to assure program performance, reporting, quality care, and generation of revenues. The following components should be monitored:
 - a) Missing user data
 - b) Coding errors
 - c) Data outcome
- d. A Quality Assurance Committee should be in place. This committee should meet at least quarterly to discuss quality assurance issues and to make recommendations for corrective action when deficiencies have been noted.
- 1) If a formal Quality Assurance Committee is in place, minutes should be kept of all quality Assurance committee meetings.

- 2) The function of the Quality Assurance Committee may be assumed by an in-house nursing or medical advisory committee with ongoing documentation of quality assurance activities.

5. MARYLAND FAMILY PLANNING CUSTOMER SATISFACTION SURVEY

Two types of customer satisfaction survey are conducted in the Maryland State Family Planning Program: The Family Planning Report Card and the Internal Customer Satisfaction Survey.

a. The Family Planning Report Card

The Family Planning Report Card is the name given to a brief client satisfaction measure administered during a one-month period in family planning clinics at least annually, preferably semi-annually.

The Family Planning Report Card is distributed to providers and is also available in English and Spanish on the CMCH website. It is short (taking no more than 7-10 minutes to complete) and easy to read. All questions are simple and direct, and the format is designed with data processing in mind. Providers using the Family Planning Report Card are instructed that they may insert questions of local interest on the form following the questions that are standard for all facilities. In jurisdictions with significant populations of clients who speak neither English nor Spanish, providers should furnish translations in accordance with the DHMH Policy on Limited English Proficiency. Reports on findings from local customer satisfaction surveys are maintained with other quality assurance materials at sites and forwarded to CMCH annually. Insights gained through the surveys should inform quality improvement efforts.

b. Customer Satisfaction Survey

One way in which MFPRH Program staff is able to evaluate the effectiveness of family planning services is by inviting providers to respond to a survey designed especially for internal customers. The survey, which is brief and user-friendly, is posted periodically on the Internet on Survey Monkey. Results from the survey are evaluated and used to improve program quality and enhance communication.

IV. Program Monitoring Site Reviews

A. Program Monitoring Site Reviews

The MFPRH Program staff conduct site reviews to determine whether MFPRH supported family planning delegate agencies are managed effectively and comply with the Federal Title X regulations [42 CFR Part 59, Subpart A]. All Title X Delegate Agency Family Planning Programs in Maryland are required to have this comprehensive site visit by the MFPRH every three years as part of the Family Planning Grant monitoring process. All program areas are reviewed: Administration, Finance, Clinical Services and Community Outreach and Information. The Minimum Program Requirements developed from the Federal Regulations are used to evaluate both Health Department and Non-Health Department Title X agencies.

1. METHODOLOGY

- a. Delegate Agencies are reviewed by the same standards of performance, called Minimum Program Requirements (MPRs). MPRs are program regulatory mandates based on the Federal Register, the Federal Office of Population Affairs (OPA) Title X Program Guidelines. The MFPRH Program Administrative Guidelines is a resource that specifically outlines what is needed to meet the program mandates.
- b. The Federal Register, being law, reads as legislation. The Office of Population Affairs Program, *Guidelines for Project Grants for Family Planning Services*, is guidance taken from the Federal Register, used to assist delegate agencies with their implementation. The Federal Register is the family planning statute itself. It outlines the policy that must be in place, but allows for interpretation by the CMCH MFPRH Program to determine what will be required to carry out the policy. The MFPRH Program Guidelines provide the most detail and specific expectations for the individual Title X Family Planning Delegate Agencies. The requirements in the MFPRH Guidelines supercede the information in the OPA Title X Standards and Guidelines. The MFPRH Guidelines do not contradict the OPA - *Guidelines for Project Grants for Family Planning Services*, they provide clarity, specific direction and in some cases additional information or requirements that may exceed those in the OPA document as determined by the State.
- c. Agencies will receive a letter three months prior to their review from MFPRH indicating when their review is scheduled, where to find needed documents to prepare for the site review and who to consult for technical assistance.
- d. The Delegate Family Planning Coordinator will be contacted by the MFPRH Program Staff for scheduling. Agencies must have a clinic scheduled during the visit to facilitate the accurate evaluation of this clinical component of the program. Sites at any location a delegate agency has may be visited during this process.

