

**MICHIGAN
TITLE X
FAMILY PLANNING PROGRAM
STANDARDS & GUIDELINES MANUAL
2011**

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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To enable persons who want to obtain family planning care to have access to such services, Congress enacted the Family Planning Services and Population Research Act of 1970 (Public Law 91-572), which added Title X, "Population Research and Voluntary Family Planning Programs" to the Public Health Service Act. Section 1001 of the Act (as amended) authorizes grants "to assist in the establishment and operation of voluntary family planning projects which shall provide a broad range of acceptable and effective medically approved methods(including natural family planning methods) and services (including infertility services and services for adolescents)." The mission of Title X is to provide individuals the information and means to exercise personal choice in determining the number and spacing of their children.

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

Title X Statute

TITLE X - POPULATION RESEARCH AND VOLUNTARY FAMILY PLANNING PROGRAMS

PROJECT GRANTS AND CONTRACTS FOR FAMILY PLANNING SERVICES

SEC. 1001 [300]

(a) The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents). To the extent practicable, entities which receive grants or contracts under this subsection shall encourage 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

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Subpart A—Project Grants for Family Planning Services

AUTHORITY: 42 U.S.C. 300a–4.

SOURCE: 65 FR 41278, July 3, 2000, unless

otherwise noted.

§ 59.1 To what programs do these regulations apply?

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

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

§ 59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

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

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

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

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

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

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

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

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

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

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

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

(c) The application shall contain—

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

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

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

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

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

(a) Each project supported under this part must:

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

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

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

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

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

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

(A) Prenatal care and delivery;

- (B) Infant care, foster care, or adoption; and
- (C) Pregnancy termination.

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

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

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

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

(9) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX or XXI agency is required.

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

1 Section 205 of Pub. L. 94-63 states: “Any (1) officer or employee of the United States,(2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any

benefit or service under a program receiving Federal financial assistance shall be fined not more than \$1,000 or imprisoned for not more than one year, or both.” services to the area proposed to be served by the applicant.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iv) Determine whether the material is suitable for the population or community to which 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 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 Clearinghouse
PO Box 30686
Bethesda, MD 20824-0686
(301)654-6190
Email: info@opaclearinghouse.org

Office of Public Health Science Websites and Links

<http://www.hhs.gov/ophs> - This link provides

Helpful websites and links:

http://www.hhs.gov/nvpo/ (National Vaccine Program Office)	http://www.hhs.gov/opa (Office of Population Affairs)	http://www.healthfinder.gov/ (Healthfinder)
http://odphp.osophs.dhhs.gov/ (Office of Disease prevention & Health Promotion)	http://ori.dhhs.gov (Office of Research Integrity)	http://healthypeople.gov/HP2020/ (Healthy People 2020)
http://www.hhs.gov/ophs/ohap (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.4woman.gov/owh (Office on Women's Health)	http://www.hhs.gov/opa/pubs/ (OPA Clearinghouse)
http://www.omhrc.gov (Office of Minority Health)	http://www.fitness.gov/ (President's Council on Physical Fitness & Sports)	http://www.hhs.gov/opa/grants/ (OPA Grants and Funding)
	http://www.hhs.gov/bloodsafety (Advisory Committee on Blood Safety)	http://www.grants.gov/ (Grant Opportunities)
		http://www.hhs.gov/pharmacy/ (Pharmacy Advisory Group)

Office of Management and Budget Instructions and Forms

This link will take you to the Public Health Service Grant for Title X, Family Planning Services, Forms and Instructions, provided by the Office of Management and Budget.

<http://www.hhs.gov/opa/grants/toolsdocs/toolsdocs.html>

Health Insurance Portability and Accountability Act of 1996

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

Administrative Simplification

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

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

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

The Privacy Rule

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

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

The Security Rule

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

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

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

Transactions and Code Sets Standards

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

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

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

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

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

Employer Identifier Standard

The Health Insurance Portability & Accountability Act of 1996 (HIPAA) requires that employers have standard national numbers that identify them on standard transactions. The Employer Identification Number (EIN), issued by the Internal Revenue Service (IRS), was selected as the identifier for employers and was adopted effective July 30, 2002. For more information, see the following CMS webpage: http://www.cms.gov/EmployerIdentifierStand/01_overview.asp

National Provider Identifier Standard

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

Additional HIPAA Internet Resources

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

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

<http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/hipaahealth-insurance-portability-accountability-act.shtml>

This resource developed by the AMA assists health care providers with HIPAA compliance.

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

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

<http://www.aishealth.com/Compliance/HIPAAResource.html>

This site includes articles on HIPAA compliance strategies and access to additional resources.

Civil Rights Act of 1964

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

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

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

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

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

B. Federal Program Guidelines and Guidance and Internet Resources

Program Guidelines, Tools and Documents for Family Planning Projects

This Internet site provides access to Office of Population Affairs documents including program guidelines, resource documents, contacts to regional agencies, and updated Compliance Standards for Family Planning Services Projects. The documents below are available from the OPA website:

<http://www.hhs.gov/opa/familyplanning/toolsdocs/index.html>

Family Planning Program	
MMWR Sexually Transmitted Diseases Treatment Guidelines, 2010	
Title X Family Planning Provider Database (Locate Family Planning providers in your area)	
Program Guidelines for Project Grants for Family Planning Services (January 2001)	
Family Planning Grantees, Delegates, and Clinics Directory	
Program Instruction Series	
Sterilization Consent Form	
2010 Family Planning Program Priorities	
Executive Summary - Title X Training Assessment	
Federal Efforts to address Applicable Child Abuse and Sexual Abuse Reporting Requirements for Title X Grantees	
Statutory Rape: A Guide to State Laws and Reporting Requirements	
Provision of Abortion-Related Services in Family Planning Services Projects	
Family Planning Annual Report	
Family Planning Annual Report - 2009 Final Report	
Family Planning Annual Report - 2008 Final Report	
Family Planning Annual Report - 2007 Final Report (Re-issued December 2009 with Errata Sheet)	
General Information	
Healthy People 2020	
Annual Update of the HHS Poverty Guidelines (2010)	

Program Priorities, Legislative Mandates, Key Issues, Training Priorities, 2011

2011 Program Priorities

1. Assuring the delivery of quality family planning and related preventive health services, where evidence exists that those services should lead to improvement in the overall health of individuals, with priority for services to individuals from low-income families;
2. Expanding access to a broad range of acceptable and effective family planning methods and related preventive health services that include natural family planning methods, infertility services, and services for adolescents, including adolescent abstinence counseling. The broad range of services does not include abortion as a method of family planning;
3. Providing preventive health care services in accordance with nationally recognized standards of care. This includes, but is not limited to, breast and cervical cancer screening and prevention services; sexually transmitted disease (STD) and HIV prevention education, testing, and referral; and, other related preventive health services;
4. Emphasizing the importance of counseling family planning clients on establishing a reproductive life plan, and providing preconception counseling as a part of family planning services, as appropriate;
5. Addressing the comprehensive family planning and other health needs of individuals, families, and communities through outreach to hard-to-reach and/or vulnerable populations, and partnering with other community-based health and social service providers that provide needed services.
6. Identifying specific strategies for addressing the provisions of health care reform ("The Patient Protection and Affordable Care Act"), and for adapting delivery of family planning and reproductive health services to a changing health care environment, and assisting clients with navigating the changing health care system.

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.

2011 Key Issues

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

2010 National Training Priority

Each year the OPA/OFP establishes national training priorities based on nationally identified training needs. The National Training Priority area identified for FY 2008 was: conducting outcome evaluation of the impact of the training activities to Title X providers on improving clinic efficiency in an effort to address increasing costs of health care without sacrificing quality. During FY 2009, outcome evaluation activities related to clinic efficiency strategies continued as the National Training Priority. During FY 2010, National Training Priority resources will be dedicated to continuation of regional activities related to clinic efficiency and evaluation of impact and outcomes, as well as participation in development of a national compendium describing these efforts, summarizing regional data, and identifying benchmarks and best practices. Additional guidance will be provided to Regional Offices to communicate to training grantees related to proposals and reporting expectations for the national training priority activities that will be supported with the FY 2010 National Training Priority supplement.

Office of Population Affairs Family Planning Program Guidelines for Family Planning Projects

The Program Guidelines for Project Grants for Family Planning Services was developed to assist grantees in providing family planning services as authorized by Title X of the Public Health Service Act. It interprets the law and regulations and provides an orientation to providing Title X funded family planning program services. These documents are available from the OPA website:

<http://www.hhs.gov/opa/familyplanning/policyplanningeval/programguidelines/index.html>

Title
Program Guidelines For Project Grants For Family Planning Services *Complete Document*
Program Guidelines for Project Grants for Family Planning Services (January 2001)
Attachment A: Title X Population Research and Voluntary Family Planning Programs (Title X Statute)
Attachment B: Title X Family Planning Program Regulations 42CFR59 Grants for Family Planning Services (10/01/2000)** <ul style="list-style-type: none"> • Subpart A - Project Grants for Family Planning Services • Subpart C - Grants for Family Planning Service Training
Attachment C: Sterilization of Persons in Federally Assisted Family Planning Projects 42CFR50 Policies of General Applicability <ul style="list-style-type: none"> • Subpart B - Sterilization of Persons in Federally Assisted Family Planning Projects
Attachment D: Regional Program Consultants and Regional Health <ul style="list-style-type: none"> • http://www.hhs.gov/opa/familyplanning/rcontacts/rcontacts_rpc.html • http://www.hhs.gov/opa/familyplanning/rcontacts/rcontacts_rha.html

**This document incorporates changes as published in the Federal Register on 07-03-2000. See the following Federal Register notices regarding the specific changes to the Title X Family Planning Regulations:

- Final Rules: Standards of Compliance for Abortion-Related Services in Family Planning Services Projects [[pdf](#)] [[html](#)]
- Final Rules Correction: Standards of Compliance for Abortion-Related Services in Family Planning Services Projects (published 08-10-2000) [[pdf](#)] [[html](#)]
- Notice: Provision of Abortion-Related Services in Family Planning Services Projects [[pdf](#)] [[html](#)]

Office of Population Affairs Title X Program Instruction Series

The following website provides a complete list of OPA-Family Planning Program Instruction Series memoranda. Copies can be downloaded from the website and are available below this table.

<http://www.hhs.gov/opa/familyplanning/toolsdocs/xinstruction.html>

Series	Title	Date
OPA 09-02	Provision of 2009 H1N1 Vaccination in Title X Family Planning Projects	10-09-2009
OPA 09-01	Clinical Services in Title X Family Planning Clinics - Consistency with Current Practice Recommendations	04-28-2009
OPA 08-1	Verification of Income for Title X Clients	09-23-2008
OPA 06-01	Compliance with State Reporting Laws	06-05-2006
OPA 05-03	Full and Open Competition for Title X Funds; Review of Applications for Title X Family Planning Grant Funds	10-17-2005
OPA 05-02	Administrative Policies	10-17-2005
OPA 05-01	Updated Safety Information for Depo-Provera Contraceptive Injection (medroxyprogesterone acetate injectable suspension)	02/10/2005
OPA 03-01	Screening for Cervical and Colorectal Cancer and Sexually Transmitted Diseases (STD)	10/29/2003

OPA 99-1	Compliance with State Reporting Laws	01/12/1999
OPA 98-1	Certifications for Encouraging Family Participation and Counseling to Minors on How to Resist Coercive Attempts to Engage In Sexual Activities	02/24/1998
OPA 97-2	Emergency Contraception	04/23/1997
OPA 97-1	Fees and Charges to Title X Low-Income Clients and Teenagers (Revised)	04/24/1997
OPA 93-1	Deferred Physical Examinations for Title X Clients	06/25/1993

*Please note that certain attachments may not be included due to copyright restrictions.

Office of Population Affairs Title X Program Instruction Series Memoranda

OPA Program Instruction Series, OPA 09-02

Department of Health & Human Services

Assistant Secretary for Health

Office of Public Health and Science
Office of Population Affairs
Washington, DC 20201

October 9, 2009

To: Regional Health Administrators, Regions I-X

From: Acting Director, Office of Population Affairs

Subject: Program Instruction Series, OPA 09-02:Provision of 2009 H1N1 Vaccination in Title X Family Planning Projects

As you may be aware, on July 24, 2009, Secretary of Health and Human Services Kathleen Sebelius renewed the April 26, 2009, declaration by then Acting Secretary Charles E. Johnson that a public health emergency exists nationwide involving novel influenza A (H1N1) virus (which will be referred to throughout this Program Instruction as 2009 H1N1). The purpose of this Program Instruction is to provide guidance to Title X Family Planning service grantees regarding the provision of the 2009 H1N1 vaccination.

CDC's Advisory Committee on Immunization Practices (ACIP) has determined that certain groups of the population are at relatively higher risk, and should receive the 2009 H1N1 vaccine as soon as it becomes available. These target groups include pregnant women, people who live with or care for children younger than 6 months of age, healthcare and emergency medical services personnel, persons between the ages of 6 months and 24 years old, and people ages 25 through 64 year of age who are at higher risk for 2009 H1N1 because of chronic health disorders or compromised immune systems. Vaccination efforts are designed to help reduce the impact and spread of 2009 H1N1.

Title X providers are encouraged, but not required, to make the 2009 H1N1 vaccine available to Title X healthcare personnel as well as to clients within Title X clinics, and may choose to provide the vaccine either as part of the Title X project, or outside of the Title X project. When the 2009 H1N1 vaccine is provided as part of the Title X project, all Title X regulations must be followed (e.g., confidentiality, schedule of discounts, nondiscrimination, etc.). In addition, grantees should be aware of other State and/or Federal requirements regarding provision of the vaccine.

Title X providers that provide the 2009 H1N1 vaccine, but not as part of the Title X project, must account for those services and the corresponding charges (e.g., staff time, etc.) separate and distinct from the Title X project.

Healthcare personnel within the Title X service system are at high risk for exposure to 2009 H1N1, and providing them with the vaccine will help to prevent the spread of H1N1 to uninfected co-workers and clinic patients. Also, among the target groups for the vaccine are pregnant women and persons between the ages of 6 months and 24 years. As documented on the most recent Family Planning Annual Report (2007 FPAR), more than half (55%) of clients who receive services in Title X-funded family planning clinics are 24 years of age or younger. Pregnant women are a priority group for receiving the 2009 H1N1 vaccine, and although prenatal services are not within the scope of Title X, pregnancy testing and early pregnancy education and counseling are among the most commonly provided services in family planning clinics. Since it may be several weeks before the pregnant woman is seen for a first prenatal visit, pregnancy testing and diagnosis at a family planning clinic is an important opportunity to provide the 2009 H1N1 vaccine before a pregnant woman may be exposed to the virus.

In addition, Title X regulations at 42 CFR Part 59, Subpart A, § 59.5 (b)(2) ("What requirements must be met by a family planning project?") stipulate that projects must, unless the Secretary determines that the project has established good cause for its omission, "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” (emphasis added). Provision of the 2009 H1N1 vaccine by Title X clinics may encourage more individuals to come to a clinic, where they could be provided with family planning services as well as the vaccine. However, note that only clients that meet the FPAR definition of a “family planning user” and receive a family planning service in addition to the 2009 H1N1 vaccine may be counted on the FPAR.

Grantees that are interested in providing the vaccine should visit the following CDC websites: http://www.cdc.gov/H1N1flu/vaccination/clinicians_qa.htm and <http://www.cdc.gov/h1n1flu/vaccination/statelocal/>. As explained in the CDC websites above, the Federal Government is the only source for the vaccine, and it is being allocated to states based on population size. The Federal Government is purchasing vaccine and supplies (syringes, alcohol swabs, sharps containers, and vaccine record cards) and distributing these at no cost to healthcare providers who make agreements with State and local public health authorities to provide the H1N1 vaccine. States are responsible for identifying providers who will participate in administration of the H1N1 vaccine, and State and local health departments are responsible for directing the flow of vaccine to providers within States. A number of States have already established registries for providers to request 2009 H1N1 vaccine allocations, and Family Planning service grantees are encouraged to work closely with their States to make their needs known and register with their State public health authorities to receive the vaccine. For more information, grantees should contact the State public health department website or the CDC 2009 H1N1 website at <http://www.cdc.gov/H1N1flu/>.

While the vaccine is free, providers are able to charge a fee for the administration of the vaccine, which is an allowable cost within the Title X program. Medicaid and the Children’s Health Insurance Program (CHIP) will pay the administration fee for those clients that are eligible under these programs. For additional information, grantees should be directed to <http://www.cms.hhs.gov/smdl/downloads/SHO092409.pdf>.

Grantees that are interested in providing the 2009 H1N1 vaccine should be aware of the Public Readiness and Emergency Preparedness (PREP) Act which provides broad liability protections, including protections associated with the administration of covered countermeasures, such as the 2009 H1N1 vaccine. Liability protections were put in place to ensure that an adequate supply of countermeasures was produced and made available in the U.S. by vaccine manufacturers. The PREP Act also provides a mechanism to compensate eligible individuals for covered injuries from a covered countermeasure. For an overview of these protections, see www.hhs.gov/disasters/emergency/manmadedisasters/bioterrorism/medication-vaccine-qa.html.

For purposes of consistency, please direct all grantee questions regarding provision of the 2009 H1N1 vaccine to Central OPA.

Evelyn M. Kappeler
Acting Director, Office of Population Affairs

cc: Regional Program Consultants for Family Planning

OPA Program Instruction Series, OPA 09-01

Department of Health & Human Services

Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Office of Population Affairs
Washington, DC 20201

Date: April 28, 2009

To: Regional Health Administrators, Regions I-X

From: Acting Director, Office of Population Affairs

Subject: **OPA Program Instruction Series, OPA 09-01: Clinical Services in Title X
Family Planning Clinics - Consistency with Current Practice Recommendations**

The purpose of this Program Instruction is to provide guidance to Title X family planning services providers regarding the delivery of clinical services that are consistent with nationally recognized standards of care. A copy of this memorandum should be provided to all Title X grantees in your region.

The “Program Guidelines for Project Grants for Family Planning Services” (Title X Program Guidelines) were last revised and distributed to all Title X family planning services providers in grantees in understanding the family planning services grant program authorized by Title X of the Public Health Service Act (42 U.S.C. 300, et seq.), and to clarify the requirements of the program, as set out in the Title X family planning services regulations (42 CFR part 59, subpart A).

Since the issuance of the Title X Program Guidelines in 2001, based upon current, science-based evidence, there have been a number of changes or modifications to the recommendations or standards of practice for quality clinical services. Many of these changes impact clinical practice the recommendations set out in the Title X Program Guidelines. This Program Instruction is being issued to provide clarification and eliminate grantee confusion regarding any inconsistencies that may exist between current practice recommendations and the Title X Program Guidelines – there are inconsistencies, Title X providers should provide care that is consistent with current nationally recognized standards.

Therefore, in order for Title X grantees to continue to provide services that are of high quality and in compliance with Title X requirements, Title X providers, in consultation with agency medical directors, should develop written clinical protocols that are consistent with the most current nationally recognized standards of care. These protocols should be reviewed on a regular basis, and modified as needed. Agency protocols should include a reference to the specific nationally recognized standard(s) of care, recommendations(s), and/or practice standards, as well

as the date of protocol review and modification. Clinical protocols should continue to incorporate considerations of individual client characteristics, including the use of specific contraceptive methods, in addition to current standards for care.

Agency policies and procedures should indicate the frequency of protocol review. In addition, agencies should ensure that training be provided to clinical staff on nationally recognized practice standards and any changes to protocols along with quality improvement/quality assurance procedures. Clinical practice should adhere to written protocols based on identified national practice standards.

Clinical protocols should reflect the current recommendations for practice or standards of care established by health agencies or professional organizations, such as the following:

- American Cancer Society: <http://www.cancer.org>
- Agency for Health Care Policy and Research, U.S. Preventive Services Task Force: <http://www.ahrq.gov/clinic/uspstfix.htm>
- Centers for Disease Control and Prevention: <http://www.cdc.gov>
- American College of Obstetricians and Gynecologists: <http://www.acog.org>
- North American Society of Pediatric and Adolescent Gynecology: <http://www.naspag.org>
- American Society for Colposcopy and Cervical Pathology: <http://www.ascep.org>
- Agency for Healthcare Research and Quality: <http://www.ahrq.gov/clinic/cpgsix.htm>
- Partners in Information Access for Public Health Resources (Department of Health and Human Services): <http://phpartners.org/guide.html>
- AIDSinfo (Department of Health and Human Services): <http://www.aidsinfo.nih.gov/>
- National Heart Lung and Blood Institute (Department of Health and Human Services): <http://www.nhlbi.nih.gov/health/indexpro.htm>

Title X grantees are responsible for ensuring that all sub-recipient agencies maintain and use written clinical protocols that are consistent with nationally recognized practice standards. Regional offices should continue to review and monitor clinical protocols of Title X grantees, delegate agencies, and clinics, particularly during site visits and comprehensive program reviews.

If you have questions, please contact Susan Moskosky, Director, Office of Family Planning on (240) 453-2888.

Evelyn M. Kappeler
Acting Director, Office of Population Affairs
cc: Regional Program Consultants for Family Planning

OPA Program Instruction Series, OPA 08-1: Verification of Income for Title X Clients

Department of Health & Human Services

Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Office of Population Affairs
Washington, DC 20201

Date: September 23, 2008

To: Regional Health Administrators, Regions I - X

From: Acting Director, Office of Population Affairs

Subject: **OPA Program Instruction Series, OPA 08-1: Verification of Income for Title X Clients**

The purpose of this Program Instruction is to provide guidance to Title X grantees regarding the extent of their discretion in verifying the family income of clients seeking services in Title X-funded clinics. Within the parameters set out by the Title X statute, regulations and Program Guidelines, 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. Written policies should be developed by grantees regarding verifying family income within the Title X project. Policies should be developed that embrace the mission and purpose of Title X, including that priority for services is to be given to persons from low-income families (as defined in the Title X regulations at 42 CFR 59.2), and that the inability to pay must not be a barrier to the receipt of services.

