

**MICHIGAN
TITLE X
FAMILY PLANNING PROGRAM
STANDARDS & GUIDELINES MANUAL
2017**

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Introduction

The Michigan Department of Health and Human Services (MDHHS) Family Planning Program philosophy is consistent with the Title X Family Planning Program. Family Planning assists individuals in determining the number and spacing of their children through the provision of affordable, voluntary family planning services including provision of a broad range of contraceptive methods, education and related preventive health services. By assisting the establishment and operation of voluntary family planning projects throughout Michigan, the program positively impacts the health and well-being of individuals and families. Services provided through family planning clinics allow women and men to make well-informed reproductive health choices. MDHHS funded family planning clinics are designed to address the unmet family planning needs of low-income women and men and provide access to populations with special needs. No one is denied services because of inability to pay.

MDHHS has primary responsibility in Michigan to administer state and federal funds for family planning. The provision of voluntary family planning services is authorized under the Michigan Public Health Code, Section 333.9131-9133. Local health departments may provide services under supervision of MDHHS and must publicize the availability of services. The MDHHS Title X Family Planning Program Standards and Guidelines provide policy and guidance for sub-recipients to provide family planning services. It is based on the Title X statute, Office of Population Affairs (OPA) Title X Guidelines, federal and state laws, regulations, and annual funding processes. The manual forms the basis for monitoring MDHHS Title X projects.

The MDHHS Title X Family Planning Program Standards and Guidelines align with the Office of Population Affairs (OPA) Title X Family Planning Guidelines published in April, 2014. The guidelines are contained in the following two documents:

1. Program Requirements for Title X Funded Family Planning Projects. This document is derived from the Title X statute, implementing regulations and other requirements under Title X of the Public Health Service Act. It describes the Title X program requirements for funded projects. <http://www.hhs.gov/opa/sites/default/files/ogc-cleared-final-april.pdf>
2. Providing Quality Family Planning Services (QFP) was developed jointly by the Centers for Disease Control and Prevention (CDC) and OPA and published as a *CDC MMWR Recommendations and Report*. The QFP presents clinical recommendations for providing family planning services based on the best available scientific evidence. The QFP is intended for providers across all practice settings and serves as the clinical guidance for Title X projects. <http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

The MDHHS Title X Family Planning Program Standards and Guidelines follows these two documents. The MDHHS document is one manual with five sections: Introduction to the Document, (I) Federal and State Laws and Resources, (II) Administrative Program Requirements, (III) Clinical Services, (IV) Program Monitoring, and (V) Training. The program administration section (Section II) describes requirements outlined in the OPA Title X program requirements document. The clinical services section (Section III) follows the outline and recommendations in the QFP document.

SECTION I

**Federal and State Legislation, Regulations
And Resources**

A. Federal Legislation, OPA and HHS Regulations, Documents and Resources

The Federal Title X Family Planning Program

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

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

The Title X Family Planning Program is administered by the Office of Population Affairs (OPA), Office of the Assistant Secretary for Health (OASH), within the U.S. Department of Health and Human Services (HHS). OASH facilitates the application process and setting funding levels according to 42 CFR 59.7(a). Award decisions are made by the Regional Health Administrator in consultation with the Deputy Assistant Secretary for Population Affairs and the Assistant Secretary for Health or their designees. The HHS Regional Offices monitor program performance of Title X grantees in each region.

The Title X Family Planning Guidelines of 2014 consist of two parts, 1) *Program Requirements for Title X Funded Family Planning Projects* (hereafter referred to as *Title X Program Requirements*) and 2) *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs* (the QFP). These two documents were developed to assist current and prospective grantees in understanding and implementing the family planning services grants program authorized by Title X of the PHS Act (42 U.S.C 300 et seq.) These documents also form the basis for monitoring grantee projects under the Title X program.

Prospective applicants and MDHHS sub-recipients should be familiar with these regulations.

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 family participation in projects assisted under this subsection.

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

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

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

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).

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(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.

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Subpart B [Reserved]

Subpart C—Grants for Family Planning Service Training

59.201 Applicability.

59.202 Definitions.

59.203 Eligibility.

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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 requirement s 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

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,

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 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 it 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 in-service training to their own staffs;

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

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

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

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

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

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

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

Title X Federal Program Guidelines, Guidance and Internet Resources

Program Guidelines, Tools and Documents

This Internet site provides access to Office of Population Affairs documents including program guidelines, resource documents, contacts to regional agencies, and Compliance Standards for Family Planning Services Projects. The documents listed below are available from the OPA website: <http://www.hhs.gov/opa/title-x-family-planning/>

Title X Policies

Legislative Mandates

<http://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/legislative-mandates/index.html#>

Statute and Regulations

<http://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/statutes-and-regulations/index.html>

Program Guidelines:

Program Requirements for Title X Funded Family Planning Projects

<http://www.hhs.gov/opa/sites/default/files/ogc-cleared-final-april.pdf>

Providing Quality Family Planning Services (QFP): Recommendations of CDC and the U.S. Office of Population Affairs

<http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

Program Priorities and Key Issues

<http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/program-priorities/>

Sterilization of Persons in Federally Assisted Family Planning Projects Regulations

<http://www.ecfr.gov/cgi-bin/text-idx?SID=abe9d67cd40497fd6c6af386c63460ee&mc=true&node=sp42.1.50.b&rgn=div6>

Provision of Abortion-Related Services in Family Planning Projects-Statutory Requirement

<http://www.gpo.gov/fdsys/pkg/FR-2000-07-03/pdf/00-16759.pdf>

Standards of Compliance for Abortion-Related Services in Family Planning Services Projects-Final rules

<http://www.gpo.gov/fdsys/pkg/FR-2000-07-03/pdf/00-16758.pdf>

Family Planning Annual Reports

<http://www.hhs.gov/opa/title-x-family-planning/research-and-data/fp-annual-reports/>

Program Priorities, Key Issues, Legislative Mandates

2017 Program Priorities

1. Assuring the delivery of quality family planning and related preventive health services, with priority for services to individuals from low-income families. This includes ensuring that grantees have the capacity to support implementation (e.g., through staff training and related systems changes) of the Title X program guidelines throughout their Title X services projects, and that project staff have received training on Title X program requirements;
2. Assessing clients' reproductive life plan/reproductive intentions as part of determining the need for family planning services, and providing preconception services as stipulated in QFP;
3. Providing access to a broad range of acceptable and effective family planning methods and related preventive health services in accordance with the Title X program requirements and the 2014 QFP. These services include, but are not limited to, contraceptive services, pregnancy testing and counseling, services to help clients achieve pregnancy, basic infertility services, STD services, preconception health services, and breast and cervical cancer screening. The broad range of services does not include abortion as a method of family planning;
4. Ensuring that all clients receive contraceptive and other services in a voluntary, client-centered and non-coercive manner in accordance with QFP and Title X requirements.
5. Identifying individuals, families, and communities in need, but not currently receiving family planning services, through outreach to hard-to-reach and/or vulnerable populations, and partnering with other community-based health and social services providers that provide needed services; and
6. Demonstrating that the project's infrastructure and management practices ensure sustainability of family planning and reproductive health services delivery throughout the proposed service area including:
 - Incorporation of certified Electronic Health Record (EHR) systems that have the ability to capture family planning data within structured fields;
 - Evidence of contracts with insurance plans and systems for third party billing as well as the ability to facilitate the enrollment of clients into private insurance and Medicaid, optimally onsite; and to report on numbers of clients assisted and enrolled; and
 - Addressing the comprehensive health care needs of clients through formal, robust linkages or integration with comprehensive primary care providers.

2017 Key Issues

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

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

Legislative Mandates

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

- None of the funds appropriated in this Act may be made available to any entity under Title X of the Public Health Service Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.
- Notwithstanding any other provision of law, no provider of services under Title X of the Public Health Service Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.

Title X the National Family Planning Program

For more than 40 years, Title X family planning centers have provided high quality and cost-effective family planning and related preventive health services for low-income women and men. Family planning centers play a critical role in ensuring access to voluntary family planning information and services for their clients based on their ability to pay.

Family planning centers offer a broad range of FDA-approved contraceptive methods and related counseling; as well as breast and cervical cancer screening; pregnancy testing and counseling; screening and treatment for sexually transmitted infections (STIs); HIV testing; and other patient education and referrals¹.

Title X Providers

The U.S. Department of Health and Human Services' Office of Population Affairs (OPA) oversees the Title X program. OPA funds a network of 4,400 family planning centers which serve about five million clients a year². Services are provided through state, county, and local health departments; community health centers; Planned Parenthood centers; and hospital-based, school-based, faith-based, other private nonprofits.

Title X staffs are specially trained to meet the contraceptive needs of individuals with limited English proficiency, teenagers, and those confronting complex medical and personal issues such as substance abuse, disability, homelessness or interpersonal and domestic violence.

The Title X Mission

Title X assists individuals and couples in planning and spacing births, contributing to positive birth outcomes and improved health for women and infants.

In addition to clinical services, Title X also funds the following program supports aimed at improving the quality of family planning services:

- Training for family planning clinic personnel through five national training programs that focus on clinical training; service delivery; management and systems improvement; coordination and strategic initiatives; and quality assurance/improvement and evaluation
- Family planning research and evaluation to improve Title X service delivery and inform the broader reproductive health care field
- Information dissemination and community-based education and outreach

Cost Effectiveness of Family Planning

Title X provides significant cost savings to taxpayers. In 2010, every public dollar spent on contraceptive services yielded an estimated \$5.68 in savings that would have been spent on Medicaid costs related to pregnancy care and delivery and to infants in their first year of life³.

Significantly, this figure does not include savings realized from the prevention and treatment of STIs and avoiding and detecting reproductive cancers. These calculations also do not measure the broader health, social or economic benefits of enabling women to time or prepare for their pregnancies³.

OPA Program Policy Notice Series

In June 2014, OPA initiated the Program Policy Notice (PPN) series that replaces the recently retired OPA Program Instruction Series. OPA Program Policy Notices will be issued periodically to define and/or clarify policies or procedures that grantees funded under the Title X Family Planning Program must follow. OPA Program Policy Notices are listed here most recent first.

Clarification regarding “How Title X Grantees may remain in compliance when integrating services with HRSA Health Center Program Grantees and look-alikes”

Integrating with Primary Care Providers

OPA Program Policy Notice 2016-11

Release Date: November 22, 2016

I. Purpose

The purpose of this Program Policy Notice (PPN) is to clarify how Title X grantees may remain in compliance with *Program Requirements for Title X Funded Family Planning Projects* when integrating services with Health Resources & Services Administration (HRSA) Health Center Program grantees and look-alikes (i.e., health centers that receive funding under Section 330 of the Public Health Service Act, which authorizes the Health Center Program, as well as those that have been determined to meet Section 330 requirements but do not receive grant funding under that program). This PPN applies only to integrated settings, and not to settings in which only Health Center Program services are provided. We address three issues commonly faced by integrated Title X and HRSA-funded health center providers:

- 1) How to bill clients receiving Title X family planning services in compliance with Title X and Health Center Program Sliding Fee Discount Schedules and billing guidelines;
- 2) How to report data to the Family Planning Annual Report (FPAR) and to the Uniform Data System (UDS) appropriately; and,
- 3) How to preserve Title X client confidentiality when billing for services provided.

II. Background

In 2014, the Office of Population Affairs (OPA) released new Title X program guidelines consisting of two parts:

- 1) *Program Requirements for Title X Funded Family Planning Projects* (Title X Program Requirements); and,
- 2) *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs* (QFP).

Title X Program Requirements align closely with the Title X statute and family planning services project implementing regulations (42 CFR part 59, subpart A), as well as other applicable federal statutes, regulations, and policies. This PPN is intended to help Title X grantees address integrated care settings with regard to Title X Program Requirements.

III. Clarification

This section provides clarification for some of the most common issues facing Title X Family Planning (FP) providers when integrating with primary care organizations, and suggests sample strategies to overcome these issues. Endnotes are provided for reference to the applicable section(s) of the Title X and HRSA Health Center Program Requirements aligned with each strategy.

Issue 1: Nominal Charge and Sliding Fee Discount Schedules (SFDS)

Strategy

The HRSA Health Center Program and the OPA Title X Program have unique Sliding Fee Discount Schedule (SFDS) program requirements, which include having differing upper limits. HRSA's policies, currently contained in Policy Information Notice (PIN) 2014-02, allow health centers to accommodate the further discounting of services as required by Title X regulations. Title X agencies (or providers) that are integrated with or receive funding from the HRSA Health Center Program may have dual fee discount schedules: one schedule that ranges from 101% to 200% of the Federal Poverty Level (FPL) for all health center services, and one schedule that ranges from 101% to 250% FPL for clients receiving **only** Title X family planning services directly related to preventing or achieving pregnancy, and as defined in their approved Title X project.

Title X agencies and providers may consult with the health center if they have additional questions regarding implementing discounting schedules that comply with Title X and Health Center Program requirements, which may result in the health center needing to consult their HRSA Health Center Program Project Officer.

To decide which SFDS to use, the health center should determine whether a client is receiving **only Title X family planning services** (Title X family planning services are defined by the service contract between the Title X grantee and health center) or **health center services in addition to Title X family planning services within the same visit**.

The following guidance applies specifically to clients who receive **only Title X family planning services** that are directly related to preventing or achieving pregnancy:

- Clients receiving only Title X family planning services with family incomes at or below 100% of the FPL must not be charged for services received. In order to comply with Title X regulations, any nominal fee typically collected by a HRSA health center program grantee or look-alike would **not be charged to the client receiving only Title X family planning services.**ⁱ
- Clients receiving only Title X family planning services with family incomes that are between 101% FPL and 250% FPL must be charged in accordance with a specific Title X SFDS based on the client's ability to pay. Any differences between charges based on applying the Title X SFDS and the health center's discounting schedule could be allocated to Title X grant funds. This allocation is aligned with the guidance provided in HRSA's PIN 2014-02, as discussed above. This PIN states that program grantees, "*may receive or have access to other funding sources (e.g., Federal, State, local, or private funds) that contain terms and conditions for reducing patient costs for specific services. These terms and conditions may apply to patients over 200 percent of the FPG [Federal Poverty Guidelines]. In such cases, it is permissible for*

a health center to allocate a portion (or all) of this patient's charge to this grant or subsidy funding source."ⁱⁱ

- Note that unemancipated minors who receive confidential Title X family planning services must be billed according to the income of the minor.ⁱⁱⁱ

The following guidance applies specifically to clients who receive **health center services in addition to Title X family planning services within the same visit**:

- For clients receiving health center services in addition to Title X family planning services, as defined above, within the same visit, the health center or look-alike may utilize its health center discounting schedule (which ranges from 101% to 200% FPL) including collecting one nominal fee for health center services provided to clients with family incomes at or below 100% FPL.

Issue 2: Fulfilling Data Reporting Requirements

Strategy

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

Further instructions on how a family planning “user” is defined can be found in the [FPAR Forms & Instructions](#) guidance document.

Issue 3: Sliding Fee Discount Schedule eligibility for individuals seeking confidential services

Strategy

For individuals requesting that Title X family planning services provided to them are confidential (i.e., they do not want their information disclosed in any way, including for third-party billing), the provider should ensure that appropriate measures are in place to protect the client's information, beyond HIPAA privacy assurances.^{iv} Providers **may not bill third-party payers** for services in such cases where confidentiality cannot be assured (e.g., a payer does not suppress Explanation of Benefits documents and does not remove such information from claims history and other documents accessible to the policy holder). Providers may request payment from clients at the time of the visit for any confidential services provided that cannot be disclosed to third-party payers, as long as the provider uses the appropriate SFDS. Inability to pay, however, cannot be a barrier to services.^v Providers may bill third-party payers for services that the client identifies as non-confidential.

Endnotes

ⁱ Section 8.4 of the Title X Program Requirements contains information related to charges, billing, and collections. The program requirements in section 8.4 most relevant to charging clients at or

below 100% of the FPL, between 101% and 250% of the FPL, and above 250% of the FPL, are as follows:

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

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

Title X Program Requirement 8.4.2. *A schedule of discounts, based on ability to pay, is required for individuals with family incomes between 101% and 250% of the FPL (42 CFR 59.5(a)(8)).*

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

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

ii HRSA Policy Information Notice PIN 2014-02, "Sliding Fee Discount and Related Billing and Collections Program Requirements." *Individuals and families with annual incomes above 200 percent of the FPG are not eligible for sliding fee discounts. However, health centers may receive or have access to other funding sources (e.g., Federal, State, local, or private funds) that contain terms or conditions for reducing patient costs for specific services. These terms and conditions may apply to patients over 200 percent of the FPG. In such cases, it is permissible for a health center to allocate a portion (or all) of this patient's charge to this grant or subsidy funding source.*

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

iv Title X Program Requirement 8.4.8. *Reasonable efforts to collect charges without jeopardizing client confidentiality must be made.*

HRSA PIN 2014-02. *Patient privacy and confidentiality must be protected throughout the (SFDS eligibility determination) process. The act of billing and collecting from patients should be conducted in an efficient, respectful and culturally appropriate manner, assuring that procedures do not present a barrier to care and patient privacy and confidentiality are protected throughout the process.*

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

Clarification regarding “Program Requirements for Title X Family Planning Projects”

Confidential Services to Adolescents

OPA Program Policy Notice 2014-01

Release Date: June 5, 2014

I. Purpose

The purpose of this Program Policy Notice (PPN) is to provide Title X grantees with information to clarify some specific requirements included in the newly released “Program requirements for Title X-Funded Family Planning Projects Version 1.0-April 2014.”

II. Background

On April 25, 2014, the Office of Population Affairs (OPA), which administers the Title X Family Planning Program, released new Title X Family Planning Guidelines consisting of two parts: 1) *Program requirements for Title X Family Planning Projects* (hereafter referred to as *Title X Program Requirements*), and 2) *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*.

The Title X Program Requirements document closely aligns with the various requirements applicable to the Title X Program as set out in the Title X statute and implementing regulations (42 CFR part 59, subpart A), and other applicable Federal statutes, regulations, and policies. The requirement that this Program Policy Notice addresses is confidential services to adolescents.

Requirements regarding confidential services for individuals regardless of age are stipulated in Title X regulations at 42 CFR § 59.5(a)(4) and § 59.11, and are repeated in the Title X Program Requirements in sections 9.3 and 10.

III. Clarification

It continues to be the case that Title X projects may not require written consent of parents of guardians for the provision of services to minors. Nor can any Title x project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services.

Title X projects, however, must comply with legislative mandates that require them to encourage family participation in the decision of minors to seek family planning services, and provide counseling to minors how to resist attempts to coerce minors into engaging in sexual activities. In addition, all Title X providers must comply with State laws requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.

Susan B. Moskowsky, MS, WHNP-BC
Acting Director, Office of Population Affairs

FPAR: Family Planning Annual Reporting Requirements and Instructions

Family Planning Annual Report

This annual reporting requirement is for family planning services delivery projects authorized and funded under Title X of the Public Health Service Act, 42 United States Code [USC] 300).

Annual submission of the Family Planning Annual Report (FPAR) is required of all Title X family planning services grantees for purposes of monitoring and reporting program performance. FPAR data are presented in summary form, which protects the confidentiality of individuals who receive Title X-funded services.

The FPAR is the only source of annual, uniform reporting by all Title X family planning services grantees. It provides consistent, national-level data on the Title X Family Planning Program and its users.

Information from the FPAR is important to OPA for several reasons. FPAR data are used to monitor compliance with statutory requirements, regulations, and guidance provided in the Program Guidelines, including:

- Monitoring compliance with legislative mandates, such as giving priority in the provision of services to low-income persons, and
- Ensuring that Title X grantees and their subcontractors provide a broad range of family planning methods and services.

OPA uses FPAR data to comply with accountability and federal performance requirements for Title X family planning funds as required by the 1993 Government Performance and Results Act (GPRA). Current GPRA performance goals for the Title X Family Planning Program include priority in the provision of family planning services to low-income individuals, access to and utilization of cervical and breast cancer screening, and access to on-site HIV testing.

OPA relies on FPAR data to guide strategic and financial planning, to monitor performance, and to respond to inquiries from policymakers and Congress about the program. The FPAR allows OPA to assemble program data about the characteristics of the population served, utilization of services, composition of revenues, and program impact. FPAR data are a basis for objective grant reviews, program evaluation, and assessment of program technical needs.

<http://www.hhs.gov/opa/title-x-family-planning/research-and-data/fp-annual-reports/>

The federal FPAR forms and instructions are available at the following link:

http://www.hhs.gov/opa/sites/default/files/fpar-reissued-oct13_0.pdf

Title X Resources and Links

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

Office of Population Affairs Publications

Providing Information and Education to the public, as well as to Title X grantees, is an important component of the Title X Program. Publications can be accessed and downloaded from the OPA website under Pregnancy Prevention and Reproductive Health. www.hhs.gov/opa. For assistance in downloading publications, contact the office via email: opa@hhs.gov.