2. PROCESS

The following are steps in the site review process:

- a. Prepare from the list of “Pre-Assessment Required Materials” to be submitted to the MFPRH. The information needed is available on the MFPRH website. The materials may

be submitted either by hard copy or electronic means. This program requires extensive protocols and other relevant materials; therefore, these items are reviewed off-site.

- b. Agencies should submit these materials, one month before the scheduled review, to the MFPRH Program. They can be mailed to the office address or e-mailed to the address listed in the letter announcing the review.

- c. Pre-Conference

The preconference is the opportunity for MFPRH staff to meet the agency personnel and get acquainted with the physical aspects of the building, schedules, and so on. It is likewise a time for the agency staff to meet the program reviewers, and let them know the individual characteristics of the program and agency lay-out. A sample plan follows:

- 1) Introductions and Overview

- a) Expected time in facility and brief summary of the process
 - b) Identify resource persons and pertinent staff

- 2) Discussion of Clinical times and Expectations

- a) The MFPRH program staff will need access to the clerical staff (intake process, etc.) and the financial staff.
 - b) The reviewer will need to know when clinics are running for observational purposes.
 - c) The reviewer will talk with staff about following clients through their entire clinical experience.
 - d) Request specific client charts
 - e) Request any additional materials that may not have been provided in advance.

- 3) Logistics

- a) Working Room
 - b) Computer terminal access for laptops

- 4) Questions and wrap-up

- d. Exit Conference

An exit conference is an opportunity for discussion between the reviewers and the delegate agency staff regarding the general findings of the review.

- e. Completed Report

Delegate Agencies can expect a written report within 30 days. Any indicator that was not met will be identified. If any MPR was found to be out of compliance it will be identified with recommendations that are needed to come into compliance. The report will also include recommendations that will program functioning.

- f. Corrective Plans of Action

The Submission of Corrective Plans of Action and deadlines for Health Departments will be coordinated through the MFPRH Program Staff. Corrective Action Plans start when

the on-site exit review is finished. Technical Assistance from MFPRH Program Staff is available to assist with developing plans that will meet program regulations.

g. MFPRH Program Response to Plan

The Corrective Plans of Action will be evaluated by MFPRH staff.

- 1) Plans may be approved with no further action needed.
- 2) Plans may be approved with conditions such as a site revisit or submission of materials to the state agency.
- 3) Plans may be rejected in which case instructions will be included advising the delegate agency about what revisions are needed for acceptance of the plan.
- 4) If for any reason an agency is not going to meet the timelines that should notify the MFPRH Program as soon they are aware of this situation is apparent.

B. Monitoring and Technical Assistance

1. MONITORING VISITS

Delegate agencies may be visited during the year prior to a Site Review (3 year review) and will be visited during the year following a Site Review. These visits will be specifically to monitor progress on improving areas needing improvement identified during the previous Site Review. Programs will have a follow-up review if there were any unmet indicators identified during their Site Review. This is done to assure that those areas have been corrected to confirm Title X compliance.

In addition, additional topics that were not discussed during the Site Review process may be reviewed. The list below is not inclusive. Each Title X Family Planning Delegate Agency has individual needs, and monitoring with technical assistance is provided on that basis.

a. Following are examples of some topics that may be covered during a monitoring visit:

- 1) Methodology used for consumer input (review of satisfaction surveys, etc.)
- 2) Policies and procedures will be reviewed to assure accurate application of the sliding fee scale, no charge or donation is required for clients with income below 100% of poverty, charges are distributed proportionally across all services and supplies. Policies that reflect that clients are never rejected because of inability to pay, and staff performance also indicates compliance.
- 3) Agency policies that reflect assurance that service provision does not require any residency or referral requirements, without subjecting individuals to any coercion to accept services or employ or not employ any particular method of family planning, and that priority of services goes to low income persons.
- 4) Financial monitoring by clinical observation for accurate application of the sliding fee scale, the donation, and billing process, and application of the poverty guidelines.
- 5) Reassessment of any indicators submitted on a Corrective Plan of Action (CPA).

2. TECHNICAL ASSISTANCE (CONSULTATION VISITS)

Consultation visits for technical assistance are available as needed. Technical assistance is provided for areas needing improvement that have been identified through the local agency plan, a site review, monitoring visit, per the request of the agency or other mechanisms. The

content and timing of the visit is mutually determined between the agency representative and the MFPRH staff. Follow-up on any areas requiring change found in the Site Review process is considered routine. Below are examples of areas that technical assistance is available. This list is not inclusive and delegate agencies may call for technical assistance on any aspect of their operation requiring regulatory clarification.