Grantee policies and procedures for documentation of family income will be reviewed by the Regional Health Administrator, and procedures for implementing will be monitored during site visits and comprehensive program reviews. In addition, policies and procedures for income verification should be reviewed and approved by the governing authority or board of the grantee organization.

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 client's self report.

This Program Instruction is being issued in response to recent questions for clarification regarding methods which may be applied to verify family income, and to ensure that Title X resources are properly directed. All requirements regarding fees and charges set out in the Title X statute and regulations, as well as all guidance regarding fees and charges provided in the Title X Program Guidelines and previously-issued Program Instructions remain in effect.

Evelyn M. Kappeler
Acting Director, Office of Population Affairs

cc: Regional Program Consultants, Regions I-X U.S. Public Health Services

OPA Program Instruction Series, OPA 06-01: Compliance with State Reporting Laws - Reminder Notification (Revised)

Department of Health & Human Services

Office of Population Affairs

Memorandum

Date: June 5, 2006

From: Deputy Assistant Secretary for Population Affairs

Subject: OPA Program Instruction Series, OPA 06-01: **Compliance with State Reporting Laws -Reminder Notification (Revised)**

To: Regional Health Administrators, Regions I-X

This memorandum serves as a reminder notification regarding the following longstanding provision governing the use of Title X funds, which is included as section 213 of the Fiscal Year 2006 HHS appropriations act (Pub. L. No. 109-149):

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.

Previously, on January 12, 1999, the Office of Population Affairs (OPA) issued OPA Program Instruction Series, OPA 99-1, "Compliance with State Reporting Laws." OPA 99-1, which is attached to this memorandum, remains in effect. A copy of this memorandum, as well as the attached OPA 99-1, should be provided to all Title X grantees in your region. Title X grantees should be reminded that they are responsible for ensuring that all sub-recipients receive the information contained in this memorandum and OPA 99-1, and for ensuring that policies and procedures are in place to appropriately address notification or reporting of child abuse, child molestation, sexual abuse, rape, or incest, or any other form of domestic violence, as required by applicable State law.

Regional Offices are responsible for periodic review of Title X grantees to ensure compliance with the provisions of the appropriations language as they relate to applicable State law. The Regional Office must undertake immediate steps to address any issues related to adherence to established policies and procedures. Outcome of all Regional Office reviews, including any corrective action, must be included in the official grant file for the applicable Title X grantee. Title X grantees are responsible for conducting periodic reviews of sub-recipient agencies for compliance, and must undertake immediate steps to address issues related to adherence to

established policies and procedures. Grantees must maintain documentation of reviews, including outcomes, and any corrective action steps necessary.

Title X providers are encouraged to work with appropriate local authorities to ensure that policies and procedures are compliant with applicable State laws. In addition, providers are encouraged to establish formal referral relationships and community collaborations with other local health care providers who may also have reporting obligations under State law, law enforcement officials, child protective services, social service experts and others in order to explore how to best address the issues involved.

Title X grantees are encouraged to ensure that periodic training regarding the provisions of this mandate is available to project staff.

Questions relating to the requirements addressed in this memorandum and/or OPA 99-1 should be addressed to the appropriate Office of Family Planning Regional Office, or the Office of Family Planning/Office of Population Affairs, as applicable.

/s/

Alma L. Golden, MD, FAAP

Attachment: OPA Program Instruction Series, OPA 99-1: Compliance with State Reporting Laws

OPA Program Instruction Series, OPA 05-03: Full and Open Competition for Title X Funds; Review of Applications for Title X Family Planning Grant Funds

**Department of Health and Human Services
Office of Public Health & Science
Office of Population Affairs**

Memorandum

Date: October 17, 2005

From: Deputy Assistant Secretary for Population Affairs

Subject: OPA Program Instruction Series, OPA 05-03: **Full and Open Competition for Title X Funds; Review of Applications for Title X Family Planning Grant Funds**

To: Regional Health Administrators, Regions I-X

I. Full and Open Competition for Title X Funds

It is important that we ensure full and open competition for all available funds for Title X family planning grants. If, at any time, the Regional Office becomes aware of an area or population in need of family planning services, they are

encouraged to make funds available for competition to serve the identified area or population. Federal family planning staff should provide appropriate technical assistance to potential applicants that includes explanation of program requirements as published in the program announcement. Appropriate input should be sought from the Office of Public Health and Science (OPHS) Office of Grants Management (OGM) staff regarding application and grants requirements.

II. Objective Review Policies

The Office of Public Health and Science follows the Awarding Agency Grants Administration Manual (AAGAM) and Grants Policy Directives (GPDs) as they apply to the objective review of grant applications. AAGAM Chapter 2.04.104.C Objective Review of Grants Applications governs the mechanism by which all applications must be reviewed, and should be referenced in organizing objective review procedures. These requirements are intended to ensure that the process for selecting applicants for funding is fair, equitable, "above board," and can withstand scrutiny; and that only those applications that offer the greatest potential for furthering the program purpose are selected for funding. Objective reviews will be based on this AAGAM chapter, and will adhere to, but not be limited to the following policies:

- Any circumstance that might introduce any conflict of interest, or appearance thereof, prejudices, biases, or pre-dispositions into the process must be avoided. Independent reviewers are required to complete both a Conflict of Interest Statement and a Confidentiality Statement;
- Applications must undergo objective review by a minimum of three qualified independent reviewers (termed the Objective Review Committee or ORC). Documentation of the review outcome must be signed by all reviewers;
- Independent reviewers should be selected from a roster of individuals with knowledge in the field under review, and must be rotated on a regular basis. The reviewer roster must document the date the reviewer was placed on the roster, and dates of participation in reviews. No reviewer shall participate as a reviewer for the same program office for more than three consecutive years;
- Each application will be ranked based on predetermined ranking criteria using only the criteria published in the program announcement and available to all potential applicants;
- The ORC will rank all applications in order by score. The approving official, as noted in the program announcement, is responsible for reviewing the application ranking document and determining which applications will be approved for funding. The approving official may consider

additional, objective information (e.g., published program priorities, published preference of special consideration, reviews of the Grants Management Office and Program Official) in determining approval for funding of a particular application. Should the application's position in the list of applications approved for funding be different than its position in the ranking list, a statement of the reasons for the difference that influenced the judgment of the approving official must be provided. This should include a justification for funding of the particular application.

III. Award of Supplemental Funds to Existing Grantees

Supplemental funds must be distributed to existing grantees based on a competitive process. Regional Offices should develop and publish an announcement of availability of supplemental funds that includes eligible entities, total funds available, total number of awards anticipated, amount or range of individual awards, purpose of supplemental awards, and criteria for review of applications.

In addition to review by the awarding Regional Office family planning program staff, competing supplemental requests should be reviewed by a party or parties outside the awarding Regional Office family planning program and decision-making authority. Documentation of review results, including reviewer signatures, must be compiled and forwarded to the OPHS Office of Grants Management for inclusion in the official grant file.

Alma L. Golden, MD, FAAP
Deputy Assistant Secretary
for Population Affairs

Attachment:

1) "Objective Review Process Policy," (April 28, 2005, memorandum from John Jarman, OPHS Executive Officer).

OPA Program Instruction Series, OPA 05-02:Administrative Policies

**Department of Health & Human Services
Office of Public Health & Science
Office of Population Affairs**

Memorandum

Date: October 17, 2005

From: Deputy Assistant Secretary for Population Affairs

Subject: OPA Program Instruction Series, OPA 05-02: **Administrative Policies**
To: Regional Health Administrators, Regions I-X

This memorandum serves as official notification of current administrative policies of the Office of Family Planning, Office of Population Affairs. The intent of these policies is to maintain effective program management and documentation of program activities as they relate to program responsibilities in administration of project grants.

I. Rescission of Grants Process Policy Notices (GPPNs)

In March 2005, the Office of Public Health and Science officially rescinded the GPPNs previously used to guide administration of family planning grants. The official references for grants management operations are the Awarding Agency Grants Administration Manual (AAGAM) and the Grants Policy Directives (GPDs). Information pertaining to the AAGAM Chapters, transmittals, and GPDs can be found at <http://intranet.grantsinfo.hhs.gov>. (See Attachment #1)

II. Official Grant File

All official grantee actions must be included in the official grant file maintained in the Office of Public Health and Science (OPHS) Office of Grants Management (OGM). This includes but is not limited to: site visit reports; program review reports; corrective action plans; grantee technical assistance and/or training reports; and any correspondence between Federal family planning staff and the grantee agency. In addition, all oral communication with grantees about pertinent issues surrounding grant activities must be documented. This record should include the following:

Date of Initiating Communication
Date of Response or Continuing Communication
Regional Office
Program Staff Person(s)
Grantee Name
Grant Number
Grantee Staff Person(s) Involved
Topic or Issue
Type of contact (telephone conversation; in person discussion, meeting, etc.)
Summary of the Discussion

A recommended form for documenting this information is attached. Family planning program staff should respond to telephone calls, emails, and other inquiries within 48 business hours.

It is incumbent on Federal family planning program staff to forward the information mentioned

in the paragraph above to the OPHS OGM at least quarterly for inclusion in the Official Grant File. (See Attachment #2)

III. Response to Request Grantee Requests Requiring Prior Approval

Requests for grantee-initiated requests requiring prior approval must be submitted either electronically or in writing to the OPHS Office of Grants Management. After concurrence with the family planning program office (as appropriate), the OPHS Office of Grants Management will respond to requests that result in the issuance of a Notice of Grant Award or official correspondence within 30 days from the date the request was received.

In the event that the request is still under consideration, the grantee shall be informed of the delay within the 30 day time frame. Examples of applicable requests include, but are not limited to, budget revisions, removal of special conditions, and program plan revisions. Grantees are expected to obtain advance approval before incurring costs or undertaking activities that require awarding office prior approval. All requests and responses must be included in the official grant file. (See Attachment #3)

IV. Financial Status Reports

Reviewing Financial Status reports is the responsibility of the OPHS Office of Grants Management. Financial Status Reports (FSR) must be submitted by grantees to the OPHS Office of Grants Management within 90 days of the end of the grantee budget period. The OPHS Office of Grants Management will notify grantees in writing within 30 days of the time the FSR becomes delinquent that failure to submit the required FSR within 30 days from the date of the letter may result in draw down restrictions or denial of future funding. (See Attachment #4)

Alma L. Golden, MD, FAAP
Deputy Assistant Secretary
for Population Affairs

Attachments:

- 1) "Notice to Formally Rescind Grant Process Policy Notices," (April 28, 2005, memorandum from John Jarman, OPHS Executive Officer).
- 2) OPHS Contact Report (sample).
- 3) "Compliance to GPD Part 3.05 (D)2 Process Requirements," (April 28, 2005, memorandum from John Jarman, OPHS Executive Officer).
- 4) "Compliance to GPD Part 1.04.104-3 (C)2q Grants Management Officer Responsibilities,

Review of Financial Status Reports," (March 4, 2005, memorandum from Karen Campbell, Director, OPHS Office of Grants Management).

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

Department of Health & Human Services

Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Washington, DC 20201

Date: February 10, 2005

From: Deputy Assistant Secretary for Population Affairs

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

To: Regional Health Administrators, Regions I-X

On November 17, 2004, the U.S. Food and Drug Administration (FDA) announced that a "black box" warning would be added to the labeling of Depo-Provera Contraceptive Injection. This warning highlights that prolonged use of Depo-Provera may result in significant loss of bone density. The loss of bone density is greater the longer the drug is administered and may not be completely reversible after discontinuation of the drug. The "black box" warning indicates that Depo-Provera Contraceptive Injection should be used as a long-term birth control method (e.g., longer than two years) only if all other methods are inadequate. In addition, the warning states that it is unknown if the use of Depo-Provera Contraceptive Injection during adolescence or early adulthood will reduce peak bone mass and increase the risk of osteoporotic fracture in later life. On November 18, 2004, U.S. Pharmaceuticals, Pfizer Inc., the pharmaceutical company that manufactures Depo-Provera, issued letters to Healthcare Professionals and Healthcare Organization Leaders, informing them of the new "black box" warning, as well as other updated safety information included in the drug's labeling (copies of these letters are attached).

Although the FDA has indicated that Depo-Provera remains a safe and effective contraceptive (see attached "FDA Talk Paper"), the "black box" warning was added to the drug's labeling to "ensure that physicians and patients have access to this important information." The addition of the "black box" warning came as a result of the FDA's and Pfizer's analysis of data from two separate studies that showed Depo-Provera's effect on bone density during prolonged use. One study began in 1994 and enrolled 540 women ages 25 to 38. The other study--which started in 1997 and will continue through 2006--enrolled approximately 400 girls ages 12 to 18 who were taking the drug and is examining ways to reverse bone mineral density loss. References for these

two studies are attached.

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

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

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

Alma L. Golden, M.D., F.A.A.P.

Attachments:

- 1) Depo-Provera Contraceptive Injection package insert, Revised November 2004.
- 2) "Dear Healthcare Professional Letter" and "Dear Healthcare Organization Leader Letter" from U.S. Pharmaceuticals Pfizer Inc, dated November 18, 2004.
- 3) FDA Talk Paper, November 17, 2004.
- 4) Requested Medical Information from Pfizer Inc., December 09, 2004. This information contains a summary of 29 studies and a review of 2 unpublished studies (includes references for the two studies cited in the Program Instruction).

cc: Regional Program Consultants Regions I-X

OPA Program Instruction Series, OPA 03-01: Screening for Cervical and Colorectal Cancer and Sexually Transmitted Diseases (STD)

Department of Health & Human Services

Office of the Secretary

Assistant Secretary for Health

Office of Public Health and Science

Washington, DC 20201

DATE: October 29, 2003

TO: Regional Health Administrators, Regions I-X
FROM: Deputy Assistant Secretary for Population Affairs
SUBJECT: OPA Program Instruction Series, OPA 03-01: **Screening for Cervical and Colorectal Cancer and Sexually Transmitted Diseases (STD)**

In January 2001, “Program Guidelines for Project Grants for Family Planning Services” (Title X Program Guidelines) were revised and distributed to all Title X providers. The purpose of the Title X Program Guidelines is to assist current and prospective grantees in understanding and utilizing the family planning services grants program authorized by Title X of the Public Health Service Act, 42 U.S.C. 300, et seq.

Currently, Title X Program Guidelines, Section 8.3, specify that the initial physical examination for females must include a Pap smear. In that same section, the Guidelines specify that colorectal cancer screening must be provided for individuals over the age of forty, both males and females.

Since 2001, a number of professional organizations that establish national standards of care have published revised recommendations for cervical and colorectal cancer screening based on current evidence. In particular, the American College of Obstetricians and Gynecologists (ACOG), the American Cancer Society (ACS), and the U.S. Preventive Services Task Force (USPSTF) are recognized groups that have established revised recommendations for standards of care in one or both of these areas.

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

It is incumbent on grantee agencies to ensure that delegate agencies and clinics have and use protocols that meet these standards. Clinical protocols of Title X grantees, delegates, and clinics will continue to be monitored by the regional office, particularly during site visits and comprehensive program reviews

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

Regardless of whether or not an annual Pap test is conducted, clinicians should screen

young, sexually active women (ages 15 - 24) at least annually for chlamydia. In high prevalence areas, gonorrhea screening should also be part of the routine annual STD screening tests for young, sexually active women. Clients who are symptomatic of other STDs should be screened according to the current Centers for Disease Control and Prevention STD Treatment Guidelines (<http://www.cdc.gov/std/treatment>). In addition to these screening tests, providers should inquire about sexual behaviors, assess ongoing risk for STDs, and counsel about risk avoidance and risk reduction.

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

Sincerely,

Alma L. Golden, M.D., F.A.A.P.
Deputy Assistant Secretary
for Population Affairs

References:

- 1) American Cancer Society: Guideline for the Early Detection of Cervical Neoplasia and Cancer, Saslow et al.; CA A Cancer Journal for Clinicians, Vol. 52:6, November/December 2002.
- 2) ACOG Practice Bulletin Number 45, Cervical Cytology Screening, August 2003.
- 3) U.S. Preventive Services Task Force (USPSTF-January 2003): Cervical Cancer - Screening.
- 4) U.S. Preventive Services Task Force (USPSTF- July 2002): Colorectal Cancer -Screening.

cc: Regional Program Consultants, Regions I - X

OPA Program Instruction Series, OPA 99-1: Compliance with State Reporting Laws

Department of Health & Human Services Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Office of Population Affairs
Washington, D.C. 20201

Date: January 12, 1999
From: Deputy Assistant Secretary for Population Affairs
Subject: OPA Program Instruction Series, OPA 99-1: **Compliance with State Reporting Laws**
To: Regional Health Administrators, Regions I-X

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

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

This memorandum is intended to serve as a formal notice to the regional offices, as well as Title X grantees, concerning compliance with State reporting laws. A copy of this memorandum should be provided to all

Title X grantees in your region, and Title X providers should refer to this memorandum as needed, if questions in this area arise.

The language of section 219 means that Title X providers must report such incidents to the appropriate State authority in accordance with requirements imposed by State laws. The reporting and notification requirements referenced in section 219 concern State laws; the authority to enforce compliance with such laws lies with the States. It is therefore important that grantees review and be familiar with the relevant reporting requirements in their individual State. Because State laws vary, it is not possible for this office to provide more specific guidance as to the requirements of particular States' laws; grantees are urged to consult with their own attorneys for specific guidance.

Identified instances of child abuse, child molestation, sexual abuse, rape, or incest present serious medical and psychological situations for patients and their families. Findings of such instances coming within the applicable State law should be documented in the medical record and reported as required by the applicable State requirements. The Office of Population Affairs encourages efforts to augment existing training programs for Title X providers to ensure optimal medical assistance in such situations. Grantees should fully understand their obligations under State law related to reporting when such acts or actions are disclosed, and they should review current protocols for responding to such reports. We also encourage enhanced counseling and education efforts targeted to the unique needs of adolescents. Title X providers are encouraged to continue to work at the local level in an interdisciplinary manner with other local health care providers who may also have reporting obligations under State law, law enforcement officials, child protective services, social service experts and others in order to explore how best to respond to these situations. To accomplish this, regional offices and Title X grantees are encouraged to utilize resources available through the regional training centers and the technical assistance contractor, as well as other available resources.

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

/s/

Denese Shervington, M.D., M.P.H.

cc: Regional Program Consultants, Regions I-X

OPA Program Instruction Series, OPA 98-1: Certifications for Encouraging Family Participation and Counseling to Minors on How to Resist Coercive Attempts to Engage In Sexual Activities

**Department of Health & Human Services
Office of the Secretary**

Assistant Secretary for Health
Office of Public Health and Science
Office of Population Affairs
Washington, D.C. 20201

Date: February 24, 1998
From: Acting Deputy Assistant Secretary for Population Affairs
Subject: OPA Program Instruction Series, OPA 98-1: **Certifications for Encouraging Family Participation and Counseling to Minors on How to Resist Coercive Attempts to Engage In Sexual Activities**
To: Regional Health Administrators, Regions I-X

The fiscal year 1998 appropriations bill for the Departments of Labor/HHS and Education (P.L. 105-78) contains language governing the use of Title X funds. Specifically, the language states:

"None of the funds appropriated in the Act may be made available to any entity under Title X of the Public Health Service Act unless the applicant for the award certifies to the Secretary 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."

To implement this requirement, each Title X grantee is required to have on file with the Office of Grants Management, an updated Title X Certification of Compliance certifying that the grantee: (1) encourages family participation in the decision of minors to seek family planning services, and (2) provides counseling to minors on how to resist coercive attempts to engage in sexual activities. Attached for your information is a copy of the revised certification. The Office of Grants Management will contact each Title X grantee to obtain the necessary signatures. Compliance with the signed certification will continue to be an item reviewed by regional office staff as part of ongoing program oversight activities and during periodic on-site program reviews.

Clinic staff should be made aware of the new certification requirement. Toward that end, we encourage sharing of this memorandum with delegate agencies and service providers. We would also like to take this opportunity to encourage grantees to review existing policies to assure that service, counseling and outreach provisions reflect the concerns contained in the appropriations language. As is always the case, it is important that client records include documentation of all counseling and information provided. We also encourage grantees to assure that appropriate training is available, including utilization of training available through the Title X training

grantees, as need be.

If you have any questions, please contact Sam Taylor, Acting Director of the Office of Family Planning at (301) 594-4008.

/s/

Thomas C. Kring
Acting Deputy Assistant Secretary
for Population Affairs

Attachment

cc: Regional Program Consultants Regions I-X

OPA Program Instruction Series, OPA 97-2: Emergency Contraception

Department of Health & Human Services

Public Health Service

Memorandum

Date: April 23, 1997
From: Acting Deputy Assistant Secretary for Population Affairs
Subject: OPA Program Instruction Series, OPA 97-2: **Emergency Contraception**
To: Regional Health Administrators Regions I-X

On February 25, 1997, the Food and Drug Administration (FDA) issued a notice in the Federal Register announcing that certain regimens of combined oral contraceptives are safe and effective for postcoital emergency contraception when initiated within 72 hours after unprotected intercourse. This action is based on the FDA's review of the published literature concerning postcoital use of currently available oral contraceptives, knowledge of the safety of oral contraceptives as currently labeled, and on the unanimous conclusion of the FDA Advisory Committee on Reproductive Health Drugs, which met on June 28, 1996, to consider the safety and efficacy of this contraceptive option.

According to Section 1001(a) of the Title X statute and Section 59.5(a)(1) of the Title X regulations, family planning projects must offer a broad range of acceptable and effective family planning methods. In considering the range of methods that will be offered in a special family planning project, Title X grantees should consider the availability of emergency contraception the same as any other method which has been established as safe and effective. As with all other prescriptive contraceptive methods, emergency contraception must be prescribed in accordance with medically accepted protocol, and in accordance with a sliding fee scale that is based on the actual cost of providing the service. Resources attached may be helpful in developing protocols for providing emergency contraception.