Department of Health and Human Services Websites

<http://www.hhs.gov/ophs> - Website provides helpful websites:

http://www.hhs.gov/nvpo/ (National Vaccine Program Office)	http://www.hhs.gov/opa (Office of Population Affairs)	http://www.healthfinder.gov/ (Healthfinder)
http://health.gov/ (Office of Disease prevention & Health Promotion)	http://ori.dhhs.gov (Office of Research Integrity)	http://www.healthypeople.gov/ (Healthy People 2020)
http://www.aids.gov/ (Office of HIV/AIDS)	http://www.surgeongeneral.gov (Office of the Surgeon General)	http://www.health.gov/nhic/ (National Health Information Center)
http://www.hhs.gov/ohrp (Office of Human Research Protections)	http://www.womenshealth.gov/ (Office on Women's Health)	http://www.hhs.gov/opa OPA Publications are now listed under topics Pregnancy Prevention & Reproductive Health)
http://www.minorityhealth.hhs.gov/ (Office of Minority Health)	http://www.fitness.gov/ (President's Council on Physical Fitness & Sports)	http://www.osha.gov/law-regs.html (OSHA Regulations)
http://www.hrsa.gov/opa/index.html (Office of Pharmacy Affairs- 340B Program)	http://www.grants.gov/ (Grant Opportunities)	http://www.hhs.gov/opa/grants-and-funding/ (OPA Grants and Funding)
http://www.hhs.gov/opa/zika/index.html (Zika Virus OPA Website)	http://www.cdc.gov/zika/index.html (Zika Virus CDC Site)	http://fpntc.org/ (National FP Training Centers)

Administrative Regulations that apply to Title X Grants

HHS Grants Policy Statement 2007: The Department of Health and Human Services Grants Policy Statement (HHS GPS) is intended to make available in a single document the general terms and conditions of HHS grant awards and apply to Title X grants.

<http://www.ahrq.gov/funding/policies/hhspolicy/index.html>

Links to HHS Department regulations that apply to Title X grants:

- 45 CFR Part 74: Uniform administrative requirements for awards and sub-awards to institutions of higher education, hospitals, nonprofits, commercial organizations; certain grants and agreements with states, local governments, and Indian tribal governments **and** 45 CFR Part 92: Uniform administrative requirements for grants and cooperative agreements to State and local governments are combined in:
- 45 CFR Part 75: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards and is available as an electronic document:
<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=88c2f29440664f74c9444e7ff44bab5a&mc=true&n=pt45.1.75&r=PART&ty=HTML>
- 45 CFR Part 80: Nondiscrimination under programs receiving Federal assistance through HHS effectuation of Title VI of the Civil Rights Act of 1964
<http://www.law.cornell.edu/cfr/text/45/part-80>
- 45 CFR Part 81: Practice and procedure for hearings under Part 80 of this Title
<http://www.law.cornell.edu/cfr/text/45/part-81>
- 45 CFR Part 84: Nondiscrimination on the basis of disability in programs and activities receiving or benefitting from Federal financial assistance
<http://www.law.cornell.edu/cfr/text/45/part-84>
- 45 CFR Part 91: Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance <http://www.law.cornell.edu/cfr/text/45/part-91>
- 37 CFR Part 401: Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements
<http://www.law.cornell.edu/cfr/text/37/part-401>
- 42 CFR Part 50, Subpart D: Public Health Service grant appeals procedure
<http://www.law.cornell.edu/cfr/text/42/part-50/subpart-D>
- 45 CFR Part 16: Procedures of the Departmental Grant Appeals Board
<http://www.law.cornell.edu/cfr/text/45/part-16>
- 45 CFR Part 100: Intergovernmental Review of Department of Health and Human Services Programs and Activities <http://www.law.cornell.edu/cfr/text/45/part-100>

Civil Rights Act of 1964

The Civil Rights Act of 1964 enforces the constitutional right to vote and provides relief against discrimination in public accommodations. It authorizes the Attorney General to protect constitutional rights in public facilities and public education, to protect civil rights, to prevent discrimination in federally assisted programs, and to establish a Commission on Equal Employment Opportunity.

Title IV of the Civil Rights Act of 1964 provides protections against discrimination under programs receiving Federal assistance through HHS. The following websites provide information relevant to family planning programs.

Overview: <http://www.eeoc.gov/eeoc/>

Protections of Employees: <http://www.eeoc.gov/employers/index.cfm>

Laws and Guidance: <https://www.eeoc.gov/laws/index.cfm>

Non-Discrimination on the Basis of Handicap in Programs Receiving Federal Financial Assistance (45CFR Part 84)

The purpose of 45 CFR Part 84 is to assure implementation of section 504 of the Rehabilitation Act of 1973, which is designed to eliminate discrimination on the basis of handicap in any program or activity receiving Federal financial assistance. It applies to each recipient of Federal financial assistance from the Department of Health and Human Services and to the program or activity that receives such assistance, including Title X projects. It is intended to assure that no qualified handicapped person, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity which receives Federal financial assistance. Facilities and services must be available to accommodate persons with disabilities.

<http://www.law.cornell.edu/cfr/text/45/part-84>

<http://www.hhs.gov/ocr/civilrights/understanding/disability/laws/disabilitylawsregandguidancemp.html>

Occupational Safety and Health Standards 29 CFR Part 1910 Subpart E

The Occupational Safety & Health Administration (OSHA) defines standards for the health and safety of employees. 29 CFR Part 1910, Subpart E provides guidance for employers regarding emergency planning.

https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10113&p_table=standards

https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10114

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Many aspects of this law impact Michigan Department of Health and Human Services and its sub-recipient 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 the patient 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: <https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/Transactions/TransactionsOverview.html>

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: <https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/Unique-Identifier/UniqueIdentifiersOverview.html>

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:

<https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/Unique-Identifier/NPIs.html>

Additional HIPAA Internet Resources

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

This site covers a variety of issues and includes the information on HIPAA Privacy for individuals and professionals.

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/HIPAAPrivacyandSecurity.pdf>

This resource developed by the CMS provides basic compliance information for health care providers.

<https://www.hhs.gov/hipaa/for-professionals/index.html>

The site includes the HIPAA statute, related materials, compliance information, and downloads prepared by The Department of Health and Human Services (HHS).

U.S. Laws and Legislation on Human Trafficking

Federal Anti-Trafficking Laws: <http://www.state.gov/j/tip/laws/>

The Trafficking Victims Protection Act (TVPA) of 2000 is the first comprehensive federal law to address trafficking in persons. The law provides a three-pronged approach: prevention, protection, and prosecution. The TVPA was reauthorized through the Trafficking Victims Protection Reauthorization Acts (TVPRA) of 2003, 2005, 2008, and 2013. Under U.S. federal law, “severe forms of trafficking in persons” include sex trafficking and labor trafficking:

- **Sex trafficking** is the recruitment, harboring, transportation, provision, or obtaining of a person for the purposes of a commercial sex act, in which commercial sex acts are induced by force, fraud, or coercion, or in which the person induced to perform such an act has not attained 18 years of age, (22 USC § 7102; 8 CFR § 214.11(a)).
- **Labor trafficking** is the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion for the purposes of subjection to involuntary servitude, peonage, debt bondage, or slavery, (22 USC § 7102).
- **Sex Trafficking of Children or by Force, Fraud, or Coercion Act** criminalizes sex trafficking, which is defined as causing a person to engage in a commercial sex act under statutorily defined conditions of force fraud, coercion or conduct involving persons under the age of 18. (18 USC § 1591) <http://www.justice.gov/crt/about/crm/1581fin.php>

The Trafficking Victims Protection Act of 2000 (TVPA) of 2000 is the cornerstone of Federal human trafficking legislation; it established several methods of prosecuting traffickers, preventing human trafficking, and protecting victims and survivors of trafficking. The act establishes human trafficking and related offenses as federal crimes, and attaches severe penalties to them. It also mandates restitution be paid to victims of human trafficking. It established the Office to Monitor and Combat Trafficking in Persons, which publishes a Trafficking In Persons (TIP) report each year. The TIP report describes efforts of countries to combat human trafficking. The act also established the Interagency Task Force to Monitor and Combat Trafficking for implementation of the TVPA. The TVPA protects victims and survivors by establishing the T visa, which allows victims and their families to become temporary U.S. residents, eligible to become permanent residents after three years.

The Trafficking Victims Protection Reauthorization Act of 2003 (TVPRA of 2003) established a federal civil right of action for trafficking victims to sue their traffickers and added human trafficking to the list of crimes that can be charged under the Racketeering Influenced Corrupt Organizations (RICO) statute. It also included provisions to protect victims and their families from deportation, and a requirement that the Attorney General report to Congress annually on activities of the U.S. government in the fight against trafficking.

The Trafficking Victims Protection Reauthorization Act of 2005 (TVPRA of 2005) included a pilot program to sheltering minor survivors of human trafficking, and grant programs to assist state and local law enforcement combat trafficking. It also expanded measures to combat trafficking internationally, including provisions to fight sex tourism and regulation of government contracts to ensure against contracting with individuals or organizations that engage in human trafficking.

The Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA of 2008) included new prevention strategies and government requirements that provide information about workers' rights to all people applying for work and education visas. It put in place new systems to gather and report human trafficking data. In addition to the prevention strategies, it expanded the protections available with the T visa, and required that all unaccompanied alien children be screened as potential victims of human trafficking. It also enhanced criminal sanctions against traffickers, and expanded definitions of various types of trafficking to facilitate prosecution.

The Trafficking Victims Protection Reauthorization Act of 2013 (TVPRA 2013) passed as an amendment to the Violence Against Women Act. It establishes programs to ensure that U.S. citizens do not purchase products made by victims of trafficking, and to prevent child marriage. It puts in place emergency response provisions within the State Department to respond quickly to disaster areas and crises where people are particularly susceptible to trafficking. It strengthens collaboration with state and local law enforcement to ease charging and prosecuting traffickers.¹

Resources:

¹The Polaris Project: <http://www.polarisproject.org/>
National Human Trafficking Resource Center: **1-888-373-7888**

Fact Sheet on Human Trafficking:
http://www.acf.hhs.gov/sites/default/files/orr/fact_sheet_human_trafficking_english.pdf

Patient Protection and Affordable Care Act of 2010 (ACA)

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act (ACA). The law puts in place comprehensive health insurance reforms, including patient rights and protections, expanded coverage, and cost savings. The law makes preventive care—including family planning and related care—more accessible and affordable for many Americans. The information and resources provided here are intended to assist Title X-funded family planning centers and other safety net providers in implementing the new law.

Affordable Care Act and the Title X Program

<http://www.hhs.gov/opa/title-x-family-planning/affordable-care-act/index.html>

About the Law

<http://www.hhs.gov/healthcare/about-the-law/index.html>

Key Features of the Affordable Care Act

<http://www.hhs.gov/healthcare/facts/timeline/index.html>

Enroll America

<http://www.enrollamerica.org/>

B. Michigan Family Planning Information Legislation, Resources, Program Requirements

Michigan Public Health Laws

Michigan Department of Health and Human Services (MDHHS) has the primary responsibility in Michigan to receive and administer state and federal funds for family planning services. Family planning services are authorized under the State of Michigan's Public Health Code, Section 333.9131. Guidelines for MDHHS administration of the federal program are based on requirements as cited in the document "Program Guidelines for Project Grants for Family Planning Services."

Additional guidelines may be required through either the federal or state directives. The program guidelines found in this document interpret the law and regulations in the form of standards and provides an orientation to the federal and state perspective on family planning. This manual is written to define minimum standards (requirements) and give recommendations (guidelines) for quality care, utilizing nationally accepted standards of practice.

The philosophy of the MDHHS Family Planning Program, consistent with that of Title X. 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. MDHHS 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 (such as teens). No one is denied services because of inability to pay.

PUBLIC HEALTH CODE (EXCERPT) Act 368 of 1978

333.9131 Family planning services; publicity; request by medically indigent individual; clinical abortions.

Sec. 9131.

(1) The department, and under its supervision a local health department, shall publicize the places where family planning services are available. The publicity shall state that receipt of public health services is not dependent on a request or nonrequest for family planning services.

(2) An effort shall not be made to coerce a medically indigent individual to request or not request family planning services. The department, and under its supervision a local health department, shall provide family planning services to a medically indigent individual upon the individual's request in accordance with standards established under section 9133. Clinical abortions shall not be considered a method of family planning.

History: 1978, Act 368, Eff. Sept. 30, 1978

Popular Name: Act 368

Appropriations

[http://www.legislature.mi.gov/\(S\(iliqdxmzjt4wj45gjwls0j2\)\)/mileg.aspx?page=AppropriationBillsPassed](http://www.legislature.mi.gov/(S(iliqdxmzjt4wj45gjwls0j2))/mileg.aspx?page=AppropriationBillsPassed)

Public Health Codes

The full text of Michigan's Public Health Code can be found at the first link. The following links offer information on specific information crucial to Title X program implementation.

Full Text:

<http://www.legislature.mi.gov/printDocument.aspx?objName=mcl-act-368-of-1978&version=txt>

HIV Testing Law:

http://www.michigan.gov/documents/mdch/FAQ_HIV_Test_Consent_2-25-2011_346590_7.pdf

Pharmacy:

[http://www.legislature.mi.gov/\(S\(5x5gcu3ujstowyqx4jnsorx\)\)/mileg.aspx?page=getObject&objectName=mcl-333-17745](http://www.legislature.mi.gov/(S(5x5gcu3ujstowyqx4jnsorx))/mileg.aspx?page=getObject&objectName=mcl-333-17745)

[http://www.legislature.mi.gov/\(S\(c2zhwkmjwxrmdx55biawhr2t\)\)/mileg.aspx?page=getObject&objectName=mcl-333-17745a](http://www.legislature.mi.gov/(S(c2zhwkmjwxrmdx55biawhr2t))/mileg.aspx?page=getObject&objectName=mcl-333-17745a)

Mental Health Services:

[http://www.legislature.mi.gov/\(S\(a1u3lonkc2j2o5iuputztyk\)\)/mileg.aspx?page=GetMCLDocument&objectName=Mcl-Act-258-of-1974&queryid=12811010&highlight=mental%20health%20services](http://www.legislature.mi.gov/(S(a1u3lonkc2j2o5iuputztyk))/mileg.aspx?page=GetMCLDocument&objectName=Mcl-Act-258-of-1974&queryid=12811010&highlight=mental%20health%20services)

Substance Abuse:

[http://www.legislature.mi.gov/\(S\(3me3trinm1wmjw255cik40155\)\)/milet.aspx?page=getobject&objectname=mcl-368-1978-6&query=on&highlight=substance AND abuse](http://www.legislature.mi.gov/(S(3me3trinm1wmjw255cik40155))/milet.aspx?page=getobject&objectname=mcl-368-1978-6&query=on&highlight=substance AND abuse)

PA 360 of 2002:

<http://legislature.mi.gov/doc.aspx?mcl-333-1091>

Confidentiality of Minors:

http://www.michigan.gov/documents/mdch/Michigan_Minor_Consent_Laws_for_Sexual_Health_292774_7.pdf

When Teens Disclose Dating Violence to Health Care Providers: A Guide to Confidentiality and Reporting Laws in Michigan, November 2010, National Center for Youth Law in collaboration with The Family Violence Prevention Fund.

http://www.michigan.gov/documents/mdch/MI_TDVConfidentialityReporting_11-15-10-final_380362_7.pdf

Adoption:

[http://www.legislature.mi.gov/\(S\(4r5mae55b14d5unrn5czok55\)\)/mileg.aspx?page=LoadVirtualDoc&BookmarkID=6495](http://www.legislature.mi.gov/(S(4r5mae55b14d5unrn5czok55))/mileg.aspx?page=LoadVirtualDoc&BookmarkID=6495)

Licensing for Health Care Professionals:

http://www.michigan.gov/lara/0,4601,7-154-35299_63294---,00.html

Drug Control License & Dispensing of Pharmaceuticals

333.17745 Drug control license; patient's chart or clinical record to include record of drugs dispensed; delegating authority to dispense drugs; storage of drugs; container; label; complimentary starter dose drug; information; compliance with MCL 333.7303a; inspection of locations; limitation on delegation; receipt of complimentary starter dose drugs by pharmacist; "complimentary starter dose" defined.

Sec. 17745. (1) Except as otherwise provided in this subsection, a prescriber who wishes to dispense prescription drugs shall obtain from the board a drug control license for each location in which the storage and dispensing of prescription drugs occur. A drug control license is not necessary if the dispensing occurs in the emergency department, emergency room, or trauma center of a hospital licensed under article 17 or if the dispensing involves only the issuance of complimentary starter dose drugs.

(2) Except as otherwise authorized for expedited partner therapy in section 5110 or as provided in section 17744a or 17744b, a dispensing prescriber shall dispense prescription drugs only to his or her own patients.

(3) A dispensing prescriber shall include in a patient's chart or clinical record a complete record, including prescription drug names, dosages, and quantities, of all prescription drugs dispensed directly by the dispensing prescriber or indirectly under his or her delegatory authority. If prescription drugs are dispensed under the prescriber's delegatory authority, the delegatee who dispenses the prescription drugs shall initial the patient's chart, clinical record, or log of prescription drugs dispensed. In a patient's chart or clinical record, a dispensing prescriber shall distinguish between prescription drugs dispensed to the patient, prescription drugs prescribed for the patient, prescription drugs dispensed or prescribed for expedited partner therapy as authorized in section 5110, and prescription drugs dispensed or prescribed as authorized under section 17744a or 17744b. A dispensing prescriber shall retain information required under this subsection for not less than 5 years after the information is entered in the patient's chart or clinical record.

(4) A dispensing prescriber shall store prescription drugs under conditions that will maintain their stability, integrity, and effectiveness and will assure that the prescription drugs are free of contamination, deterioration, and adulteration.

(5) A dispensing prescriber shall store prescription drugs in a substantially constructed, securely lockable cabinet. Access to the cabinet shall be limited to individuals authorized to dispense prescription drugs in compliance with this part and article 7.

(6) Unless otherwise requested by a patient, a dispensing prescriber shall dispense a prescription drug in a safety closure container that complies with the poison prevention packaging act of 1970, 15 USC 1471 to 1477.

(7) A dispensing prescriber shall dispense a drug in a container that bears a label containing all of the following information:

(a) The name and address of the location from which the prescription drug is dispensed.

(b) Except as otherwise authorized under section 5110, 17744a, or 17744b, the patient's name and record number.

(c) The date the prescription drug was dispensed.

(d) The prescriber's name or, if dispensed under the prescriber's delegatory authority, the name of the delegatee.

- (e) The directions for use.
- (f) The name and strength of the prescription drug.
- (g) The quantity dispensed.
- (h) The expiration date of the prescription drug or the statement required under section 17756.
- (8) A dispensing prescriber who dispenses a complimentary starter dose drug to a patient shall give the patient the information required in this subsection, by dispensing the complimentary starter dose drug to the patient in a container that bears a label containing the required information or by giving the patient a written document that may include, but is not limited to, a preprinted insert that comes with the complimentary starter dose drug and that contains the required information. The information required to be given to the patient under this subsection includes all of the following:
 - (a) The name and strength of the complimentary starter dose drug.
 - (b) Directions for the patient's use of the complimentary starter dose drug.
 - (c) The expiration date of the complimentary starter dose drug or the statement required under section 17756.
- (9) The information required under subsection (8) is in addition to, and does not supersede or modify, other state or federal law regulating the labeling of prescription drugs.
- (10) In addition to meeting the requirements of this part, a dispensing prescriber who dispenses controlled substances shall comply with section 7303a.
- (11) The board may periodically inspect locations from which prescription drugs are dispensed.
- (12) The act, task, or function of dispensing prescription drugs shall be delegated only as provided in this part and sections 16215, 17048, 17076, 17212, and 17548.
- (13) A supervising physician may delegate in writing to a pharmacist practicing in a hospital pharmacy within a hospital licensed under article 17 the receipt of complimentary starter dose drugs other than controlled substances as defined by article 7 or federal law. When the delegated receipt of complimentary starter dose drugs occurs, both the pharmacist's name and the supervising physician's name shall be used, recorded, or otherwise indicated in connection with each receipt. A pharmacist described in this subsection may dispense a prescription for complimentary starter dose drugs written or transmitted by facsimile, electronic transmission, or other means of communication by a prescriber.
- (14) As used in this section, "complimentary starter dose" means a prescription drug packaged, dispensed, and distributed in accordance with state and federal law that is provided to a dispensing prescriber free of charge by a manufacturer or distributor and dispensed free of charge by the dispensing prescriber to his or her patients. 1978, Act 368, -- Am. 2014, Act 525, Imd. Eff. Jan. 14, 2015

Sexual Coercion Legislation

Sexual coercion can occur by several different means. A perpetrator may be in a position of authority over a minor, use a weapon, violence or threat of violence, or may be a member of the minor's household. Michigan statutes describing criminal sexual conduct are found at these links:

For a summary of Michigan Sexual Assault laws see: Sexual Assault Prevention & Awareness Center (SAPAC), Sexual Assault Laws at: <http://sapac.umich.edu/article/95>

Felony Criminal Sexual Conduct (mcl-720-520c)

[http://www.legislature.mi.gov/\(qlov2kqges0ash55unx2mxnp\)/mileg.aspx?page=GetMCLDocument&objectname=mcl-750-520c](http://www.legislature.mi.gov/(qlov2kqges0ash55unx2mxnp)/mileg.aspx?page=GetMCLDocument&objectname=mcl-750-520c)

Felony Criminal Sexual Conduct (mcl-720-520d)

[http://www.legislature.mi.gov/\(S\(zll5p122a0j0u3nn4kx1zfru\)\)/mileg.aspx?page=GetObject&objectname=mcl-750-520d](http://www.legislature.mi.gov/(S(zll5p122a0j0u3nn4kx1zfru))/mileg.aspx?page=GetObject&objectname=mcl-750-520d)

Misdemeanor Criminal Sexual Conduct (mcl-750-520e)

[http://www.legislature.mi.gov/\(ast5ns55wvnujh55b54mba55\)/mileg.aspx?page=GetMCLDocument&objectname=mcl-750-520e](http://www.legislature.mi.gov/(ast5ns55wvnujh55b54mba55)/mileg.aspx?page=GetMCLDocument&objectname=mcl-750-520e)

Child Protection & Mandated Reporting Legislation

In Michigan the following professionals are considered mandatory reporters of child abuse and neglect:

- Physicians; coroners; dentists; registered dental hygienists; medical examiners; nurses; persons licensed to provide emergency medical care; audiologists;
- School administrators; school counselors; school teachers; regulated child care providers;
- Psychologists; marriage and family therapists; licensed professional counselors; certified social workers; social workers; social work technicians;
- Law enforcement officers.
- Members of the clergy

The following links provide further assistance:

DHS Mandated Reporters Page

http://www.michigan.gov/dhs/0,1607,7-124-5452_7119_44443---,00.html

Michigan Mandated Reporters Resource Guide

http://www.michigan.gov/documents/dhs/Pub-112_179456_7.pdf

Michigan Child Protection Law (Act 238 Of 1975)

http://www.michigan.gov/documents/DHS-PUB-0003_167609_7.pdf

Michigan Human Trafficking Law

The Michigan law banning human trafficking went into effect on August 24, 2006. The law was strengthened in 2010 and the changes took effect on April 1, 2011. These changes included enhanced restitution for human trafficking victims. Victims can ask for all costs suffered as a consequence of their bondage, such as medical costs, and can also ask for a restitution order that recognizes the value of the years of their life lost due to the crime.