- a. Assistance with the application of billing and collections procedures (total charges less discount); third party payer billing instructions (total charges no discount); charges are determination by cost analysis; and clients are not denied services based on inability to pay.
- b. Assisting with the orientation of project staff to Title X regulations, new staff must receive specific orientation about confidentiality of services, Title X history, regulations and guidelines.
- c. Guidance about the development and implementation of method-specific consent forms with follow-up and assurance of compliance.
- d. Support and information about the Family Planning Data System.

APPENDIX A
Federal Legislation and Requirements

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. See Program Guidelines for Family Planning Project Grants, which interprets the law and regulations in operational terms and provides a general orientation to the Federal perspective on family planning.

Title X Statute

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 family¹ participation in projects assisted under this subsection.

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

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

(d) For the purpose of making grants and contracts under this section, there are authorized to be appropriated \$30,000,000 for the fiscal year ending June 30, 1971; \$60,000,000 for the fiscal year ending June 30, 1972; \$111,500,000 for the fiscal year ending June 30, 1973, \$111,500,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; \$115,000,000 for fiscal year 1976;

\$115,000,000 for the fiscal year ending September 30, 1977;

\$136,400,000 for the fiscal year ending September 30, 1978;

\$200,000,000 for the fiscal year ending September 30, 1979;

\$230,000,000 for the fiscal year ending September 30, 1980;

\$264,500,000 for the fiscal year ending September 30, 1981;

\$126,510,000 for the fiscal year ending September 30, 1982;

\$139,200,000 for the fiscal year ending September 30, 1983;

\$150,030,000 for the fiscal year ending September 30, 1984; and

\$158,400,000 for the fiscal year ending September 30, 1985.

¹ So in law. See section 931(b)(I) of Public Law 97-35 (95 Stat. 570). Probably should be "family".

FORMULA GRANTS TO STATES FOR FAMILY PLANNING SERVICES

SEC. 1002 [300a]

- (a) The Secretary is authorized to make grants, from allotments made under subsection (b), to State health authorities to assist in planning, establishing, maintaining, coordinating, and evaluating family planning services. No grant may be made to a State health authority under this section unless such authority has submitted, and had approved by the Secretary, a State plan for a coordinated and comprehensive program of family planning services.
- (b) The sums appropriated to carry out the provisions of this section shall be allotted to the States by the Secretary on the basis of the population and the financial need of the respective States.
- (c) For the purposes of this section, the term "State" includes the Commonwealth of Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, the District of Columbia, and the Trust Territory of the Pacific Islands.
- (d) For the purpose of making grants under this section, there are authorized to be appropriated \$10,000,000 for the fiscal year ending June 30, 1971; \$15,000,000 for the fiscal year ending June 30, 1972; and \$20,000,000 for the fiscal year ending June 30, 1973.

TRAINING GRANTS AND CONTRACTS; AUTHORIZATION OF APPROPRIATIONS

SEC. 1003 [300a-1]

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

RESEARCH

SEC. 1004 [300a-2]

The Secretary may:

- (1) conduct, and
- (2) make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for, research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.

INFORMATIONAL AND EDUCATIONAL MATERIALS

SEC. 1005 [300a-3]

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

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

REGULATIONS AND PAYMENTS

SEC. 1006 [300a-4]

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

which the fiscal year 1975 grant was made.

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

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

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

(2) no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge.

For purposes of this subsection, the term "low-income family" shall be defined by the Secretary in accordance with such criteria as he may prescribe so as to insure that economic status shall not be a deterrent to participation in the programs assisted under this title.

(d)

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

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

VOLUNTARY PARTICIPATION

SEC. 1007 [300a-5]

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

PROHIBITION OF ABORTION

SEC. 1008 ¹ [300a-6]

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

¹ Section 1009 was repealed by section 601(a)(1)(G) of Public Law 105-362 (112 Stat. 3285).

PUBLIC HEALTH SERVICE HHS PT. 59

(2) The trainee is not eligible or able to continue in attendance in accordance with its standards and practices.