/s/

Thomas Kring

Attachments (3)

- (1) ACOG Practice Patterns on Emergency Oral Contraception, Number 2, October 1996.
- (2) Federal Register, Vol. 62, No. 37, Tuesday, February 25, 1997, "Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception."
- (3) Gynetics Announcement of Intent to Market "Yuzpe Method" of Emergency Contraception in 1998.

OPA Program Instruction Series, OPA 97-1: Fees and Charges to Title X Low-Income Clients and Teenagers (Revised)

Department of Health & Human Services

Public Health Service

Memorandum

Date: April 24, 1997
From: Acting Deputy Assistant Secretary for Population Affairs
Subject: OPA Program Instruction Series, OPA 97-1: **Fees and Charges to Title X Low-Income Clients and Teenagers (Revised)**
To: Regional Health Administrators Regions I-X

This memorandum superseded OPA Program Instruction Series OPA 86-5, "Fees and Charges to Title X Low-Income Clients and Teenagers."

In response to recent questions, this memorandum provides guidance on Title X policy regarding fees for services, in particular the process for charging fees to low income clients and unemancipated minors. Applicable regulations and guidelines remain unchanged.

Projects should be aware that Title X regulations require them to :

- not charge fees to clients from low-income families;
- make all reasonable efforts to obtain third party reimbursement for services; charge fees for services to all other clients, with a schedule of discounts based on ability to pay;
- design fee schedules to recover the reasonable cost of providing service; and
- not refuse services because of users' inability to pay.

It is important to note that in providing services, Title X projects must assure that priority is given to persons from low-income families. Low income families are those whose annual income is not above 100 percent of the Poverty Income Guidelines issued by the Department. Clients

from low income families may not be charged for service, including the provision of contraceptives or related medical services.

Clients from families with annual incomes between 100 and 250 percent of the Income Poverty Guidelines must be charged for services. Charges for services must be in accordance with a fee schedule, which has discounts based on ability to pay. In addition, clients from families with incomes above 250 percent of the Income Poverty Guidelines must be charged a full fee to recover the reasonable cost of providing services.

When a client is unable to pay, for good cause (as determined by the project director), for family planning services the fee may be waived. The project must determine, as accurately as possible, the client's ability to pay based upon family income. This determination and notice of any applicable waiver should be made prior to the delivery of services and must be conducted each time a client requests services.

When considering charges to minors for services, several conditions must be taken into account. If the minor is unemancipated and confidentiality of services is not a concern, the family's income must be considered in determining the charge for the services. When a minor requests confidential services, without the involvement of a principal family member, charges for services must be based on the minor's income.

Income actually available to the minor, such as wages from part-time employment, stipends and allowances paid directly to the minor, should be considered in determining the minor's ability to pay for services. Those services normally provided by parents/guardians, e.g., food, shelter, transportation, tuition, etc., should not be included in determining a minor's income.

Under certain circumstances where confidentiality is restricted to limited members of the family, e.g., one parent is aware of the minor seeking services but the other is not because of disagreement regarding the minor's right to receive family planning services, the charges shall be based on the minor's income if the minor's confidentiality would be breached in seeking the full charge.

It is not allowable to have a general policy of no fee or flat fees for the provision of services to minors. Nor is it allowable to have a schedule of fees for minors that are different from other populations receiving family planning services.

Projects must seek payment from third parties who are authorized or legally obligated to pay for services unless, in doing so, patient confidentiality would be compromised. Also, since discounts or waivers are only applicable to individual clients, billing statements to third parties should show total charges without any applicable discount or waiver.

I appreciate your continued cooperation in assuring that grantees are in compliance with Title X requirements, and I hope this memorandum provides additional clarification on this matter.

/s/

Thomas Kring

OPA Program Instruction Series, OPA 93-1: Deferred Physical Examinations for Title X Clients

Department of Health & Human Services
Public Health Service
Memorandum

Date: June 25, 1993
From: Acting Deputy Assistant Secretary for Population Affairs
Subject: OPA Program Instruction Series, OPA 93-1: **Deferred Physical Examinations for Title X Clients**
To: Regional Health Administrators Regions I-X

The issue of deferral of physical examination for clients beginning oral contraceptives was recently addressed by the Food and Drug Administration's (FDA) Fertility and Maternal Health Drugs Advisory Committee. Current FDA labeling criteria for oral contraceptives require a complete medical history and physical examination prior to initiation or recommencement of oral contraceptives. The Committee recommended to the FDA that oral contraceptive labeling be revised to permit the provision of oral contraceptives prior to a physical examination, and it is likely that this will be approved by FDA in the near future.

Title X has traditionally taken the position that grantees should conform to current FDA policy as expressed in its labeling standards for contraceptives. OPA continues to be of the view that this policy is appropriate and is, as a general practice, reluctant to waive Guideline criteria which involve conformance with requirements under FDA labeling instructions.

However, it is highly probable that prescription of oral contraceptives prior to physical examination will be regularly allowable in Title X projects in the near future, as it appears likely that the FDA will change its labeling instructions in this regard. The evolution of standards of practice in this area, and the strong support of the FDA Advisory Committee and national reproductive health organizations during the discussion of this issue point to the resultant probability that FDA will indeed change its requirements.

Therefore, until FDA makes a final decision on this issue, the Office of Population Affairs is providing authorization to Regional Health Administrators to waive current policy on the requirement for a physical examination on a case-by-case basis. To ensure patient safety, no request for waiver of current standards should be approved unless the following requirements are met:

-- Physical examination and any blood work should not be delayed for more than 3 months after the initial visit. Substantial justification is warranted for projects that propose as a general practice to defer the examination beyond the 3-month period. In no case may deferral of the physical examination be extended beyond a maximum of 6 months.

-- Counseling regarding contraceptive choice, STD protection and the need for a physical examination (after deferral) must be provided to each client at the initial visit.

-- Written informed consent and medical protocols for delayed examinations must be developed and approved by the project's medical committee.

Informed Consent:

-- Clients must sign an informed consent form describing the special process for the delayed examination and explaining the patient package insert information accompanying oral contraceptives.

Medical Protocols must:

-- Outline what medical, educational and counseling services will be provided at each point leading up to the examination (i.e., initial visit, follow-up counseling, telephone follow-up, visit for physical examination and blood work).

-- Provide for verification through a highly sensitive pregnancy test that the client is not pregnant.

-- Provide that the project will obtain at the initial visit a comprehensive medical history (including menstrual history, pregnancy history, contraceptive history, and sexual history) which demonstrates that the client is healthy and has no contraindications for oral contraceptives.

-- Provide that the project will ensure that clients have no symptoms or reported contact with sexually transmitted diseases (STDs); are provided with information on oral contraceptives and condoms for STD prevention; and have a negative breast examination for women over age 30.

-- Provide that the project will ensure that any medical problems associated with the delayed examinations must be documented.

If you have any questions, please contact me or Dr. Barbara Tausey, OPA Chief Medical Officer.

Jerry Bennett

FPAR: Family Planning Annual Reporting Requirements and Instructions

Family Planning Annual Report

The Family Planning Annual Report (FPAR) is one of the reporting requirement that must be submitted from the Delegate Agencies to Michigan Department of Community Health on a quarterly, Michigan Department of Community Health must submit the consolidated FPAR to The Office of Population Affairs on an annual basis. The following is a summary of the report made available at the following OPA website:

<http://www.hhs.gov/opa/familyplanning/fpar/index.html>

Summary

This annual reporting requirement is for family planning services delivery projects authorized and funded under the Population Research and Voluntary Family Planning Programs (Section 1001 of 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 (45 Code of Federal Regulations [CFR] Part 742 and 45 CFR Part 923). FPAR data are presented in summary form, which protects the confidentiality of individuals who receive Title X-funded services (42 CFR Part 59).

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. First, FPAR data are used to monitor compliance with statutory requirements, regulations, and operational guidance set forth in the *Program Guidelines for Project Grants for Family Planning Services ("Program Guidelines")*, which include:

- Monitoring compliance with legislative mandates, such as giving priority in the provision of services to low-income persons [Section 1006(c) of Title X of the Public Health Service Act, 42 USC 300], and
- Ensuring that Title X grantees and their subcontractors provide a broad range of family planning methods and services [Section 1001(a) of Title X of the Public Health Service Act, 42 USC 300].

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 human immunodeficiency virus (HIV) testing at Title X-funded clinics.

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 comparable and relevant program data to answer questions about the characteristics of the population served by Title X projects, utilization of services offered, composition of revenues, and program impact. FPAR data are the basis for objective grant reviews, program evaluation, and assessment of program technical needs.

This link will take you to the Family Planning Annual Report, Forms and Instructions, reissued in October, 2007 and provided by the Office of Population Affairs.

http://www.hhs.gov/opa/familyplanning/toolsdocs/fpar_forms_instructions_reissued_oct2007.pdf

Delegate Agency FPAR Requirement

Michigan Department of Community Health currently requires delegate agencies to submit FPAR reports on a semi-annual basis. Mid year reports are used to evaluate program performance and reporting. Each delegate agency must submit its FPAR report to the Michigan Department of Community Health, Women's Reproductive Health Unit, accurately and timely. Tables 15 and 16 have been added to the Michigan FPAR in response to Michigan legislative requirements. Delegate agencies should direct any questions regarding data needed or the collection of data to their agency consultant for assistance. Any instruction specific to the State of Michigan or Region V Office of Population Affairs will be given when the request for the report is submitted by MDCH. The data needed for this report must be collected prior to submission of the report, therefore, it is essential that each delegate agency fully understands and accurately collects the data throughout the year. Failure to comply with submitting this report accurately and timely will result in sanctions to the program.

II. Michigan Family Planning Information

Michigan Public Health Laws

Michigan Department of Community Health (MDCH) 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 MDCH 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 MDCH 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. MDCH 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\(5x5gcu3ujstowyqx4jnscorx\)\)/mileg.aspx?page=Home](http://www.legislature.mi.gov/(S(5x5gcu3ujstowyqx4jnscorx))/mileg.aspx?page=Home)

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 Laws - Summary:

http://www.michigan.gov/mdch/0,1607,7-132-2940_2955_2982_46000---,00.html

Pharmacy:

[http://www.legislature.mi.gov/\(S\(5x5gcu3ujstowyqx4jnscorx\)\)/mileg.aspx?page=getObject&objectName=mcl-333-17745](http://www.legislature.mi.gov/(S(5x5gcu3ujstowyqx4jnscorx))/mileg.aspx?page=getObject&objectName=mcl-333-17745)

Mental Health Services:

[http://www.legislature.mi.gov/\(S\(a1u3lonkc2j2o5iupuptztyk\)\)/mileg.aspx?page=GetMCLDocument&objectName=Mcl-Act-258-of-1974&queryid=12811010&highlight=mental%20health%20services](http://www.legislature.mi.gov/(S(a1u3lonkc2j2o5iupuptztyk))/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)

Adolescent Confidentiality:

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

[http://www.legislature.mi.gov/\(S\(5x5gcu3ujstowyqx4jnscorx\)\)/milex.aspx?page=getobject&objectName=mcl-Act-238-of-1975&query=on&highlight=child AND abuse](http://www.legislature.mi.gov/(S(5x5gcu3ujstowyqx4jnscorx))/milex.aspx?page=getobject&objectName=mcl-Act-238-of-1975&query=on&highlight=child AND abuse)

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)

<http://mare.org/AdoptionInfo.pdf>

Age of Majority:

[http://www.legislature.mi.gov/\(z4tq10ysq4uw4v55wl32xouh\)/renderHTMLfromVD.aspx?BookmarkID=6622](http://www.legislature.mi.gov/(z4tq10ysq4uw4v55wl32xouh)/renderHTMLfromVD.aspx?BookmarkID=6622)

Immunization:

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

http://www.michigan.gov/documents/mdch/3childcarerequire_final_310267_7.pdf

Sexual Coercion Legislation

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

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)

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)

Mandated Child Abuse Reporter Legislation

In Michigan the following is a list of professionals that 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 will provide further assistance in this subject:

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

Child Protective Services Legislation

Child Protection Law in Michigan is strictly prescribed by the state legislature. Following is a link to the Michigan Child Protection Law (Act 238 Of 1975):

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

MDCH Family Planning Minimum Program Requirements

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 Michigan Department of Community Health accreditation and site review process to determine program compliance. They are based on the Title X Family Planning Program statute, the Office of Population Affairs (OPA) Family Planning Standards and Guidelines, and the Michigan Department of Community Health Family Planning Standards and Guidelines.

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

The Accreditation/Site Review Tool identifies the measurements used to determine compliance with each MPR indicator. These indicators are used in the site review process to evaluate

compliance with grant requirements. Any indicator determined to be out of compliance must to be corrected. The Family Planning Indicator tool can be found on the Michigan Local Public Health Accreditation website at: <http://www.accreditation.localhealth.net/> and on the MDCH Family Planning website at: <http://www.michigan.gov/familyplanning>

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

These Minimum Program Requirements are contained in the Comprehensive Planning, Budgeting, and Contract (CPBC) Procedures as requirements to be met in the contracting process between local health departments and the Michigan Department of Community Health. They are also part of the contract process with Non-Local Health Departments in the annual budget and contracting procedures between the agency and the Michigan Department of Community Health.

Michigan Department of Community Health Minimum Reporting Requirements (MPR)

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

These documents include the:

FPAR (Family Planning Annual Report)
Family Planning Needs Assessment and Health Care Plan

The State of Michigan, Department of Community Health also requires that delegate agencies report project outputs (unduplicated number of clinic users) as a comparison to the State funded minimum performance expected.

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

The list of forms that follows summarize the reports and their timelines. The forms on this list will also be given to delegate agencies during their contracting process.

**Michigan Department of Community Health
Minimum Reporting Requirements (MPR)
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		Annual Report (Jan- Dec) due January 15
Table 2	Client visit record		
Table 3	Client visit record		
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 Requirement	
Table 16	Client visit record		
Family Planning Needs Assessment and Health Care Plan	Program Statistics	Federal Requirement	Due September 15

Project Outputs:

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

Needs Assessment and Annual Plan Instructions

Michigan Department of Community Health's Family Planning Program, as part of its federally required grant mandate, must have every delegate agency develop and submit a needs assessment and annual health care plan as described below:

- I. Program Specific Assurances and Requirements
 - A. Each delegate agency must serve a minimum of 95% of proposed Title X users to access its total amount of allocated funds. In addition, each delegate agency must work with the Department to jointly establish and achieve a minimum target for Plan First! caseload enrollment. Semi-annual FPAR data will be used to determine total Title X users and Plan First! enrollees.
 - B. Each delegate agency will be required to adhere to Michigan's Minimum Program Requirements (MPRs). The MPRs are written based on the Federal Regulations for Title X Family Planning Programs (the law) and the Office of Population Affairs (OPA) Family Planning Standards and Guidelines. The MPRs are located on the MDCH Family Planning website at www.michigan.gov/familyplanning.
- II. Needs Assessment
 - A. Demographic description of the service delivery area including objective data pertaining to individuals in need of family planning services (Examples include but are not limited to maternal and infant mortality/morbidity rates, estimates of women/teens in need of services,, teen birth rates and pregnancy rates, rates of unintended pregnancy, STI and HIV rates/prevalence and indicators of the poverty status of the populations to be served). Also discuss cultural and linguistic barriers to service.
 - B. Geographic description of the service area including any geographic, topographic, and other barriers to service.
 - C. Identification and discussion of high priority populations and target areas, with special emphasis on low-income women and men.
 - D. Identify other major health care providers and agencies providing similar services in your service delivery area, and the existing need for additional services.
 - E. Describe linkages or possible linkages with other health and social agencies related to reproductive health.
- III. Health Care Annual Plan
 - A. A narrative description of the program and the manner in which the applicant intends to conduct it in order to meet all applicable federal and state requirements.
 - B. Report on previous year goals and objectives.
 - C. Identify project goals and objectives for the coming year that are SMART (specific, measurable, attainable, realistic, and time specific) and address Title X priorities. Submit on the required work plan format. (Located online: www.michigan.gov/familyplanning)
 - D. Provide a list of members of your Family Planning Advisory Council and/or Information and Education Committee, meeting schedule, bylaws (if available), minutes from the past years meetings, and identify Family Planning Advisory Council and/or Education Committee's function in the provision of family

planning services in your region. Section 6.9 of the Standards and Guidelines Manual.

- E. A written formal plan for Community Education Activities based on regional needs. SMART (see C.) objectives should be used. Section 6.9.1 of the MDCH Standards and Guidelines Manual.
- F. A written formal plan for Community Promotion Activities that targets priority populations. SMART (see C.) objectives should be used. Section 6.9.2 of the MDCH Standards and Guidelines Manual.
- G. A written plan/policy for addressing the needs of clients with Limited English Proficiency (LEP). Section 5.6 of Standards and Guidelines Manual.
- H. Identify all services to be provided to clients under Title X by completing the *Family Planning Services Provided* Worksheet (Located online: www.michigan.gov/familyplanning)
- I. Verify and update the attached *Michigan Family Planning Delegate Agency Monthly Clinic Schedules* with agency's clinic locations and hours of operation. (Attachment)
- J. Submit a completed and signed *Contraceptive Protocol Waiver for Use Outside of Package Labeling* for FY 10/11. (online: www.michigan.gov/familyplanning)
- K. Describe staffing in all clinic locations, including qualification of all staff members.
- L. Provide the most recent organizational chart for the agency.
- M. List your agency's BCCCP/FP Joint Project coordinator, the number of clients referred into the program last year and the number projected for this fiscal year.
- N. Project the number of men, women and teens to be served by your facility. Include the total number of clients to be served in the following categories: at or below 100% of poverty, above 100% but not more than 150%, above 150% but not more than 200%, above 200% but not more than 250% of poverty, and above 250% of poverty. See FPAR Table 4 for last year's figures.
- O. Project the number of Plan First clients to be served.
- P. Provide a current sliding fee scale and fee schedule.

Specific instructions and the date for submission of this needs assessment and annual health care plan are sent to the project coordinator annually. Questions related to these instructions or submission should be directed to the delegate agency's administrative consultant.

Project requirements are described in Section 3.4(A)(1-20) Project Requirements.

Financial Management Audit Requirements

Financial Management Audit Requirements

Following are the Audits that are required of all Family Planning Title X Delegate Agencies.

This section applies to contractors designated as sub-recipients (Health Department & Non-Health Department Delegate Agencies.) Contractors designated as vendors are exempt from the provisions of this section.

A. Single Audit

Provide, consistent with regulations set forth in the Single Audit Act Amendments of 1996, P.L. 104-156, and Section 320 of Office of Management and Budget (OMB) Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations," (as revised) a copy of the Contractor's annual Single Audit reporting package, including the Corrective Action Plan, to the Department.

The federal OMB Circular A-133 requires either a Single Audit or program-specific audit (when a contractor is administering only one federal program) of agencies that expend \$500,000 or more in federal awards during the Contractor's fiscal year.

Contractors who have a Single Audit conducted as a result of \$500,000 or more in expenditures of Federal awards must submit the Single Audit reporting package, management letter, if issued, and Corrective Action Plan to the Department even if Federal funding received from the Department results in less than \$500,000 in expenditures.

The Contractor must also assure that the Schedule of Expenditures of Federal Awards includes expenditures for all federally funded grants.

B. Financial Statement Audit

Contractors exempt from the Single Audit requirements that receive \$500,000 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. Contractors exempt from the Single Audit requirements that receive less than \$500,000 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 MDCH-funded programs, including, but not limited to fraud, going concern uncertainties, financial statement misstatements, and violations of contract and grant provisions.

C. Other Audits

The Department or federal agencies may also conduct or arrange for additional audits to meet their needs.

D. Notification

When a Contractor is exempt from both the Single Audit requirements and the Financial Statement Audit requirements because funding is below the thresholds described above and there are no disclosures that may negatively impact MDCH-funded programs, the Contractor must submit an Audit Status Notification Letter that certifies these exemptions. The Audit Status Notification Letter must be signed by the Contractor's Financial Director or their designee. Attachment E contains the required Audit Status Notification Letter. Contractors should not send the completed letter to the Department with their signed agreement, but should submit as directed in item 7.

E. Due Date

The Single Audit reporting package, management letter, if one is issued, and Corrective Action Plan; Financial Statement Audit and management letter, if one is issued; or Audit Status Notification Letter shall be submitted to the Department within nine months after the end of the Contractor's fiscal year.

F. Penalty

Delinquent Single Audit or Financial Statement Audit

If the Contractor does not submit the required Single Audit reporting package, management letter, and Corrective Action Plan; or the Financial Statement Audit and management letter within nine months after the end of the Contractor'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 \$100,000) until the required filing is received by the Department. The Department may retain the amount withheld if the contractor is more than 120 days delinquent in meeting the filing requirements.

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.

G. Where to Send

A copy of the Single Audit reporting package, management letter, if one is issued, and Corrective Action Plan; Financial Statement Audit and management letter, if one is issued; or the Audit Status Notification Letter must be forwarded to:

Michigan Department of Community Health Office of Audit
Quality Assurance and Review Section
Capital Commons Center
P.O. Box 30479
Lansing, Michigan 48909-7979
400 S. Pine Street
Lansing, Michigan 48933

As an alternative to paper filing, the audit report and related documentation may be submitted electronically. The audit report and related documentation should be assembled as one document in the following order:

Financial Statement Audit Report/Single Audit Report, Corrective Action Plan or other information as applicable to MDCH grants, and Management Letter (Comments and Recommendations).

Another alternative is to send notification to the above address that the required audit materials may be accessed, in Adobe PDF, from the Contractor's website.

H. Management Decision

The Department shall issue a management decision on findings and questioned costs contained in the Contractor's Single Audit within six months after the receipt of a complete and final audit report. The management decision shall include whether or not the audit finding is sustained; the reasons for the decision; and the expected Contractor 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 Contractor, including a request for auditor verification of documentation, as a way of mitigating disallowed costs.

In addition to the above audits, an extensive review financial component of the delegate agencies is done every three years with the routine comprehensive site review. If any concerns are noted at that time, a corrective action plan is expected, along a revisit or other following to the degree necessary.