The human trafficking law was overhauled in 2014. The 2014 legislation includes safe harbor provisions, stronger tools to hold traffickers accountable, and created a standing Human Trafficking

Commission within the Department of Attorney General and a Human Trafficking Health Advisory Board within the Department of Health and Human Services. Most of the new legislation took effect on January 14, 2015. (For a summary of the 2014 Human Trafficking Laws, see below.)

http://www.michigan.gov/ag/0,4534,7-164-60857_60859---,00.html

Michigan law prohibits:

1. Forced labor or services (MCL 750.462b) by force, fraud, or coercion
 - Force includes, but is not limited to, physical violence, threat of physical violence or actual physical restraint or confinement or threat of actual physical restraint of confinement, without regard to whether injury occurs.
 - Fraud includes, but is not limited to, a false or deceptive offer of employment or marriage.
 - Coercion includes but is not limited to:
 - a. Threatening to harm or physically restrain any individual or the creation of any scheme, plan, or pattern intended to cause an individual to believe that failure to perform an act would result in psychological, reputational, or financial harm to, or physical restraint of any individual.
 - b. Abusing or threatening abuse of the legal system, including threats of arrest or deportation without regard to whether the individual being threatened is subject to arrest or deportation.
 - c. Knowingly destroying, concealing, removing, confiscating, or possessing any passport or other immigration document or any other government identification document from any individual, regardless of whether the documents are fraudulent or fraudulently obtained.
2. Debt Bondage (MCL 750.462c)
3. Enterprise Liability; Financially Benefitting (MCL 750.462d)
4. Trafficking a Minor (MCL 750.462e)
 - Covers both sex trafficking and labor trafficking of a minor
 - No Force, Fraud or Coercion required in the case of minors
 - Regardless of whether the person knows the age of the minor

Increased Protections for Victims in the 2014 Michigan Human Trafficking Legislation:

Safe Harbor - Safe harbor was one of the key reforms in the 2014 Michigan human trafficking legislation.

1. 2014 PA 336 provides Safe Harbor to minor sex trafficking victims by presuming that a minor found engaging in prostitution is a victim of human trafficking and mandates law enforcement to refer the minor victims for appropriate treatment within the Department of Health and Human Services.
2. 2014 PA 342 provides Safe Harbor to minor sex trafficking victims by establishing probate court jurisdiction for minor human trafficking victims who are dependent and in danger of substantial harm.

3. 2014 PA 335 provides Safe Harbor by allowing victims of human trafficking to clear their criminal record of crimes they were forced to commit by their traffickers.
4. 2014 PA 334 provides adult human trafficking victims safe harbor through a diversion process to avoid prostitution convictions.

Stronger Tools to Hold Traffickers Accountable in the 2014 Human Trafficking Legislation:

1. Increases the crime of buying sex from a minor to a felony.
2. Overhauls the human trafficking portion of the penal code in line with the 2014 human trafficking provisions.
3. Removes the statute of limitations in cases where trafficking is punishable by life and otherwise lengthened the statute of limitations for bringing charges against traffickers.
4. Strengthens penalties against sex-buyers (johns) by revising the definition of Sex Offender to include the new crime of soliciting prostitution from a minor and includes those engaging in trafficking minors for sex; and requires johns to be placed on sex offender registry.
5. Removes outdated gender-specific references regarding prostitution, and increases fines for operating a place of prostitution.
6. Updates the Crime Victim's Rights Act to account for the 2014 human trafficking laws.
7. Makes human trafficking of a child an offense that must be reported by mandatory reporters to Child Protective Services.
8. Reflects changes in the sentencing guidelines for increased penalties against criminals soliciting sex from minors under 16 years of age.
9. Amends civil nuisance provisions to allow human trafficking violations to qualify as a nuisance.

Michigan Human Trafficking Resources:

<https://www.traffickingresourcecenter.org/state/michigan>

National Human Trafficking Resource Center: 1-888-373-7888

Fact Sheet on Human Trafficking:

http://www.acf.hhs.gov/sites/default/files/orr/fact_sheet_human_trafficking_english.pdf

Expedited Partner Therapy Legislation

Public Act 525 of 2014 (MCL 333.5110) authorized the use of expedited partner therapy (EPT) in Michigan for certain sexually transmitted diseases as designated by the state of health department.

In January 2015, the department designated chlamydia and gonorrhea as diseases for which the use of EPT is appropriate. Following is a copy of the legislation:

[http://www.legislature.mi.gov/\(S\(nj1cpiegpl0cokontzv2ooxv\)\)/documents/mcl/pdf/mcl-333-5110.pdf](http://www.legislature.mi.gov/(S(nj1cpiegpl0cokontzv2ooxv))/documents/mcl/pdf/mcl-333-5110.pdf)

MDHHS developed the following document to provide guidance for health care providers using EPT: http://michigan.gov/documents/mdch/EPT_for_Chlamydia_and_Gonorrhea_-_Guidance_for_Health_Care_Providers_494241_7.pdf

MDHHS developed the following information sheet for patient and partners being offered expedited partner therapy (EPT):

http://michigan.gov/documents/mdch/EPT_Information_Sheet_for_Patients_and_Partners_494242_7.pdf

Additional Michigan Resources

Zika virus resources:

CDC Zika Website: <http://www.cdc.gov/zika/>

MDHHS Webpage for Michigan Residents and Healthcare providers:

<http://www.michigan.gov/emergingdiseases/0,4579,7-186-77096---,00.html>

Immunizations:

http://www.michigan.gov/documents/They-re-Not-Just-For-Kids_7195_7.pdf

HIV Testing Counseling and Referral Services:

http://www.michigan.gov/mdhhs/0,5885,7-339-71550_2955_2982---,00.html

Genetics:

<https://migrc.org/>

Michigan Medicaid Policy Information:

Links to the Medicaid Provider Manual and Medicaid Policy Bulletins

http://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_42542_42543_42546_42553-188444--,00.html

The Medicaid Provider Manual contains chapters on: Family Planning Clinics, Healthy Michigan Plan, Medicaid Health Plans, and Pharmacy which are particularly relevant to Title X clinics.

<http://www.mdch.state.mi.us/dch-medicaid/manuals/MedicaidProviderManual.pdf>

Medicaid Billing and Reimbursement Information:

Procedure codes and fee screens are found on MDHHS Provider Specific Information.

http://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_42542_42543_42546_42551-159815--,00.html

CHAMPS enrollment and specific billing questions or concerns should be directed to the Medicaid Provider Helpline, either by phone 1-800-292-2550 or e-mail ProviderSupport@michigan.gov.

MDHHS Family Planning Minimum Program Requirements (MPRs)

ELEMENT DEFINITION:

Family Planning services offer comprehensive preventive reproductive health care that includes: general health assessment and examination; routine screening 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 socio/economic 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.

MINIMUM PROGRAM REQUIREMENTS:

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). **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (a)(1).
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 participate in any other program. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (a)(2).
3. 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).
4. 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).
5. 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).
6. 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).
7. 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).

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 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).
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 agency is required. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (a)(9).
10. Provide for an advisory committee. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (a)(11).
11. Provide for medical services related to family planning (including physician's consultation, examination prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (b)(1).
12. Provide for social services related to family planning, including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance. **Reference:** 42 CFR CH. 1 (10-1-00 Edition) §59.5 (b)(2).
13. 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).
14. Provide for orientation and in-service training for all project personnel. **Reference:** 42 CFR CH.1 (10-1-00 Edition) §59.5 (b)(4).
15. 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).
16. 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).

17. 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).
18. 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).
19. 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).
20. 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).
21. 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 MDHHS accreditation/ site review process to determine program compliance. They are based on the Title X Statute [42 CFR CH. 1 (10-1-00 Edition) §59] and are consistent with, the Office of Population Affairs (OPA) Program Requirements, and the MDHHS Title X Family Planning Program Standards and Guidelines. Each indicator refers to a minimum standard that must be in place to be in compliance for MDHHS Family Planning Program grant status as a family planning sub-recipient.

The Accreditation/Site Review Tool identifies the minimum program requirements, references, and the measurements used to determine compliance with each MPR indicator. Indicators determined to be out of compliance must to be corrected. The Family Planning Indicator tool can be found on the Michigan Local Public Health Accreditation website: <https://accreditation.localhealth.net/> and on the MDHHS Family Planning website at: <http://www.michigan.gov/familypplanning>

Compliance with the Minimum Program Requirements (MPRs) is attested to in the contract process between sub-recipients and MDHHS. The Comprehensive Agreement between MDHHS and local health departments and the Standard Agreement between private non-profit sub-recipients and MDHHS include these assurances.

Michigan Department of Health and Human Services

Minimum Reporting Requirements (MRRs)

The federally mandated minimum program reporting requirements for sub-recipients are explained here. Required reporting documents must be submitted to MDHHS by the stated deadlines. These requirements are subject to change as legislative, fiduciary and other aspects of the program change.

These documents include the:

- The Family Planning Annual Report (FPAR)
- Family Planning Health Care Plan

These reports must be submitted accurately and timely. The information is used for essential activities not limited to legislative reporting, federal reporting requirements for the State, budgeting, funding allocations, 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.

Title X Family Planning Sub-recipients must also comply with Michigan's mandatory reporting law under the Child Protection Law and must have policies and procedures in place that comply with mandatory reporting under Michigan's Child Protection Law.

The following list summarizes the required Title X reports, their forms and due dates. This list is provided to sub-recipients as part of the contracting process and required forms are provided to sub-recipients prior to their due dates.

Michigan Department of Health and Human Services Minimum Reporting Requirements Family Planning Program

Required Report	Source Document	Reason/Use	Due Date
FPAR Profile Sheet		Federal Requirement	MID –Year Report (Jan-June) due July 15
Table 1	Client visit record		
Table 2	Client visit record		
Table 3	Client visit record		Annual Report (Jan- Dec) due January 10
Table 4	Client visit record		
Table 5	Client visit record		
Table 6	Client visit record		
Table 7	Client visit record		
Table 8	Client visit record		
Table 9	Client visit record		
Table 10	Client visit record		
Table 11	Client visit record		
Table 12	Client visit record		
Table 13	Client visit record		
Table 14	General ledger or Accounting reports		
Table 15	Accounting reports	Michigan	
Table 16	Client visit record	Requirement	
Family Planning Needs Assessment and Health Care Plan	Program Statistics	Federal Requirement	Due September 15

Project Outputs:

<i>Target Measure</i>	Total Performance Expectation	State Funded Minimum Performance Expected	
Unduplicated number of Clinic Users		<i>Percent</i> 95%	Number

Michigan Title X Family Planning

Annual Health Care Plan Guidance

The Annual Health Care Plan highlights a family planning agency's progress during the current fiscal year, along with identifying plans for next fiscal year, including priority population(s) and targeted service area(s), describing the agency's capacity to provide Title X services, and outlining service delivery plans. This document provides family planning agencies guidance on the submission requirements for the Annual Health Care Plan narrative and accompanying documents.

- I. Program Description
 - A. Highlight significant program achievements, milestones, or other notable accomplishments during this past fiscal year.
 - B. Highlight program and community changes (e.g., staffing or administrative changes, supply issues, local policy/community issues, or provider relationships) that occurred this past fiscal year, focusing on service delivery and priority population(s) affects, and potential solutions.
- II. Priority Population(s) and Target Service Area(s)
 - A. Provide a brief description of the agency's priority population(s) and target service area(s).
 - B. Insert the table below into this section's narrative and indicate the projected number of unduplicated users during calendar year 2017 for each table row. For demographic categories, refer to FPAR Table 1. For income level, refer to FPAR Table 4.

Demographic Category	Unduplicated Users 2017
Males	
Females	
Teens	
Income Level	Unduplicated Users 2017
At or below 100% of poverty	
Above 100% but no more than 150%	
Above 150% but not more than 200%	
Above 200% but not more than 250% of poverty	
Above 250% of poverty	

- III. Agency Capacity & Staffing Structure
 - A. Provide a copy of the agency's current family planning organizational chart as an attachment.
 - B. Identify and report all services to be provided to clients under Title X by completing the *Family Planning Services Provided* document (See [Family Planning website](#), 'Information for Providers').

- C. Include the agency's current *Sliding Fee Scale* and *Fee Schedule*. Submit as an attachment.
 - D. Verify and submit the agency's coordinator information, main office hours, agency clinic location(s), and clinic hours of operation on the *Family Planning Agency Clinic Locations & Schedules* (Attachment A).
- IV. Program Work Plan
 - A. Provide a brief progress report on the previous year's goals, objectives, and activities using the *Family Planning Work Plan Progress Report* (See [Family Planning website](#), 'Information for Providers'), including community education and promotion activities.
 - B. Develop project goals and objectives for next fiscal year that are specific, measurable, attainable, realistic, and time specific (S.M.A.R.T.), and address Title X priorities. Submit on the required work plan format, *Family Planning Work Plan* (See [Family Planning website](#), 'Information for Providers') as an attachment. Include at least one project goal and objective for Community Education Activities (See Section 11.2 of the *Michigan Title X Family Planning Standards and Guidelines Manual*) and at least one project goal and objective for Community Promotion Activities (See Section 11.3 of the *Michigan Title X Family Planning Standards and Guidelines Manual*). Goals and objectives should reflect regional needs and engage priority populations.
- V. Family Planning Advisory Council (See Section 11.1 of the *Michigan Title X Family Planning Standards and Guidelines Manual*).
 - A. Provide a brief description of the Advisory Council's purpose, highlighting successes, challenges, and notable outcomes from last fiscal year.
 - B. Include the following Advisory Council documents as attachments: next fiscal year's meeting schedule, member roster, and minutes from the last held Council meeting.
- VI. Information and Education (I&E) Committee (See Sections 12.1 thru 12.7 of the *Michigan Title X Family Planning Standards and Guidelines Manual*).
 - A. Provide a brief description of the I. & E. Committee's function, highlighting member composition.
 - B. Include the current fiscal year's meeting schedule and the member roster as an attachment. The roster should indicate what community populations/groups the member represents (e.g., agency or professional organization name, or teen, male, client, or parent).
 - C. Describe the I. & E. Committee's review and approval process for educational materials, including review tools used, how reviewer feedback is gathered, and how member determinations are documented.
- VII. Quality Family Planning (QFP) Service Project Progress Report
 - A. Provide a brief progress report on the agency's QFP quality improvement goals, objectives, and activities using the *Quality Family Planning Service Project Progress Report* (See [Family Planning website](#), 'Information for Providers').

Financial Management Audit Requirements

Financial Management Audit Requirements

Following are the Audits that are required of all Family Planning Title X sub-recipient agencies.

This section applies to agencies designated as sub-recipients (health department & private non-profit agencies.) Grantees designated as vendors are exempt from the provisions of this section.

1. Required Audit or Notification Letter

Grantees must submit to the Department a Single Audit, Financial Statement Audit, or Audit Status Notification Letter as described below (A.-C.). If submitting a Single Audit or a Financial Statement Audit, Grantees must also submit a Corrective Action Plan for any audit findings that impact MDHHS-funded programs and management letter (if issued) with a response.

A. Single Audit

Grantees that are a state, local government or non-profit organization that expend \$500,000 (\$750,000 for fiscal years beginning on or after December 26, 2014) or more in federal awards during the Grantee's fiscal year must submit a Single Audit to the Department, regardless of the amount of funding received from the Department. The Single Audit must comply with the requirements of the Single Audit Act Amendments of 1996, and Office of Management and Budget (OMB) Circular A-133 "Audits of States, Local Governments, and Non-Profit Organizations," as revised for fiscal years beginning before December 26, 2014; and Title 2 Code of Federal Regulations, Subpart F for fiscal years beginning on or after December 26, 2014.

B. Financial Statement Audit

Grantees exempt from the Single Audit and Financial Related Audit requirements that receive \$500,000 (\$750,000 for fiscal years beginning on or after December 26, 2014) or more in **total funding** from the Department in State and Federal grant funding must submit a copy of the Financial Statement Audit prepared in accordance with generally accepted auditing standards (GAAS), and management letter, if one is issued. Grantees exempt from the Single Audit and Financial Related Audit requirements that receive less than \$500,000 (\$750,000 for fiscal years beginning on or after December 26, 2014) of total Department grant funding must submit a copy of the Financial Statement Audit prepared in accordance with GAAS if the audit includes disclosures that may negatively impact MDHHS-funded programs, including, but not limited to fraud, going concern uncertainties, financial statement misstatements, and violations of contract and grant provisions.

C. Audit Status Notification Letter

Grantees exempt from the Single Audit and Financial Statement Audit requirements (A. and B. above) must submit an Audit Status Notification Letter that certifies these exemptions. The template Audit Status Notification Letter and further instructions are available at <http://www.michigan.gov/mdhhs> by selecting Inside MDHHS – MDHHS Audit – Audit Reporting

2. Other Audits

The Department or federal agencies may also conduct or arrange for additional audits to meet their needs. In addition to the above audits, comprehensive site reviews are performed every three years, and detailed fiscal reviews are performed every two to three years. If any concerns are noted, a corrective action plan is expected. Revisits occur as deemed necessary.

3. Due Date and Where to Send

The required audit and any other required submissions (i.e. Corrective Action Plan and management letter with a response), or Audit Status Notification Letter must be submitted to the Department within nine months after the end of the Grantee's fiscal year by e-mail to the Department at MDHHS-AuditReports@michigan.gov. The required materials must be assembled in a PDF file compatible with Adobe Acrobat (read only). The subject line must state the agency name and fiscal year end. The Department reserves the right to request a hard copy of the audit materials if for any reason the electronic submission process is not successful.

4. Penalty

A. Delinquent Single Audit or Financial Statement Audit

If the Grantee does not submit the required Single Audit or Financial Statement Audit, including any management letter with a response and applicable Corrective Action Plan within nine months after the end of the Grantee's fiscal year, the Department may withhold from the current funding an amount equal to five percent of the audit year's grant funding (not to exceed \$200,000) until the required filing is received by the Department. The Department may retain the amount withheld if the Grantee is more than 120 days delinquent in meeting the filing requirements. The Department may terminate the current grant if the Grantee is more than 180 days delinquent in meeting the filing requirements.

B. Delinquent Audit Status Notification Letter

Failure to submit the Audit Status Notification Letter, when required, may result in withholding from the current funding an amount equal to one percent of the audit year's grant funding until the Audit Status Notification Letter is received.

5. Management Decision

The Department shall issue a management decision on findings and questioned costs contained in the Grantee's Single Audit within six months after the receipt of a complete and final audit report. The management decision includes whether or not the audit finding is sustained; the reasons for the decision; and the expected Grantee action to repay disallowed costs, make financial adjustments, or take other action. Prior to issuing the management decision, the Department may request additional information or documentation from the Grantee, including a request for auditor verification of documentation, as a way of mitigating disallowed costs.

SECTION II

Administrative Program Requirements for Title X Family Planning Projects

B. Overview of Title X Program Requirements

The MDHHS Title X Family Planning Program Standards and Guidelines align with the Office of Population Affairs (OPA) Title X Family Planning Guidelines published in April, 2014 which replace the 2001 Program Guidelines for Project Grants for Family Planning Services. The new guidelines are contained in the following two documents:

1. Program Requirements for Title X Funded Family Planning Projects. This document is derived from the Title X statute, implementing regulations and other requirements under Title X of the Public Health Service Act. It describes the Title X program requirements for funded projects. <http://www.hhs.gov/opa/sites/default/files/ogc-cleared-final-april.pdf>
2. Providing Quality Family Planning Services (QFP) was developed jointly by the Centers for Disease Control and Prevention (CDC) and OPA and published as a *CDC MMWR Recommendations and Reports*. The QFP presents clinical recommendations for providing family planning services consistent with the best available scientific evidence. The QFP is intended for providers across all practice settings and serves as the clinical guidance for Title X projects. <http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

The Administrative Program Requirements section of the MDHHS Title X Family Planning Standards and Guidelines Manual, 2014 focus on the requirements outlined in the Program Requirements for Title X Funded Family Planning Projects and defines administrative requirements for MDHHS Family Planning programs. The Clinical Services section follows the outline and recommendations in the QFP and defines clinical requirements for MDHHS Family Planning programs.

C. Eligibility, Application and Grant Process

1. APPLICABILITY

The requirements set forth in this document apply to the award of grants to MDHHS Title X sub-recipients under the MDHHS grant awarded under section 1001 of the PHS Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects in Michigan. These projects consist of the educational, comprehensive medical, and social services necessary to assist individuals to determine freely the number and spacing of their children.