[45 FR 73658, Nov. 6, 1980. Redesignated at 61 FR 6131, Feb. 16, 1996]

§ 58.232 What additional Department regulations apply to grantees?

Several other Department regulations apply to grantees. They include, but are not limited to:

42 CFR part 50, subpart D—Public Health Service grant appeals procedure
45 CFR part 16—Procedures of the Departmental Grant Appeals Board
45 CFR part 46—Protection of human subjects
45 CFR part 74—Administration of grants
45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964
45 CFR part 81—Practice and procedure for hearings under part 80 of this title
45 CFR part 83—Regulation for the administration and enforcement of sections 794 and 855 of the Public Health Service Act
45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance
45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
45 CFR part 93—New restrictions on lobbying [49 FR 38116, Sept. 27, 1984. Redesignated and amended at 61 FR 6131, Feb. 16, 1996]

§ 58.233 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[61 FR 6131, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 58.234 Additional conditions.

The Secretary may impose additional conditions in the grant award before or at the time of the award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

[45 FR 73658, Nov. 6, 1980. Redesignated at 61 FR 6131, Feb. 16, 1996]

Subparts E–F [Reserved]

PART 59—GRANTS FOR FAMILY PLANNING SERVICES

Subpart A—Project Grants for Family Planning Services

Sec.

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

Subpart B [Reserved]

Subpart C—Grants for Family Planning Service Training

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

Subpart A—Project Grants for Family Planning Services

AUTHORITY: 42 U.S.C. 300a–4.
SOURCE: 65 FR 41278, July 3, 2000, unless otherwise noted.

§ 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 300) to

assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

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

§ 59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

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

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

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

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

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

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

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

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

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

- (a) Application for a grant under this subpart shall be made on an authorized form.
- (b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations

of this subpart, must sign the application.

(c) The application shall contain—

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

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

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

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

§ 59.5 what requirements must be met by a family planning project?

(a) Each project supported under this part must:

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

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

(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 subgrantees which have previously provided or propose to provide family planning 1 Section 205 of Pub. L. 94-63 states: “Any (1) officer or employee of the United States,(2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than \$1,000 or imprisoned for not more than one year, or both.” services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential sub-grantee in the ongoing policy decision making of the project.

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

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

(1) Provide for medical services related to family planning (including physician’s consultation, examination prescription, and

continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

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

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

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

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

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

(4) Provide for orientation and inservice training for all project personnel.

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

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

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

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

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

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community’s needs for family planning services. [65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

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

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

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

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

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

(3) *Function.* In reviewing materials, the Advisory Committee shall:

(i) Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct;

(iv) Determine whether the material is suitable for the population or community to which is to be made available; and

(v) Establish a written record of its determinations.

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

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of patients, and, in particular, the number of low-income patients to be served;

(2) The extent to which family planning services are needed locally;

(3) The relative need of the applicant;

(4) The capacity of the applicant to make rapid and effective use of the federal assistance;

(5) The adequacy of the applicant's facilities and staff;

(6) The relative availability of nonfederal resources within the community to be served and the

degree to which those resources are committed to the project; and

(7) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

§ 59.8 How is a grant awarded?

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

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

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

§ 59.9 For what purpose may grant funds be used?

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

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

Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include: 37 CFR Part 401—Rights to inventions made by nonprofit organizations and small business firms under

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

§ 59.11 Confidentiality.

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

§ 59.12 Additional conditions.

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

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

Subpart B [Reserved]

Subpart C—Grants for Family Planning Service Training

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

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

§ 59.201 Applicability.

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

§ 59.202 Definitions.

As used in this subpart:

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

§ 59.203 Eligibility.

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

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

§ 59.204 Application for a grant.

- (a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe. 1 The application shall contain a

full and adequate description of the project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart, and a budget and justification of the amount of grant funds requested, and such other pertinent information as the Secretary may require.

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

1 Applications and instructions may be obtained from the Program Director, Family Planning Services, at the Regional Office of the Department of Health and Human Services for the region in which the project is to be conducted, or the Office of Family Planning, Office of the Assistant Secretary for Health, Washington, DC 20201. any additional conditions of the grant.

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

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

59.205 Project requirements.

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

(a) Assurances that:

(1) No portion of the Federal funds will be used to train personnel for programs where abortion is a method of family planning.