III. Program Standards and Guidelines

1.0 Introduction to the Program Guidelines

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

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

1.1 DEFINITIONS

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

The word “should” indicates recommended program guidelines and policies. These guidelines and policies reflect current acceptable medical or professional practices and are highly recommended by the Michigan Department of Community Health in order to fulfill the intent of Title X. The words “can” and “may” indicate suggestions for consideration by individual projects.

“MDCH” refers to Michigan Department of Community Health as the entity that receives a Federal grant and assumes legal and financial responsibility and accountability for the awarded funds and for the performance of the activities approved for funding.

The "project" consists of those statewide activities described in the Michigan Department of Community Health (MDCH) grant application submitted to the Office of Population Affairs (OPA), Family Planning Program and supported under the approved budget. For more information about the OPA family planning program, go to <http://www.hhs.gov/opa/>.

“Delegate agencies” are those entities that provide family planning services with Federal Title X funds under a negotiated, written contract with MDCH. “Service sites” are those locations where Title X family planning services are provided by MDCH or the delegate agency.

References made throughout this document to Title X law and Federal policy can be explored in the Title X Regulations section of this manual. Michigan Department of Community Health (MDCH) official family planning policy is also included in this manual.

2.0 The Law, Regulations and Guidelines

The philosophy of the MDCH Family Planning Program is 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 morbidity and mortality. Services provided through family planning clinics allow women and men to make well-informed reproductive health choices. MDCH funded family planning clinics are specifically created to address the unmet family planning needs of women and men living below or slightly above poverty, but still considered low income, and to provide access to those with special needs (including teens). No one is denied services because of inability to pay.

- A. To enable persons voluntary access to family planning services, Congress enacted the Family Planning Services and Population Research Act of 1970 (Public Law 91-571), which added Title X, "Population Research and Voluntary Family Planning Program," to the Public Health Services Act. Section 1001 of the Act (as amended by Public Laws 94-63 and 95-613), "The Secretary is authorized to make grants to and enter into contracts with public and nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services and services to adolescents)." The mission of Title X is to provide individuals the information and means to exercise personal choice in determining the number and spacing of their children.

The regulations governing Title X (42 CFR, Part 59, Subpart A), published in the Federal Register on June 3, 1980, amended on February 2, 1988, and on July 3, 2000 are the requirements of the Secretary, Department of Health and Human Services, for the provision of family planning services funded under Title X, and implement the statute as authorized under Section 1001 of the Public Health Services Act.

- B. The Michigan Department of Community Health, (MDCH) has the primary responsibility in Michigan to receive and administer state and federal funds for family planning services. Family planning is a mandated health service under the State of Michigan's Public Health Code, Section 333.9131-9133. Guidelines for MDCH administration of the federal program are based on requirements as cited in the document *Program Guidelines for Project Grants for Family Planning Services* available at the following website: <http://www.hhs.gov/opa/>. Additional guidelines may be required through either the federal or state annual funding process, or as MDCH deems necessary.
- C. The program guidelines found in this document interpret the law and regulations in the form of standards and provide a general orientation to the federal and state perspective on family planning. This manual is written to define minimum standards (requirements) and give recommendations for quality care. This manual is designed to be used for the:
1. Orientation of all new family planning staff members
 2. Annual quality assurance review procedures required of all delegate agencies

2.1 MDCH FAMILY PLANNING PROGRAM ACCREDITATION/SITE REVIEWS

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

There is a difference in the way the visits are coordinated for Health Department Delegate agencies as compared to Non-Health Department delegate agencies. For Local Public Health Department delegate agencies, the mandatory comprehensive site reviews, referred to as “Accreditation” visits, are part of the Michigan Local Public Health Accreditation Program. Family Planning is one of the categorical programs that are reviewed in a health department as part of the accreditation process.

The Michigan Local Public Health Accreditation Program seeks to assure and enhance the quality of local public health in Michigan by identifying and promoting the implementation of public health standards for local public health departments, and evaluating and accrediting local health departments on their ability to meet these standards. Family Planning program accreditation visits are coordinated, under contract through MDCH, by Michigan Public Health Institute (MPHI). This coordination includes scheduling, providing guidance to locate the tools, etc. Health Department staff receives correspondence from MPHI regarding these issues.

Non-Health Department program reviews, referred to as site reviews, are coordinated by the MDCH program staff. All Site/Accreditation reviews are conducted by MDCH Family Planning program reviewers. Site/Accreditation reviews are conducted using the same methodology, assessment tools and federally mandated program requirements.

Both health departments and non-health department programs may use the following website for more information about the Accreditation Process, Minimum Program Requirements, Pre-Materials Required, Guidance Documents and Self-Assessment tools:

<http://www.accreditation.localhealth.net/>. This site provides detailed information about Site Reviews, Monitoring Visits and Technical Assistance. The site review tool designed for the Non-Health Department delegate agencies is also available on the MDCH family planning website, <http://www.michigan.gov/familyplanning>.

3.0 The Application Process

3.1 ELIGIBILITY

Any public or nonprofit private entity located in Michigan is eligible to apply for a Title X family planning services project grant through MDCH (Federal Register 59.2, 59.3). Grants will be made to foster projects most responsive to local needs. Entities **must** furnish evidence of non-profit status in accordance with instructions accompanying the project grant application. Agencies **must** ensure that Title X funding will be expended solely for the Title X program under the terms and conditions of the grant.

Specific criteria have been established by Title X and MDCH to ensure that any delegate agency funded by Title X is able to meet the program requirements set forth by law. Any agency meeting these criteria may submit a competitive bid application to MDCH for consideration as a delegate agency. These criteria are as follows:

- A. A public or private non-profit entity located in the State of Michigan is eligible to apply for a Title X service grant as a delegate agency.
- B. Delegate agency status will be approved only to those entities that provide comprehensive family planning methods (see Section 8.0 of the Standards and Guidelines for details).
- C. Grants cannot be made to entities that propose to offer only a single method or an unduly limited number of family planning methods. An organization offering a single or limited number of family planning methods may receive Title X assistance by participating as a special service provider if a formal agreement is in place with a project or facility offering a broad range of family planning services.
- D. The organization has a governing board that is representative of the community or a program specific family planning advisory council.

MDCH has the right to delete agency status for the following reasons:

- A. A local health department currently served by a non-profit agency emerges as having greater capacity to deliver expanded services and desires to become the county jurisdictional entity for family planning. Local health departments have the primary responsibility to meet the health needs of vulnerable populations (Public Health Code, 2000: Section 333.2473).
- B. Delegate status is a time limited special project. In this case deletion will occur at end of specified project time but the agency may apply for consideration for continuing funding.
- C. Chronic non-compliance (as determined by the State of Michigan) on any of the following:
 - 1. Family Planning Annual Report (FPAR)
 - 2. Financial Audit
 - 3. Adherence to contract requirements
 - 4. Program Review criteria and/or failure to establish an approved annual health care plan and follow-up on cited deficiencies.

Delegate agency status will not be removed without formal written notification by MDCH. Delegate agencies will be given enough advance notice to allow them the opportunity to respond to a change in status prior to termination of funding. The only exception will be funding of a time limited special project. In this case, MDCH will automatically delete this project at the end of the special funding period; MDCH retains the option of granting or rejecting requests by the project for additional or continuation funding.

3.2 NEEDS ASSESSMENT

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

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

Any delegate agency considering expanding their service area or the services provided by their agency **must** also submit a needs assessment justifying this expansion. This **must** be approved by MDCH prior to implementation if additional funding will be required.

3.3 THE APPLICATION

The Michigan Department of Community Health receives funds from the Department of Health and Human Services' Office of Population Affairs to administer the Title X Family Planning Program in Michigan. In competitive grant years, interested applicants in Michigan **must** submit a competitive bid application as set forth by MDCH. Applicants **must** follow the format and content as detailed in the competitive bid guidance. The application and technical assistance are available from the MDCH. The grant application will cover at least a three year period.

Annually, agencies awarded Title X funding in the competitive bid process **must** submit an application for continuing delegate status which includes a needs assessment and an annual health care plan. The plans **must** be submitted to MDCH and follow the guidance provided by MDCH (See the Michigan Family Planning Information Section of this document and Section 6.2 of the Standards and Guidelines for details). Technical assistance is available. The annual health care plan **must** include:

- A. A detailed needs assessment as described in Section 3.2 of the Standards and Guidelines.
- B. A narrative description of the program and the manner in which the applicant intends to conduct it in order to meet all applicable federal and state requirements.
- C. An annual plan including project objectives that are specific, measurable, attainable, realistic and time specific and will carry out the requirements of Title X. A report on the previous years goals and objectives **must** be included if applicable.
- D. An estimate of the number of clients to be served, including information on the anticipated number of teens, men, and low-income women.
- E. A budget that includes an estimate of project income and costs, with justification for the amount of grant funds is submitted through the contract process and reviewed and approved by MDCH Family Planning staff.
- F. A description of standards used and qualifications of all project personnel.
- G. A current organizational chart.
- H. A description of all services to be provided to clients under Title X. List clinic locations and clinic hours, including supply pick-up times.
- I. A description of the function of the Family Planning Advisory Council and/or Information and Education Committee, including a meeting schedule, list of members and other requirements as detailed in Section 6.9 of the Standards and Guidelines.
- J. A written plan for Community Education Activities based on regional needs and incorporating Section 6.9.3 of the Standards and Guidelines.
- K. A written plan for Community Promotion Activities that target priority populations and incorporating Section 6.9.2 of the Standards and Guidelines.

- L. A written plan for addressing the needs of clients with Limited English Proficiency (LEP) and incorporating Section 5.6 of the Standards and Guidelines.
- M. Written assurance of the policy that abortions are not provided as a method of family planning in the program.
- N. Other pertinent information as required by MDCH and detailed in the annual health care plan guidance. (Federal Register 59.4(c)(4)).

The application **must** address the following points, which are part of the criteria MDCH will use to decide which family planning projects to fund and in what amount:

- A. The number of patients, and in particular, the number of low-income patients to be served
- B. The extent to which family planning services are needed locally
- C. The relative need of the applicant
- D. The capacity of the applicant to make rapid and effective use of the funds
- E. The adequacy of the applicant's facilities and staff
- F. The relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project
- G. The degree to which the project plan adequately provides for the Title X requirements.

The application **must** not include activities that cannot be funded under Title X, such as abortion, fundraising, or lobbying activities.

3.4 PROJECT REQUIREMENTS

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

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

- C. Provide services in a manner that will protect each individual's dignity and will respect the diverse cultural and social practices of the service area population. (Section 5.0)
- D. Provide services impartially to all without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies or marital status in accordance with Title VI of the Civil rights Act of 1996. (Section 5.0) In addition, all delegate agencies **must** have a policy that assures meaningful access to family planning services for persons with limited English proficiency. This means that language assistance **must** be provided that results in accurate and effective communication at no cost to the client. (Section 5.6)
- E. Not provide abortions as a method of family planning. A project **must** offer pregnant women the opportunity to be provided information and counseling on prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination. Information on any of these options **must** be factual, neutral and nondirective. (Section 8.6)
- F. Persons from low-income families are given priority in the provision of services. Agencies **must** strive to increase use of services by historically under-served segments of the population (people of color, non-English speaking persons, persons abusing substances, homeless persons, etc.).
- G. Low-income individuals (below 100% of poverty) are not charged except where third party payment is authorized. (Section 6.3.1)
- H. Clients **must** not be denied services or be subjected to any variation in quality of service because of inability to pay. Charges will be made to persons other than low-income individuals (at or below 100% poverty) based on the following: (Section 6.3.1)
 - 1. Current Federal Department of Health and Human Services (DHHS) Poverty Guidelines
 - 2. Sliding fee scale schedule provided by MDCH.
 - 3. Periodic cost analysis of all services provided.
- I. Individuals from families with an annual income above 250% poverty will be charged to recover the reasonable cost of providing services. (Section 6.3.1)
- J. Reasonable effort is made to recover third party payment from all sources. (Section 6.3.1)
- K. Establish a Family Planning Advisory Council to provide community participation and to review, on a regular basis, program and policy issues and establish an Information and Education Committee to review educational materials to assure that they are suitable for the population or community to which they are to be made available (Refer to Section 4.0, A3 and Section 6.8 of the Standards and Guidelines for specific requirements)
- L. Provide for medical services related to family planning including: (Sections 7 and 8)
 - 1. Physician's consultation
 - 2. Examination
 - 3. Prescription
 - 4. Continuing supervision of clients
 - 5. Laboratory examination
 - 6. Contraceptive supplies

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7. Referral to other medical facilities when medically indicated
 8. Effective usage of contraceptive devices and practices
- M. Provide for social services related to family planning including: (Sections 7 and 8)
1. Counseling
 2. Referral to and from other social and medical services agencies
 3. Referral to any ancillary services which may be necessary to facilitate clinic attendance
- N. Provide informational and educational programs designed to: (Sections 6.9.2 and 6.9.3)
1. Achieve community understanding of program objectives
 2. Inform community of availability of services
 3. Promote continued participation in the project by persons to whom family planning services may be beneficial
- O. Orientation and in-service training are provided for all project personnel. (Section 6.6)
- P. Services are provided without residency requirement or physician referral.
- Q. Medical services are provided under the direction of a physician with special training or experience in family planning. (Section 6.5)
- R. All services purchased for the project participants are authorized by the project director or director's designee.
- S. Provide for coordination and use of referral arrangements with other appropriate providers supported by other federal programs. (Section 7.4)
- T. Agreements on methods and rates of payments for medical care by contracted or referral providers are in place and are reasonable and necessary.
- U. Provide an opportunity for a broadly based representation from the service population and those in the community knowledgeable about family planning needs, to participate in the development, implementation and evaluation of the project. (Section 6.9)
- V. Other requirements which apply to grants made under Title X as detailed in the MDCH Standards and Guidelines.

3.5 NOTICE OF GRANT AWARD

The notice of grant award will inform the MDCH how long MDCH intends to support the project without requiring it to re-compete for funds. This period of funding is called the "project period." The project will be funded in increments called "budget periods." The budget period is normally twelve months, although shorter or longer budget periods may be established for compelling administrative or programmatic reasons.

4.0 Grant Administration

All delegate agencies **must** comply with MDCH and federal grants administration requirements (Public Health Service Grants Policy Statement), including the following:

- A. All Family Planning Directors **must** be familiar with the MDCH Family Planning Standards and Review Manual and the Title X law and regulations.
- B. All delegate agencies receiving Title X funds **must** provide services of high quality which meet minimum program standards.
- C. Delegate agencies **must** have a Family Planning Advisory Council which will review general program/policy issues and make recommendations to the agency on organization, management and operation of the Family Planning Program.
 - 1. The composition of these boards or advisory committees **must** be representative of the population in the community served and include persons knowledgeable about family planning.
 - 2. Number of members serving on each group **must** be a minimum of five and should be no more than nine. Permission to waive this standard with good cause **must** be submitted to MDCH.
 - 3. Each group **must** meet at least twice a year to:
 - a. Review the delegate program plan, assess accomplishments and suggest future program goals and objectives.
 - b. Review the agency's progress toward meeting the needs of the priority population in the service area and for making the clinic service and policies more responsive to their needs and preferences.
 - 4. Minutes **must** be kept of all meetings.
 - 5. Meetings may be conducted utilizing electronic technology.
- D. Delegate agencies **must** have an Information and Education Committee which reviews all new educational materials. The Family Planning Advisory Council may take on this role. (See Section 6.8 of the Standards and Guidelines for details).

5.0 Legal Issues

- A. Written protocols and operating procedures are required to meet the standards of the legal issues described in 5.0 through 5.6.
- B. Services **must** be provided without regard to religion, race, color, national origin, creed, handicap, sex, number of pregnancies, marital status, age, sexual orientation, and contraceptive preference in a manner that protects the dignity of the individual.

5.1 VOLUNTARY PARTICIPATION

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

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

5.2 CONFIDENTIALITY

Every delegate agency **must** assure client confidentiality and provide safeguards for individuals against the invasion of personal privacy, as required by the Privacy Act. No information obtained by the project staff about individuals receiving services may be disclosed without the individual's written consent, except as required by law or as necessary to provide services to the individual, with appropriate safeguards for confidentiality. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual [59.11]. Confidentiality under Title X cannot be invoked to circumvent Michigan reporting requirements for Child Abuse and Neglect.

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

5.3 CONFLICT OF INTEREST

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

5.4 LIABILITY COVERAGE

- A. Liability insurance coverage **must** be assured for all segments of the program funded under the Title X grant, including all personnel providing direct patient services.
- B. Liability insurance coverage should be considered for members of the Governing Board and Advisory/Education Committee.

5.5 HUMAN SUBJECTS CLEARANCE (RESEARCH)

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

- A. Delegates considering clinical or sociological research **must** adhere to legal requirements governing human subject research, specifically with regard to informed consent.
 - 1. MDCH **must** approve human subject research. The following criteria **must** be met:
 - a. Informed consent of client
 - b. Approval of research by a properly constituted committee of the MDCH institution (MDCH).
- B. All delegate agency requests for research approval **must** be submitted to MDCH and in turn MDCH **must** forward requests to the regional DHHS office and the Office of Population Affairs for final approval.

5.6 LIMITED ENGLISH PROFICIENCY (LEP)

- A. All delegate agencies **must** ensure meaningful access to services for persons with limited English proficiency.
- B. All delegate agencies **must** develop and implement a written plan regarding the process for providing language assistance to LEP clients. Guidance can be found in Federal Register/Vol. 67, No 22/Friday 1, 2002/Notices and Federal Register/Vol 68, No. 153/Friday, August 8, 2003/Notices.
- C. The scope and complexity of the plan **must** consider:
 - 1. Size of the LEP population eligible to be served or likely to be encountered.
 - 2. Frequency of contact with the LEP population.
- D. All LEP plans **must** include:
 - 1. Statement of the agency's commitment to provide meaningful access for LEP persons.
 - 2. Statement that services will not be denied to a client because s/he is limited English proficient.

3. Statement that clients will not be asked or required to provide their own interpreter. Because of the concerns for confidentiality and the sensitive nature of the information that clients may disclose during services, the use of family and friends as interpreters is strongly discouraged.

If the client chooses to use family or friends, first inform the client of the right to receive free interpreter services and permit the use of family/friends only after the offer has been declined and documented.

4. At minimum, delegate agencies **must** include and address the following within their LEP Plans:
 - a. Identify LEP individuals who need language assistance.
 - b. Language assistance measures
 - c. Oral interpretation
 - d. Written translation
 - e. Training staff
 - f. Providing notice to LEP persons
 - g. Monitoring and updating the LEP plan.
5. MDCH will provide technical assistance for the development of the LEP plan.
6. Each delegate agency **must** submit its LEP plan with their Annual Health Care Plan for review by MDCH.
7. MDCH will review delegate agencies' LEP practices and policies during site review.

6.0 Project Management

6.1 STRUCTURE OF THE MDCH

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

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

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

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

6.2 PLANNING AND EVALUATION

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

- A. Annual Health Care Plan **must** include:
 - 1. A needs assessment that includes (see section 3.2 for details):
 - a. Geographic description of the service area.
 - b. Demographic description of the service area.

- c. Description of existing services and need.
- d. Need indicators.
- e. Description of linkage with other providers.
- 2. A Progress Report on the previous year's objectives.
- 3. Goals and objectives
 - a. Identify overall goals and specific measurable objectives for the coming year, including time-frames for completion and an evaluation component. Objectives **must** include plans for community participation, program promotion, and community education. Goals and objectives should be *S.M.A.R.T.* (Specific, Measurable, Attainable, Realistic and Time Sensitive).
- 4. Community Participation
 - a. Provide a list of members of your agency board of directors or the advisory/education committee if different, and the agencies or population they represent.
 - b. Provide a written formal plan for Community Promotion Activities that targets priority populations. (See Section 6.9.2 of the Standards and Guidelines for details)
 - c. Provide a written formal plan for Community Education Activities based on regional needs. (See Section 6.9.3 of the Standards and Guidelines for details)
- 5. Service Plan
 - a. Identify all services to be provided to clients under Title X including services hours and clinic locations (Title X Regulations 59.5).
 - b. Provide a written plan for addressing Limited English Proficiency (LEP). (See Section 5.6 of the Standards and Guidelines for details)
- 6. Projected Caseload
 - a. Based on the number of unduplicated users in your most recent performance contract, project the number of adolescents (age 15-18), the number of clients at or below 100% of poverty, above 100% but not more than 150% of poverty, above 150% but not more than 185 % of poverty, above 186% of poverty but not more than 200% of poverty, above 200% but not more than 250% of poverty level, and above 250% of poverty level.

See the **Michigan Family Planning Information** in the resource section of this document for specific instructions for completing the Needs Assessment and Annual Health Care Plan.

6.3 FINANCIAL MANAGEMENT

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

6.3.1 CHARGES, BILLING, AND COLLECTIONS

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

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

- A. Charges **must** be based on a cost analysis of all services provided by the project. At the time of services, clients who are responsible for paying any fee for their services **must** be given bills directly. In cases where a third party is responsible, bills **must** be submitted to that party.
- B. A schedule of discounts **must** be developed and implemented with sufficient proportional increments so that inability to pay is never a barrier to service. A schedule of discounts is required for individuals with family incomes between 101% and 250% of the Federal poverty level. Fees **must** be waived for individuals with family incomes above this amount who, as determined by the service site project director, are unable, for good cause, to pay for family planning services.
- C. Clients whose documented income is at or below 100% of the Federal poverty level **must** not be charged, although projects **must** bill all third parties authorized or legally obligated to pay for services.
- D. Individual eligibility for a discount **must** be documented in the client's record/file.
- E. Bills to third parties **must** show total charges without applying any discount.
- F. 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 MDCH level or delegate/contract agency level is required.
- G. Bills to clients **must** show total charges less any allowable discounts.
- H. Eligibility for discounts for minors who receive confidential services **must** be based on the income of the minor.
- I. Reasonable efforts to collect charges without jeopardizing client confidentiality **must** be made.
- J. A method for the "aging" of outstanding accounts **must** be established.
- K. Voluntary donations from clients are permissible. However, clients **must** not be pressured to make donations, and donations **must** not be a prerequisite to the provision of services or supplies. Donations from clients do not waive the billing/charging requirements set out above.
- L. Client income should be re-evaluated at least annually.