2. DEFINITIONS

Terms used throughout this document include:

TERM	DEFINITION
The Act or Law	Title X of the Public Health Service Act, as amended
Annual Requirements	Where this manual requires activities to be carried out annually, they must be conducted within a 12 month period .
Family	A social unit composed of one person, or two or more persons living together, as a household
Low-income family	A family whose total annual income does not exceed 100% of the most recent Federal Poverty Guidelines; also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. Un-emancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.
Grantee	MDHHS is the grantee that receives Title X funding for the state of Michigan and assumes legal and financial responsibility and accountability for performance of approved activities under the grant.
Sub-recipients	Those entities that provide family planning services with Title X funds under a written agreement with a grantee. May also be referred to as delegates or contract agencies.
Service Site	The clinics or other locations where services are provided by the grantee or sub-recipient.
Project	Activities described in the grant and supported under the approved budget. The “scope of the project” as defined in the funded application consists of activities that the approved Title X family planning project budget supports.
Nonprofit	A private agency, institution, or organization for which no part of the entity’s net earnings benefit, or may lawfully benefit, any private stakeholder or individual.
Must	Throughout this document, the words must or required indicate mandatory program requirements.

Should	The word should , as used in this document, indicates recommended program guidelines and policies that reflect current standards of practice and are strongly recommended by MDHHS in order to fulfill the intent of Title X.
May	The words can or may , as used in this document, indicate suggestions for consideration by individual projects.
Minors	The term Minors refers to clients under the age of 18 and is used with reference to legal/statutory mandates regarding provision of services, confidentiality, required counseling, protections, and legal requirements for mandatory reporting of suspected abuse of minors.
Provider	The term provider refers to any staff member who is involved in providing family planning services to a client; includes physicians, physician assistants, nurse practitioners, nurse-midwives, nursing staff and other staff providing client services. (QFP p.4)
Family Planning Services	The QFP defines family planning services within a broader framework of preventive health services. Family Planning Services include: contraceptive services for clients who want to prevent pregnancy and space births; pregnancy testing and counseling; assistance to achieve pregnancy; basic infertility services; STD services(including HIV/AIDS); and preconception health services. (QFP p.4) They are considered musts for family planning programs.
Related Preventive Health Services	Related Preventive Health Services include services that are considered beneficial to reproductive health, linked to family planning services, and appropriate to deliver within a family planning visit (e.g., breast and cervical cancer screening) (QFP p.5) They are considered musts for family planning programs.
Other Preventive Health Services	Other Preventive Health Services include preventive health services for women and women not linked to reproductive health (e.g., screening for lipid disorders, skin cancer, colorectal cancer or osteoporosis.) These services are beyond the scope of family planning, but should be available either on-site or referral to appropriate providers. (QFP p.5) Family programs must have appropriate unpaid referral sources for these services.

Family Planning Encounter	A family planning encounter is a face-to-face contact between a client and family planning provider. The purpose of a family planning encounter is to provide family planning and related preventive health services to clients who want to prevent, space or achieve healthy pregnancies or want family planning advice, education or counseling. For purposes of FPAR, the encounter must take place in a Title X service site and must be documented in the client record. (Title X FPAR Forms & Instructions, 2013, page 7,8)
Family Planning Provider	The term family planning provider refers to any staff member involved in providing family planning services to a client; includes physicians, physician assistants, nurse practitioners, nurse-midwives, nursing staff and other staff providing client services. (QFP p.4). For purposes of FPAR, Clinical Services Providers include: physicians, physician assistants, nurse practitioners, and certified nurse midwives; and Other Services Providers include: licensed nurses, nurse assistants, laboratory assistants, health educators, social workers, or clinic aids providing family planning services. (Title X FPAR Forms & Instructions, 2013, page 7)
Family Planning Service Site	The term service site refers to clinics or other locations where Title X family planning services are provided by the grantee or sub-recipient. (Title X FPAR Forms & Instructions, 2013, page 8)
Family Planning Client or User	The term family planning client refers to an individual of reproductive age who is in need of family planning and related preventive health services. (QFP, page 2) For purposes of FPAR, a family planning user is an individual who has at least one family planning encounter at a Title X family planning service site during the reporting period. (Title X FPAR Forms & Instructions, 2013, page 7)
MCIR	The Michigan Care Improvement Registry (MCIR) is Michigan's online immunization registry.
Risk Assessment	The term Risk Assessment as used in this document, means an objective identification of risk behaviors and situations that may lead to recognized adverse health conditions. Risk assessment leads to screening recommendations, appropriate interventions, or treatment.
Screening	The term Screening , as used in this document, means testing to identify an unrecognized disease or health condition to enable early intervention and management. Screening initiatives help lead to earlier diagnosis to reduce mortality and suffering from diseases.

3. ELIGIBILITY

Any public or nonprofit private entity located in Michigan is eligible to apply for a Title X family planning services project grant through MDHHS as the Title X Grantee for Michigan.

- A. Eligible applicants **must** demonstrate past experience delivering primary care, adolescent or women's health care or family planning services. Potential applicants include:
 - 1. Public and private non-profit health agencies
 - 2. Local health departments
 - 3. Community health centers
 - 4. Federally Qualified Health Centers
 - 5. Rural and Urban Health Centers
 - 6. Tribal Indian health centers
 - 7. Faith based organizations
- B. Entities **must** furnish evidence of non-profit status in accordance with instructions accompanying the project grant application.
- C. Applicants **must** have providers who are or can become Medicaid enrolled providers as well as bill private third party payers.
- D. Eligible applicants providing services beyond the Title X family planning program **must** ensure that Title X funds will be expended solely for the Title X program under the terms and conditions of the grant.
- E. Eligible applicants **must** demonstrate and assure ability to meet program requirements set forth by the Title X statute, OPA Title X regulations and MDHHS Family Planning Minimum Program Requirements.
- F. Applicants **must** have the capacity to provide a broad range of family planning methods. Grants cannot be made to entities that propose to offer only a single method or unduly limited number of family planning methods. An organization offering a single or limited number of family planning methods may receive Title X assistance only by participating as a special service with a formal agreement in place with a project offering a broad range of family planning services.
- G. The organization **must** have a governing board that is representative of the community or have a program specific family planning advisory council representative of the community.
- H. Local health departments have the primary responsibility to meet the health needs of vulnerable populations, but may elect not to provide family planning services directly. (Public Health Code, 2000: Section 333.2473).

- I. Pursuant to PA 360 (2002) Section 333.1091, MDHHS **must** give priority in the allocation of funds within a service area where there are competing qualified applicants to qualified entities that do not engage in performing elective abortions within a facility owned or operated by the entity; do not maintain a policy that considers elective abortion part of a continuum of family planning or reproductive health services; and/or is not affiliated with another entity that engages in providing abortion services. (Section I, page 42)

4. APPLICATION

The Michigan Department Health and Human Services receives funds from the Department of Health and Human Services' Office of Population Affairs to administer the Title X Family Planning Program in Michigan. MDHHS conducts a competitive bid process available to any public or nonprofit entity interested in providing Title X family planning services in Michigan. Applicants **must** submit a competitive bid application as set forth by MDHHS. Applicants **must** follow the format and content as detailed in the competitive bid guidance. The application and technical assistance are available from the MDHHS. The grant application covers at least a three year period.

Annually, agencies awarded Title X funding in the competitive bid process **must** submit an application for continuing grantee sub-recipient status which includes a needs assessment and an annual health care plan. These annual plans **must** be submitted to MDHHS and follow the guidance provided by MDHHS (See the Michigan Family Planning Information in Section I of this document for details). Technical assistance is available. The plan **must not** include activities that cannot be funded under Title X, such as abortion or lobbying activities.

5. FUNDING

Funding support for the Michigan Title X Family Planning Program include the Title X Federal grant, State of Michigan appropriations, revenue from first and third party collections and donations. Annually, the Federal grant award and State appropriations are determined and funds are distributed to sub recipients based on a funding formula.

Title X funds support local infrastructures to deliver family planning services with a priority focus on the low income population with the greatest need. The proxy for the population in need is women 15-44 years old at or below 100% of the Federal Poverty Level. Each county has 1) an estimated caseload of Title X users (clients) for which a \$183 per user is allocated; and 2) the total amount of funding available.

Awardees are selected for a minimum three-year funding cycle (with the potential to extend one or more additional cycles). The initial annual agreement covers the Fiscal Year of the funding cycle, Michigan Department of Health and Human Services contract year. Awardees in good standing and who meet all minimum requirements will maintain sub recipient status at least through the three year funding cycle, depending on the availability of funds.

In subsequent years, sub recipients **must** submit a non-competitive annual plan. Each year continuing funding is contingent upon the availability of funds; timely, accurate submission of reports; an approved annual plan; satisfactory progress toward completion of the current year's contract objectives and meeting family planning's Minimum Program Requirements and Reporting Requirements.

In addition to the grant awards, sub recipients receive separate supplemental support in the form of bulk purchase condoms and laboratory testing services for Chlamydia and Gonorrhea via the MDHHS Laboratory. Colposcopy services are provided through MDHHS's Breast and Cervical Cancer Control Program (BCCCCP).

Due to funding dependent upon Federal and State appropriations, allocations may vary and are subject to change.

Any change in scope of services provided by the sub-recipient, including expanding or reducing services or the service area, **must** be approved by MDHHS prior to implementation.

6. NOTICE OF AWARD

The notice of funding award will inform the MDHHS Title X sub-recipient of the initial year allocation based on the annual appropriation and minimum caseload supported by the allocation. Notices will identify the Michigan county/counties for which funding is appropriated and will identify any conditions of funding not addressed in the application. The project period between competitive bids is at least three years. The project is funded in budget periods, normally twelve months, based on the legislative appropriation process.

7. USE OF GRANT FUNDS

All funds granted for Title X family planning services projects **must** be expended only for the purpose for which the funds were awarded and in accordance with the approved application and budget. Funds may not be used for prohibited activities, such as abortion as a method of family planning, or lobbying. Funds **must** be used in accordance with the Title X family planning services projects regulations, MDHHS annual contract, and HHS grants administration regulations. HHS grants administration regulations can be accessed in the HHS Grants Policy Statement, 2007 (Section I, page 34)

C. Project Management and Administration

8. PROJECT MANAGEMENT AND ADMINISTRATION

All sub-recipient agencies receiving Title X finds **must** provide high quality family planning services which are competently and efficiently administered.

- A. Sub-recipient agencies **must** have written policies and operating procedures in place to meet the standards of the legal issues described in Section 8.1 through 8.7

8.1 Voluntary Participation

Family planning services **must** be provided solely on a voluntary basis (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a) (2)).

- i. Clients **must not** be coerced to accept services or to use or not use any particular method of family planning (42 CFR 59.5 (a) (2)).
- ii. A client's acceptance of family planning services **must not** be a prerequisite to eligibility for, or receipt of, any other services, assistance from, or participation in any other program that is offered by the grantee or sub-recipient (Section 1007, PHS Act; 42 CFR 59.5 (a)(2)).
- iii. Personnel working within the family planning project **must** be informed that they may be subject to prosecution if they coerce or try to coerce any person to undergo an abortion or sterilization procedure (Section 205, Public Law 94-63, as set out in 42 CFR 59.5(a)(2) footnote 1).
- iv. Sub-recipients **must** assure in their general consent for services that family planning services are provided on a voluntary basis, without coercion to accept services or any particular method of family planning and without prerequisite to accept any other service.

8.2 Prohibition of Abortion

Title X grantees and sub-recipients **must** be in full compliance with Section 1008 of the Title X statute and 42 CFR 59.5(a)(5), which prohibit abortion as a method of family planning.

- A. Sub-recipients **must** have written policies that clearly indicate that no Title X funds will be used in programs where abortion is a method of family planning.
- B. Additional guidance on this topic can be found in the July 3, 2000, Federal Register Notice entitled *Provision of Abortion-Related Services in Family Planning Services Projects*, 65 Fed. Reg. 41281 and the final rule entitled *Standards of Compliance for Abortion-Related Services in Family Planning Services Projects*, 65 Fed. Reg. 41270. (Section I, page 23).

8.3 Structure and Management

Family planning services under the MDHHS Title X grant are provided by sub-recipient agencies operating under the umbrella of the MDHHS Title X Family Planning Program. As the grantee, MDHHS is accountable for the quality, cost, accessibility, acceptability, reporting, and performance of the grant-funded activities provided by sub-recipients.

- 8.3.1 As the grantee, MDHHS **must** have a written contract with each sub-recipient and **must** maintain and provide updated MDHHS Title X Family Planning Standards and

Guidelines Manual for sub-recipient agencies consistent with Title X Program Requirements and other applicable requirements (45 CFR parts 74 and 92).

Sub-recipient agencies **must** have an updated copy of the MDHHS Standards and Guidelines available at each service site.

MDHHS **must** perform a comprehensive program review of each sub-recipient agency a minimum of every three years and is responsible for providing technical assistance and consultation as needed to ensure that agencies are in compliance.

- 8.3.2 Where a sub-recipient agency wishes to subcontract any of its responsibilities or services, a written agreement that is consistent with Title X Program Requirements **must** be in place and **must** be approved by MDHHS. Sub-recipients **must** identify subcontracted responsibilities or services in their annual plan. (45CFR parts 74 and 92).
- 8.3.3 All services purchased for project participants **must** be authorized by the project director or his/her designee on the project staff (42 CFR 59.5(b) (7)).
- 8.3.4 Where required services are provided by referral, the sub-recipient **must** have written agreements for the provision of services and reimbursement of costs as appropriate. Services provided through a contract/arrangement **must** be paid for under agreements that include a reasonable schedule of rates. (42 CFR 59.5(b) (9)).
- 8.3.5 Sub-recipient agencies **must** be given an opportunity to participate in the establishment of MDHHS policies and guidelines (42 CFR 59.5 (a) (10)).
- 8.3.6 Sub-recipient agencies **must** maintain a financial management system that meets Federal standards, as applicable, requirements in the contract, and which complies with Federal standards that support effective control and accountability of funds. Documentation and records of all income and expenditures **must** be maintained. (45CFR parts 74.20 and 92.20).
- 8.3.7 Sub-recipient agencies **must** adhere to MDHHS Title X reporting requirements (MRR). (Section I, pages 52,53)
 - A. Mid-Year and End-Year Family Planning Annual Report (FPAR)
 - B. Family Planning Needs Assessment and Health Care Plan (Annual Plan)
 - C. Sub-recipients **must** have written policies and procedures for mandatory reporting of child abuse and neglect, sexual abuse, as well as compliance with human trafficking laws.

8.4 Charges, Billing, and Collections

The sub-recipient **must** implement written policies and procedures for charging, billing, and collecting funds for the services provided by the projects. Clients **must not** be denied project services or be subjected to any variation in quality of services because of inability to pay.

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

A. Projects **must** rely on client self-report when assessing a Title X client's income directly. However, Title X regulations allow grantees discretion to use income verification data provided by clients because of participation in other programs operated by the organization. While not allowed to require income verification directly of Title X clients, nor require participation in another program as pre-requisite for family planning services; projects that have access to income verification data because of a client's participation in another program may use that data rather than rely solely on client self-report. Such income data should be recent, i.e., less than eleven months old.

8.4.2 A schedule of discounts **must** be developed for individuals with family income between 101% and 250% of the FPL, to assure that services are billed based on ability to pay, (42 CFR 59.5(a) (8)). MDHHS policy requires that the schedule of discounts **must** be developed with sufficient proportional increments to assure services are billed based on ability to pay. Sub-recipients **must** use the mandated quartile proportional increments that MDHHS distributes each year in developing their schedule of discounts. Sub-recipients may request and **must** receive an MDHHS approved waiver to use other proportional increments.

A. Individual eligibility for a discount **must** be documented in the client's record/file. Client income should be re-evaluated at least annually.

B. At the time of services, clients who are responsible for paying any fee for their services should be offered bills directly. Bills to clients should show total charges less any allowable discounts. Sub recipients **must** have the capacity to provide a bill to a client who requests a bill.

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

8.4.4 For persons from families whose income exceeds 250% of the FPL, charges **must** be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.(42 CFR 59.5(a) (8)) Sub-recipients **must** document their process for determining how the schedule of fees is designed to recover the reasonable cost of providing services. Sub-recipients are encouraged to review their program costs and reassess their schedule of fees on an annual basis.

- A. While not recommended to do so, sub-recipients may elect to set their fee schedule below what would recover the actual cost of providing services, based on their specific community needs and circumstances. To elect this option, the sub-recipient **must** have a policy in place that identifies the percentage of costs the fee schedule is designed to recover and the policy **must** be approved by the sub-recipient's administrative board
- 8.4.5 Eligibility for discounts for minors who receive confidential services **must** be based on the income of the minor (42 CFR 59.2).
 - A. Sub-recipients **must not** have a policy of no fees or flat fees for the provision of services to minors, and **must not** have a fee schedule for minors that are different from the fee schedule for other populations receiving family planning services.
- 8.4.6 Where there is legal obligation or authorization for third party reimbursement, including public or private sources, all reasonable efforts **must** be made to obtain third party payment without the application of any discounts(42 CFR 59.5(a)(9)).

The client's family income **must** be taken into account before determining whether copayments or additional fees are charged. With regard to insured clients, clients whose family income is at or below 250% FPL **must not** pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.
- 8.4.7 Where reimbursement is available from Title XIX or Title XX of the Social Security Act, a written agreement with the Title XIX or the Title XX state agency at either the grantee level or sub-recipient agency is required (42 CFR 59.5(a)(9)]
- 8.4.8 Reasonable efforts to collect charges without jeopardizing client confidentiality **must** be made.
 - A. Sub-recipients **must** have a method for the "aging" of outstanding accounts. The agency's written policies on billing and collections must include the policy on aging accounts and writing off outstanding accounts.
- 8.4.9 Voluntary donations from clients are permissible; however, clients **must not** be pressured to make donations, and donations **must not** be a prerequisite to the provision of services or supplies.

8.5 Project Personnel

Title X projects **must** have approved personnel policies and procedures.

- 8.5.1 Sub-recipient agencies **must** establish and maintain personnel policies that comply with applicable Federal and State requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, Title I of the Americans with Disabilities

Act, and the annual appropriations language. These policies should include, but are not to be limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, and grievance procedures.

- A. Personnel records **must** be kept confidential.
- B. Performance evaluations of program staff **must** be conducted according to the agency personnel policy.
- C. Organizational chart and personnel policies **must** be available to all personnel.
- D. Job descriptions **must** be available for all positions and updated as needed.

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

8.5.3 Family Planning projects **must** be administered by a qualified project director/family planning coordinator. Family Planning directors/coordinators **must** be familiar with the MDHHS Family Planning Standards and Review Manual, the Title X statute and regulations. Sub-recipients **must** notify MDHHS of change or extended absence of the project director/family planning coordinator, or significant change in project personnel to assure ongoing communication and coordination of the Family Planning Program.

8.5.4 Family Planning projects **must** provide medical services under the supervision of a physician/medical director with special training or experience in family planning (42 CFR 59.5 (b) (6)).

- A Michigan's pharmacy law requires that the physician who has responsibility for the dispensing of prescription medications at a service site have a Drug Control License delegating authority to dispense prescription drugs. This dispensing license is in addition to the medical license required for writing prescriptions. Sub-recipients **must** have in place a drug control license for each location in which the storage and dispensing of prescription drugs occur, in compliance with Act 368 of 1978 sec 333.17745 and 333.17745a. (Section I, pp. 42-44)

Providers other than physicians performing medical functions **must** do so under protocols and/or standing orders approved by the medical director.

- A. Physical assessment, diagnosis, treatment, and provision of medication and devices **must** be performed by a physician or licensed certified mid-level clinician. These mid-level clinicians include nurse practitioners, certified nurse midwives, and physician assistants.
- B. All mid-level practitioners **must** maintain current licensure and certification by the standards defined by Public Act 368 of 1978 as amended, Part 4, R338.10406, as defined by the Michigan Department of Licensing and Regulation, Board of Nursing, in the General Rules, or by the Council of Allied Health Education (for the

Certification of Physician Assistants); and that other health professionals and para-professionals may be utilized to perform non-medical responsibilities, or assist in medical functions as approved by the medical director.

- 8.5.5 Appropriate salary limits apply as required by law. Salary limitations are identified in the Title X Notice of Award, reflecting the current federal appropriations law.

8.6 Staff Training and Project Technical Assistance

Title X grantees are responsible for the training of all project staff.

- 8.6.1 Sub-recipients **must** provide for the orientation and in-service training of all project personnel, including the staff of sub-recipient agencies and service sites (42 CFR 59.5(b)(4)) and should provide periodic staff meetings to review program activities.
- A. Sub-recipients should document attendance at training and continuing education programs.
 - B. All staff should be offered the opportunity to attend/access training programs, particularly National Training Center (NTC) programs, MDHHS training programs, and the annual Family Planning Update at least once per year.
 - C. Funds for training and continuing education should be included in each year's operating budget.
 - D. Registered nurses and mid-level practitioners should be offered appropriate educational opportunities so as to comply with requirements of the licensure/certification process.
 - E. Sub-recipients are encouraged to participate in the training needs assessment developed by MDHHS and MPHI to assist MDHHS in planning future training programs and determining changes needed in established training programs.
 - F. Sub-recipients should have appropriate clinical resource books available for staff such as: CDC Providing Quality Family Planning Services Recommendations of CDC and OPA; CDC U.S. Selected Practice Recommendations for Contraceptive Use, 2013 (SPR); Contraceptive Technology, 20th edition; and CDC, United States Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2010.
- 8.6.2 Staff **must** be trained on mandatory reporting requirements for child abuse, child molestation, sexual abuse, rape or incest, and on human trafficking at least every two years.
- 8.6.3 Staff **must** be trained on encouraging family involvement in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities at least every two years.
- 8.6.4 Staff **must** be trained regarding prevention, transmission and infection control in the health care setting of sexually transmitted infections including HIV as required by OSHA regulations.