(2) No portion of the Federal funds will be used to provide professional training to any student as part of his education in pursuit of an academic degree.

(3) No project personnel or trainees shall on the grounds of sex, religion, or creed be excluded from participation in, be denied the benefits of, or be subjected to discrimination under the project.

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

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

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

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

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

the objectives of the training program.

(g) Provision of a method and criteria by which trainees will be selected.

§ 59.206 Evaluation and grant award.

(a) Within the limits of funds available for such purpose, the Secretary may award grants to assist in the establishment and operation of those projects which will in his judgment best promote the purposes of section 1003 of the Act, taking into account:

(1) The extent to which a training program will increase the delivery of services to people, particularly low-income groups, with a high percentage of unmet need for family planning services;

(2) The extent to which the training program promises to fulfill the family planning services delivery needs of the area to be served, which may include, among other things:

(i) Development of a capability within family planning service projects to provide pre- and inservice training to their own staffs;

(ii) Improvement of the family planning services delivery skills of family planning and health services personnel;

(iii) Improvement in the utilization and career development of paraprofessional and paramedical manpower in family planning services;

(iv) Expansion of family planning services, particularly in rural areas, through new or improved approaches to program planning and deployment of resources;

(3) The capacity of the applicant to make rapid and effective use of such assistance;

(4) The administrative and management capability and competence of the applicant;

(5) The competence of the project staff in relation to the services to be provided; and

(6) The degree to which the project plan adequately provides for the requirements set forth in § 59.205.

(b) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either: (1) On the basis of his estimate of the actual indirect costs reasonably related to the project, or (2) on the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as travel or supply costs) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

- (c) Allowability of costs shall be in conformance with the applicable cost principles prescribed by Subpart Q of 35 CFR part 74.
- (d) All grant awards shall be in writing, shall set forth the amount of funds granted and the period for which support is recommended.
- (e) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantee must make separate application annually at such times and in such form as the Secretary may direct.

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

§ 59.207 Payments.

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

§ 59.208 Use of project funds.

- (a) Any funds granted pursuant to this subpart as well as other funds to be used in performance of the approved project shall be expended solely for carrying out the approved project in accordance with the statute, the regulations of this subpart, the terms and conditions of the award, and, except as may otherwise be provided in this subpart, the applicable cost principles prescribed by subpart Q of 45 CFR part 74.
- (b) Prior approval by the Secretary of revision of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.
- (c) The Secretary may approve the payment of grant funds to trainees for:
- (1) Return travel to the trainee's point of origin.
 - (2) Per diem during the training program, and during travel to and from the program, at the prevailing institutional or governmental rate, whichever is lower.

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

§ 59.209 Civil rights.

Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d *et seq.*) and in particular section 601 of such Act which provides that no person in the United States shall, on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or

activity receiving Federal financial assistance. A regulation implementing such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR part 80).

§ 59.210 Inventions or discoveries.

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

§ 59.211 Publications and copyright.

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

§ 59.212 Grantee accountability.

(a) Accounting for grant award payments.

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

(b) [Reserved]

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

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

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

- (i) Any amount not accounted for pursuant to paragraph (a) of this section;
- (ii) Any credits for earned interest pursuant to paragraph (c)(1) of this section;
- (iii) Any other amounts due pursuant to subparts F, M, and O of 45 CFR part 74.

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

[36 FR 18465, Sept. 15, 1971, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.213 [Reserved]

§ 59.214 Additional conditions.

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

§ 59.215 Applicability of 45 CFR part 74.

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

45 CFR PART 74

Subpart:

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

[38 FR 26199, Sept. 19, 1973]

PART 59a—NATIONAL LIBRARY OF MEDICINE GRANTS

Subpart A—Grants for Establishing, Expanding, and Improving Basic Resources

Sec.

59a.1 Programs to which these regulations apply.

59a.2 Definitions.

59a.3 Who is eligible for a grant?

59a.4 How are grant applications evaluated?

59a.5 Awards.

59a.6 How may funds or materials be used?

59a.7 Other HHS regulations that apply.

Subpart B—Establishment of Regional Medical Libraries

59a.11 Programs to which these regulations apply.

59a.12 Definitions.

59a.13 Who is eligible for a grant?

59a.14 How to apply.

59a.15 Awards.

59a.16 What other conditions apply?