6.3.2 FAMILY PLANNING ANNUAL REPORT

The Family Planning Annual Report (FPAR) Table 14 **must** be compiled using current financial data and **must** be accurate and complete. Table 14 **must** be submitted with the following information included:

- A. Administrative costs and cost per medical encounter should be reasonable for the size and complexity and type of project.
- B. Income from Title XIX (Medicaid) **must** be shown on FPAR Table 14 as appropriate.
- C. Voluntary donations are not considered patient collections, but **must** be reported as other revenue (14 of Table 14, FPAR).

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

6.3.3 FINANCIAL AUDIT

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

6.4 FACILITIES AND ACCESSIBILITY OF SERVICES

Facilities in which project services are provided should be geographically accessible to the population served and should be available at times convenient to those seeking services, i.e., they should have evening and/or weekend hours in addition to daytime hours.

The facilities should be adequate to provide the necessary services and should be designed to ensure comfort and privacy for clients and to expedite the work of the staff. Facilities **must** meet applicable standards established by the Federal, state and local governments (e.g., local fire, building and licensing codes).

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

If sterilizations are performed on-site by the delegate, they **must** conform to facility standards as established by federal Title X guidelines.

In an effort to assure accessible and acceptable client services, it is **strongly** encouraged that each delegate agency offer late afternoon, evening, and/or weekend clinic hours.

Emergency situations may occur at any time. All projects **must** therefore have written plans and procedures for the management of medical and non medical emergencies. (Section 7.3)

6.5 PERSONNEL

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

A. These policies **must** cover the following items: [59.5(b)(10)].

1. Staff recruitment and selection methods.
2. Methodology for performance evaluation.
3. Staff promotion.
4. Staff termination.
5. Compensation and benefits.
6. Grievance procedures.
7. Staff orientation.
8. Nondiscrimination in hiring employees.
9. Patient confidentiality issues.
10. Duties, responsibilities, and qualifications of each staff position.
11. Licenses for those positions requiring licensure.

B. Policies should cover the following items as appropriate:

1. A system for replacing key staff members in case of illness, vacation or unexpected absence.
2. Use of volunteer employees.
3. Use of contractual consultants in providing service.
4. Project personnel should reflect racial and ethnic diversity of population being served and be sensitive to the cultural needs of the client population.

C. Delegates **must** ensure that:

1. Delegate projects **must** be administered by a qualified program coordinator.
 - a. The program coordinator should have appropriate skills to provide both management direction and patient services to the family planning program.
 - b. The program coordinator's time should be reasonably allocated between management and patient care.
 - c. The program coordinator should participate in the development and evaluation of the following:
 - i. Annual service plan
 - ii. Annual program plan and budget
 - iii. The quality assurance Plan
 - iv. The client data or tracking system

- v. Program development, implementation, and evaluation
 - vi. In-service training of clinical staff
 - vii. Clinic procedure and protocol manual(s)
 - d. The program coordinator should serve as a liaison between the family planning program and the medical community.
 - e. The program coordinator should participate in the hiring, evaluating, and terminating of all staff within the family planning program.
2. The medical care component of the project operates under the supervision of a medical director who is a **licensed and qualified physician with training or experience in family planning**. If colposcopy and related services are provided the supervising physician **must** be trained in colposcopy/cryotherapy as part of an OB/GYN residency or provide to MDCH documentation of a minimum two-day training course or its equivalent.
 3. Clinicians other than physicians performing medical functions 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 and/or certified mid-level (non-physician) clinician. These mid-level clinicians (non-physicians) shall 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.
 - c. Upon the completion of the training program and supervised preceptorship, a nurse **must** take and pass the appropriate national certification exam for her specialty before using the designation “certified.” A waiver may be granted per individual nurse, to practice in the above capacity if it is necessary to take the national certification exam more than once.

The following documents **must** be submitted to MDCH so appropriate assessment can be made regarding waiver consideration:

- i. Listing of current job duties
 - ii. Training/experience of nurse
 - iii. Current curricula vitae of nurse and physician
 - iv. Description of how physician supervises/evaluates
 - v. Proof of liability insurance for physician and nurse
 - vi. Request from program director and supervising physician
 - vii. A specific training/continuing education plan for the next twelve months.
4. Personnel records **must** be kept confidential.
 5. Organizational chart and personnel policies **must** be available to all personnel.
 6. Job descriptions **must** be available for all positions, reviewed annually, and updated as needed.
 7. Annual evaluation of all project personnel **must** be conducted.

- a. The written evaluations are discussed with the employee and are kept in the employee's personnel files.
- b. Annual peer reviews **must** be conducted of all project clinicians/providers.
8. All clinicians employed in the family planning program **must** agree to follow the clinic protocols and procedures and/or standing orders.
9. Personnel policies should be reviewed and updated as needed.
10. The agency **must** be in compliance with OSHA regulations regarding transmission of blood borne disease (e.g. HIV, Hepatitis B, etc.).

6.6 TRAINING AND TECHNICAL ASSISTANCE

- A. Delegates **must** provide for orientation and in-service training for all project personnel.
 1. The agency should document attendance at training and continuing education programs.
 2. All staff should be offered the opportunity to attend training programs, particularly Region V training programs, MDCH training programs, and the annual family planning update at least once per year.
 3. All staff, including administrative and support staff, as well as direct service providers, **must** be trained regarding prevention, transmission and infection control in the health care setting of sexually transmitted infections including HIV (See Section 8.8).
 4. Funding for training and continuing education should be included in each year's operating budget.
 5. Registered nurses and mid-level practitioners should be offered appropriate educational opportunities so as to comply with requirements of the licensure/certification process.
 6. Staff **must** be trained in the unique social practices, customs and beliefs of under-served populations of their service area.
- B. Delegates should conduct an annual assessment of the training needs of their staff; and an evaluation of the scope and effectiveness of all educational programs offered.
 1. Educational opportunities should be developed to assist in meeting identified needs.
 2. These training needs should be shared with the state training program or the training advisory committee.
 3. Evaluation of educational programs should be used to assist the delegate in planning future in-service training programs and determining any changes needed in established training programs.
- C. Delegates should have one person assigned to develop in-house training capabilities.
- D. Delegates should have appropriate clinical resource books available for staff such as:
 1. Family Planning Perspectives (AGI)
 2. The most current annual edition of Contraceptive Technology and monthly editions of Contraceptive Technology Update.
 3. Drug Facts and Comparisons, or current PDR

6.7 REPORTING REQUIREMENTS

All delegate agencies **must** comply with MDCH minimum reporting requirements, including the Office of Population Affairs (OPA) Family Planning Annual Report (FPAR) at intervals specified by MDCH. In addition, the delegate agency **must** file an annual health care plan and report of expenditures, and **must** report user, encounter, revenue, and contraceptive method data on the FPAR, as described in the OPA FPAR Forms and Instruction manual, available on the OPA website: <http://www.hhs.gov/opa/familyplanning/toolsdocs/index.html>

- A. FPAR reports are required semi-annually: (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. Any problem identified in the FPAR report will be addressed by the MDCH agency consultant upon review by email or telephone consultation, and, if needed, through subsequent on-site consultation.
 - 2. A family planning user reported on FPAR is an individual who has at least one family planning encounter at a Title X service site during the reporting period. The same individual may be counted as a family planning user only once during a reporting period.
 - 3. A family planning encounter is a documented, face-to-face contact between an individual and a family planning provider that takes place in a Title X service site. The purpose of a family planning encounter—whether clinical or non-clinical—is to provide family planning and related preventive health services to female and male clients who want to avoid unintended pregnancies or achieve intended pregnancies. To be counted for purposes of the FPAR, a written record of the service(s) provided during the family planning encounter must be documented in the client record.
- B. Sterilization reporting requirements **must** be met.
 - 1. All projects **must** be in compliance with Title X regulations on minimum age, waiting period between signing of consent and surgical procedure and informed consent. Documentation that these requirements have been met should be found in the client's chart and/or the sterilization log (See Attachment C of the federal Program Guidelines, Jan. 2001 and Section 8.4 of this manual for specific guidance.)
- C. All MDCH family planning annual plan and budget reporting requirements **must** be met.

6.7.1 INDICATORS FOR FUNDING

- A. The family planning funding formula, which is used to allocate funds from MDCH to the delegate agencies, will be annually reviewed by the Family Planning Advisory Council, with final approval by the Michigan Department of Community Health.

6.8 REVIEW AND APPROVAL OF INFORMATIONAL AND EDUCATIONAL MATERIALS

An advisory committee of five to nine members (the size of the committee can differ from these limits with written documentation and approval from MDCH) who are broadly representative of the community **must** review and approve all informational and educational materials developed

or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X. Oversight responsibility for I & E committees rests with the MDCH. The MDCH may delegate I & E operations for the review and approval of materials to delegate/contract agencies.

Information and Education (I & E) Committee(s) **must**:

- A. Consider the educational and cultural backgrounds of the individuals to whom the materials are addressed;
- B. Consider the standards of the population or community to be served with respect to such materials;
- C. Review the content of the material to assure that the information is factually correct;
- D. Determine whether the material is suitable for the population or community to which it is to be made available; and
- E. Establish a written record of its determinations [59.6].

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

6.9 COMMUNITY PARTICIPATION, EDUCATION, AND PROJECT PROMOTION

- A. Title X MDCH and delegate/contract agencies **must** provide an opportunity for participation in the development, implementation, and evaluation of the project (1) by persons broadly representative of all significant elements of the population to be served, and (2) by persons in the community knowledgeable about the community's needs for family planning services. [59.5(b)(10)].
- B. The governing board, a program specific family planning advisory committee, or the Information and Education Committee may be used to fulfill the community participation requirement provided this group meets the above requirements.
 - 1. The committee fulfilling the community participation function **must** meet two times a year or more often as appropriate.
 - 2. Meetings may be conducted using electronic technology.
 - 3. Boards and advisory committees for family planning services should be broadly representative of the population served.
- C. Community participation may also be accomplished in the following ways, so long as the above requirements are met:
 - 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.

- D. The delegate agency's Annual Health Care Plan **must** include a plan for community participation for its project.

6.9.1 COMMUNITY EDUCATION

- A. Each family planning project **must** provide for community education programs [59.5(b)(3)]. This should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.
- B. Community education program should enhance community understanding of the family planning project, make known the availability of services to potential clients, and encourage participation by persons to whom family planning may be beneficial.
- C. A written plan inclusive of goals, objectives, and measurement criteria **must** be submitted with the agency's Annual Health Care Plan. The plan should be based on an assessment of the needs of the service delivery area.
- D. A variety of strategies used in community education programming may include:
 1. Distribution of educational materials
 2. Educational sessions to schools, community groups, agencies and professionals
 3. Assisting community groups in the development of family health related curricula
 4. A system for handling community requests for information and materials

6.9.2 PROJECT PROMOTION

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

6.10 PUBLICATIONS AND COPYRIGHT

Unless otherwise stipulated, publications resulting from activities conducted under the grant need not be submitted to Department of Health and Human Services (DHHS) for prior approval. The word "publication" is defined to include computer software. MDCH should ensure that publications developed under Title X do not contain information which is contrary to program requirements or to accepted clinical practice. Federal grant support **must** be acknowledged in any publication.

Except as otherwise provided in the conditions of the grant award, the author is free to arrange for copyright without DHHS approval of publications, films, or similar materials developed from work supported by DHHS. Restrictions on motion picture film production are outlined in the Public Health Service Grants Policy Statement.

Any publications of the delegate agency **must** be approved by the delegate's Information and Education Advisory Committee prior to disbursement.

Any such copyrighted materials shall be subject to a royalty-free, non-exclusive, and irrevocable right of the Government to reproduce, publish, or otherwise use such materials for Federal purposes and to authorize others to do so [45 CFR 74.36][45 CFR 92.34].

6.11 INVENTIONS OR DISCOVERIES

- D. Delegates **must** comply with government-wide regulations 37 CFR Part 401, regarding any inventions or discoveries made by any activities that are federally funded.
- E. Delegates **must** assure that no contracts, assignment or other arrangements inconsistent with the grant obligation are entered into or continued and that all personnel involved in the grant activity are aware of and comply with such obligations.

Part II

7.0 Client Services

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

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

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

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

7.1 SERVICE PLANS AND PROTOCOLS

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

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

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

- American Cancer Society: <http://www.cancer.org>
- Agency for Health Care Policy and Research, U.S. Preventive Services Task Force: <http://www.ahrq.gov/clinic/uspstfix.htm>
- Centers for Disease Control and Prevention: <http://www.cdc.gov>
- American College of Obstetricians and Gynecologists: <http://www.acog.org>

- North American Society of Pediatric and Adolescent Gynecology: <http://www.naspag.org>
- American Society for Colposcopy and Cervical Pathology: <http://www.asccp.org>
- Agency for Healthcare Research and Quality: <http://www.ahrq.gov/clinic/cpgsix.htm>
- Partners in Information Access for Public Health Resources (Department of Health and Human Services): <http://phpartners.org/guide.html>

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

Under exceptional circumstances, a waiver of a particular requirement in the guidelines **must** be submitted to MDCH. In submitting a request for such an exception, the delegate agency **must** provide epidemiological, clinical, and other supportive data to justify the request and the duration of the waiver. All waivers **must**, in turn, be forwarded by MDCH to the Region V Family Planning Office.

7.2 PROCEDURAL OUTLINE

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

- A. Service delivery to all clients **must** include the following:
 1. Assuring clients are treated courteously and with dignity and respect.
 2. Assurance of confidentiality.
 3. The opportunity to participate in planning their own medical treatment.
 4. Encouraging clients to voice any questions or concerns they may have.
 5. Materials and/or interpreter available for those with limited ability to read or understand English and for those who may be blind or hearing impaired.
 6. Explanation of all procedures, range of available services, and agency fees and financial arrangements.
- B. Client education, including use of relevant educational materials such as pamphlets, audio-visuals, and brochures, **must** be offered.
 1. Education **must** include information about all contraceptive methods and may include information about basic male and female reproductive anatomy and physiology.
 2. HIV/STI education and information **must** be offered to clients.
 3. Client education should be individualized as much as possible based upon client needs and knowledge.
- C. Individual counseling, an interactive process to assist the client in making an informed choice **must** be offered.
 1. **Must** be done prior to client making informed choice regarding a contraceptive method.
 2. Clients **must** be provided HIV/STI risk assessment, counseling regarding risk reduction and offered testing or referral for testing.
- D. A signed general consent covering examination and treatment, and where applicable a method specific informed consent, **must** be obtained.
- E. A personal, family medical and social history **must** be obtained.
- F. A physical examination, including necessary clinical procedures, **must** be provided.
 1. New clients may defer the required initial physical exam:

- a. Clients **must** be counseled about the importance of preventive services, and the dangers and health risks involved if they defer or decline them.
 - b. Physical exam and other related prevention services should not be deferred more than 3 months and **must** not be deferred beyond 6 months, unless the clinician documents a compelling reason.
 - c. If the client decides to decline or defer a service, both the counseling that took place and the reason for the deferral **must** be documented in the client record.
 - d. On future visits, these clients should be encouraged to have a physical exam and appropriate laboratory testing performed.
- G. Laboratory testing **must** be provided, as indicated.
- H. Medications and/or supplies **must** be provided, as indicated/requested.
- 1. **Must** provide written specific instructions on how to use chosen birth control method
 - 2. **Must** include danger signs and when, where, and how to obtain emergency care, return schedule and follow-up
- I. Follow-up and Referral **must** be provided, as indicated.
- 1. Planned mechanism of client follow-up
 - a. Suggested return visit date
 - b. Contact information for emergencies after hours
 - 2. Performance of any necessary clinical procedures
 - 3. Provision of referrals as needed

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

7.3 EMERGENCIES

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

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

- D. There **must** be a procedure in place for maintenance of emergency resuscitative drugs, supplies, and equipment.
- E. Protocols **must** also be in place for non-medical emergencies including:
 - 1. Fire
 - 2. Natural disaster
 - 3. Robbery
 - 4. Power failure
 - 5. Harassment.

7.4 REFERRALS AND FOLLOW-UP

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

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

- E. For services determined to be necessary but which are beyond the scope of the project (such as thyroid abnormalities), clients **must** be referred to other providers for care. When a client is referred for non family planning or emergency clinical care, agencies **must**:
 - 1. Make arrangements for the provision of pertinent client information to the referral provider (client may hand carry referral information).
 - 2. Obtain the client consent for referral arrangements, except as necessary to provide care or as required by law.
 - 3. Document that the client was advised of the referral and the importance of follow-up.
 - 4. Document that the client was advised of their responsibility to comply with the referral.
 - 5. Maintain appropriate safeguards for confidentiality.

- F. Agencies **must** maintain a current list of providers including health care providers, local health and human service departments, hospitals, voluntary agencies, and health service projects supported by other federal programs to be used for referral purposes.
 - 1. Referral lists **must** be current and updated annually.
 - 2. Providers should be selected by procedures which assure fairness in selection and identify providers of acceptable quality.
 - 3. When possible, clients should be given a choice of providers.

SECTION 8.0 REQUIRED SERVICES

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH FAMILY PLANNING STANDARDS AND GUIDELINES

8.0 REQUIRED SERVICES

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

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

8.1 CLIENT EDUCATION

- A. Delegate agencies **must** have written client education plans that include goals and content outlines to ensure the consistency and accuracy of the education. The education **must** provide clients with the information needed to make informed decisions about their reproductive health. Client education **must** be documented in the client record.

The education provided **must** be appropriate to the client's age, level of knowledge, language, socio-cultural background and be presented in an unbiased manner. The education plan should include content on the educational focus for initial, annual, other revisits and supply visits.

1. Following are educational topic areas that **must** be provided:
 - a. Birth control methods:
 - i. Hormonal Contraceptives (oral, injectable, implant, patch, ring)
 - ii. Abstinence
 - iii. Natural family planning
 - iv. Barrier Methods (male & female condoms, diaphragm, sponge, cervical cap, spermicide)
 - v. Intrauterine Devices
 - vi. Sterilization (tubal surgery, tubal implant, vasectomy)
 - vii. Emergency Contraception
 - b. Instruction in breast self awareness and testicular self-exam
 - c. Education on reducing the risk of Sexually Transmitted Infections (STIs), including Human Immunodeficiency Virus (HIV)
 - d. Information on the range of available services, purpose and sequence of clinic procedures.
 - e. Information on the importance of recommended screening tests and other procedures involved in the family planning visit.
2. Following educational topic areas should be provided as indicated:
 - a. Clients should be offered information about basic male and female anatomy and physiology and the value of fertility regulation in maintaining individual and family health.

- b. Information on reproductive health and health promotion, disease prevention, including nutrition, exercise, smoking cessation and alcohol and drug abuse, domestic violence and sexual abuse.
- 3. Education should include information on clinical services that are available and what to expect during clinic appointments.
 - a. Individualized educational needs should be identified and addressed during the visit
 - b. The client should receive information about routine screening tests and other procedures involved in the family planning visit.
- 4. A variety of teaching methods may be used, for example:
 - a. One-on-one instruction with the client
 - b. Videotape or DVD
 - c. Pamphlets or other written media
 - d. Group education.

B. Informed Consent

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

- 1. The general consent form should inform the client of all routine clinic procedures that will be provided, including pregnancy testing, supplies or medications.
- 2. Education and consent forms for the contraceptive provided **must** be part of the service plan. A contraceptive method specific consent form **must** be completed before a prescription birth control method is provided.
 - a. To provide informed consent for contraception, the client **must** receive information on the specific method of birth control and its use, safety, effectiveness, benefits, risks, complications, discontinuation issues, adverse effects, danger signs and effectiveness in preventing sexually transmitted infections.
 - b. There **must** be a separate consent for each prescriptive method.
 - c. The method specific consent form **must** be updated when there is a change to a different prescriptive method or when there is a change in information regarding the prescriptive method (such as a black box warning.)
 - d. The method specific consent should be updated when there is a major change in the client's health status.
- 3. A specific Sterilization Consent that complies with Federal sterilization regulations [42 CFR Part 50, Subpart B], which addresses informed requirements, **must** be complied with when a sterilization procedure is performed or arranged by the delegate agency.
- 4. All consent forms **must**:
 - a. Be written in the primary language of the client or translated and witnessed by an interpreter.
 - b. Be part of the client's record.
 - c. Not require parental or partner consent to receive services.
- 5. All consent forms should:
 - a. Be approved by the delegate agency medical director.

- b. Contain a statement that the client has been counseled, provided with the appropriate information and materials, and understands the content of both.

8.2 COUNSELING

The main reason for counseling is to assist clients to reach informed choices about their reproductive health and continued use of family planning methods and services. The counseling process should be designed to help clients resolve uncertainty, ambivalence, and anxiety about their reproductive health and increase their ability to make decisions that fit their lifestyle.

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

A. Method Counseling

Method counseling is an individualized discussion that includes the following:

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

B. Sexually-Transmitted Infection (STI) and HIV (Human Immunodeficiency Virus) Counseling

All clients **must** receive accurate counseling on STIs and HIV. Counseling refers to an individualized discussion with a client that involves personal risks for STIs and HIV and the steps to be taken by the individual to reduce their risks. Clients with at risk behaviors for STIs and HIV **must** be advised about risk reduction and if clinical evaluation is needed.

1. All delegate agencies **must** offer the following HIV components:
 - a. Education about HIV infection and Acquired Immune Deficiency Syndrome (AIDS)
 - b. Individualized risk assessment and risk reduction counseling
 - c. If the delegate agency does not provide HIV testing on-site, they **must** provide the client with a referral list of health care providers who can provide this service.