- 8.6.5 Staff **must** be trained and understand their role in an emergency or natural disaster as required by OSHA regulations.
- 8.6.6 Staff **must** be trained in the unique social practices, customs and beliefs of underserved populations of their service area at least every two years.
- 8.6.7 Clinical staff involved in dispensing medications **must** be trained regarding the nature and safety of pharmaceuticals dispensed in the clinic at least every two years.

8.7 Planning and Evaluation

MDHHS **must** ensure that the project is competently and efficiently administered (42 CFR 59.5 (b) (6) and (7)). In order to adequately plan and evaluate program activities, MDHHS develops written goals and objectives for the year, project period, that are specific, measurable, achievable, realistic, time-framed, consistent with Title X Program Requirements, and based on a needs assessment.

- A. Sub-recipient agencies **must** submit written goals and objectives (Family Planning Work Plan) for the year with their annual plans that are specific, measurable, achievable, time-framed and consistent with Title X Program requirements as part of their annual plan. Objectives must include an evaluation component. Instructions for the annual plan and work plan are available in the Michigan Information in Section I of this document and are emailed to Family Planning Coordinators annually. Templates for the Family Planning Program Work Plan are available on the MDHHS Family Planning website at: www.michigan.gov/familyplanning.

9. PROJECT SERVICES AND CLIENTS

Projects funded under Title X are intended to enable all persons who want to obtain family planning care to have access to such services. Projects **must** provide for comprehensive medical, informational, educational, social, and referral services related to family planning for clients who want such services. Sub-recipients **must** have written policies and procedures in place to assure the following:

- 9.1 Priority for project services **must** be to persons from low-income families (Section 1006(c) (1), PHS Act; 42 CFR 59.5(a) (6)).
- 9.2 Services **must** be provided in a manner which protects the dignity of the individual (42 CFR 59.5 (a) (3)).
- 9.3 Services **must** be provided without regard to religion, race, color, national origin, creed, handicap, sex, number of pregnancies, marital status, age, sexual orientation, and contraceptive preference. (42 CFR 59.5 (a) (4)).

- 9.4 Projects **must** provide for social services related to family planning including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance (42 CFR 59.5 (b)(2)).
- 9.5 Projects **must** provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs (42 CFR 59.5 (b)(8)).
- 9.6 All family planning services **must** be provided using written clinical protocols that are in accordance with nationally recognized standards of care, signed by the medical director responsible for program medical services. MDHHS will review protocols at the comprehensive program review.
- 9.7 All projects **must** provide for medical services related to family planning and the effective usage of contraceptive devices and practices (including physician's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) as well as necessary referrals to other medical facilities when medically indicated (42 CFR 59.5(b)(1)).
- A. Necessary referrals include, but are not limited to emergencies that require referral. Efforts may be made to aid the client in finding potential resources for reimbursing the referral provider, but projects are not responsible for the cost of this care.
- 9.8 All projects **must** provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). A service site that offers only a single or very limited number of family planning methods may participate only as part of a project where the entire project offers a broad range of family planning services. MDHHS **must** be informed of these arrangements. (42 CFR 59.5(a) (1)).
- 9.9 Services **must** be provided without the imposition of any residency requirement or requirement that the client be referred by a physician (42 CFR 59.5(b) (5)).
- 9.10 Projects **must** provide pregnancy diagnosis and counseling to all clients in need of this service (42 CFR 59.5(a) (5)).
- 9.11 Projects **must** offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:
- A. Prenatal care and delivery;
- B. Infant care, foster care, or adoption; and
- C. Pregnancy termination.

If requested to provide such information and counseling, projects **must** provide neutral, factual information and nondirective counseling on each of the options, and referral

upon request, except with respect to any options(s) about which the pregnant woman indicates she does not wish to receive such information and counseling (42 CFR 59.5(a)(5)).

- 9.12 Sub-recipient agencies **must** comply with applicable legislative mandates set out in the HHS appropriations act. Grantees **must** have written policies in place that address these legislative mandates:
- A. Projects **must** encourage family participation in the decision of minors to seek family planning services and **must** provide counseling to minors on how to resist efforts to coerce the minor into engaging in sexual activities.
 - B. Projects **must** comply with state laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, or incest. No provider of services under Title X is exempt from any laws requiring mandatory reporting.

10. CONFIDENTIALITY

Every project **must** have policies, procedures, and safeguards in place to ensure client confidentiality.

- 10.1 Safeguards to ensure confidentiality **must** include:
- A. Assurance of confidentiality included in agency policies and procedures.
 - B. A confidentiality assurance statement in the medical record, such as in the general consent for services.
 - C. A confidentiality assurance statement signed by all family planning project personnel.
 - D. Title X projects must not require written consent of parents or guardians for the provision of services to minors; nor can Title X staff notify a parent or guardian before or after a minor has received title X family planning services.
- 10.2 Information obtained by the project staff about an individual receiving services **must not** be disclosed without the individual's documented consent, except as required by law or as may be necessary to provide services to the individual, with appropriate safeguards for confidentiality.
- 10.3 Information regarding clients and services **must** otherwise be disclosed only in summary, statistical, or other form that does not identify the individual (42 CFR 59.11).
- 10.4 Confidentiality under Title X **must** not be invoked to circumvent mandated reporting requirements for child abuse and neglect.
- 10.5. Efforts should be made to assure that written and verbal exchanges between clients and clinic/clerical staff kept private, so that other clients in the site do not know client identity or reason for the visit.

11. COMMUNITY PARTICIPATION, EDUCATION, AND PROJECT PROMOTION

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

- 11.1 Title X grantees and sub-recipient agencies **must** provide an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served; and by persons in the community knowledgeable about the community's needs for family planning services (42 CFR 59.5(b)(10)).
- A. Sub-recipient agencies **must** fulfill this requirement using a governing board, program specific family planning advisory committee (FPAC), or other appropriate advisory group which reviews general program/policy issues and make recommendations to the agency on organization, management and operation of the Family Planning Program.
1. The composition of the board or advisory committee **must** be broadly representative of the population served in the community and include persons knowledgeable about family planning.
 2. Each group **must** meet at least once a year to:
 - a. Review the agency's program plan, assess accomplishments and suggest future program goals and objectives.
 - b. Review the agency's progress toward meeting the needs population in the service area and maintaining services and policies responsive to the needs of the community.
 - c. The FPAC or advisory group, or a subcommittee of the FPAC or advisory group, may also serve the function of the Information and Education (I. & E.) Advisory Committee, so long as requirements of sections 12.1-12.7 are met.
 3. Minutes **must** be kept of all meetings.
 4. Meetings may be conducted utilizing electronic technology.
- B. Other recommendations for community participation include the following:
1. Use of client satisfaction surveys.
 2. Inclusion of teens and low-income women on the Advisory Council.
 3. Asking for client input on educational and informational materials.
 4. Use of client surveys or focus groups designed to elicit what services may be seen as needed by clients but not available.
- 11.2 Projects **must** establish and implement planned activities to facilitate community awareness of and access to family planning services (42 CFR 59.5(b) (3)). Each family planning project **must** provide for community education programs (42 CFR 59.5(b) (3)). Community education program(s) should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.

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

12. APPROVAL OF INFORMATION AND EDUCATION MATERIALS

Sub-recipient agencies are responsible to maintain an Information and Education (I. & E.) Advisory Committee that follows Title X requirements for the review and approval of educational materials. The requirements of the I. & E. committee are as follows:

- 12.1 Every sub-recipient agency **must** have a review and approval process of all informational and educational (I. & E.) materials developed or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X (Section 1006(d) (1), PHS Act; 42 CFR 59.6(a)).

The I. & E. Committee may also serve the community participation functions of a family planning advisory committee (FPAC) or advisory group described above in section 11.1.A, as long as it meets the requirements of both groups.

- 12.2 I. & E. Committee membership **must** include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of the population or community for which the materials are intended (42 CFR 59.6 (b) (2)).
- A. Family Planning Program staff may provide administrative and clinical support to the committee, but may not be voting members of the advisory committee.
 - B. The committee may include professionals who work directly with population groups for which materials are intended, but the priority should be to include client and community members where possible.
 - C. The agency **must** demonstrate efforts to recruit client and community members to assure broad representation the populations served. See “Information & Education Committee Member Recruitment Tips and Resources” at: www.michigan.gov/familyplanning.
 - D. The description of I. & E. Committee composition submitted to MDHHS with the Annual Plan **must** include how the composition represents the populations served in terms of demographic factors such as race, color, national origin, handicapped conditions, sex, and age.
 - E. The I. & E. Committee roster submitted to MDHHS with the Annual Plan **must** identify what community populations/groups the member represents (e.g., agency or professional organization name, or teen, male, client, or parent).

- 12.3 The sub-recipient agency I. & E. Committee **must** be made up of five to nine members, except that this size provision may be waived by the Office of Population Affairs (OPA) where a good cause has been shown (42 CFR 59.6(b)(1)).
- A. If an agency wishes to request a waiver to the five to nine membership requirement, a written request indicating the good cause reasons must be submitted to the MDHHS Family Planning Program consultant for MDHHS review and submission to OPA for approval.
- 12.4 MDHHS delegates the I. & E. materials review and approval process to the sub-recipient agencies; however, the oversight responsibility of the I. & E. review process rests with MDHHS as the grantee. MDHHS monitors this committee and review process with the Annual Plan review and as part of the on-site comprehensive program review.

Each sub-recipient's I. & E. committee **must** have a process for the review and approval of materials prior to their distribution that includes the following:

- A. A written description of the I. & E. Committee review and approval process **must** be included in a policy statement, by-laws, or other committee documents made available to members.
- B. All new information or education materials are distributed to committee members, along with a clinic brochure review form for each item, prior to the committee meeting. Agencies should allow at least two weeks for members to review materials prior to a meeting.
1. The I. & E. Committee may delegate responsibility for the review of the factual, technical, and clinical accuracy to appropriate project staff; however, final responsibility for approval of the materials rests with the committee.
- C. The I. & E. Committee **must** use an MDHHS approved clinic brochure review form to document their review and individual determinations regarding approval for each educational material.
1. An approved clinic brochure review form is located on the MDHHS website at www.michigan.gov/familyplanning.
2. Sub-recipients wishing to modify or use a different form must submit it to their MDHHS program consultant for approval.
- D. At the I. & E. Committee meeting, members discuss their comments and recommendations and make a determination regarding appropriateness of the materials for the intended community or target audience.
1. In their review of materials, the committee **must** consider the following:
- a) The educational and cultural backgrounds of the individuals the materials are intended to serve

- b) The standards of the population or community the materials are intended to serve
 - c) Review the content to assure that the information is factually accurate
 - d) Determine whether the materials are suitable for the population or community they are intended to serve
- E. Committee approval of materials requires, at least one half of voting members in attendance.
- F. The I. & E. Committee **must** meet at least once a year; and should meet as often as is needed to review and approve new materials prior to their use. Meetings may be conducted utilizing electronic technology.
- G. A written record of the determinations and approval process **must** be established and maintained (Section 1006(d), PHS Act; 42 CFR59.6 (b)) including the following:
 - 1. Minutes **must** be kept of all meetings and **must** reflect the determination for each item reviewed.
 - 2. Completed review forms or a compiled summary of individual review forms **must** be maintained to document member determinations.
 - 3. A master listing of materials that have been approved by the committee with dates the items were approved **must** be maintained.
- H. Staff overseeing the I. & E. Committee **must** determine when existing materials are reviewed or updated to assure continued accuracy and appropriateness.

12.5 Any publication or other media developed by the grantee or sub-recipient using federal funds must acknowledge federal grant support (45CFR 74.36; 45CFR 92.34).

13. ADDITIONAL ADMINISTRATIVE REQUIREMENTS

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

13.1 Facilities and Accessibility of Services

Title X service sites should be geographically accessible for the population being served. Sub-recipients are strongly encouraged to consider clients' access to transportation, clinic locations, hours of operation, and other factors that influence clients' ability to access services.

Title X clinics **must** have written policies that are consistent with the HHS Office for Civil Rights policy document, *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons* (August 4, 2003) (HHS Grants Policy Statement 2007, II-23). (Section I, page 34.)

- A. Sub-recipient agencies **must** ensure meaningful access to services for persons with limited English proficiency (LEP).

- B. Sub-recipient agencies **must** have a written plan regarding the process for providing language assistance to LEP clients.
- C. The scope and complexity of the plan should consider the size of LEP populations likely to be encountered and frequency of contact with the LEP populations.
- D. 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. The use of family and friends as interpreters is discouraged. If the client chooses to use family or friends, the client is informed of the right to free interpreter services and use of family or friends occurs only after the offer is declined and documented.
 - 4. LEP plans **must** include following:
 - a. Identify LEP individuals who need language assistance.
 - b. Language assistance, oral interpretation, and/or written translation
 - c. Staff training
 - d. Providing notice to LEP persons
 - e. Routine updating of the LEP plan

Projects **must not** discriminate on the basis of disability and, when viewed in their entirety, facilities **must** be readily accessible to people with disabilities (45 CFR part 84) (Section I, page 35)

13.2 Emergency Management

All grantees, sub-recipients, and Title X clinics **must** to have a written plan for the management of emergencies (29 CFR 1910, subpart E), and clinic facilities **must** meet applicable standards established by Federal, State, and local governments (e.g., local fire, building, and licensing codes). (Section I, page 35)

Health and safety issues within the facility fall under the authority of the Occupational Safety and Health Administration (OSHA). Disaster plans and emergency exits are addressed under 29 CFR 1910, subpart E. The basic requirements of these regulations include:

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

13.3 Standards of Conduct

Sub-recipients **must** establish policies to prevent employees, consultants, or members of governing/advisory bodies from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others (HHS Grants Policy Statement 2007, II-7). (Section I, page 34)

13.4 Human Subjects Clearance (Research)

Research conducted within Title X projects may be subject to Department of Health and Human Services regulations regarding the protection of human subjects (45 CFR Part 46). Sub-recipients **must** advise the MDHHS in writing of research projects involving Title X clients or resources in any segment of the project.

- A. MDHHS **must** approve human subject research through submission to the MDHHS Institutional Research Board (IRB) process.
- B. MDHHS will advise the OPA Regional Office in writing of any approved research project that involves Title X clients (HHS Grants Policy Statement 2007, II-9). (Section I, page 34)

13.5 Financial and Reporting Requirements

Financial audits of sub-recipients **must** be conducted in accordance with the HHS grants administration regulations (45 CFR parts 74.26 and 92.26), as applicable, by auditors meeting established criteria for qualifications and independence (OMB A-133) (Section I, pp. 34, 56)

Sub-recipients **must** comply with MDHHS minimum reporting requirements, including the Office of Population Affairs (OPA) Family Planning Annual Report (FPAR) as described in the OPA FPAR Forms and Instruction manual at intervals specified by MDHHS. In addition, sub-recipients **must** file an annual health care plan, and **must** have policies and procedures in place to follow Michigan mandatory reporting requirements under the Michigan Child Protection Act and compliance with Michigan's Human Trafficking law. (Section I, pages 32, 45-47 & 52, 53).

- A. MDHHS requires semi-annual FPAR reports: (1) a mid-year report covering the reporting period January through June and (2) an annual report covering the reporting period January through December.
 - 1. Sub-recipients **must** have a system in place for collecting all required data elements for the FPAR.
 - 2. Sub-recipients **must** have a system in place for validating the data reported in the FPAR.
- B. MDHHS requires agencies file an annual needs assessment and health care plan (Annual Plan) following MDHHS instructions.
- C. MDHHS requires agencies to have policies and procedures in place for mandatory reporting requirements under Michigan's Child Protection Act and training on Michigan's Human Trafficking Law.

Sub-recipients **must** have program data reporting systems which accurately collect and organize data for program reporting and which support management decision making and act in accordance with other reporting requirements as required by HHS.

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

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

14. ADDITIONAL CONDITIONS

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

15. CLOSEOUT

Upon the end of grant support sub-recipients **must** submit the following in compliance with their MDHHS contract:

- A. A final Financial Status Report (FSR)
- B. A final Family Planning Annual Report (FPAR) report
- C. A final progress report regarding:
 - 1. Accounting for any remaining inventory, contraceptive supplies and materials purchased with Title X funds. Supplies may be distributed to other sub-recipients.
 - 2. Notification and transfer, where appropriate, of Title X clients, including arrangements for clients to obtain copies of their medical records and a list of alternative family planning services providers where transfer of clients is not available.
 - 3. Identification of any equipment purchased with Title X funds with acquisition cost more than \$5,000 for appropriate transfer or retention.

Following closeout, the sub-recipient remains obligated to return funds due as a result of any later refunds, corrections, or transactions, and MDHHS may recover amounts based on the results of an audit covering any part of the period of grant support (HHS Grants Policy Statement, II-90). (Section I, page 34)

16. OTHER APPLICABLE HHS REGULATIONS AND STATUTES

The following HHS Department-wide regulations that apply to grants under Title X: (Section I, pages 34, 35)

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

The following statutes are applicable to grants under Title X: (Section I, pages 36-40)

- A. The Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191)
- B. The Trafficking Victims Protection Act of 2000, as amended (Public Law 106-386)
- C. Sex Trafficking of Children or by Force, Fraud, or Coercion (18 USC 1591)
- D. The Patient Protection and Affordable Care Act (Public Law 111-148)

SECTION III

Clinical Services

Clinical Services

17. INTRODUCTION

The MI Family Planning Clinical Standards and Guidelines were adapted from the document, Providing Quality Family Planning Services (QFP), 2014 that provides recommendations developed collaboratively by CDC and the Office of Population Affairs (OPA) of the U.S. Department of Health and Human Services (HHS). The QFP document describes how to provide quality family planning services to men and women. The goal of family planning services is to assist individuals to achieve the desired number and spacing of children and to increase the chances that children will be born healthy. Quality Title X Family Planning includes these attributes: confidentiality, safety, effectiveness, client-centered approach, timeliness, efficiency, accessibility, equity and cost effectiveness. Quality Family Planning Services include the following clinical elements:

- Contraceptive services
- Pregnancy testing and counseling
- Achieving desired pregnancy (fertility awareness)
- Basic infertility service
- Preconception health services
- Sexually transmitted disease (STD) services

Title X providers **must** offer all family planning services (listed above), related preventive health services (discussed on page 102-104) and referral for specialist care, as needed. Other preventive health services that are beyond the scope of Title X may be offered either on-site or by referral. Information about preventive services that are beyond the scope of Title X is available at <http://www.uspreventiveservicestaskforce.org>.

All family planning projects **must** offer family planning services and related preventive health services to female and male clients, including adolescents. All projects **must** provide for medical services related to family planning and the effective use of contraceptive devices and practices including provider's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies, as well as necessary referrals to other medical facilities when medically indicated (42 CFR 59.5(b)(1)). This includes, but is not limited to emergencies that require referral. (See referrals on page 95) Efforts may be made to aid the client in finding potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of this care.

18. SERVICE PLANS AND PROTOCOLS

The service plan is the component of a sub-recipient's annual health care plan which is developed by staff and the medical director which identifies the services to be provided to clients under Title X.

- A. All sub-recipient agencies **must** offer a broad range of effective and medically (FDA) approved family planning methods and services either on-site or by referral [59.5(a)(1)]. All sub-recipient agencies **must** have written clinical protocols approved by MDHHS and signed by the agency's medical director, which outline procedures for the provision of each service offered. Sub-recipient agencies **must** have written protocols available at each clinical site. The clinic staff **must** use approved protocols for the provision of all family planning services.
- B. Clinical protocols **must** be written in accordance with the QFP document, Michigan Title X Family Planning Program Standards and Guidelines, State of Michigan laws and nationally recognized standards for medical care. Clinical Protocols **must** be current (i.e., updated within the past 12 months) and signed annually by the medical director. The Michigan Title X Family Planning Standards and Guidelines Manual **must** be available at each clinical site.

19. 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. All the QFP services identified in the introduction **must** be offered to all clients and documented in the medical record.

- A. Service delivery to all clients **must** include the following:
 - 1. Assuring clients are treated courteously and with dignity and respect.
 - 2. Professional recommendations for how to address the needs of diverse clients, such as Lesbian, Gay, Bi-sexual, Transgender, Questioning (LGBTQ) persons or persons with disabilities should be consulted and integrated into procedures, as appropriate. Providers should avoid making assumptions about a client's gender identity, sexual orientation, race, or ethnicity; all requests for services should be treated without regard to these characteristics. Similarly, services for adolescents should be provided in a "youth-friendly" manner.
 - 3. Assurance of confidentiality and the provision of privacy
 - 4. Opportunity to participate in planning their own medical treatment.
 - 5. Encouraging clients to voice any questions or concerns they may have.
 - 6. 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.
 - 7. Explanation of all procedures, range of available services, and agency fees and financial arrangements.
- B. Individual client education **must** be offered.
- C. Individual counseling (an interactive process to assist the client in making an informed choice) **must** be offered and/or provided prior to client making an informed choice regarding family planning services. Adolescent counseling **must** include the following:
 - 1. Title X providers of family planning services **must** offer confidential services to adolescents and observe relevant state laws related to mandatory reporting of child abuse and neglect and human trafficking (Section I. page 45). Adolescents **must** be informed that services are confidential, except that in special cases (e.g. child abuse) reporting is required.

2. Title X providers **must** encourage and promote communication between the adolescent and his or her parent(s) or guardian(s) about sexual and reproductive health. Adolescents who come to the service site alone **must** be encouraged to talk to their parents or guardians.
3. Title X providers **must** provide counseling on how to resist attempts to coerce adolescents into engaging in sexual activities.
- D. A language appropriate general consent **must** be signed by the client prior to providing services.
- E. A medical history **must** be obtained appropriate to the type of services provided.
- F. A physical examination, including necessary clinical procedures, **must** be provided, as indicated.
- 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 medications, if dispensed.
 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. Provision of referrals as needed
 2. Planned mechanism of client follow-up
 - a. Suggested return visit date
 - b. Contact information for emergencies after hours
 - c. Discuss access to primary care services
- J. Emergency arrangements **must** be available for after hours and weekend care and should be posted, given to, and/or explained to clients.
- K. Return visits should assess the on-going plan of care and needed family planning related services.