59a.17 Other HHS regulations that apply.

SOURCE: 56 FR 29189, June 26, 1991, unless otherwise noted.

Subpart A—Grants for Establishing, Expanding, and Improving Basic Resources

AUTHORITY: 42 U.S.C. 286b–2, 286b–5.

§ 59a.1 Programs to which these regulations apply.

(a) The regulations of this subpart apply to grants of funds, materials, or both, for establishing, expanding, and improving basic medical library resources as authorized by section 474 of the Act (42 U.S.C. 286b–5).

(b) This subpart also applies to cooperative agreements awarded for this purpose. In these circumstances, references to “grant(s)” shall include “cooperative agreements(s).”

§ 59a.2 Definitions.

Undefined terms have the same meaning as provided in the Act. As used in this subpart:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

Project period—See § 59a.5(c).

Related instrumentality means a public or private institution, organization, or agency, other

than a medical library, whose primary function is the acquisition, preservation, dissemination, and/or processing of information relating to the health sciences.

Secretary means the Secretary of Health and Human Services and any other official of the Department of Health and Human Services to whom the authority involved is delegate

Health Insurance Portability and Accountability Act of 1996

Many aspects of this law impact the Maryland Family Planning and Reproductive Health Program and its delegate agencies. Much information is available on implementation and compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA.) The websites listed below will provide comprehensive information. The following is a summary of the HIPAA statute:

Administrative Simplification

To improve the efficiency and effectiveness of the health care system, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, included Administrative Simplification provisions that required HHS to adopt national standards for electronic health care transactions and code sets, unique health identifiers, and security. At the same time, Congress recognized that advances in electronic technology could erode the privacy of health information. Consequently, Congress incorporated into HIPAA provisions that mandated the adoption of Federal privacy protections for individually identifiable health information.

HHS published a final Privacy Rule in December 2000, which was later modified in August 2002. This Rule set national standards for the protection of individually identifiable health information by three types of covered entities: health plans, health care clearinghouses, and health care providers who conduct the standard health care transactions electronically. Compliance with the Privacy Rule was required as of April 14, 2003 (April 14, 2004, for small health plans).

HHS published a final Security Rule in February 2003. This Rule sets national standards for protecting the confidentiality, integrity, and availability of electronic protected health information. Compliance with the Security Rule was required as of April 20, 2005 (April 20, 2006 for small health plans). All of the HIPAA Administrative Simplification Rules are located at 45 CFR Parts 160, 162, and 164.

The Privacy Rule

The Office of Civil Rights administers and enforces the HIPAA Privacy Rule which establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The Rule also gives patients rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections. The Privacy Rule is located at 45 CFR Part 160 and Subparts A and E of Part 164.

<http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html>

The Security Rule

The HIPAA Security Rule establishes national standards to protect individuals' electronic personal health information that is created, received, used, or maintained by a covered entity. The Security Rule requires appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information. The Security Rule is located at 45 CFR Part 160 and Subparts A and C of Part 164.

<http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/index.html>

Other HIPAA Administrative Simplification Rules are administered and enforced by the Centers for Medicare & Medicaid Services, and include:

Transactions and Code Sets Standards

On January 16, 2009, HHS published two final transactions and code set rules to adopt updated HIPAA standards; these rules are available at the Federal Register.

Transactions are electronic exchanges involving the transfer of information between two parties for specific purposes. For example, a health care provider will send a claim to a health plan to request payment for medical services. The Health Insurance Portability & Accountability Act of 1996 (HIPAA) named certain types of organizations as covered entities, including health plans, health care clearinghouses, and certain health care providers. HIPAA also adopted certain standard transactions for Electronic Data Interchange (EDI) of health care data. These transactions are: claims and encounter information, payment and remittance advice, claims status, eligibility, enrollment and disenrollment, referrals and authorizations, and premium payment. Under HIPAA, if a covered entity conducts one of the adopted transactions electronically, they must use the adopted standard. This means that they must adhere to the content and format requirements of each standard. HIPAA also adopted specific code sets for diagnosis and procedures to be used in all transactions. The HCPCS (Ancillary Services/Procedures), CPT-4 (Physicians Procedures), CDT (Dental Terminology), ICD-9 (Diagnosis and hospital inpatient Procedures), ICD-10 (As of October 1, 2013) and NDC (National Drug Codes) codes with which providers and health plan are familiar, are the adopted code sets for procedures, diagnoses, and drugs.