2. Delegate agencies are encouraged, but not required to provide HIV testing on-site. Delegate agencies choosing to provide HIV testing on-site should follow the 2006 U.S Centers for Disease Control (CDC) recommendations for HIV testing, but **must** follow Michigan laws regarding HIV testing.
 - a. CDC recommends routine screening for clients in all health-care settings after the client is notified that testing will be performed unless the client declines (opt-out screening) and persons at high risk for HIV be offered testing at least annually. CDC does not recommend a separate written consent for HIV testing, considering a general consent sufficient, and does not recommend prevention counseling with HIV screening, unless state laws require otherwise.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>
 - b. Michigan law related to HIV testing changed as of January 2011(PA 320 of 2010). Practitioners and health facilities that order HIV testing for the purpose of diagnosing HIV must provide the following: (<http://www.michigan.gov/hivstd>).
 1. *Pretest information:* The following information must be provided to patients, either verbally or in writing, prior to ordering an HIV test. A brochure that contains the required pretest information is available on the Michigan Department of Community Health website: http://www.michigan.gov/documents/DCH-0675electronicversion_163987_7.pdf
 2. *Consent:* After receiving the required pretest information, a patient may decline an offer for HIV testing. Written consent on a separate form is no longer required. Consent may be incorporated into the general consent for medical care process. Otherwise, verbal consent will suffice.
 3. *Documentation in the medical record:* Both provision of the required pretest information and whether the patient declined or agreed to HIV testing must be documented and maintained in the patient’s medical record.
 4. *Test results:* In addition to the existing requirement to inform patients of positive HIV results and provide appropriate counseling, there is a new requirement to inform patients of negative HIV test results through normal health care provider procedures which may include patient visits, mail, or telephone communication.
 - c. CDC recommends HIV screening be included in the routine prenatal care screening tests for all pregnant women unless the client declines (opt-out screening.) Michigan law related to HIV testing for pregnant women require routine opt-out screening be included in routine prenatal care screening for pregnant women.
 - d. Agencies choosing to provide HIV testing on-site **must** develop links so that clients whose confirmatory testing yields positive results receive referrals for appropriate clinical and supportive care.

C. Counseling services to adolescent clients **must** meet Title X requirements and **must** be documented in the client record. See Section 8.7 B of this manual.

8.3 HISTORY, PHYSICAL ASSESSMENT, AND LABORATORY TESTING

A. History

At the initial comprehensive clinical visit, a complete medical history **must** be obtained on female and male clients. At minimum, the history **must** include the following:

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

B. Physical Assessment (female)

For many clients, Family Planning programs are the only continuing source of health information and clinical care. Therefore, an initial complete physical exam, including height and weight, examination of the thyroid, heart, lungs, extremities, breasts (beginning at age 21), abdomen, pelvis, and rectum, should be performed. The primary reason for family planning visits is fertility regulation but, other health maintenance screening is important and should be encouraged.

Clinics **must** provide and stress the importance of the following to all clients:

1. Blood pressure evaluation
2. Clinical breast exam (CBE) as age appropriate, including instruction in breast self-awareness.
 - a. CBE for average-risk asymptomatic women beginning at age 21 through age 39, performed at least every three years.
 - b. CBE beginning at age 40 and performed annually, including information about screening mammography recommendations.

3. Pelvic examination including vulvar evaluation and bimanual exam, beginning at age 21 and only as indicated for 13-20 years of age.
4. Pap testing as indicated
5. Colo-rectal cancer screening, beginning at age 50
6. STI and HIV risk assessment and screening or referral, as indicated

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

Delegate agencies protocols **must** be developed to ensure that:

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

C. Physical Assessment (male)

Family planning clinics are an important source of reproductive health care for male clients. A physical exam should be provided that includes: height and weight, examination of the thyroid, heart, lungs, breasts (beginning at age 21), abdomen, extremities, genitals and rectum. Examination should also include palpation of the prostate, as appropriate, and instructions in self-examination of the testes. Clinics should stress the importance of the following to male clients:

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

D. Laboratory Testing

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

Specific laboratory tests are required for the provision of specific methods of contraception. These tests are also indicators of health status and are useful for diagnostic reasons. These tests are provided to the client unless written results of the test done within 12 months are obtained and placed in the medical record.

1. Pregnancy testing **must** be provided on site as indicated.
2. Laboratory testing **must** be provided if indicated for a specific method of contraception.
3. Pap testing **must** be provided on site as indicated.

Note: Delegate agencies **must** comply with the current MDCH Family Planning Pap test protocol. See the MDCH Family Planning website, www.michigan.gov/familyplanning.

4. HIV testing, or referral for testing, as indicated

5. Colo-rectal cancer screening, beginning at age 50
 6. The following laboratory testing **must** be provided if required in the provision of a specific contraceptive method. They may be provided, either on site or by referral, for health maintenance and/or for diagnostic purposes as indicated.
 - a. Anemia assessment
 - b. Gonorrhea and Chlamydia testing
 - c. Vaginal wet mount
 - d. Diabetes testing
 - e. Cholesterol and lipids
 - f. Hepatitis B testing
 - g. Genital Herpes testing
 - h. Syphilis serology (VDRL, RPR)
 - i. Rubella titer
 - j. Urinalysis
 7. The following testing may be provided either on site or by referral for health maintenance and/or diagnostic purposes as indicated.
 - a. Condylomata Acuminata (HPV)
 - b. Trichomonas
 - c. Candidiasis
 - d. Bacterial Vaginosis
 8. Quality control, equipment maintenance and proficiency testing for on-site lab testing **must** be in place.
 9. Assurance of high quality lab testing for off-site labs **must** include:
 - a. Compliance with Clinical Laboratory Improvement Amendments (CLIA) regulations. Following is a CLIA website for more information: <http://www.cms.hhs.gov/clia>
 - b. A system for assessing credentials of contracting labs should be in place.
 - c. Competitive bidding should take place prior to contracting with an outside lab.
 - d. Cytology services **must** be provided by laboratories compliant with state licensure regulations
 10. A procedure **must** be established for referral and follow-up for abnormal tests that includes the following:
 - a. Documentation of the appropriate management for abnormalities
 - b. Notification of the client
 - c. Protection of the client's confidentiality
 - d. Follow-up with the client of significant lab results
 - e. Referral for necessary services if not provided on-site
 - f. When initial contact is not successful, a reasonable further effort should be made, consistent with the severity of the abnormality.
 11. Agencies should provide testing for a variety of STIs as indicated. If testing is provided, delegate agencies **must** have STI treatment protocols and follow-up procedures in place that are consistent with current CDC guidelines.
- E. When indicated the following lab tests and procedures may be provided or referred:
1. Microscopic exam of vaginal smears and wet mounts.
 2. Microscopic exam and/or culture and sensitivity of urine.
 3. Selected blood tests including fasting and/or random blood sugar, cholesterol, and other lipid panels.

- F. Written protocols for abnormal Pap testing follow-up **must** be in place and include the following:
1. Client **must** be notified within six weeks; however, if the client needs a referral to the Michigan Breast and Cervical Cancer Control Program (MI BCCCP) for diagnostic services, she **must** receive follow-up services no later than 90 days after the Pap test was performed.
 2. Follow-up contact **must** be noted in the client's medical record.
 3. Results of the follow-up **must** be noted in the client's medical record.
 4. If unable to contact client, a certified letter should be sent to those clients who have any high grade lesions or cancer on their Pap test result.

G. Revisits

Revisit schedules **must** be individualized based on the client's need for education, counseling, and clinical care beyond that provided at the initial and annual visits.

Clients selecting hormonal contraceptives, intrauterine devices (IUDs), or diaphragms for the first time should be scheduled for a revisit, if needed, to reinforce proper use, check fit, side effects, and provide additional information.

A new or established client who chooses to continue a method already in use need not return for a revisit unless a need for reevaluation is determined on the basis of findings at the initial visit.

Pertinent history **must** be updated at subsequent physical exam visits.

8.4 FERTILITY REGULATION (CONTRACEPTION)

- A. Written protocols and operating procedures **must** be in place that meets the following standards:
1. A broad range of Federal Drug Administration (FDA) approved methods of contraception **must** be made available on site or through referral.
 2. Current FDA guidelines as to relative and absolute contraindications should be followed when prescribing contraceptives. A Contraceptive Waiver form signed by the delegate agency medical director **must** be reviewed annually and submitted to MDCH when any change in off label prescribing practices occur. See the MDCH Family Planning website www.michigan.gov/familyplanning .
 3. More than one method may be used simultaneously by the client. Clients with high-risk sexual behavior patterns should be encouraged to use condoms correctly and consistently in addition to any other chosen method to reduce the risks of STIs/HIV and pregnancy.
- B. Methods of contraception that **must** be provided and for which written protocols **must** be in place include:

Reversible contraception

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. Intrauterine Devices (IUD/IUS) **must** be provided, either on site or by paid referral.
4. Education materials and information regarding all methods including, hormonal contraceptives, abstinence, natural family planning, barrier methods, intrauterine devices, sterilization, and emergency contraception.
5. The agency formulary **must** indicate
 - a. Methods maintained and available on site
 - b. Methods available on site within two weeks of client request
 - c. Methods available by paid referral.
 - d. Methods available by unpaid referral.
6. Agencies are encouraged to review current practice and the needs of their client population and maintain the most frequently used methods where feasible.
7. Agencies are strongly encouraged to provide emergency contraception and maintain supplies on site.

C. Emergency Contraception

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

1. Written protocol **must** be in place.
2. The client requesting emergency contraception should have a negative, highly sensitive pregnancy test to exclude a pre-existing pregnancy if indicated by the client's history.
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.
2. Delegate agencies **must** have a list of community providers where clients can be referred for sterilization. Paid referrals for sterilization are not required.
3. Delegate agencies are encouraged to provide counseling and complete the federal consent process when referring clients to community providers for sterilization, to facilitate the process.
4. Delegate agencies performing sterilization procedures **must** meet Federal regulations for sterilization informed consent. This includes assuring that:
 - a. The client's decision to be sterilized is voluntary and made with full knowledge of the permanence, risks, and benefits associated with both male and female sterilization

- b. The individual is at least 21 years of age
- c. The individual is mentally competent
- d. The individual is voluntarily giving consent in accordance with Federal Regulation Procedures of 50.204, Subpart B, 43 FR 52165
- e. At least 30 days, but not more than 180 days, have passed between the date of the informed consent and the date of the sterilization procedure, except in the case of premature delivery or emergency abdominal surgery. Consent to be sterilized at the time of a premature delivery or emergency abdominal surgery may be given if at least 72 hours have passed after he or she gave informed consent. In the case of premature delivery, the informed consent **must** have been given at least 30 days before the expected date of delivery.

8.5 INFERTILITY SERVICES

Agencies **must** have written protocols and operating procedures that make basic infertility (Level I) services available to women and men desiring such services. Level II services may be offered in projects with infertility trained clinicians. Level III are services are beyond the scope of Title X projects and require outside referral.

Infertility may be due to either or both male and female factors, therefore, to be valuable; the infertility assessment should include both partners.

Infertility services are categorized as follows:

Level I

This level of service **must** be offered and includes:

1. Initial infertility interview or assessment
2. Education
3. Physical examination
4. Counseling
5. Appropriate referral.

Education and counseling should include human reproduction and sexuality, the risk and benefits to any proposed diagnostic and therapeutic measures and sufficient information for informed consent.

Level II

This level of service is optional, but if provided protocols **must** be in place to assure:

1. A clinician with special infertility training supervises these services.
2. Assessment of ovulation function through basal body temperature and/or endometrial biopsy is offered.
3. Post-coital testing and semen analysis is offered.

Level III

These services are more complex than Level I and II services and are considered beyond the scope of the Title X program.

8.6 PREGNANCY DIAGNOSIS AND COUNSELING

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

Written protocols and procedures **must** meet the following standards:

A. Pregnancy diagnosis services include:

1. Informed consent
2. History
3. Pregnancy testing with high sensitivity
4. Physical exam, including pelvic exam.

When a physical exam is not performed at the time of the pregnancy test, the client **must** be counseled about the importance of a physical assessment, preferably within 15 days.

This physical exam can be done on-site, by a provider of the client's choice, or through a referral.

B. 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

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)].

Clients with positive pregnancy tests who elect to continue the pregnancy should receive a referral for early prenatal care and information about the importance of early prenatal care. Clients planning to carry their pregnancies to term should be given information about good health practices during early pregnancy, especially those which serve to protect the fetus during the first three months (e.g., good nutrition, avoidance of smoking, drugs, alcohol and exposure to x-rays).

C. Clients with a negative pregnancy diagnosis should be given information about the availability of contraceptive and infertility services and offered an appointment, as appropriate. If the pregnancy test is negative, but other indicators are present for pregnancy, the client should be encouraged to have a repeat pregnancy test within the appropriate time frame. Clients with a negative pregnancy test should have the cause of their delayed menses investigated.

- D. If an ectopic pregnancy is suspected, the client **must** be referred for immediate diagnosis and treatment. Clients with a history of pelvic inflammatory disease (PID) (due to Chlamydia and other STIs) are at high risk for ectopic pregnancies. Follow-up with these clients **must** occur and all contact **must** be documented in the medical record.
- E. Personnel involved in pregnancy diagnosis and counseling **must** have knowledge of:
1. Pregnancy testing procedures
 2. Prenatal care and delivery
 3. Infant care, foster care and adoption
 4. Pregnancy termination
 5. Local availability of referral services
 6. Methods of contraception
 7. Federal and state requirements regarding mandatory reporting, options counseling, and abortion laws
 8. Non-directive counseling skills and techniques
 9. Documentation needed for the client record

8.7 ADOLESCENT SERVICES

- A. Adolescent clients require skilled counseling and age-appropriate information. An atmosphere in which the adolescent is comfortable asking questions should be created. The agency **must** address in their annual plan service delivery to adolescents, including the total number of adolescents the agency anticipates serving. Delegate agencies **must** not require written consent of the parents or guardians for the provision of services to minors. The delegate agency **must** not notify parents or guardians before or after a minor has requested and received Title X family planning services.
1. Appointments should be available to them for counseling and clinical services as soon as possible. Adolescents seeking contraceptive services **must** be informed about all methods of contraception. It is important not to assume that the adolescent is sexually active because they came for family planning services. As the contraceptive needs of adolescents frequently change, counseling should prepare them to use a variety of methods effectively.
- B. The agency **must** have protocols and operating procedures that address the following requirements related to adolescent health:
1. Adolescent counseling services **must** consist of:
 - a. Assurance of confidentiality of services
 - b. An atmosphere in which the adolescent is comfortable in asking questions.
 - c. Informed on all methods of contraception, including abstinence
 - d. Discussion of sexually transmitted infections, including HIV infection, and safer sex practices to reduce risks for STI/HIV.
 - e. Encourage participation in the agency's medical services, including physical exam, laboratory testing, and treatment as indicated
 - f. Encourage family participation in the decision of minors to seek family planning services.

- g. Provide counseling on how to resist attempts to coerce adolescents into engaging in sexual activities.
 - h. Inform adolescents that in special cases, (e.g. suspected child abuse) that reporting to authorities is required.
- C. The delegate should have specialized projects or services for adolescents. These may include the following:
- 1. Peer counselors
 - 2. Special clinic hours for adolescents
 - 3. School/community education programs
 - 4. Priority appointments to schedule within 2-4 days
 - 5. A youth representative to the local family planning advisory committee
 - 6. An agency representative to serve on community or school district on teen sexuality issues, teen pregnancy programming or adolescent health issues.

8.8 IDENTIFICATION OF ESTROGEN-EXPOSED OFFSPRING

- A. Women born between 1940 and 1970 **must** be assessed for in-utero DES exposure. The children of women who received DES or similar hormones during pregnancy may have abnormalities of their reproductive systems or other fertility related risks. Clients exposed to exogenous estrogen **must** receive information, education and special screening either on-site or by referral.
- 1. Suggested ways for identifying and treating estrogen exposed offspring include:
 - a. History assessment includes in-utero estrogen exposure, particularly diethylstilbestrol (DES)
 - b. Female clients who were exposed prenatally should be counseled about the risk of developing a rare cervico-vaginal tumor and pregnancy complications. A referral for colposcopy should be offered.
 - c. Male clients should be counseled about their risk of certain lesions of the genital tract and decreased fertility.

9.0 Related Services

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

9.1 GYNECOLOGIC SERVICES

Family planning delegate agencies should provide for the diagnosis and treatment of minor gynecologic problems to avoid fragmentation or lack of health care for clients with these conditions. Problems such as vaginitis or urinary tract infection may be amenable to on-the-spot diagnosis and treatment, following microscopic examination of vaginal secretions or urine dip stick testing. These services should be provided.

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

All delegate agencies **must** participate in the Breast and Cervical Cancer Control Program (BCCCP) for client cervical cancer diagnostic services unless other arrangements for payment are in place.

9.2 SEXUALLY TRANSMITTED INFECTIONS (STI) AND HIV/AIDS

The increasing incidence and prevalence of STIs, particularly among adolescents, requires that family planning delegate agencies increase their efforts to provide education and information about the more common STIs and HIV/AIDS. Delegate agencies should make available detection and treatment of the more common STIs.

At-risk clients should be urged to undergo examination and treatment as indicated, either directly or by referral. When treatment is provided on-site, appropriate follow-up measures **must** be undertaken.

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

- A. Written protocols and operating procedures for sexually transmitted infections **must** be in place when STI services are provided by the delegate agency and must include the following:
 - 1. Screening should follow current Centers for Disease Control and Prevention STI Treatment Guidelines.
 - a. Chlamydia tests should be provided annually for sexually active females 24 and under. Clients who test positive should be re-tested 3 months following treatment for early detection of re-infection. Clients who do not present at 3 months for re-test should be re-tested the next time they present for services in the 12 months following treatment of the initial infection. Females over 24 should be tested only if other risk

- factors are present (infected partner, symptoms, history of STI or multiple partners in the last year.)
 - b. CDC screening recommendations indicate targeted chlamydia screening for men only when resources permit and do not hinder chlamydia screening efforts in young women 24 and under.
 - c. Gonorrhea testing should be offered annually to high risk clients 24 and under who reside in high prevalence areas. Females over 24 should be tested only if other risk factors are present (infected partner, symptoms, history of STI or multiple partners in past year.)
 - d. Routine Gonorrhea screening of males at low risk is not recommended
 - 2. When treatment for any STI is provided on-site, the delegate **must** follow current Centers for Disease Control and Prevention STI Treatment Guidelines and ensure appropriate follow-up measures are taken with all persons treated.
 - 3. Delegate agencies **must** comply with state and local STI reporting requirements.
 - 4. Providers should encourage their clients with STIs to notify their sex partners and urge them to seek medical evaluation and treatment.
 - 5. Test for syphilis as indicated.
 - 6. Test for other STIs as indicated.
- B. HIV/AIDS written protocols and operating procedures **must** be in place to meet the following required HIV/AIDS services: (see Section 8.2.B.)
- 7. Education on HIV infection and AIDS
 - 2. HIV risk assessment, counseling regarding risk reduction and referral services
 - 3. Testing or referral for testing
 - 4. All clinical staff **must** receive in-service training regarding:
 - a. HIV infection and its prevention
 - b. Transmission and infection control in a health care setting
 - 5. Education on HIV infection should be included in appropriate community educational sessions

9.3 SPECIAL COUNSELING

Clients should be offered appropriate counseling and referrals as indicated regarding:

- 1. Future planned pregnancies
 - a. Preconception counseling should be provided if the client's history indicates
- 2. Management of a current pregnancy
- 3. Individual concerns, as indicated, such as:
 - a. Substance use and abuse,
 - b. Sexual abuse,
 - c. Relationship violence,
 - d. Genetic issues,
 - e. Nutrition,
 - f. Sexual concerns.

9.4 GENETIC INFORMATION AND REFERRAL

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

- A. Basic information regarding genetic conditions and referral should be offered to clients in need of this service.
 - 1. Initial screening consists of a careful family history of the client and the client's partner.
 - a. More complete screening and counseling may be offered directly (by a genetic counselor who functions in association with clinical genetics team capable of providing comprehensive services) or indirectly (through referral to a comprehensive genetic service program).
 - b. Linkages should be established with a comprehensive genetic service program.
 - 2. In-service training in genetics should be arranged for project staff to enable them to provide basic genetic information.
 - 3. Literature and informational materials regarding the availability of genetic services, including but not limited to prenatal diagnosis, should be available in the appropriate language to all clients on request.
 - 4. When genetic services are offered they should:
 - a. Be supported by a program of public information and education which is sensitive to the concerns of local ethnic and religious groups and uphold the dignity of individuals with congenital physical or mental limitations.
 - b. Include education and counseling to all clients on a voluntary basis.
 - c. Include referral for testing or further screening as indicated.

9.5 HEALTH PROMOTION/DISEASE PREVENTION

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

- A. For many clients, family planning programs are their only continuing source of health information and medical care. Delegate agencies should, whenever possible, provide or coordinate access to services intended to promote health and prevent disease.
- B. Health promotion/disease prevention information should include the following:
 - 1. Cancer detection - breast, cervical, testicular and colon
 - 2. Harmful effects of smoking and smoking cessation resources
 - 3. Automobile safety, including seat belt and child car seat resources
 - 4. Sexual risk behaviors
 - 5. Substance abuse
 - 6. Mental health problems
 - 7. Weight control

8. Regular exercise
9. Violence prevention; including domestic assault, relationship abuse, and human trafficking

9.6 POSTPARTUM CARE

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

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

10.0 Clinic Management

10.1 EQUIPMENT AND SUPPLIES

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

- A. Equipment and supplies **must** be safe, adequate, and appropriate to the type of care offered by the project.
- B. It is the responsibility of the project coordinator, in consultation with the medical director, to assure proper selection and maintenance of equipment and supplies.
- C. Equipment maintenance and calibration **must** be performed and documented based on manufacturer instructions.
- D. Appropriate MDCH procedures, as outlined in the contract agreement, **must** be followed for purchase and disposition of equipment costing \$5,000 or more.

10.2 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. To preserve the principal of equality, prescriptions may be written only for items on the approved formulary.