20. CLIENT ENCOUNTERS

- A. The client's written general consent for services **must** be obtained prior to receiving any clinical services. (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a) (2))
 1. The general consent for services **must** include that services are voluntary, provided without coercion to accept services or any particular method of family planning, without prerequisite to accept any other service, and that services are confidential.
- B. Client encounters with women and men of reproductive age may require different services (i.e., contraceptive services, pregnancy testing and counseling, achieving pregnancy, STD services and related preventive health services). For all clients, the following questions will determine what family planning services are most appropriate for a given visit and **must** be asked and documented.
 1. **What is the client's reason for the visit?**
 2. **Does the client have another source of primary health care?**
 3. **What is the client's reproductive life plan?**
 - a. Providers should assess the client's reproductive life plan by asking questions such as: Do you have children now? Do you want to have (more) children? How many (more) children would you like to have and when? See reproductive life plan guidance at: <http://www.cdc.gov/preconception/rlptool.html>

- C. Client encounters with women and men of reproductive age should also include a Zika risk assessment, including asking about past and future travel plans for the client and partner(s).

Note: The following two charts provide a checklist of recommended family planning and related preventive health services (QFP pp 22, 23). MDHHS may require additional elements.

Family Planning and Related Preventive Health Services for Women

Screening components	Family planning services (provide services in accordance with the appropriate clinical recommendation)					
	Contraceptive services ¹	Pregnancy testing and counseling	Basic infertility services	Preconception health services	STD services ²	Related preventive health services
History	Reproductive life plan	✓	✓	✓	✓	
	Medical history	✓	✓	✓	✓	✓
	Current pregnancy status	✓				
	Sexual health assessment	✓		✓	✓	
	Intimate partner violence			✓		
	Alcohol & other drug use			✓		
	Tobacco use	✓ (combined hormonal methods for clients ≥35 years)		✓		
	Immunizations			✓	✓ ⁴ (HPV & HBV)	
	Depression			✓		
	Folic acid			✓		
Physical examination	Height, weight & BMI	✓ (hormonal methods) ³		✓		
	Blood pressure	✓ (combined hormonal methods)		✓ ⁴		
	Clinical breast exam			✓		✓ ⁴
	Pelvic exam	✓ (initiating diaphragm or IUD)	✓ (if clinically indicated)	✓		
	Signs of androgen excess			✓		
	Thyroid exam			✓		
Laboratory testing	Pregnancy test	✓ (if clinically indicated)	✓			
	Chlamydia	✓ ³			✓ ⁴	
	Gonorrhea	✓ ³			✓ ⁴	
	Syphilis				✓ ⁴	
	HIV/AIDS				✓ ⁴	
	Hepatitis C				✓ ⁴	
	Diabetes			✓ ⁴		
	Cervical cytology					✓ ⁴
	Mammography					✓ ⁴

Source: Centers for Disease Control and Prevention (CDC). (2014, April 25). Providing quality family planning services: Recommendations CDC and the U.S. Office of Population Affairs. *MMWR. Morbidity and Mortality Weekly Reports*. Retrieved from <http://www.cdc.gov/mmwr/pdf/rr6304.pdf>

Abbreviations: BMI = body mass index; HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus; IUD = intrauterine device; STD = sexually transmitted disease.

¹ This table presents highlights from CDC's recommendations on contraceptive use. However, providers should consult appropriate guidelines when treating individual patients to obtain more detailed information about specific medical conditions and characteristics (Source: CDC, U.S. medical eligibility criteria for contraceptive use 2010. *MMWR* 2010; 59[No. RR-4]).

² STD services also promote preconception health but are listed separately here to highlight their importance in the context of all types of family planning visits. The services listed in this column are for women without symptoms suggestive of an STD.

³ Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (US Medical Eligibility Criteria 1) or generally can be used (US Medical Eligibility Criteria 2) among obese women. (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010; 59[No. RR-4]). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

⁴ Indicates that screening is suggested only for those persons at highest risk or for a specific subpopulation with high prevalence of an infection or condition.

⁵ Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's STD Treatment Guidelines (Sources: CDC. STD treatment guidelines. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at <http://www.cdc.gov/std/treatment>. CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR 2010; 59[No. RR-12]). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. Medical Eligibility Criteria 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. Medical Eligibility Criteria 3) (Source: CDC. US medical eligibility criteria for contraceptive use 2010. MMWR 2010; 59[No. RR-4]). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

Family Planning and Related Preventive Health Services

For Men



		Family planning services (provide services in accordance with the appropriate clinical recommendation)				
	Screening components	Contraceptive services ¹	Basic infertility services	Preconception health services ²	STD services ³	Related preventive health services
History	Reproductive life plan	✓	✓	✓	✓	
	Medical history	✓	✓	✓	✓	
	Sexual health assessment	✓	✓	✓	✓	
	Alcohol & other drug use			✓		
	Tobacco use			✓		
	Immunizations			✓	✓ (HPV & HBV) ⁴	
	Depression			✓		
Physical examination	Height, weight & BMI			✓		
	Blood pressure			✓ ⁴		
	Genital exam		✓ (if clinically indicated)		✓ (if clinically indicated)	✓ ⁴
Laboratory testing	Chlamydia				✓ ⁴	
	Gonorrhea				✓ ⁴	
	Syphilis				✓ ⁴	
	HIV/AIDS				✓ ⁴	
	Hepatitis C				✓ ⁴	
	Diabetes			✓ ⁴		

Source: Centers for Disease Control and Prevention (CDC). (2014, April 25). Providing quality family planning services: Recommendations of CDC and the U.S. Office of Population Affairs. *MMWR, Morbidity and Mortality Weekly Reports*. Retrieved from <http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

Abbreviations: BMI = body mass index; HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus; STD = sexually transmitted disease.

¹ No special evaluation needs to be done prior to making condoms available to males. However, when a male client requests advice on pregnancy prevention, he should be provided contraceptive services as described in the section "Provide Contraceptive Services."

² The services listed here represent a sub-set of recommended preconception health services for men that were recommended and for which there was a direct link to fertility or infant health outcomes (Source: Frey, K., Navaro, S., Kotelchuck, M., Lu, M. The clinical content of preconception care: preconception care for men. *Am J Obstet Gynecol* 2008;199, [6 Suppl. 2]:S389-95).

³ STD services also promote preconception health, but are listed separately here to highlight their importance in the context of all types of family planning visit. The services listed in this column are for men without symptoms suggestive of an STD.

⁴ Indicates that screening is suggested only for individuals at highest risk or for a specific subpopulation with high prevalence of infection or other condition.

21. CONTRACEPTIVE SERVICES

Written protocols and operating procedures **must** be current and in place for contraceptive services. Sub-recipient agencies **must** offer contraceptive services to clients who wish to delay or prevent pregnancy. The delivery of preconception, STD, and related preventive health services **must** not be a barrier to a client's ability to receive services related to preventing or achieving pregnancy. Receiving services related to preventing or achieving pregnancy is the priority; if other family planning services cannot be delivered at the initial visit, follow-up visits should be scheduled.

A. Contraceptive services must include:

1. A broad range of FDA-approved contraceptive methods. All methods of contraception **must** have written protocols in place.
 - a. Current CDC Medical Eligibility Criteria (MEC) **must** be followed when prescribing contraceptives.
 - b. More than one method may be used simultaneously by the client (hormonal method and condoms). 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. Broad Range Contraceptives includes:

1. Hormonal Contraceptives
 - a. At least two delivery methods of combined hormonal contraceptives **must** be available on site.
 - b. At least one delivery method of progestin-only contraceptives **must** be available on site.
 - c. 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. At least one type of long acting reversible contraceptive (LARC) method **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 (i.e., sterilization)
6. Agencies **must** maintain a formal referral agreement for any required broad range method not provided on site.
7. A referral resource list should be provided for contraceptives not available in the clinic.
8. Agencies are encouraged to review current practice and the needs of their client population and maintain the most frequently used methods where feasible.

9. Agencies are strongly encouraged to provide emergency contraception and maintain supplies on site.
10. Prescriptions may be written for contraceptives on the clinic formulary or on the client's insurance plan formulary. Accepting a prescription **must** not pose a barrier for the client.

C. Emergency Contraception

Emergency contraception has been found by the FDA to be safe and effective for use when initiated after unprotected intercourse. The provision of emergency contraception is strongly encouraged but not required for delegate agencies. Emergency Contraception education and referral **must** be provided to all female clients when not provided on site. When delegate agencies provide emergency contraception the following **must** occur:

1. Written protocol **must** be in place.
2. If indicated by the client's history, a negative, highly sensitive pregnancy test is necessary to exclude a pre-existing pregnancy.
3. Birth control counseling should accompany or follow any method used for emergency contraception purpose in order to discourage women from using emergency contraception as a routine method of contraception.

D. Permanent Contraception (Sterilization)

1. Education and information regarding sterilization **must** be provided for both male and female clients, if indicated.
2. Sub-recipient agencies **must** have a list of community providers where clients can be referred for sterilization. Paid referrals for sterilization are not required.
3. Sub-recipient agencies performing sterilization procedures **must** meet Federal regulations for sterilization informed consent.

E. The clinic visit: A medical history **must** be taken prior to prescribing contraception to ensure that methods of contraception are safe for the client.

1. For a female client, the medical history **must** include:
 - a. Reproductive life plan
 - b. Menstrual history
 - c. Gynecologic history
 - d. Obstetrical history
 - e. Contraceptive use
 - f. Allergies
 - g. Medications
 - h. Immunizations (use of the MI. Care Improvement Registry "MCIR" is strongly recommended)
 - i. Recent intercourse
 - j. Reproductive history
 - k. Infectious or chronic health condition (present)
 - m. Zika risk assessment
 - m. Other characteristics and exposures (e.g., age, postpartum, breastfeeding) that might affect the client's medical eligibility criteria (MEC) for contraceptive methods.
 - n. Social history/risk behaviors
 - o. Sexual history and risk assessment
 - p. Mental health

- q. Intimate partner violence
 - r. Interest in Sterilization, if age appropriate (≥ 21 per federal law requirement)
2. For a male client, the medical history **must** include:
- a. Reproductive life plan
 - b. Use of condoms
 - c. Allergies (i.e., condoms)
 - d. Medications
 - e. Immunizations (use of the MI. Care Improvement Registry “MCIR” is strongly recommended)
 - f. Recent intercourse
 - g. Partner history (use of contraception, pregnant, has children, had a miscarriage or termination)
 - h. Infectious or chronic health condition (present)
 - i. Zika risk assessment
 - j. Contraceptive experiences and preferences
 - k. Sexual history and risk assessment
 - l. Interest in sterilization, if age appropriate (≥ 21 per federal law requirement)

NOTE: Taking of a medical history **must** not be a barrier to making condoms available in the clinical setting (i.e., a formal visit **must** not be a prerequisite for a client to obtain condoms).

F. Physical and Laboratory Assessment

1. For a female client the following **must** be provided:
 - a. BP (when providing combined hormonal method and screening for hypertension)
 - 1) All clients—screen yearly
 - 2) If BP $<120/80$ —screen yearly, continue yearly
 - 3) If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit if average BP $>140/90$ recheck at next visit or in 1 week and refer if sustained BP $>140/90$.
 - b. Bimanual exam and cervical inspection (prior to IUD insertion, fitting diaphragm or cervical cap)
 - c. Pap screening and clinical breast exam (based on current recommendations for timing and testing components). See Related Preventive Health Services section.
 - d. Chlamydia testing **must** be offered annually for all females < 25 years, Sexually active women ≥ 25 years with risk factors (infected partner, partner with other concurrent partners, symptoms, history of STI or multiple partners in the last year) (See page 101 in the STD section referencing the IPP pre-paid forms)
 - e. CT and GC testing **must** be available for clients requesting IUD insertion, if indicated.
2. For a male client, laboratory tests are not required unless indicated by history.
3. Consider referral for Zika screening if indicated.

G. Client Education and Counseling

Contraceptive counseling is to help a client choose a method of contraception and use it correctly and consistently. Clients (adolescents and adults) who are undecided on a contraceptive method **must** be informed about all methods that can be used safely based on

the 2010 CDC Medical Eligibility Criteria. When educating clients about the broad range of contraceptive methods, information **must** be medically accurate, balanced, and provided in a nonjudgmental manner. To assist clients in making informed decisions, providers should educate clients in a manner that can be readily understood and retained. Documentation of education/counseling **must** be in the client's medical record.

1. When educating clients about contraceptive methods that can be used safely, clients must understand the following:
 - a. Method effectiveness
 - b. Correct and consistent use of the method
 - c. Benefits and Risks
 - d. Potential Side effects
 - e. Protection from STDs, including HIV
 - f. Starting the method
 - g. Danger signs
 - h. Availability of emergency contraception (provide on-site or by prescription)
 - i. Follow-up visit (to obtain selected method)
2. Quality contraceptive counseling includes the following:
 - a. Establish and maintain rapport
 - b. Assess the client's need and personalize the discussion
 - c. Work with the client to establish a plan
 - d. Provide information in a manner that can be understood by the client
 - e. Confirm the client's understanding
 - 1) The teach-back method may be used to confirm the client's understanding by asking the client to repeat back messages about effectiveness, risks, benefits, appropriate method use, protection from STDs and follow-up. (QFP pp. 45-46)
3. Documentation of counseling must be included in the client record (i.e., checkbox or written statement).
4. Client information sheets should be used for education.
5. When counseling male clients, discussion should include information about female-controlled methods where appropriate (including emergency contraception), encourage discussion of contraception with partners, and provide information about how partners can access contraceptive services. Male clients should also be reminded that condoms should be used correctly and consistently to reduce risk of STDs, including HIV.
6. When counseling any client, encourage partner communication about contraception, as well as understanding partner barriers (e.g. misperceptions about side effects) and facilitators (e.g., general support) of contraceptive use.
7. A procedure consent form **must** be signed by the client prior to inserting an IUD or implant.
8. Clinical evaluation of a client electing permanent sterilization should be guided by the provider who performs the procedure.
9. Provide Zika education and prevention strategies.

H. Counseling Adolescent Clients

Comprehensive information **must** be provided to adolescent clients about how to prevent pregnancy. Adolescent services should be provided in a "youth- friendly" manner, which means that they are accessible, equitable, acceptable, appropriate, comprehensive, effective, and efficient for youth. Information should clarify that:

1. Avoiding sex (i.e., abstinence) is an effective way to prevent pregnancy and STDs. If the adolescent indicates that she or he will be sexually active, provide information about contraception and help her or him to choose a method that best meets her or his individual needs, including the use of condoms to reduce the risk of STDs/HIV. Long-acting reversible contraception is a safe and effective option for many adolescents, including those who have not been pregnant or given birth.
2. Title X providers of family planning services **must** offer confidential services to adolescents and observe relevant state laws related to mandatory reporting of child abuse and neglect and human trafficking (Section I.B of this manual). Adolescents **must** be informed that services are confidential, except that in special cases (e.g. child abuse) reporting is required.
3. Title X providers **must** encourage and promote communication between the adolescent and his or her parent(s) or guardian(s) about sexual and reproductive health. Adolescents who come to the service site alone **must** be encouraged to talk to their parents or guardians.
4. Title X providers **must** provide counseling on how to resist attempts to coerce adolescents into engaging in sexual activities.

I. Counseling Returning Clients

When providing contraceptives for returning clients, an assessment should include the following:

1. Method concerns
2. Method use (consistent, correct)
3. Any changes in client's history (i.e., risk factors, medications)

If appropriate, provide additional contraceptives and discuss a follow-up plan.

J. Preventive Health Promotion and Referral

1. Title X providers should refer pregnant, parenting and postpartum adolescents to home visiting and other programs (MIHP, Nurse Partnership) that have been demonstrated to provide needed support and reduce rates of repeat teen pregnancy.
2. Title X providers should provide a referral resource list for mental health and risky social, ETOH, tobacco, substance use.
3. Title X providers should provide a referral resource list for immunizations as indicated.

22. PRECONCEPTION HEALTH SERVICES

Preconception describes anytime that a woman of reproductive potential is not pregnant but at risk of becoming pregnant, or when a man is at risk for impregnating his female partner. A written protocol and procedure **must** be current, available and consistent with national standards of care. Agencies **must** offer preconception health services to females and males as part of core family planning services. Preconception health services promote health before conception

thereby reducing pregnancy-related adverse outcomes (low birth weight, premature birth, infant mortality), promote birth outcomes and improve the health of male and female clients even if they choose not to have children.

The clinic visit includes:

A. Medical history for females **must** include:

1. Reproductive life plan
2. Sexual risk assessment
3. Reproductive history
4. History of prior pregnancy outcomes
5. Environmental exposures
6. Medications
7. Genetic conditions
8. Family history
9. Intimate partner violence
10. Social history/risk behaviors
11. Immunizations (MCIR is strongly recommended)
12. Depression
13. Zika risk assessment

B. Medical history of males **must** include:

1. Reproductive life plan
2. Sexual health assessment
3. Past medical and surgical history that impairs reproductive health
4. Genetic conditions
5. History of reproductive failures, or conditions that can reduce sperm quality (obesity, diabetes, varicocele)
6. Social history/risk behaviors
7. Environmental exposures
8. Immunizations status (MCIR is strongly recommended)
9. Depression
10. Zika risk assessment

C. Physical Examination for all clients:

1. Height, weight, BMI (screen for obesity)
2. BP (screen for hypertension- based on American Heart Assn. recommendations)
 - a. All clients—screen yearly
 - b. If BP <120/80---screen yearly, continue yearly
 - c. If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit and if average BP >140/90 recheck at next visit or in 1 week and refer if sustained BP >140/90.
1. Laboratory testing must be recommended based on risk assessment: Diabetes screening (for type 2 diabetes in asymptomatic males and females adults) with sustained BP (either treated or untreated) >139/80 (USPSTF)
2. Consider referral for Zika screening if indicated.

E. Client Plan/Education

1. Some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (e.g., an obstetrician or midwife).
2. Encourage to take a daily supplement containing (400-800 mcg) of folic acid (or a prenatal vitamin).
3. Avoid smoking, alcohol and other drugs
4. Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish)
5. Offer/Refer for any needed STD screening (including HIV)
6. Refer for age appropriate vaccinations, if indicated
7. Provide Zika education and prevention strategies

F. Referral:

1. If client desires, refer for further diagnosis and treatment
2. Refer male and female clients for additional services if screening results indicate presence of health condition or as indicated (i.e., tobacco cessation, obesity, diabetes, depression, immunizations).

23. ACHIEVING PREGNANCY SERVICES

A written protocol and procedure **must** be current, available, and consistent with national Standards of care. Agencies **must** offer services on achieving pregnancy to females and males who want to become pregnant as part of their core family planning services. The goal is to address the needs of clients who wish to become pregnant in accordance with current standards of practice.

Achieving Pregnancy services will be offered to clients who respond to the reproductive life plan questions stating they desire to become pregnant. Achieving pregnancy services include: Identifying and assessing clients who desire pregnancy; providing counseling and education (including key messages on achieving pregnancy) and addressing misperceptions that many women, men and adolescents have about fertility and infertility. Clients who have been trying to achieve pregnancy for 12 months or longer with regular unprotected intercourse should be offered basic infertility services.

A. Client assessment includes:

1. Reproductive Life Plan
2. When she or they want to get pregnant
3. Length of time she or they have been trying to become pregnant.
 - a. If less than 1 year, provide counseling on maximizing fertility success
4. History of pregnancies or infertility
5. Partner involvement and support system issues
 - a. Support system issues may include: family and community support, LGBTQ considerations, single parent considerations, cultural/familial considerations, and awareness of other concerns or influences.
6. Zika risk assessment, including past travel for both client and partner in the past 8 months, as well as future travel plans for both client and partner

- B. Medical history includes:
1. Immunizations
 2. Medications
 3. Present infectious or chronic health conditions
 4. Genetic conditions
 5. Environmental exposures
 6. Social history/risk behaviors
 7. Sexual health assessment and risk assessment
 8. Mental health
 9. Medical history for **females must** Include:
 - a. Reproductive history
 - b. Obstetrical/Gynecology history
 - c. Family history
 - d. Intimate partner violence
 10. Medical history for **males must** include:
 - a. Past medical or surgical history that might impair reproductive health
 - b. Medical conditions associated with reproductive failure that could reduce sperm quality
- C Assessing and updating the client's physical, sexual and medical history may reveal additional issues in the person's health history that need to be addressed. The results can also help determine the need for additional information like fertility awareness or other health services such as: STD screening, preconception care, infertility services, possible need for Zika screening, and other preventative health services.
- D. Client education and counseling includes:
1. Importance of regular preventive health and chronic disease management
 2. Some medications might be contraindicated in pregnancy and current medications will need to be reviewed by the prenatal care provider (obstetrician, physician, or midwife)
 3. Encourage daily supplement containing (400-800 mcg) of folic acid or a prenatal vitamin
 4. Avoid smoking, alcohol and other drugs.
 5. Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish)
 6. Offer/refer for any needed STD screening, including HIV
 7. Offer/refer for age appropriate vaccinations, as indicated
 8. Nutritional counseling and recommended weight loss if client is overweight
 9. Provide Zika education and prevention strategies
 10. Counseling provided **must** be documented in the record
- E. Education on maximizing fertility awareness and success includes:
1. Fertility awareness/ Techniques to predict ovulation
 - a. Education about peak days and signs of fertility (including the 6-day interval ending on the day of ovulation that is characterized by slippery, stretchy cervical mucus and other possible signs of ovulation)

- b. Education on methods or devices designed to determine or predict the time of ovulation (e.g., over-the-counter ovulation kits, digital telephone applications, or cycle beads) should be discussed
- 2. Lifestyle influences
 - a. Advise that vaginal intercourse every 1-2 days beginning soon after the menstrual period ends can increase the likelihood of becoming pregnant (women with regular menstrual cycles)
 - b. Information that fertility rates are lower among women who are very thin or obese, and those who consume high levels of caffeine (e.g., more than five cups a day)
 - c. Discourage smoking, alcohol, recreational drugs, and use of commercially available vaginal lubricants that may reduce fertility
 - d. Education on Zika risks and the importance of Zika prevention for couples seeking pregnancy
 - e. Encourage a daily supplement containing folic acid or prenatal vitamin
 - f. Encourage males to avoid hot tubs
- F. Referral

If desired, clients should be provided a current referral listing for further diagnosis and treatment.