To view these rules and information sheets for both sets of standards see the following link on the CMS website:

http://www.cms.gov/TransactionCodeSetsStand/01_Overview.asp#TopOfPage

Finally, HIPAA adopted standards for unique identifiers for Employers and Providers, which must also be used in all transactions, as required by the standard.

Employer Identifier Standard

The Health Insurance Portability & Accountability Act of 1996 (HIPAA) requires that employers have standard national numbers that identify them on standard transactions. The Employer

Identification Number (EIN), issued by the Internal Revenue Service (IRS), was selected as the identifier for employers and was adopted effective July 30, 2002. For more information, see the following CMS webpage: http://www.cms.gov/EmployerIdentifierStand/01_overview.asp

National Provider Identifier Standard

The National Provider Identifier (NPI) is a Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Standard. The NPI is a unique identification number for covered health care providers. Covered health care providers and all health plans and health care clearinghouses must use the NPIs in the administrative and financial transactions adopted under HIPAA. The NPI is a 10-position, intelligence-free numeric identifier (10-digit number). This means that the numbers do not carry other information about healthcare providers, such as the state in which they live or their medical specialty. The NPI must be used in lieu of legacy provider identifiers in the HIPAA standards transactions. As outlined in the Federal Regulation, The Health Insurance Portability and Accountability Act of 1996 (HIPAA), covered providers must also share their NPI with other providers, health plans, clearinghouses, and any entity that may need it for billing purposes. For more information, see the following CMS webpage: <http://www.cms.gov/NationalProvIdentStand/>

Additional HIPAA Internet Resources

<http://www.hhs.gov/ocr/hipaa/>

This site from the Office of Civil Rights covers a variety of issues and includes the HIPAA Statute, as well as a number of links that provide more specific information.

<http://www.cms.hhs.gov/HIPAAGenInfo/>

The site includes the HIPAA statute, related materials, compliance information and downloads prepared by Centers for Medicare and Medicaid Services (CMS.)

Civil Rights Act of 1964

The Civil Rights Act of 1964, is an act to enforce the constitutional right to vote, to confer jurisdiction upon the district courts of the United States to provide injunctive relief against discrimination in public accommodations to authorize the Attorney General to institute suits to protect constitutional rights in public facilities and public education, to extend the Commission on Civil Rights, to prevent discrimination in federally assisted programs, to establish a Commission on Equal Employment Opportunity, and for other purposes.

This law has had significant impact on our lives and operations. The following websites provide detailed information on civil rights that can be used in conjunction with family planning programs.

The following links provide further information on civil right for use in conjunction with your family planning program:

<http://www.eeoc.gov/policy/vii.html>

<http://www.eeoc.gov/laws/guidance/compliance.cfm>

APPENDIX B
Maryland Health Codes and Other Rules

Mandated Child Abuse Reporter Legislation

Article - Family Law

§ 5-704.

(a) Notwithstanding any other provision of law, including any law on privileged communications, each health practitioner, police officer, educator, or human service worker, acting in a professional capacity in this State:

(1) (i) who has reason to believe that a child has been subjected to abuse, shall notify the local department or the appropriate law enforcement agency; or

(ii) who has reason to believe that a child has been subjected to neglect, shall notify the local department; and

(2) if acting as a staff member of a hospital, public health agency, child care institution, juvenile detention center, school, or similar institution, shall immediately notify and give all information required by this section to the head of the institution or the designee of the head.

(b) (1) An individual who notifies the appropriate authorities under subsection (a) of this section shall make:

(i) an oral report, by telephone or direct communication, as soon as possible:

1. to the local department or appropriate law enforcement agency if the person has reason to believe that the child has been subjected to abuse; or

2. to the local department if the person has reason to believe that the child has been subjected to neglect; and

(ii) a written report:

1. to the local department not later than 48 hours after the contact, examination, attention, or treatment that caused the individual to believe that the child had been subjected to abuse or neglect; and

2. with a copy to the local State's Attorney if the individual has reason to believe that the child has been subjected to abuse.

(2) (i) An agency to which an oral report of suspected abuse is made under paragraph (1) of this subsection shall immediately notify the other agency.