A. According to PH Code Act 368 of 1978

([http://www.legislature.mi.gov/\(fe4w2m45sywsn33ibepsztea\)/mileg.aspx?page=GetMCLDocument&objectname=mcl-act-368-of-1978&queryid=9521433](http://www.legislature.mi.gov/(fe4w2m45sywsn33ibepsztea)/mileg.aspx?page=GetMCLDocument&objectname=mcl-act-368-of-1978&queryid=9521433)) as amended under Pharmacy Practice and Drug Control 333.17745, a dispensing prescriber 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:

1. 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. In Title X clinics all medications **must** be pre-packaged.
 - b. Prescription medications dispensed (including samples) **must** be labeled and labels **must** contain the following information:
 - i. Name/address of dispensing agency
 - ii. Date of prescription
 - iii. Name of client
 - iv. Name, strength, quantity of drug dispensed
 - v. Directions for use, including frequency of use
 - vi. Prescriber's name
 - vii. Expiration date
 - viii. Record number
 - 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 education pertaining to the nature and safety aspects of pharmaceuticals is provided to staff involved in the provision of medications to clients.
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:
 - i. Contraceptive and therapeutic pharmaceuticals **must** be kept in a secure place, either under direct observation or locked.

- ii. Access to pharmaceuticals **must** be limited to health care professionals responsible for distributing these items.
 - iii. 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. Delegate 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.

B. Prescriptive Methods for Transfer Clients

- 1. Clients who received a full exam within the last twelve months by another provider may request that records be sent to the Title X clinic.
- 2. A client history **must** be completed and an informed consent form **must** be obtained. The clinician will review the transfer records and decide if current prescription can be continued. The clinician **must** document the prescription in the client's record.
- 3. If the clients' last exam occurred over twelve months ago, the client is to be treated as a new client and follow clinical protocols as a new client.

10.3 MEDICAL RECORDS

A. General Policy

- 1. A medical record **must** be established for each client who receives clinical services, including all pregnancy testing/counseling clients and emergency contraception clients.
- 2. Medical records are maintained in accordance with the accepted medical standards and state laws with regard to record retention. Records **must** be:
 - a. Complete, legible, and accurate
 - b. Signed and dated by the clinician health professional making each entry
 - i. Each entry includes date, name and title of the clinician/health professional
 - ii. Each entry is a permanent part of the record
 - c. Readily accessible
 - d. Systematically organized to facilitate retrieval and compilation of information
 - e. Confidential
 - f. Safeguarded against loss or use by unauthorized persons

- g. Secured by lock when not in use
- h. Available upon request to the client
- 3. HIPPA regulations regarding personal health information **must** be followed.
- 4. Guidance regarding records management is available from the Michigan Department of Technology, Management and Budget, Records Management Services.
<http://www.michigan.gov/recordsmanagement>

B. Record Contents

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

- 1. Personal data:
 - a. Name
 - b. Address, phone number(s), and how to contact
 - c. Age
 - d. Sex
 - e. Marital status (as required for State of Michigan)
 - f. Income Assessment
 - g. Unique client number
 - h. Race and ethnicity (as required for FPAR)
- 2. Medical history
- 3. Physical exam
- 4. Documentation of clinical findings, diagnostic/therapeutic orders
 - a. Laboratory test results and follow-up done for abnormal results
 - b. Treatments and special instructions
 - c. Documentation of continuing care, referral and follow-up
 - d. Documentation of scheduled revisits
- 5. Contraceptive method chosen by the client
- 6. Informed consents
- 7. Documentation of all counseling, education, and social services given
- 8. Documentation of deferrals, reason for deferral, and refusal of services
- 9. Date and signature of clinician or health professional for each entry, including documentation of telephone encounters of a clinical nature.
 - a. Signature includes name and title of provider
 - b. A signature log, if full name and title are not used in medical record
- 10. A confidentiality assurance statement in the client's record.
- 11. A problem list should be maintained at the front of the chart listing identified problems to facilitate continuing evaluation and follow-up.

C. Confidentiality and Release of Records

A system **must** be in place to maintain confidentiality of client records.

- 1. A confidentiality assurance statement **must** appear in the client's record.
- 2. HIV, mental health, and substance use information **must** be handled according to state law.
- 3. The written consent of the client is required for the release of personally identifiable information, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality.

- a. Consent form for release of information, signed by the client, specifies to whom information may be disclosed.
- b. Only the specific information requested may be released.
4. Information collected for reporting purposes **must** be disclosed only in summary, statistical, or other form which does not identify individuals
5. Upon request, clients transferring to other providers **must** be provided with a copy or summary of their record to expedite continuity of care.
6. Upon request, clients **must** or be given access to their medical record

10.4 QUALITY ASSURANCE AND AUDIT

- A. Delegate agencies **must** have a quality assurance system in place that provides for the ongoing evaluation of family planning personnel and services. The quality assurance system should include:
 1. An established set of clinical, administrative and programmatic standards by which conformity is maintained.
- B. Delegate agencies **must** have a quality assurance system in place that includes the following elements:
 1. A tracking system that identifies clients in need of follow up and/or continuing care **must** be in place.(Section 7.4 Referrals and Follow-up)
 2. A system to assure that professional licenses and CPR certifications are current **must** be in place. (Sections 6.5 Personnel & 7.3 Emergencies)
 3. Medical Audits to determine conformity with agency protocols, current standards, and acceptable medical practices **must** be conducted monthly by the medical director.
 - a. A minimum of two to three charts per clinician **must** be reviewed by the medical director monthly.
 4. Chart Audits/ Record Monitoring to determine completeness and accuracy of the medical record **must** be conducted monthly by the quality assurance committee or identified personnel.
 - a. Chart audits **must** represent a minimum of three percent (3%) of the agency's monthly caseload, randomly selected and reviewed by staff.
 - b. All clinical sites should be represented in the sampling.
 - c. Topic audits are strongly suggested.
 5. Annual performance evaluations **must** be performed for all family planning program staff, including the medical director. (Section 6.5 Personnel)
 6. Annual peer review of all clinician/providers **must** be conducted. (Section 6.5 Personnel)
 7. Clinical Protocols and procedures **must** be reviewed and signed annually by the medical director. (Section 7.1 Service Plans and Protocols)
 8. Infection control policies and procedures reflecting current CDC recommendations and OSHA regulations **must** be in place. (Sections 6.5 Personnel & 6.6 Training and technical Assistance)
 9. Laboratory audits to assure quality and CLIA compliance **must** be in place. (Section 8.3. D. 8 & 9)
 10. Equipment maintenance and calibration **must** be documented. (Section 10.1 Equipment and Supplies)
 11. Annual financial audit **must** be conducted, as applicable. (Section 6.3.3 Financial Audit)

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

IV. Program Monitoring

Site Reviews

Site Reviews for Non-Health Department Title X Family Planning Delegate Agencies

Purpose

Non-Health Department Title X delegate agencies undergo a site review conducted by the Michigan Department of Community Health Family Planning Program staff every three years. The site review is conducted to determine whether MDCH supported family planning delegate agencies are managed effectively, and are in compliance with federal Title X regulations. [42 CFR Part 59, Subpart A]. All program areas are reviewed: Administration, Finance, Clinical Services and Community Outreach and Information.

Methodology

Both Local Health Departments and Non-Health Department Delegate Agencies are reviewed by the same standards of performance, called Minimum Program Requirements (MPRs). MPRs are program regulatory mandates based on the Federal Register, the Federal Office of Population Affairs (OPA) Title X Program Guidelines. The MDCH's Family Planning Program Standards and Guidelines is a resource that specifically outlines what is needed to meet the program mandates. These resources are consistent in their expectations for programs but each document differs in its presentation based on the type of document it is.

The Federal Register, being law, reads as legislation. The Office of Population Affairs Program, *Guidelines for Project Grants for Family Planning Services*, is guidance taken from the Federal Register, used to assist delegate agencies with their implementation. The Federal Register is the family planning statute itself. It outlines the policy that must be in place, but allows for interpretation by the State (MDCH) to determine what will be required to carry out the policy. The MDCH *Standards and Guidelines* provide the most detail and specific expectations for the individual Title X Family Planning Delegate Agencies. The requirements in the MDCH *Standards and Guidelines* supercedes the information in the OPA Title X Standards and Guidelines. The MDCH Standards and Guidelines do not contradict the OPA - *Guidelines for Project Grants for Family Planning Services*, they provide clarity, specific direction and in some cases additional information or requirements that may exceed those in the OPA document as determined by the State.

Agencies will receive a letter three months prior to their review from MDCH indicating when their review is scheduled, where to find needed documents to prepare for the site review and who to consult for technical assistance.

The Agency Family Planning Coordinator will be contacted by the MDCH, Family Planning Program Staff for scheduling. Agencies must have a clinic scheduled during the visit to facilitate the accurate evaluation of this clinical component of the program. Sites at any location a delegate agency has may be visited during this process.

Process

Non-Health Department site reviews are coordinated and conducted by Michigan Department of Community Health, Family Planning staff. A nurse practitioner reviews the clinic service portion of the program and public health consultants from MDCH review the administrative portion of the program including community outreach and information, and finance.

The following are steps in the site review process:

- A. Complete the “Self-Assessment Tool”, an internal program review which is the first step in the preparation process. This should be started about four months prior to the review. The “Self-Assessment Tool” can be found at the Accreditation website at: <http://accreditation.localhealth.net/Tools.htm>. Unless the agency requests otherwise, the Family Planning Coordinator will serve as the contact for this process.
- B. Prepare from the list of “Pre-Assessment Required Materials” to be submitted to the MD. The information needed is available on the Accreditation website. The materials may be submitted either by hard copy or electronic means. This program requires extensive protocols and other relevant materials; therefore, these items are reviewed off-site.

IMPORTANT: The Pre-Assessment Required Materials and the Fiscal Questionnaire can be found at the following website:

<http://www.accreditation.localhealth.net/Tool2006/TOC-%20Self-Assessment.doc>

From the accreditation website, go to TOOLS→ USER GUIDE, you will find it near the end of the section, beginning on Page 17.

- C. Agencies should submit these materials, one month before the scheduled review, to the MDCH, Family Planning Program. They can be mailed to the office address or e-mailed to the address listed in the letter announcing the review.
- D. There are a variety of reviewers that complete the site review. However, all use the same Family Planning Minimum Program Requirements (MPRs) to evaluate each program.

Pre-Conference

The Administrative Reviewer will take the lead in scheduling and confirming the pre-site review meeting. This takes place immediately prior to the beginning of the review. The agency may invite anyone who will be able to provide information regarding the clinical, administrative, or educational aspects of the program, its operations and logistics.

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

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

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

- Logistics
 - a. Working Room
 - b. Rest Room
 - c. Computer terminal access for laptops

- Questions and wrap-up

Exit Conference

An exit conference is an opportunity for discussion between the reviewers and the delegate agency staff regarding the general findings of the review. Health Department exit conferences are coordinated by MPHI, if desired.

Non-Health Department agencies will also have the opportunity for an exit interview, if desired. This can be decided at the beginning of the review when other logistical items are being worked out.

- Completed Report

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

- Corrective Plans of Action

The Submission of Corrective Plans of Action and deadlines for Health Departments will be coordinated through MPHI. For Non-Local Health Departments, the plans will be submitted to MDCH. Corrective Action Plans start when the on-site exit review is finished. Technical Assistance from MDCH Family Planning Consultants is available to assist with developing plans that will meet program regulations.

- MDCH Family Planning Response to Plan

The Corrective Plans of Action will be evaluated by State of Michigan staff.

- Plans may be approved with no further action needed.
- Plans may be approved with conditions such as a site revisit or submission of materials to the state agency.
- Plans may be rejected in which case instructions will be included advising the delegate agency about what revisions are needed for acceptance of the plan.

If for any reason an agency is not going to meet the timelines that should notify the State Agency as soon they are aware of this situation is apparent.

Accreditation Reviews for Title X Family Planning Delegate Agencies within Michigan Local Public Health Departments

All Title X Delegate Agencies have a comprehensive agency review every three years to determine whether MDCH supported family planning delegate agencies are managed effectively and are in compliance with Title X regulations [42 CFR Part 59, Subpart A]. Building on the work of the Institute of Medicine and the National Association of County Health Officials, the Michigan Departments of Agriculture, Community Health and Environmental Quality and other state agencies developed and are committed to implementing the Michigan Local Public Health Accreditation Program. The process builds on many of the principles outlined in [The Future of Public Health](#) and The National Association of County Health Officials' 1991 Assessment Protocol for Excellence in Public Health ([APEXPH](#)), and aims to institute a baseline standard for the attributes and services that define a local health department. The Michigan Local Public Health Accreditation Program, by its mission, seeks to assure and enhance the quality of local public health in Michigan by identifying and promoting the implementation of public health standards for local public health departments, and evaluating and accrediting local health departments on their ability to meet these standards.

All Family Planning Program areas: Administration, Finance, Clinical Services and Community Outreach and Information will be reviewed. The Michigan Department of Community Health contracts with the Michigan Public Health Institute (MPHI) to coordinate the accreditation process for the Family Planning Program. Several other state-contracted programs are also reviewed during the accreditation process. For more information about the accreditation program visit the following website: <http://www.accreditation.localhealth.net/>.

Accreditation Visits and Site Reviews for Health Department and Non-Health Department Title X Family Planning Programs

There are different types of providers, who are delegate agencies for Family Planning Title X grant services. There are currently Health Departments, Planned Parenthoods, Hospital-based sites, and there are sites provided through the Federally-Qualified Health Plans. These providers are divided into two categories: Health Departments and Non-Health Departments. Both categories of agencies, Local Health Departments and Non-Health Department Delegate Agencies, are reviewed by the same standards of performance, called Minimum Program Requirements (MPRs). MPRs are program regulatory mandates based on the Federal Register, the Federal Office of Population Affairs (OPA) Title X Program Guidelines.

The Michigan Department of Community Health's Family Planning Program Standards and Guidelines is a resource that specifically outlines what is needed to meet the program mandates. These resources are consistent in their expectations for programs but each document differs in its presentation based on the type of document it is. The Federal Register, being law, reads as legislation. The Office of Population Affairs Program, Guidelines for Project Grants for Family Planning Services, is guidance used by the States to assist delegate agencies with implementation. The Federal Register Title X [42 CFR {art 59, Subpart A}] is the Family Planning Statute itself. It outlines the policy that must be in place, but allows for interpretation by the State (MDCH) to determine what will be required to carry out the policy. The MDCH Standards and Guidelines provide the most detail and specific expectations for the individual Title X Family Planning Delegate Agencies. The requirements in the MDCH Standards and Guidelines supersede the information in the OPA Guidelines for Project Grants for Family Planning Services. The MDCH Standards and Guidelines do not contradict the OPA - Guidelines for Project Grants for Family Planning Services, they provide clarity, specific direction and in some cases additional information or requirements that may exceed those in the OPA document as determined by the State.

Detailed instructions are available on the accreditation website:

<http://www.accreditation.localhealth.net> about expectations and planning information that is needed to prepare for an Accreditation/Site Review. Agencies must have a clinic scheduled during their site visit to facilitate the accurate evaluation of this component of the program. Any clinic locations a delegate agency has may be visited during this process.

MPHI handles the coordination of the dates, and the instructions for website use. The Health Department should begin with a self-assessment. The tools for this can be found at the accreditation website at: <http://accreditation.localhealth.net/Tools.htm>. Technical Assistance for the Family Planning Program is provided through MDCH, Family Planning staff.

IMPORTANT: A User Guide has been developed for agencies to use during the ` Required Materials and the Fiscal Questionnaire can be found at the following website:

<http://www.accreditation.localhealth.net/Tool2006/TOC-%20Self-Assessment.doc>

From the accreditation website, go to TOOLS→ USER GUIDE, you will find it near the end of the section, beginning on Page 17.

Monitoring and Technical Assistance

Monitoring Visits

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

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

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

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

Technical Assistance (Consultation Visits)

Consultation visits for technical assistance are available as needed. Technical assistance is provided for areas needing improvement that have been identified through the local agency plan, a site review, monitoring visit, per the request of the agency or other mechanisms. Technical assistance visits are pre-arranged between the Family Planning Consultant and the Family Planning Coordinator or delegated representatives. The content and timing of the visit is mutually determined between the agency representative and the program consultant. Follow-up on any areas requiring change found in the Site Review/Accreditation process is considered routine. Below are examples of areas that technical assistance is available. This list is not inclusive and delegate agencies may call for technical assistance on any aspect of their operation requiring regulatory clarification.

- Any areas needing improvement or clarification in the agency's Annual Plan will be discussed, with recommendations being given.
- Assistance with the application of billing and collections procedures (total charges less discount); third party payer billing instructions (total charges no discount); charges are determination by cost analysis; and clients are not denied services based on inability to pay.
- Assisting with the orientation of project staff to Title X regulations, new staff must receive specific orientation about confidentiality of services, Title X history, regulations and guidelines.
- Guidance about the development and implementation of method-specific consent forms with follow-up and assurance of compliance.
- Support and information about the FPAR (Family Planning Annual Report).
- Resource information for the implementation of the "Plan First!" family planning Medicaid waiver within the projects.

Technical assistance can be arranged by contacting the family planning program consultant.

V. MDCH Title X Training

Coordinators Meeting

The 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 changes or issues. In addition, essential information is presented from the Michigan Department of Community Health Management and Consultant staff, surrounding clinic practice and management issues that are in the forefront in Title X Family Planning Clinics during the year. The meeting is also a unique opportunity for the Coordinators to network with their colleagues and share their individual experience and expertise.

There are detailed evaluations collected at each workshop. The planning of future meetings utilizes the information obtained in the review of evaluations from the previous year. Trends in requests for information, suggestions for improvement, and any other pertinent information obtained through the evaluation reviews are considered in the planning.

This meeting is coordinated by the Michigan Public Health Institute (MPHI) and the Michigan Department of Community Health. Meetings are now available through video conferencing. This media allows for more participation because of reduced travel and the cost-effectiveness of the presentation style. The conference can be offered in more locations throughout the State in this form than it can be when it has to be live at each location.

MPHI publishes a calendar annually with all the educational offerings for the year in it. The date for the Coordinator's Meeting is listed here. This brochure is circulated to all delegate agencies. The dates and locations of the programs are listed to allow ample time to save the dates. Visit the MPHI website for more information and calendars:

https://events.mphi.org/iebms/wri/wri_p1_display.aspx?oc=10&cc=EVENTMGT

Annual Conference

Michigan Department of Community Health's (MDCH) 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. Since this is a workshop format the meeting generally is scheduled for at least two days.

This annual conference is called the Michigan Update. The workshop meeting place is rotated geographically to provide access to all areas in Michigan. There are expert speakers on a variety of topics are brought in. In addition, MDCH Administrative and Management Staff are available and provide pertinent program information.

In addition to this educational workshop, there are numerous other opportunities to obtain education and updates related to family planning. These trainings can be completed at a time convenient for the individual. Continuing Education and Contact Hours are available whenever possible.

Below are websites that provide education that can be useful to Title X Family Planning Program providers:

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

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

Staff and Delegate Agency Training

Family Planning Training and Advisory Committee (TAC) is a standing committee of the MDCH, Family Planning Program. This committee plans staff and delegate 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 MDCH 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:

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

The purpose of TAC is to determine training topics, content and make trainer recommendations for MDCH 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 delegate agency training needs. MPHI offers online registration with all pertinent information including directions, visit <http://www.mphi.eductrng.net/calendar.cfm> for information and instructions. The training planning team takes every opportunity to offer professional contact hours and continuing education opportunities at every event planned.

Federal Meetings and Conference

Information about The Family Planning program, authorized under Title X of the Public Health Service Act, is administered within the OPA by the Office of Family Planning (OFP), although its budget line is located within the Health Resources and Services Administration (HRSA). The program is funded at \$288 million in fiscal year 2005. Susan Moskosky is the Director, OFP. There is an annual meeting held each year for all Title X Family Planning MDCH. There are program representatives from each State that attend this meeting. The United States is divided into Regions. Michigan is located in Region V.

Following is information about Region V Training:

The Region V Title X Family Planning Training Program was established in 1999 to act as one of ten Regional Training Centers funded by the US Office of Population Affairs, Department of Health and Human Services, Title X Family Planning Services. The program delivers education and training to health care providers and staff in federally funded Title X family planning programs in the six-state Region V area. Region V is comprised of Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin.

The Region V Family Planning Training Program offices are located in Milwaukee, Wisconsin, and program staff work closely with the Region V Family Planning Advisory Committee. Committee members include representatives from each regional Title X MDCH, state Health Departments and community organizations. The Clinical Advisory Subcommittee, comprised of clinician representatives from each state, works with the program's expert clinical staff to design clinical training programming

The National Family Planning Program was created in 1970 as Title X of the Public Health Service Act (P.L.910572). It is a categorical grant program that provides funding for comprehensive family planning services. The nationally funded Title X program is administered by the Office of Family Planning within the Office of Population Affairs (<http://www.hhs.gov/opa/>)

Family planning clinics are often the entry point into the health care system for the young and for low income persons, as well as a principal source of health care for many, particularly those who are uninsured and do not qualify for Medicaid. Title X has no residential requirement for receipt of services and no one can be refused services based on the inability to pay. In addition to contraceptive services, Title X clinics provide basic gynecologic care, screening for breast cancer, cervical cancer and sexually transmitted diseases-including HIV, infertility services, and reproductive health education and referrals.

Title X family planning service funds are allocated to ten Department of Health and Human Services Regional Offices including Region V. DHHS Region V is comprised of six states: Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin. The Regional Office solicits applications, manages a competitive review process, makes awards and monitors program performance.

In Region V, Title X also supports The Family Planning Training Program at HCET

Office of Population Affairs has developed the training priorities that follow. The State Of Michigan Family Planning Program Training uses these priorities when planning the delegate agency and staff curriculum:

2010 National Training Priority

Each year the OPA/OFP establishes national training priorities based on nationally identified training needs.