24. PREGNANCY DIAGNOSIS AND COUNSELING

Agencies **must** provide pregnancy diagnosis and counseling to all clients in need of this service (42 CFR 59.5(a) (5)). 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 protocol and procedure **must** be current, available and consistent with national standards of care.

- A. Pregnancy diagnosis services include:
 - 1. General Consent for Services
 - 2. Reproductive Life Plan Discussion
 - 3. Medical history (including chronic medical illnesses, physical disability, psychiatric illness)
 - 4. Zika risk assessment
 - 5. Pregnancy testing (qualitative urine with high sensitivity)
 - 6. Pregnancy test results **must** be given to the client
 - 7. Counseling and referral resource list as appropriate
 - 8. Chlamydia testing **must** be offered to females <25 years of age and to females >25 years with risk factors.
- B. If the pregnancy test is positive, the clinical visit should include:
 - 1. An estimation of gestational age so that appropriate counseling can be provided.
If a woman is uncertain about the date of her last normal menstrual period, a pelvic examination might be needed to help assess gestational age.
 - 2. Information about the normal signs and symptoms of early pregnancy
 - 3. Instructions on when to report any concerns to a provider for further evaluation.
 - 4. If ectopic pregnancy or other pregnancy abnormalities or problems are suspected, the client **must** be referred for immediate diagnosis and management.

- 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. Referral to appropriate providers of follow-up care **must** be made at the request of the client, as needed. For example, providers **must** provide a resource listing or directory of providers to help the client identify options for care.
- F. Providers also should assess the client's social support and refer her to appropriate counseling or other supportive services, as needed.
- G. For clients who are considering or choose to continue the pregnancy, a prenatal care referral **must** be provided and initial prenatal counseling **must** be provided that includes:
 - 1. Pregnant women with risk factors should be tested for STDs (including HIV) at the time of their positive pregnancy test if there will be delays in obtaining prenatal care (more than 2 months).
 - 2. Advise that some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (e.g., an obstetrician or midwife).
 - 3. Encourage to take a daily supplement containing (400-800 mcg) of folic acid (or a prenatal vitamin).
 - 4. Avoid smoking, alcohol, and other drugs.
 - 5. Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish).
 - 6. Refer for age appropriate vaccinations if indicated.
 - 7. Referral for Zika screening if indicated.
- H. Clients with a negative pregnancy diagnosis and do not want to become pregnant **must** be offered information about family planning services as indicated, such as:
 - 1. The value of making a reproductive life plan
 - 2. Contraceptive services (or scheduled for an appointment)
 - 3. Counseling to explore why the client thought she was pregnant and sought pregnancy testing services
 - 4. Assessed for difficulties using her current method of contraception, if indicated.
- I. Women who are not pregnant and who are trying to become pregnant **must** be offered information about family planning, as indicated, such as:
 - 1. Services to help achieve pregnancy or basic infertility services
 - 2. Preconception health education
 - 3. STD services
 - 4. Reproductive life plan
 - 5. Zika education and prevention strategies

25. BASIC INFERTILITY SERVICES

A written protocol and procedure **must** be current, available and consistent with national standards of care. Agencies **must** offer basic infertility care as part of core family planning services. Infertility is defined as the failure of a couple to achieve pregnancy after 12 months or longer of regular unprotected intercourse.

- A. Infertility visit to a family planning clinic focuses on determining potential causes of the inability to achieve pregnancy and making any needed referrals for specialist care. Evaluation of both partners should begin at the same time. Earlier evaluation (6 months of regular unprotected intercourse) is justified for:
 - 1. Women aged >35 years
 - 2. Those with a history of oligo-amenorrhea (infrequent menstruation)
 - 3. Those with known or suspected uterine or tubal disease or endometriosis
 - 4. Those with a partner known to be sub-fertile (the condition of being less than normally fertile though still capable of effecting fertilization).
- B. An early evaluation may be warranted if risk factors of male infertility are known to be present or if there are questions regarding the male partner's fertility potential.
- C. Basic Infertility Care for Women. The infertility visit should focus on:
 - 1. Understanding the client's reproductive life plan and difficulty in achieving pregnancy.
 - 2. The medical history **must** include:
 - a. Past surgeries
 - b. Previous hospitalizations
 - c. Serious illnesses or injuries
 - d. Medical conditions associated with reproductive failure (e.g., thyroid disorders, hirsutism, or other endocrine disorders)
 - e. Childhood disorders
 - f. Cervical cancer screening results and any follow-up treatment
 - g. Medication
 - h. Allergies
 - i. Social history/risk behaviors
 - j. Family history of reproductive failures
 - k. Reproductive history (i.e., time trying to achieve pregnancy; coital frequency and timing)
 - l. Level of fertility awareness
 - m. Previous evaluation and treatment results; gravidity, parity, pregnancy outcome(s), and associated complications; age at menarche, cycle length and characteristics, and onset/severity of dysmenorrhea
 - n. Sexual history (pelvic inflammatory disease, history of/exposure to STDs)
 - o. Review of systems (symptoms of thyroid disease, pelvic or abdominal pain, dyspareunia, galactorrhea, and hirsutism)
 - p. Zika risk assessment

3. A physical examination **must** be offered if clinically indicated:
 - a. Height, weight, and body mass index (BMI) calculation
 - b. Thyroid examination (i.e., enlargement, nodule, or tenderness)
 - c. Clinical breast examination (CBE)
 - b. Signs of androgen excess
 - c. A pelvic examination (i.e., pelvic or abdominal tenderness, organ enlargement/mass; vaginal or cervical abnormality, secretions, discharge; uterine size, shape, position, and mobility; adnexal mass or tenderness; and cul-de-sac mass, tenderness, or nodularity).
- D. Basic Infertility Care for Men. Infertility services provided to the male partner of an infertile couple should include:
 1. Client's reproductive life plan
 2. Medical history **must** include:
 - a. Reproductive history (methods of contraception, coital frequency and timing; duration of infertility, prior fertility; sexual history; and gonadal toxin exposure, including heat).
 - b. Medical illnesses (e.g., diabetes mellitus)
 - c. Prior surgeries
 - d. Past infections
 - e. Medications (prescription and nonprescription)
 - f. Allergies
 - g. Lifestyle exposures
 - h. Sexual health assessment.
 - i. Female partners' history (pelvic inflammatory disease, STDs, and problems with sexual dysfunction)
 - j. Zika risk assessment
 3. A physical examination **must** be offered if clinically indicated:
 - a. Examination of the penis (including the location of the urethral meatus)
 - b. Palpation of the testes and measurement of their size
 - c. Presence and consistency of both the vas deferens and epididymis
 - d. Presence of a varicocele
 - e. Secondary sex characteristics
 4. Male clients concerned about their fertility should be offered a semen analysis via an unpaid laboratory requisition. If this test is abnormal, they should be referred for further diagnosis (i.e., second semen analysis, endocrine evaluation, post-ejaculate urinalysis, or others deemed necessary) and treatment. The semen analysis is the first and most simple screen for male fertility.
- E. Infertility Counseling
 Counseling provided during the clinic visit is guided by information elicited from the client during the medical and reproductive history and findings from the physical exam. Provide Zika education and prevention strategies.
- F. Referral:
 1. Clients (female and male) **must** be referred for further diagnosis and treatment if indicated or requested.
 2. Consider referral for Zika screening if indicated

26. SEXUALLY TRANSMITTED DISEASE SERVICES

Written protocols and operating procedures for sexually transmitted infections **must** be in place when STD/HIV services are provided. Screening and treatment **must** follow current Centers for Disease Control (CDC) STD Treatment and HIV testing guidelines.

- A. Assess client's Reproductive Life Plan
- B. Medical history
 - 1. Allergies
 - 2. Medications
 - 3. Medical conditions
 - 4. Sexual health assessment, based on gender identify, current anatomy and sexual behavior (partners, practices, protection, past history of STDs, pregnancy prevention)
 - 5. Immunizations (Hep B, HPV)
 - 6. Zika risk assessment
- C. Physical Exam as indicated (based on history or symptoms)
- D. Laboratory testing including the following:
 - a. Chlamydia:
 - a. Testing **must** be offered annually for all females < 25 years. Sexually active women ≥ 25 years with risk factors (infected partner, partner with other concurrent partners, symptoms, history of STD or multiple partners in the last year) should be offered testing-
 - b. Clients who test positive for Chlamydia 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.
 - c. Chlamydia screening for males can be considered at sites with high prevalence (adolescent clinics, correctional facilities, STD clinics) or males who have sex with males (MSM). Males with Chlamydia should be re-tested 3 months following treatment.
 - d. The MDHHS family planning program supports the MDHHS Infertility Prevention Project (IPP) by allocating pre-paid test forms for CT/GC to each sub-recipient agency based on population prevalence. These forms are intended for clients who are uninsured, underinsured or request confidential testing services. Use of these pre-paid forms should be based on the following criteria:
 - 1) Priority goes to females under 25
 - 2) Females 29 and under are eligible for testing with a pre-paid form
 - 3) Based on historic positivity, males presenting in our family planning sites are eligible for testing with a pre-paid form.
- 2. Gonorrhea
 - a. Testing **must** be offered annually to sexually active women <25 with high risks (previous gonorrhea, presence of other STDs, new or multiple sex partners, inconsistent condom use, commercial sex work, drug use) and those who reside in

- high prevalence areas. Other risk factors that place women at increased risk include infected partner, symptoms, history of STD or multiple partners in past year.
- b. All males with symptoms suggestive of gonorrhea (urethral discharge or dysuria or whose partner has gonorrhea) should be tested and empirically treated.
 - c. Males who have sex with males (MSM) should be tested at sites of exposure. Clients with gonorrhea infection should be re-tested for re-infection 3 months after treatment. 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.
 - d. Pre-paid IPP forms may be used for testing based on guidance provided above in 1.d.
3. Syphilis
 - a. Testing should be offered to male and female clients at high risk:
 - 1) MSM,
 - 2) Commercial sex workers,
 - 3) Persons who exchange sex for drugs,
 - 4) Those in adult correctional facilities,
 - 5) Living in high prevalence areas).
 4. HIV/AIDS
 - a. Testing should be routinely recommended for all male and female clients 13-64 years of age.
 - b. Annual testing is recommended for high risk individuals:
 - 1) injection drug users and their partners
 - 2) persons who exchange sex for money or drugs
 - 3) sex partners of HIV infected persons
 - 4) MSM or heterosexual persons who themselves or whose sex partner have had more than one sex partner since their most recent HIV test
 - c. Opt out screening can be provided if included in the general medical consent.
 5. Hepatitis C
 - a. Testing should be recommended once for female and male clients without risks (if born during 1945-1965). If testing is positive, refer for additional care and management of HCV infection and related conditions. Assess for alcohol use and refer for intervention if indicated.
 - b. Clients with high risk behaviors /conditions (e.g., past or current injection of illegal drugs, HIV infected) should be recommended to have annual testing.
 6. Hepatitis B
 - a. Screening is not recommended for the general population.
 - b. Testing should be recommended for high risk populations (persons from high prevalence areas, HIV positive, IV drug users, MSM, Hep.B household contacts.)
 7. Zika Virus
 - a. Risk assessment questions should be asked of all clients. Has the client or partner(s) traveled to a Zika impacted area in the past 8 months?
 - b. Consider referral for testing if sexually active and at seeking pregnancy
 - c. All clients should be educated regarding Zika risks and prevention strategies
- E. STD treatment should be provided on-site. When treatment for any STD is provided on-site, the sub-recipient **must** follow current Centers for Disease Control and Prevention STD

Treatment Guidelines ensure all clients are treated in a timely manner and appropriate follow-up measures are provided.

- F. Expedited Partner Therapy (EPT) should be offered as indicated for clients testing positive for chlamydia and gonorrhea.
 - 1. Michigan's Public Act 525 of 2014 (MCL 333.5110) authorized the use of expedited partner therapy (EPT) for certain sexually transmitted diseases as designated by the state department of health. The department designated chlamydia and gonorrhea as diseases for which the use of EPT is appropriate. Guidance for providers and information for clients are available at www.michigan.gov/hivstd or in section I of this manual (pages 47, 48)
- G. Counseling
 - 1. Educate on risk reduction and available testing or referral for testing.
 - 2. Encourage vaccination for HPV and Hepatitis B if indicated
 - 3. Encourage condom use to prevent STD/HIV infection
 - 4. Encourage clients with STDs to:
 - a. Notify their sex partners and urge them to seek medical evaluation and treatment
 - b. Refrain from unprotected sexual intercourse during the period of STD treatment
 - c. Return for re-testing in 3 months if indicated
 - 5. Educate on Zika risks and prevention strategies
- H. Referral
 - 1. Clients with Hepatitis C and HIV infection should be linked to medical care and treatment.
 - 2. Clients should be referred for needed immunizations.
- I. Mandatory Reporting
 - 3. Sub-recipient agencies **must** comply with state and local STD reporting requirements.

27. GYNECOLOGIC SERVICES

Family planning 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. Written protocols and operating procedures **must** be available, current and consistent with national standards of care. 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.

28. RELATED PREVENTIVE HEALTH SERVICES

Written protocols and operating procedures **must** be available, current and consistent with national standards of care. All sub-recipient agencies **must** comply with the current MDHHS Family Planning Breast and Cervical Cancer Screening Protocol and **must** participate in the Family Planning/Breast and Cervical Cancer Control Program (FP/BCCCP) Joint Project for diagnostic services (i.e., breast ultrasound, mammogram and colposcopy) for uninsured or underinsured clients. Coordination of care **must** go through the BCCCP Coordinator unless other referral/payment arrangements are in place.

- A. Clinics **must** offer and/or provide and stress the importance of the following to all clients:

1. Clinical Breast Exam (CBE) performed at least every three years for average-risk asymptomatic women beginning at age 21 through age 39, and annually for women ≥ 40 years.
 2. Pap testing as indicated:
 - a. Age 21 to 65, every 3 years if Pap test is negative, OR
 - b. Age 30 to 65, every 5 years if using co-testing (pap and HPV) and both are negative
 3. Pelvic examination (including vulvar evaluation and bimanual exam) should be performed with routine pap testing and **must** be provided if medically indicated.
- B. Clinics **must** stress the importance of:
1. Screening mammography for women aged 50-74 years on a biennial basis.
 2. Screening for women age 40-50, should be based on patient preference, personal/family history, or other conditions that support screening.
- C. Clinics should conduct a genital examination for adolescent males and document:
1. Skin and hair distribution (observation)
 2. Hydrocele, varicocele, (observation and palpation)
 3. Signs of STD (observation and/or palpation)

29. QUALITY MANAGEMENT

A. 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.

1. Referral procedures **must** be sensitive to clients' concerns for confidentiality and privacy.
2. Client consent for release of information to providers **must** be obtained, except as may be necessary to provide care or as required by law
3. 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:
 - a. A system to document referrals and follow up procedures **must** be in place.
 - b. Follow-up procedures **must** include the following:
 - 1) A method to identify clients needing follow-up
 - 2) A method to track follow-up results on necessary referrals (such as, Pap and breast follow-up)
 - 3) Documentation in the client record of contact and follow-up.
 - 4) Documentation of reasons, actions and follow-up where recommendations were not followed and/or protocols not acted upon.
 - c. Referral procedures should include that the client be given an explanation of the referral and need for follow-up including:
 - 1) Reason and importance of the referral
 - 2) Services to be received from the referral agency
 - 3) Address of the referral provider/agency
 - 4) Any instructions needed to follow through with the referral
 - 5) When to return to the family planning clinic

4. Sub-recipient agencies **must** provide all Quality Family Planning Service components 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.
5. 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**:
 - a. Document that the client was advised of the referral and the importance of follow-up
 - b. Document that the client was advised of their responsibility to comply with the referral
6. Sub-recipients **must** maintain a current referral list that includes health care providers, local health and human service departments, hospitals, voluntary agencies, and health service projects supported by other federal programs.
 - a. Referral lists **must** be current and updated annually
 - b. When possible, clients should be given a choice of providers

B. Pharmaceuticals

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.

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. Prescriptions may be written for contraceptives/medications on the clinic formulary or on the client's insurance plan formulary.

1. According to PH Code Act 368 of 1978 ([http://www.legislature.mi.gov/\(S\(wjwslol3kv501nx23qrash4c\)\)/mileg.aspx?page=getObject&objectName=mcl-333-17745](http://www.legislature.mi.gov/(S(wjwslol3kv501nx23qrash4c))/mileg.aspx?page=getObject&objectName=mcl-333-17745)) as amended under Pharmacy Practice and Drug Control 333.17745, a dispensing prescriber, except as authorized for expedited partner therapy (EPT) in section 5110 or section 17744a/17744b, shall only dispense drugs to his/her clients. Written protocols and operating procedures for the distribution, security and record keeping of pharmaceuticals and supplies **must** meet the following required standards:
 - a. The medical director of the family planning program is responsible for all policies and procedures pertaining to the general handling of pharmaceuticals.
2. Prescription of pharmaceuticals is done under the direction of a physician (who **must** have a drug control license for each location in which the storage and the dispensing of prescription drugs occur). The physician may dispense indirectly under his/her delegated authority to a R.N. or certified mid-level clinician. Pre-labeled, pre-packaged oral contraceptives may be distributed if delegated by a dispensing prescriber.
 - a. All medications dispensed in Title X clinics **must** be pre-packaged.

- b. Prescription medications dispensed (including samples) **must** be labeled and labels **must** contain the following information:
 - 1) Name and address of location from which the prescription drug is dispensed
 - 2) Name of the client, unless prescription is authorized for EPT
 - 3) Date the prescription drug is dispensed
 - 4) Name, strength, and quantity of drug dispensed
 - 5) Directions for use, including frequency of use
 - 6) Prescriber's name (medical director and prescribing practitioner)
 - 7) Expiration date of prescription drug
 - 8) Record number of client
 - c. 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.
 - d. There **must** be documentation that in-service training pertaining to the nature and safety aspects of pharmaceuticals is provided at least every two years to staff involved in the provision of medications to clients (i.e., new staff orientation, staff meeting, and quiz).
3. The inventory, supply and provision of pharmaceuticals may be delegated to appropriately qualified health professionals.
- a. Family planning health professionals delegated to deliver prescriptions drugs **must** be trained in all aspects of pharmaceutical and supply distribution
 - b. Delegate agencies **must** have proper segregation between requisition, procuring, receiving and payment functions for pharmaceuticals and supplies.
 - c. Delegate agencies **must** have an inventory system to control purchase, use, reordering of pharmaceuticals and supplies.
 - d. Delegate agencies **must** have adequate controls over access to medications and supplies including:
 - 1) Contraceptive and therapeutic pharmaceuticals **must** be kept in a secure place, either under direct observation or locked.
 - 2) Access to pharmaceuticals **must** be limited to health care professionals responsible for distributing these items.
 - 3) Safeguards **must** be in place for assuring that supplies purchased through the 340 B program are provided only to clients of the family planning program.
 - e. A system **must** be in place to monitor the expiration date on drugs and ensure disposal of all expired drugs.
 - f. A system for silent notification in case of drug recall **must** be in place.
 - g. Inventory levels should not exceed a six month supply.
4. 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.
5. An adequate supply and variety of drugs and devices **must** be available to meet their client's contraceptive needs.
- a. Purchase and use of generic drugs based on therapeutic equivalence as published by the FDA or in the Formularies of Therapeutic Equivalence accepted by the State Board of Pharmacy is acceptable.

- b. Sub recipient agencies may elect to identify certain supplies on the formulary, such as more expensive or infrequently used methods, that will be ordered upon client request and be available within two weeks of the request.
- 6. At a minimum, each site that provides medical services **must** have the following:
 - a. Emergency drugs and supplies for treatment of vaso-vagal reaction.
 - b. Emergency drugs and supplies for treatment of anaphylactic shock.
- 7. Prescriptive Methods for Transfer Clients
 - a. An informed (general) consent form **must** be obtained and a client history **must** be completed/reviewed. A BP **must** be taken if the client desires to continue on a combined hormonal contraceptive. The provider will review the transfer records and decide if current prescription can be continued. The provider **must** document the prescription in the client's record.

C. Medical 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.

- 1. At a minimum, written protocols **must** address:
 - a. Vaso-vagal reactions/Syncope (fainting)
 - b. Anaphylaxis
 - c. Cardiac arrest
 - d. Shock
 - e. Hemorrhage
 - f. Respiratory difficulties
- 2. Protocols **must** also be in place for emergencies requiring EMS transport, after hour's management of contraceptive emergencies and clinic emergencies.
- 3. All staff **must** 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.
- 4. There **must** be a procedure in place for maintenance of emergency resuscitative drugs, supplies, and equipment.