(ii) This paragraph does not prohibit a local department and an appropriate law enforcement agency from agreeing to cooperative arrangements.

(c) Insofar as is reasonably possible, an individual who makes a report under this section shall include in the report the following information:

(1) the name, age, and home address of the child;

(2) the name and home address of the child's parent or other person who is responsible for the child's care;

(3) the whereabouts of the child;

(4) the nature and extent of the abuse or neglect of the child, including any evidence or information available to the reporter concerning possible previous instances of abuse or neglect; and

(5) any other information that would help to determine:

(i) the cause of the suspected abuse or neglect; and

(ii) the identity of any individual responsible for the abuse or neglect.

Minor Consent

Maryland's Minor Consent Law (Article 20-102 of the Maryland Annotated Code)

This law permits minors to receive contraceptive services on a confidential basis. The law states that “a minor has the same capacity as an adult to consent to treatment for or advice about drug abuse, alcoholism, venereal disease, pregnancy, and contraception other than sterilization.” This means minors can get the following services without parental knowledge or consent:

- Pregnancy testing
- Birth control
- Exams
- Testing and treatment of sexually transmitted infections (STIs)

Planned Parenthood encourages adolescents to communicate with their parents and guardians when seeking contraceptive health care, but does not require that they do so. According to a report in the *Journal of the American Medical Association (JAMA)*, most adolescents already inform parents about their use of reproductive health services.

Definition of a Minor: In Maryland, a minor is anyone under the age of 18 years who is not married or the parent of a child.

Maryland's Parental Notification for Abortion Law (Article 20-103 of the Maryland Annotated Code)

Maryland law requires that one parent or guardian be notified before a minor has an abortion. The parent/guardian does not need to consent (agree) with the minor's choice, but does need to know the minor is planning to have an abortion. Maryland's parental notification law says specifically that no notification is required if, in the judgment of the doctor performing the abortion:

- The minor is mature and capable of giving her informed consent to the procedure, OR
- Notification would not be in the minor's best interest, OR
- Notice may lead to physical or emotional abuse of the minor, OR
- The minor patient does not live with her parent or guardian, OR
- A reasonable effort to give notice has been unsuccessful.

Article - Health - General

§ 20-102.

(a) A minor has the same capacity as an adult to consent to medical treatment if the minor:

- (1) Is married; or
- (2) Is the parent of a child.

(b) A minor has the same capacity as an adult to consent to medical treatment if, in the judgment of the attending physician, the life or health of the minor would be affected adversely by delaying treatment to obtain the consent of another individual.

(c) A minor has the same capacity as an adult to consent to:

- (1) Treatment for or advice about drug abuse;
- (2) Treatment for or advice about alcoholism;
- (3) Treatment for or advice about venereal disease;

- (4) Treatment for or advice about pregnancy;
- (5) Treatment for or advice about contraception other than sterilization;
- (6) Physical examination and treatment of injuries from an alleged rape or sexual offense;
- (7) Physical examination to obtain evidence of an alleged rape or sexual offense; and
- (8) Initial medical screening and physical examination on and after admission of the minor into a detention center.

(c-1) The capacity of a minor to consent to treatment for drug abuse or alcoholism under subsection (c)(1) or (2) of this section does not include the capacity to refuse treatment for drug abuse or alcoholism in an inpatient alcohol or drug abuse treatment program certified under Title 8 of this article for which a parent or guardian has given consent.

(d) A minor has the same capacity as an adult to consent to psychological treatment as specified under subsection (c)(1) and (2) of this section if, in the judgment of the attending physician or a psychologist, the life or health of the minor would be affected adversely by delaying treatment to obtain the consent of another individual.

(e) A physician, psychologist, or an individual under the direction of a physician or psychologist who treats a minor is not liable for civil damages or subject to any criminal or disciplinary penalty solely because the minor did not have capacity to consent under this section.

(f) Without the consent of or over the express objection of a minor, the attending physician, psychologist or, on advice or direction of the attending physician or psychologist, a member of the medical staff of a hospital or public clinic may, but need not, give a parent, guardian, or custodian of the minor or the spouse of the parent information about treatment needed by the minor or provided to the minor under this section, except information about an abortion.

Nurse Dispensing in Local Health Departments:

http://www.mbp.state.md.us/forms/dr_nurse.pdf