The National Training Priority area identified for FY 2008 was: conducting outcome evaluation of the impact of the training activities to Title X providers on improving clinic efficiency in an effort to address increasing costs of health care without sacrificing quality.

During FY 2009, outcome evaluation activities related to clinic efficiency strategies continued as the National Training Priority.

During FY 2010, National Training Priority resources are dedicated to continuation of regional activities related to clinic efficiency and evaluation of impact and outcomes, as well as participation in development of a national compendium describing these efforts, summarizing regional data, and identifying benchmarks and best practices.

Additional guidance will be provided to Regional Offices to communicate to training grantees related to proposals and reporting expectations for the national training priority activities that will be supported with the FY 2010 National Training Priority supplement.

For more detailed information visit the website at:

<http://www.hhs.gov/opa/familyplanning/policyplanningeval/trainingpriorities/index.html>

For more information about the Federal Administration visit the following website-

<http://www.hhs.gov/opa/>

Program Mandates and Priorities can be found at the following website-

<http://www.hhs.gov/opa/familyplanning/policyplanningeval/policyplanningeval.html>

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.

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

- Revisioning Task Force
Develops and shares the FPAC identity including structure, membership and partnerships with other networks.
- Resource Enhancement Task Force
Identifies and disseminates information that outlines strategies or identifies opportunities to maximize fiscal resources utilized in reproductive health settings.
- Policy Advancement Task Force
Develops and coordinates a strategic policy agenda for family planning services.
- Quality Medical Services Task Force
Provides leadership on quality service delivery in reproductive health.

Contact Information

For more information about the FPAC, including membership and task force participation, contact:

Deanna Charest
Women's Health Unit
Michigan Department of Community Health
Division of Family and Community Health
517-335-8861
charestd@michigan.gov

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
FAMILY PLANNING ADVISORY COUNCIL

BY-LAWS

SHARED MISSION

Through collaborative leadership and advocacy, the Family Planning Advisory Council (referred to as the FPAC through the remainder of these by-laws) supports and improves the reproductive health of Michigan residents.

SHARED VISION

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

FPAC VALUES

- In everything we do, we scan the environment and engage our stakeholders.
- We value integrating the latest technology in all we do.

ARTICLE I

OFFICE

The principle office of Michigan Department of Community Health Family Planning Advisory Council shall be the Michigan Department of Community Health, Bureau of Family, Maternal and Child Health, P.O. Box 30195, 109 W. Michigan Avenue, Lansing, Michigan 48909.

ARTICLE II

KEY PRIORITIES

1. We develop and share our identity.
2. We build the right infrastructure for maximum success of FPAC.
3. We establish strategic partnerships with statewide and national networks.
4. We provide leadership for quality service delivery.
5. We utilize state-of-the-art information technology to assure family planning information is available.
6. We have a coordinated and strategic policy agenda carried out by an engaged network of stakeholders.

7. We seek opportunities to maximize existing or leverage new resources for programs that provide family planning.

ARTICLE III

MEMBERSHIP OF THE MICHIGAN DEPARTMENT OF COMMUNITY HEALTH FAMILY PLANNING ADVISORY COUNCIL

Section I - Size

The Advisory Council shall consist of no fewer than fifteen (15) and not more than thirty (30) members.

Section II - Timing and Frequency of Appointment of Members

- A. A nominating committee appointed by the chairperson shall be established to recruit and recommend appointments. The nominating committee shall submit a slate of candidates to the Family Planning Advisory Council at the Fall meeting for approval. The Michigan Department of Community Health has final approval of the slate.
- B. New members shall be appointed in the Winter of each year to fill expiring terms.

Section III - Term of Office

Terms of office shall be either one, two or three years. A member may serve successive terms.

Section IV - Vacancies

Vacancies on the Michigan Department of Community Health Family Planning Advisory Council shall be filled in accordance with Article III, Section II, A and B.. Each person so appointed to fill a vacancy shall remain a member for the duration of the term of office to be filled.

Section V - Power to Appoint other Consultants and Agents

The Michigan Department of Community Health Family Planning Advisory Council shall have the ability to appoint such other non-voting consultants and agents as the Advisory Council may deem necessary for the transactions of the affairs of the Advisory Council.

Section VI - Funding

- A. The reimbursable expenses incurred, if any, by the FPAC members will be reimbursed in accordance with the Michigan Department of Community Health travel expense policies.

- B. In addition, the Family Planning Program of the Bureau of Family, Maternal and Child Health shall provide administrative support necessary for the effective operation of the Council, such as postage, staff time, etc.

ARTICLE IV

OFFICERS

Section I - Election of Officers

- A. The FPAC shall elect a chairperson, a vice-chairperson, and a secretary. All the foregoing officers must be Advisory Council members.
- B. The nominating committee will present a slate of officers to the Council at the annual fall meeting for approval. The Michigan Department of Community Health has final approval for the slate of officers..
- C. Each officer will be elected to a two-year term. Successive terms are permissible.

Section II - Removal of Officers

Any officer may be removed by a majority vote of the FPAC members whenever, in the judgement of the Council, the goals of the Family Planning Program would be better served without that individual.

Section III - Duties of Chairperson

- A. Preside at all meetings of the FPAC at which she/he is present.
- B. Have general responsibility for issues arising between meetings and active management of the affairs of the FPAC and shall see that all orders and resolutions of the Council are carried into effect.
- C. Develop agenda for meeting in cooperation with the Family Planning Program's staff.
- D. Have the general powers of supervision and management usually vested in the office of the Chairperson of the Council. Any meeting procedure problem shall be resolved with Robert's Rule of Order.

Section IV - Duties of Vice-Chairperson

The Vice-chairperson shall, in the absence or disability of the Chairperson, perform her/his duties and exercise her/his powers, and shall perform such duties as the Advisory Council may prescribe.

Section V - Duties of Secretary

- A. Participate in all general meetings of the FPAC. Record all votes and minutes of Council proceedings and develop other correspondence as requested by the Council.
- B. The secretary may delegate any of her/his duties, powers, and authorities unless such delegation be disapproved by the FPAC.
- C. Perform other duties as may be prescribed by the Advisory Council or Chairperson.

ARTICLE V

FUNCTIONS OF THE FAMILY PLANNING ADVISORY COUNCIL

- A. The FPAC shall have the following authority and responsibility:
 - 1. Bring together individuals and representatives from communities and organizations who have a commitment to family planning and who can contribute in the development and improvement of family planning in Michigan.
 - 2. Review and make recommendations on accessibility, availability and quality of care for family planning services in Michigan.
 - 3. Review and make recommendations on proposed federal or state family planning legislation, and proposed federal or state family planning policies.
 - 4. Review statewide family planning funding sources and make recommendations for securement of sufficient funding levels.
 - 5. Advise the Michigan Department of Community Health, Bureau of Family, Maternal and Child Health on policy, planning and priorities of need of family planning services.
 - 6. Promote communication and advocate policy change at state, regional and national levels in order to strengthen Family Planning in Michigan.
 - 7. Review and recommend educational and promotional materials for family planning services, including materials used in the Title X Family Planning Program.
 - 8. Act as an advisory council for the Michigan Title X Family Planning Program including review and recommendations on accessibility, availability and quality of care. This shall include review and recommendations on policy changes, Michigan's Title X work plan, the funding formula used with delegate agencies, the Family Planning Standards and Guidelines Manual, and annual program performance reports.

- B. In addition, the FPAC shall:
1. Hold regularly scheduled meetings, at least quarterly and special meetings at the call of the chairperson. A calendar of the meetings for the year shall be established at the fall meeting.
 2. Adopt By-Laws.
 3. Maintain standing committees and/or task force groups to address the needs of the Council. Each committee/task force elects a chair and is assigned an MDCH liaison/staff person to assist in the business of the group.
 - a. Nominating Committee - The committee shall annually select a slate of general members and officers for consideration and approval by the full Family Planning Advisory Council.
 - b. Quality Medical Services Task Force/Medical Advisory Committee - The committee shall be responsible for review and recommendations in the interest of quality family planning service delivery in Michigan, including keeping the Council informed on current research trends and development in family planning. The committee also acts as the medical advisory group for the Title X Family Planning Program, reviewing general clinical aspects of the Program. The MDCH Family Planning Program Medical Director shall be a standing member to this committee.
 - c. Re-visioning Task Force - The group develops and shares the FPAC identity including structure, membership and partnerships with other networks. The task force also leads the development and maintenance of a long range plan and annual plan for the Council. The task force chair shall be the Advisory Council chair.
 - d. Resource Enhancement Task Force – The task force identifies and disseminates information that outlines strategies or identifies opportunities to maximize fiscal resources utilized in reproductive health settings.
 - e. Policy Advancement Taskforce - The task force is responsible for developing and coordinating a strategic policy agenda for family planning services. The group promotes family planning on a state, regional, and national level.
 4. The Council will seek and obtain input from teens and consumers when needed.
 5. Ad hoc committees may be established at the discretion of the chairperson including but not limited to, an Information/Education committee to review all state level educational materials for the Title X program.
- C. Advisory Council shall encourage new approaches in the delivery of services for family planning.

- D. The FPAC in establishing the above mentioned policies shall NOT:
1. Establish any policy which is inconsistent with the federal and/or state regulation set forth or which prevents the fulfillment of obligations imposed under any grant.
 2. Involve itself in a specific agency grievance against the Michigan Department of Community Health.

ARTICLE VI

MEETINGS OF THE MICHIGAN DEPARTMENT OF COMMUNITY HEALTH FAMILY PLANNING ADVISORY COUNCIL

Section I - Place of Meeting

All meetings of the FPAC membership shall be at the principle office of the Council in the City of Lansing, unless otherwise approved by the Advisory Council.

Section II - Annual Meeting

An annual meeting of the Advisory Council shall be held in the fall of each year. Officers and council members shall be elected at each annual meeting, and such other business may be transacted as may come before the meeting. Notice of the Annual Meeting shall be given to each member at least thirty (30) days prior.

Section III - Regular Meetings of the Advisory Council

Regular meetings of the Advisory Council shall be held as directed or approved by the vote of a majority of the members.

Section V - Special Meetings of the Advisory Council

Special meetings of the Advisory Council may be called by the Chairperson and shall be called by the Chairperson upon a written request of any six (6) council members. Ten (10) days written notice shall be given for special meetings of the Council. Notices of special meetings shall state the purpose(s) of the meeting.

Section VI - Voting Rights

Each member of the Advisory Council, at every meeting, respectively; shall be entitled to one (1) vote in person or by conference call. If the business of the Council requires action, electronic voting, such as email, is permitted.

Section VII - Absenteeism

In the event that a member of the Advisory Council is absent from any two (2) consecutive meetings, he/she shall be contacted by the Chairperson to determine continuing interest. In the event that the individual is not interested in continuing, his/her membership shall terminate immediately, and the vacancy thus created may be filled as herein provided.

Section VIII - Quorum

A majority of the total membership of the Advisory Council shall constitute a quorum for amending By-Laws or voting on any other major issue. The vote of a majority of members of the quorum shall decide any questions properly brought before the meeting.

Section IX - Public Meetings

All meetings of the Advisory Council shall be open to the public.

ARTICLE VII

BOOKS, RECORDS AND ACCOUNTABILITY TO MEMBERSHIP

Section I - Maintenance of Records

The proper officers and agents of the Advisory Council shall keep and maintain records of the Advisory Council affairs and lists of members. The secretary or designee shall maintain a master file.

Section II - Annual Report

At each annual meeting the Advisory Council will make a report of the membership on the activities of the Family Planning Program.

ARTICLE VIII

AMENDMENTS

The By-Laws of the Advisory Council may be amended, altered, added to, repealed, in whole or in part, after being submitted in writing to the membership at least thirty (30) days prior to the date to be voted on, by the affirmative vote of two-thirds of the Advisory Council members present and voting at any regular or special meeting of the Council.

Rev. 2010

Glossary of Terms

Approval or Authorization of the Awarding or Cognizant Federal Agency

Documentation evidencing consent prior to incurring a specific cost. If such costs are specifically identified in a Federal award document, approval of the document constitutes approval of the costs. If the costs are covered by a State-wide/local cost allocation plan or an indirect cost proposal, approval of the plan constitutes the approval.

Award

Means grants, cost reimbursement contracts and other agreements between a State, local and Indian tribal government and the Federal Government.

Awarding Agency

Means (a) with respect to a grant, cooperative agreement, or cost reimbursement contract, the Federal agency, and (b) with respect to a sub-award, the party that awarded the sub-award.

Black-Box Warnings

A black box warning is a type of warning that appears on prescription drugs that may cause serious adverse effects. It is so named for the black border that usually surrounds the text of the warning.

Can and May

used in this document indicate suggestions for consideration by individual projects.

Claim

Means a written demand or written assertion by the governmental unit or grantor seeking, as a matter of right, the payment of money in a sum certain, the adjustment or interpretation of award terms, or other relief arising under or relating to the award. A voucher, invoice or other routine request for payment that is not a dispute when submitted is not a claim. Appeals, such as those filed by a governmental unit in response to questioned audit costs, are not considered claims until a final management decision is made by the Federal awarding agency.

Client / Medical Record

This definition comes from the Title X program guidelines, and clarifies the type of documentation that must be maintained to document each family planning encounter. It is a record established for every family planning user who obtains clinical services, screening or laboratory services, and/or educational or counseling services and is a confidential record, accessible only to authorized staff and secured by lock when not in use. A Client/Medical Record includes Client identification/contact information (personal data); Medical history and information on allergies and adverse reactions to identified drugs; Physical exam data; Laboratory test orders, results, and follow-up; Treatment and special instructions; Informed consent forms; Documentation on the refusal of services, and Allows for entries by non-clinical services providers such as counseling and social service staff.

Clinical Laboratory Improvement Amendments (CLIA)

The act that sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It implements sections 1861 (e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to all laboratories as defined under "laboratory" in Sec. 493.2 of this part. This part also applies to laboratories seeking payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification.

Clinical Services Provider

Medical provider, such as: Physicians (family and general practitioners, specialists); Physician's assistants; Nurse practitioners; Certified nurse midwives; Other licensed health providers (e.g., nurses) permitted by state-specific regulations to provide clinical family planning services

Comprehensive Planning and Budgeting Contract's (CPBC)

This is a budget incorporation process performed between the Contract Management Section (CMS) and local health departments. Incorporation occurs through the amendment processes. In the amendment following the receipt of the budget documents, the original budget for the current fiscal year, is amended into the agreement. This process occurs twice a year or as needed.

Contract

Means a mutually binding legal relationship obligating the seller to furnish the supplies or services (including construction) and the buyer to pay for them. It includes all types of commitments that obligate the government to an expenditure of appropriated funds and that, except as otherwise authorized, are in writing. In addition to bilateral instruments, contracts including but not limited to: awards and notices of awards; job orders, under which the contract becomes effective by written acceptance or performance; and, bilateral contract modifications. Contracts do not include grants and cooperative agreements covered by 31 U.S.C. 6301 et seq.

Cost

Means an amount as determined on a cash, accrual, or other basis acceptable to the Federal awarding or cognizant agency. It does not include transfers to a general or similar fund.

Cost Allocation Plan

Means central service cost allocation plan, public assistance cost allocation plan, and indirect cost rate proposal. Each of these terms is further defined in this section.

Cost Objective

Means a function, organizational subdivision, contract, grant, or other activity for which cost data are needed and for which costs are incurred.

Delegate/Contract Agencies

Those entities that provide family planning services with Federal Title X funds under a negotiated, written agreement with a MDCH.

Family

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

Family Planning Annual Report (FPAR)

Refers to the sole source of annual, uniform reporting by all title X family planning services grantees. The report is used to provide consistent, national-level data.

Family Planning Encounter

Contact between an individual and a family planning provider that is: documented (i.e., written record); face-to-face, and takes place at Title X service site and takes place for the stated purpose of providing services to individuals who want to avoid unintended pregnancies or achieve intended pregnancies. A family planning visit represents a single family planning encounter. There are two types of family planning encounters: 1) with a clinical services provider; and 2) with a non-clinical services provider. The type of encounter is defined by the type of provider rather than the type of care rendered.

Family Planning Provider

Agency staff that assumes primary responsibility for assessing a client and documenting services in the client record and that exercise independent judgment as to the services rendered to the client during an encounter.

Family Planning Service Site

Given the different modes and locations for delivering Title X-funded services, a definition of what constitutes a Family Planning Service Site an established unit that offers family planning services -- clinical, educational, and referral -- that comply with Title X program guidelines. In non-clinic settings, the phrase “established unit” implies that the arrangement for providing Title X funded care is based on a formal agreement between the Title X agency and the site, and that services are not provided as a one-time service, but rather are delivered on some type of regular basis. Examples are: health department clinics; family planning clinics; hospital out-patient departments/clinics; homeless shelters; detention and correctional facilities; and equipped mobile vans or mobile personnel

Family Planning User

An individual who has at least one family planning encounter at a Title X service site during the reporting period. An individual may be counted as a family planning user only once during a reporting period. Terms “user” and “client” are synonymous and are used interchangeably. Definition of a Family Planning User has not changed.

Federally Recognized Indian Tribal Government

Means the governing body or a governmental agency of any Indian tribe, band, nation, or other organized group or community (including any native village as defined in Section 3 of the Alaska Native Claims Settlement Act, 85 Stat. 6880 certified the Secretary of the Interior as eligible for the special programs and services provided through the Bureau of Indian Affairs.

Governmental Unit

Means the entire State, local, or federally-recognized Indian tribal government, including any component thereof. Components of governmental units may function independently of the governmental unit in accordance with the term of the award.

Grantee Department or Agency

Means the component of a State, local or federally-recognized Indian tribal government which is responsible of the performance or administration of all or some part of a Federal award.

Health and Human Services

The United States Department of Health and Human this is the government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA, Title II) ACT OF 1996; Public Law 104-191; 104th Congress

An act to amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes. The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA, Title II) require the Department of Health and Human Services (HHS) to establish national standards for electronic health care transactions and national identifiers for providers, health plans, and employers. It also addresses the security and privacy of health data. Adopting these standards will improve the efficiency and effectiveness of the nation's health care system by encouraging the widespread use of electronic data interchange in health care.

Indirect Cost Rate Proposal

Means the documentation prepared by a governmental unit or component thereof to substantiate its request for the establishment of an indirect cost rate as described in Attachment E of this Circular.

Local Government

Means a county, municipality, city town, township, local public authority, school district, special district, interstate district, council of governments (whether or not incorporated as a non-profit corporation under State law), any other regional or interstate government entity, or any agency or instrumentality of a local government.

Low-Income Family

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). This term can also fit a family member whose income is above the poverty level but, who, as determined by the Project Director is not able to pay for family planning services.

Method-Specific Consent Forms

A consent form that contains all the information to make an informed choice about a prescriptive contraceptive. The information must be specific to the contraceptive method including its benefits and risks, effectiveness, potential side effects, complications, discontinuation issues and danger signs.

Michigan Department of Community Health (MDCH)

the entity that receives the Federal Title X grant and assumes legal and financial responsibility and accountability for the awarded funds and for the performance of the activities (project activities and delegate agencies) approved for funding.

Midwestern Professional Resources & Education Services, Inc. (MPRES)

is a non profit 501 (c)(3) agency offering services in two major program areas: reproductive health care education and research. Since the summer of 1999, the founding members of MPRES have operated the Region V/Title X Family Planning Training Program funded through the US Department of Health and Human Services. This program provides general training, research and technical support to healthcare providers and agencies that receive federal support to provide subsidized reproductive healthcare in a six state region. In addition, MPRES is committed to seeking additional public and private grant funds to support similar educational programming through other national granting bodies, state reproductive health entities, and private organizations.

Non-Clinical Services Providers

Are agency staff that provide client counseling, education, referral services, and non-invasive routine and other indicated tests. Examples are: Health educators; Social workers; and Clinic aides.

Non-Clinical Services Record

It is a confidential record, accessible only to authorized staff and secured by lock when not in use. If a family planning user receives no clinical services, a record still must be established for that client. Like a medical record, this client record must contain sufficient information to identify the client, indicate where and how the client can be contacted, and document fully the encounter. This record is confidential, accessible only to authorized staff, and secured by lock when not in use.

Non-Profit

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

Performance Expectations

This is the unduplicated count of Family Planning User's an agency is expected to see annually.

Plan First!

The new Michigan Medicaid Family Planning Section 115 waiver program that expands income eligibility to 185% of poverty for women aged 19-44 years old for family planning services only.

Project

Refers to those statewide activities described in the Michigan Department of Community Health (MDCH) grant application submitted to the Office of Population Affairs (OPA), Family Planning Program and supported under the approved budget.

Program Standards

Refers to minimally required services and standards as identified in the MDCH Family Planning Program Standards and Guidelines.

The Region V / Title X Family Planning Training Program

Established in 1999 to act as one of ten Regional Training Centers funded by the US Office of Population Affairs, Department of Health and Human Services, Title X Family Planning Services. The program delivers education and training to health care providers and staff in federally funded Title X family planning programs in the six-state Region V Area. Region V is comprised of Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin.

Required or Must

Used throughout this document indicate mandatory program policy requirements.

Service Sites

Clinical locations where Title X family planning services are provided by the MDCH or delegate/contract agency.

Should

Used in this document indicates recommended program guidelines and policies. This reference typically applies to guidelines and policies that reflect current acceptable medical or professional practices and are highly recommended by the Michigan Department of Community Health in order to fulfill the intent of Title X.

Sliding Fee Scale

The schedule of discounts that is proportional and applied to all clients with family incomes between 101% and 250% of the Federal poverty level. This must be developed based on a cost analysis of all services provided by the project. The scale should assure that no one is denied services for inability to pay.

State

Refers to any of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State exclusive of local government.

Title X

Refers to Public Health Service Act, 42 U.S.C. 300, *et seq.* Law and Federal policy can be explored in its entirety in the Title X Regulations section of this manual. Michigan Department of Community Health (MDCH) official family planning policy will also be included in this manual. References to specific chapters will be in brackets, e.g. [45 CFR Part 74, Subpart C]