D. Medical Records

- 1. General Policy
 - a. A medical record **must** be established for each client who receives clinical services, including pregnancy testing/counseling clients and emergency contraception clients.
 - b. Medical records are maintained in accordance with the accepted medical standards and state laws with regard to record retention. Records **must** be:
 - 1) Complete, legible, and accurate
 - 2) Signed and dated by the clinician health professional making each entry
 - a) Each entry includes date, name and title of the clinician/health professional
 - b) Each entry is a permanent part of the record
 - 3) Readily accessible
 - 4) Confidential
 - 5) Safeguarded against loss or use by unauthorized persons
 - 6) Available upon request to the client
 - c. HIPPA regulations regarding personal health information **must** be followed.

- d. Guidance regarding records management is available from the Michigan Department of Technology, Management and Budget, Records Management Services.
<http://www.michigan.gov/recordsmanagement>
2. 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:
- a. Personal data:
 - 1) Name
 - 2) Address, phone number(s), and how to contact
 - 3) Age
 - 4) Sex
 - 5) Marital status (as required for State of Michigan)
 - 6) Income Assessment
 - 7) Unique client number
 - 8) Race and ethnicity (as required for FPAR)
 - 9) Medical history
 - 10) Allergies recorded in a prominent, consistent location
 - b. Physical exam
 - c. Documentation of clinical findings, diagnostic/therapeutic orders
 - 1) Laboratory test results and follow-up done for abnormal results
 - 2) Treatments and special instructions
 - 3) Documentation of continuing care, referral and follow-up
 - 4) Documentation of scheduled revisits
 - d. Contraceptive method chosen by the client
 - e. Informed consents
 - f. Documentation of all counseling, education, and social services given
 - g. Documentation of deferrals, reason for deferral, and refusal of services
 - h. Date and signature of clinician or health professional for each entry, including documentation of telephone encounters of a clinical nature.
 - 1) Signature includes name and title of provider
 - 2) A signature log, if full name and title are not used in medical record
 - i. A confidentiality assurance statement in the client's record.
 - j. A list of identified problems should be maintained to facilitate continuing management and follow-up.
3. Confidentiality and Release of Records
- A system **must** be in place to maintain confidentiality of client records.
- a. A confidentiality assurance statement **must** appear in the client's record.
 - b. HIV, mental health, and substance use information **must** be handled according to state law.
 - c. 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.
 - 1) Consent form for release of information, signed by the client, specifies to whom information may be disclosed.
 - 2) Only the specific information requested may be released.

- d. Information collected for reporting purposes **must** be disclosed only in summary, statistical, or other form which does not identify individuals
- e. Upon request, clients transferring to other providers **must** be provided with a copy or summary of their record to expedite continuity of care.
- f. Upon request, clients **must** be given access to their medical record

E. Quality Improvement

Sub-recipient agencies **must** have a system in place that provides for the ongoing evaluation for conducting quality improvement.

1. The quality improvement system should include the selection and measurement of activities of at least one quality measure such as suggested measures on table 4 in the QFP on page 24.
2. The quality improvement system **must** include the following elements:
 - a. A tracking system that identifies clients in need of follow up and/or continuing care **must** be in place. (Referrals and Follow-up)
 - b. A system to assure that professional licenses and CPR certifications are current **must** be in place. (Personnel & Emergencies)
 - c. Medical Audits to determine conformity with agency protocols, current standards, and acceptable medical practices **must** be conducted quarterly by the medical director.
 - 1) Minimum of two to three charts per clinician **must** be reviewed by the medical director quarterly.
 - d. Chart Audits/ Record Monitoring to determine completeness and accuracy of the medical record **must** be conducted at least quarterly by the quality assurance committee or identified personnel.
 - 1) Chart audits **must** represent a minimum of three percent (3%) of the agency's quarterly caseload, randomly selected and reviewed by staff.
 - 2) All clinical sites should be represented in the sampling.
 - 3) Topic audits are strongly suggested.
 - e. Clinical protocols and procedures **must** be reviewed and signed annually by the medical director.
 - f. Infection control policies and procedures reflecting current CDC recommendations and OSHA regulations **must** be in place.
 - g. Laboratory audits to assure quality and CLIA compliance **must** be in place.
 - h. Equipment maintenance and calibration **must** be documented. (Equipment and Supplies)
 - i. A process to implement corrective actions when deficiencies are noted **must** be in place.
3. Sub-recipient agency quality improvement systems should include:
 - a. Annual peer review of all clinician/providers should be conducted. (Personnel)
 - b. Regularly scheduled staff meetings to update and/or review medical or service delivery topics. Minutes should be kept of these meetings.
 - c. Routine check of emergency drugs and supplies
 - d. A process to elicit consumer feedback should be in place.
 - e. Periodic review of forms used by the agency for completeness and applicability
 - f. Routine monitoring of critical incident/occurrence reports
 - g. Periodic review of credentials of contracted laboratories

- h. Periodic patient flow analysis
 - i. Periodic review of provider liability insurance coverage.
 - j. 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:
 - 1) Missing user data
 - 2) Coding errors
 - 3) Data outcome
4. A Quality Improvement Committee should be in place. This committee should meet monthly to discuss quality assurance issues and to make recommendations for corrective action when deficiencies have been noted.
- a. If a formal Quality Improvement Committee is in place, minutes should be kept of all committee meetings.
 - b. The function of the Quality Improvement Committee may be assumed by an in-house nursing or medical advisory committee with ongoing documentation of quality improvement activities.

SECTION IV

Program Monitoring

Accreditation and Program Site Reviews

ACCREDITATION AND SITE REVIEWS FOR TITLE X FAMILY PLANNING PROGRAMS

The MDHHS Title X Family Planning Program contracts with several types of providers to provide Family Planning Title X grant services, including: local public health departments, Planned Parenthood affiliates, hospital-based clinic sites, and private non-profit health providers. For contracting and accreditation purposes, these providers are divided into two categories: local public health departments and private non-profit sub-recipients. Both categories of sub-recipients are reviewed using the Minimum Program Requirements (MPRs), regulatory requirements, and OPA Title X Program Guidelines.

The MDHHS Title X Family Planning Program Standards and Guidelines is the primary resource that outlines what is needed to meet Title X program requirements. The following resources are consistent in these program expectations: The Federal Register Title X [42 CFR Part 59, Subpart A], the Family Planning Statute which defines the legislative requirements for the program. The OPA Title X Program Guidelines, consisting of Program Requirements for Title X Funded Family Planning Projects, 2014 and Providing Quality Family Planning Services, 2014 (QFP) is the guidance issued to grantees to assist with implementation of these requirements. These are available on the OPA website and in the federal resource section of this document. The MDHHS Title X Family Planning Standards and Guidelines provide the most detailed and specific expectations, taking into account Michigan laws and Michigan specific requirements.

Accreditation Reviews for Local Public Health Department Family Planning Programs

All Title X sub-recipients have a comprehensive program review every three years to assure that MDHHS supported family planning service sites in compliance with Title X regulations and are managed effectively.

MDHHS contracts with Michigan Public Health Institute (MPHI) for the Michigan Local Public Health Accreditation Program to coordinate comprehensive accreditation site reviews for all local public health departments on a three year cycle. For local public health departments that provide family planning services, the required Title X program site reviews are incorporated into the Michigan Local Public Health Accreditation process. This is accomplished through collaboration between the MDHHS Family Planning Program and the MPHI Local Public Health Accreditation Program to coordinate the program review process for these sub-recipients. All family planning program areas: administration, finance, clinical services and community outreach and education are reviewed. For more information about the accreditation program see: <https://accreditation.localhealth.net/>

Program Site Reviews for Private Non-Profit Title X Family Planning Programs

Private non-profit Title X sub-recipients also undergo a comprehensive program review conducted by the MDHHS Family Planning Program staff every three years. The program site review is conducted to assure that MDHHS supported family planning service sites are managed effectively, and are in compliance with federal Title X regulations. All program areas are reviewed: administration, finance, clinical services and community outreach and education.

Methods

Both local health departments and private non-profit programs are reviewed by the same standards of performance, compliance with the MPRs. All programs are reviewed using the same tool and indicator guide.

Reviews of private non-profit sub-recipients are coordinated by the MDHHS Family Planning Program staff. Local public health department sub-recipient program reviews are coordinated through MPHI and MDHHS Family Planning staff. All sub-recipients submit their required pre-materials directly to the MDHHS Family Planning Program six weeks prior to the site review. Multiple services sites operated by a sub-recipient program may be visited during the process.

The MDHHS Family Planning Program review team consists of an administrative reviewer and a clinical reviewer. The clinical reviewer is responsible for reviewing the clinic service portion of the program including clinic protocols, contraceptive supplies, clinic observation and medical review; and the administrative reviewer, the administrative portions of the program including, policy review, observation, , community outreach and education, staff training, billing and collections, and data collection processes.

Process

The following are steps in the site review process:

1. The MPR Indicator Guide for Family Planning, list of required Pre-Materials and Fiscal Questionnaire are available at the MDHHS Family Planning website or on the MPHI Local Public Health Accreditation website:
 - a. <http://www.michigan.gov/familyplanning>
 - b. <https://accreditation.localhealth.net/>
2. Pre-Materials are to be submitted to the MDHHS Family Planning program at six weeks prior to the scheduled review. The materials may be submitted either electronically or mailed in the form of a CD, storage drive, or hard copy.
3. Unless otherwise requested by the program, the family planning coordinator serves as the contact with MDHHS for the review process.
4. Agencies have the option to request a pre-accreditation conference call or meeting to ask questions as they prepare for the site review.
5. The on-site program review is a two day process. Programs **must** have at least one clinic session scheduled during the visit to facilitate the evaluation of administrative and clinical components of the program. Programs are encouraged to schedule clinic sessions on the initial day of the site review, if there are not clinics on both days.

- a. Upon request an entrance pre-conference can be scheduled. The pre-conference occurs immediately at the beginning of the review to enable reviewers and program staff to meet prior to beginning the review. The program may include any staff person who will be able to provide information regarding clinical, administrative, education or financial aspects of the program. This is an opportunity for the reviewers to meet program personnel and get acquainted with the building, schedules, etc. It is a time for program staff to make reviewers aware of individual characteristics of the program and organization, as well as clarify the review process.
 - b. The exit conference is an opportunity for discussion between the reviewers and the program staff regarding the general findings of the review. Health department programs request an exit conference through MPHI, if desired. Private non-profit programs have the opportunity to set the exit conference at the beginning of the review as logistical items are being discussed.
 - c. Completed program review reports for local health department programs are submitted within one week to MPHI and the local health department is notified that the compiled on-site review report has been posted on the Local Public Health Accreditation Program website within 30 days of the on-site review. Completed program review reports for private non-profit family planning programs are received from MDHHS within 30 days. Any indicator that was not met is identified in the report with recommendations for correction. The report may also include commendations and recommendations for program improvement. Corrective plans of action **must** be submitted and accepted for all unmet indicators.
6. Corrective plans of action (CPA) submission and deadlines for local health department sub-recipients are coordinated through MPHI. Private non-profit programs submit their corrective action plans directly to the MDHHS Family Planning program. Technical assistance is available to assist with developing the plans from MDHHS Family Planning consultants.
- a. CPAs are due within sixty days of the final day of the review, approximately 30 days following receipt of the report.
 - b. Local health department programs submit their corrective action plans to MPHI and any requested support materials to MDHHS family planning review staff.
 - c. Private non-profit programs submit their corrective action plans and requested support materials directly to MDHHS family planning reviewers.
 - d. Plan may be approved with no further action needed, with conditions such as subsequent site visit or submission of support materials to MDHHS, or may be rejected with revisions required.
 - e. Implementation of CPA **must** be completed within one year of the review to continue accreditation.

TECHNICAL ASSISTANCE AND MONITORING VISITS

Sub-recipient agencies are visited during the year prior to the accreditation/site review (3 year review) or approximately one year following a site review. These visits are to provide technical assistance and to monitor progress in areas needing improvement identified during the previous accreditation/site review. This is done to assure that those areas have been corrected to confirm Title X compliance.

In addition, program issues and changes are discussed at these visits and any technical assistance requested by the agency is provided.

MDHHS PROGRAM AUDITS

The Bureau of Audit, Reimbursement, and Quality Assurance is responsible for conducting financial audits of one third of sub recipient agencies each year and managing Single Audit (A-133) information sent in by third party auditors for agencies expending over \$500,000 (\$750,000 for fiscal years beginning on or after December 26, 2014) in Federal grant funding. (Section I, page 56, 57)

There is one full time audit position assigned to the Family Planning unit to conduct fiscal audits and to ensure Title X fiscal policies are being followed. The audits verify that Title X activities are separate and distinct from non-Title X activities and proper financial reporting in accordance with contractual and regulatory requirements.

The audit staff uses a comprehensive procedural checklist to test various financial areas of the grantee. The audit results are compiled into a preliminary report for grantee review and a response on corrective action measures. Once the reply is reviewed, a final report is issued with recommendations. The audits are entered into an audit tracking system for future reference and monitoring. Program consultants review sub-recipient agency financial audits and findings as part of the comprehensive program review conducted every three years.

SECTION V

MDHHS and National Title X Training Programs

MDHHS COORDINATORS MEETING

The Family Planning Coordinators Meeting is held annually to update all Family Planning Coordinators throughout the State. This meeting provides a venue for sharing pertinent information related to program and policy issues or changes. In addition, essential information is presented from the Michigan Department of Health and Human Services management and administrative and clinical consulting staff regarding clinical and management issues pertinent to Title X Family Planning clinics.

This meeting is coordinated by the Michigan Public Health Institute (MPHI) and the Michigan Department of Health and Human Services. This meeting is available as a webinar conference that allows for questions and answers. This media allows for broad participation of agency coordinators across the state in an effort to address cost-effectiveness and reduced travel funds. The Coordinators meeting video is archived and made available for viewing at the MPHI website. https://mphibweb.ungerboeck.com/wri/wri_p1_display.aspx?oc=10&cc=EVENT

MICHIGAN ANNUAL FAMILY PLANNING UPDATE

The Michigan Department of Health and Human Services (MDHHS) Title X Family Planning Program sponsors and a comprehensive training workshop for anyone involved with family planning service. The scope of the audience is wider than the Annual Coordinator's Meeting. The conference follows a workshop format and is scheduled for two days.

This annual conference is called the Michigan Family Planning Update. The conference location is rotated geographically to provide access to all areas in Michigan. Expert presenters are invited to address on a variety of topics in both general session and workshop formats. Continuing education and contact hours are available where possible. In addition, MDHHS administrative, clinical and management staff are available to provide pertinent program information. This conference also provides an important venue for family planning providers, administrators and staff to network. Selected sessions, reflecting OPA training priorities, are videotaped and archived on the MPHI website for family planning providers and staff who are unable to attend the conference.

https://mphibweb.ungerboeck.com/wri/wri_p1_display.aspx?oc=10&cc=EVENT

ADDITIONAL MDHHS STAFF AND SUB-RECIPIENT TRAININGS

In addition to the coordinator meeting and family planning conference, MDHHS in cooperation with MPHI, provides a number of other training opportunities related to family planning throughout the year. These trainings are provided through a combination of face to face workshops and webinar offerings. Continuing education and contact hours are available whenever possible.

MPHI publishes a calendar online with all the educational offerings for the year. This calendar is available on the MPHI website. Visit the MPHI website for more information and registration: https://mphibweb.ungerboeck.com/wri/wri_p1_display.aspx?oc=10&cc=EVENT

Participant evaluations are collected after each workshop and training. The MDHHS Training Advisory Committee (TAC) uses the information obtained in the evaluations from the previous year for planning future meetings and trainings. Trends in requests for information, suggestions for improvement and for future trainers, as well as other information obtained through these evaluations are considered in the planning.

MDHHS FAMILY PLANNING TRAINING AND ADVISORY COMMITTEE (TAC)

Family Planning Training and Advisory Committee (TAC) is a standing committee of the MDHHS, Family Planning Program. This committee plans staff and sub-recipient agency training for the year. The meetings are coordinated by contract with the Michigan Public Health Institute's (MPHI) Education and Training Team under the advisement of MDHHS staff.

The TAC Mission Statement and Objectives

TAC has adopted the following Mission Statement: To improve the quality of reproductive health for Michigan's citizens by providing culturally competent education and training opportunities that strengthen the capacity and ability of Title X service providers to prevent sexually-transmitted infection's and reduce unintended pregnancies.

TAC's Objectives are:

1. Adhere to Title X, Region V training, education and promotion priorities for service delivery areas;
2. Determine education and training gaps of Title X health service providers;
3. Enhance family planning service delivery through training and education.

The purpose of TAC is to determine training topics, content and make trainer recommendations for MDHHS funded family planning programs. Each training session is linked to the Region V OPA Priorities and topic linkage to Health People 2010's Reproductive Health Objectives.

The training offered is based on a Training Needs Assessment. This is an electronic survey is used to plan and identify staff and agency training needs. MPHI offers online registration with all pertinent information including directions, visit:

https://mphi-web.ungerboeck.com/wri/wri_p1_display.aspx?oc=10&cc=EVENT

The training planning team takes every opportunity to offer professional contact hours and continuing education opportunities at every event planned.

NATIONAL MEETINGS, CONFERENCE AND NATIONAL TRAINING CENTERS (NTCS)

The National Family Planning Program authorized in 1970 as Title X of the Public Health Service Act (P.L.910572). The nationally funded Title X program is administered by the Office of Family Planning in the Office of Population Affairs within the Department of Health and Human Services. Information about the Family Planning program is available on the OPA Website at: <http://www.hhs.gov/opa/title-x-family-planning/>. The Family Planning Program is administered through ten Public Health Service Regional Offices throughout the United States. Michigan is part of Region V and the MDHHS Family Planning Program obtains program consultation and direction through the Region V Program Consultant located in Chicago, Illinois.

The Title X program, under Section 1003, provides training grants for personnel working in family planning services projects, with the purpose of promoting and improving the delivery of family planning services. Until 2012, each of the ten Regional Program Offices administered a training grant to focus on staff needs within their region. In 2012, in order to more effectively and efficiently meet Title X training needs in the rapidly evolving health care environment, OPA moved from a regional training model to a national training model. National Training Centers were funded to work in collaboration with OPA to address the needs of the entire Title X family planning network in the following areas:

1. National Training Center for Coordination and Strategic Initiatives (CSI)
2. National Training Center for Management and Systems Improvement (MSI)
3. National Training Center for Family Planning Service Delivery (NTC-SD)
4. National Training Center for Quality Assurance, Quality Improvement and Evaluation (QA/I/E)
5. National Clinical Training Center (CTC)

For more information about these centers see: <http://www.hhs.gov/opa/title-x-family-planning/training/national-training-centers/>

To access upcoming NTC training events or archived online programs and resources visit: <http://www.fpntc.org/>

THE MICHIGAN FAMILY PLANNING ADVISORY COUNCIL (FPAC)

Overview

The Michigan Family Planning Advisory Council (FPAC) is a group of diverse individuals committed to improving access to family planning services for the people of Michigan. Having the skills and resources to plan the timing and size of families improves birth outcomes, protects the health of parents, and reduces the likelihood of that family living in poverty. Towards that end, individuals representing the state government, local health departments, Planned Parenthoods, hospitals, adolescent health centers, advocacy agencies, social workers, and community members have joined together to enhance access to family planning services.

History

Michigan has received Title X of the Public Health Services Act (Title X) funding since 1972. The Title X Program is the only federal program devoted solely to the provision of family planning and reproductive health care. A requirement of the Title X program is to have community participation in the program by: 1) persons broadly representative of all significant elements of the population served; and 2) persons knowledgeable about the community's needs for family planning services. Since 1972, Michigan has met this requirement through the statewide FPAC. At that time, Title X providers were one of the only sources of family planning services for low-income men and women in Michigan. Today, federally qualified health centers proliferate in Michigan and provide low-cost health services including family planning. In 2006, Michigan Medicaid was approved for a demonstration waiver that expanded family planning coverage to eligible females with incomes up to 185 percent of the federal poverty level (FPL), called Plan First! In 2014, Michigan received approval to implement the Affordable Care Act's (ACA) Medicaid expansion through a Section 1115 demonstration waiver, called the Healthy Michigan Plan. Under this plan, the state provides Medicaid coverage to all newly eligible adults with income up to and including 138% of the federal poverty level. Over 600,000 adults are enrolled in coverage through the waiver. Plan First! was phased out in June 2016.

In 2009, the FPAC completed a strategic planning process. The group decided it would benefit the state to broaden their focus from only Title X programs to include other sources of family planning services in Michigan. The Title X programs remain the cornerstone of family planning services for low-income Michigan men and women and remain a focus. The FPAC acknowledges the philosophy in the Title X regulations and continues to seek members representing the population served and knowledgeable about the state's need for family planning services.

Shared Mission

Through collaborative leadership and advocacy, the Family Planning Advisory Council (FPAC) supports and improves the reproductive health of Michigan residents.

Shared Vision

The FPAC is a highly visible and sought after partnership that assures innovative and quality policies, programs and services benefiting generations to come.

Key Priorities

The FPAC:

- Develops and shares our identity.
- Builds the right infrastructure for maximum success.
- Establishes strategic partnerships with local, state and national networks.
- Coordinates a strategic annual policy agenda.
- Maximizes existing or leverage new resources for programs that provide family planning.
- Provides leadership for quality service delivery.
- Utilizes state-of-the-art technology to assure family planning information is available.

Participants

Current membership includes individuals representing the state government, local health departments, Planned Parenthoods, hospitals, adolescent health centers, advocacy agencies, social workers, and community members.

Structure

The FPAC meets three times per year in Lansing, with a conference call option to increase accessibility. The FPAC agenda is carried forward through the work of the following task forces under the leadership of the Executive Committee.

- Policy Advancement Task Force
Develops and coordinates a strategic policy agenda for family planning services
- Medical Advisory Sub-Committee
Provides leadership on delivery of quality services in reproductive health